LAW & MEDICINE

What Every Physician Should Know

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DEFINING THE STANDARD OF CARE

The "standard of care" is a phrase that is familiar to every clinician and regularly used in the course of clinical discussions. The standard of care is not, however, just a figure of speech. Instead, it is a highly technical term which describes the central legal obligation of every clinician to every patient.

The entire medical malpractice arena revolves around the standard of care and virtually every malpractice case comes down to the standard of care. Accordingly, the ability to define the standard of care is a skill that every clinician must possess.

APPLICABILITY OF THE STANDARD OF CARE

The standard of care is the measure by which every clinical decision is judged. This is true whether the decision is made by a primary care physician, a specialist, a resident or a nurse practitioner. It is true whether the patient has hypertension or a fractured femur. And, it does not matter whether the patient is noncompliant or has healthcare insurance. The standard of care always applies.

The standard of care is the measure by which every clinical decision is judged.

In making a clinical decision or performing a procedure, a clinician must deliver the standard of care. If he fails to do so, then he is potentially liable for any adverse outcome that may result. In fact, this sequence of events is the definition of medical malpractice. Specifically:

- Clinician fails to deliver the standard of care; and,
- This causes patient to suffer adverse event/outcome.

Fortunately, the standard of care is not just a legal obligation. It is also our primary defense to any allegation of medical malpractice. And, in terms of efficacy in the courtroom, it is a universally recognized and complete defense. In short, a clinician who delivers the standard of care cannot be successfully sued for malpractice, regardless of the patient's outcome.

Deliver the standard of care, and don't worry about the consequences.

At times, the legal system can be overly complex. But, defending oneself against an allegation of medical malpractice is comparatively simple: just prove that you delivered the standard of care. Although it is always preferable for the patient to have a good outcome (as these patients never sue), the standard of care is the standard of care, regardless of the result.

TECHNICAL DEFINITION

The law defines the standard of care as being what a reasonable, prudent and cautious physician (or nurse, pharmacist, etc.) would do under the circumstances. This definition has two parts. The first part describes the behavioral characteristics that the physician must exhibit, namely those of reason, prudence and caution.

Although these terms are not commonly used in the clinical arena, they describe traits that we all hold to be selfevident. "Reason" describes the process of weighing risks and benefits in a scholarly manner. It requires one to be knowledgeable, unemotional, and to ask for assistance whenever appropriate. For, it would be unreasonable to proceed without sufficient information or knowledge, if that information could be readily obtained.

The legal standard of care is derived from the core principles of medicine.

"Prudence" means that the clinician must approach the matter using the same care that he employs when managing his own affairs. That is, treat it as if it were your own. This requires thoroughness, diligence and attentiveness.

"Caution" refers to the element of carefulness. It does not mean that we should display fear or trepidation. In a sense, the requirement of caution incorporates the founding principle of medicine – in our efforts to help the patient, we must be careful that we "First, do no harm." The exercise of caution does not mean that we must try to avoid invasive or high risk approaches. For, in certain situations, an invasive, risk-laden procedure may be the most cautious and careful approach to take.

The second part of the definition "under the circumstances" refers to the situation in which the decision must be made. Sometimes, the circumstances are such that the reasonable, prudent and cautious approach, in accordance with the best available literature, is simply not possible. Although we should always aspire to deliver the "treatment of choice," our desire to do so may be negated by the patient's personal preferences, noncompliance, insurance coverage, allergies or finances.

Under these less-than-ideal circumstances, the standard of care will also be less than ideal. It is, however, still the standard of care. This is an important aspect of the standard of care. It continuously molds itself to the literature and the circumstances. The standard of care is never perfect, and it is sometimes "second rate." But, it is the standard of care nonetheless.

> "Second rate" medicine is sometimes the standard of care.

Although "reason, prudence and caution under the circumstances" provides general guidance, the definition lacks clinical precision and is therefore not overly useful at the bedside. By replacing the legalese with clinical terminology, we can convert the standard of care into a more recognizable form. Namely, in clinical terms, the standard of care is "the best available combination of risk and benefit."

The standard of care is "the best available combination of risk and benefit."

This definition compares favorably with the formal legal definition (i.e., "reason, prudence and caution under the circumstances"). Weighing of "risk and benefit" requires the reason, prudence and caution referred to in the legal definition. And, "the best available" portion incorporates the reality of the situation to which "under the circumstances" refers.

Regardless of which definition is used, the resulting behavior becomes the standard of care. And, from a medical malpractice perspective, this is all that matters.

EXPERTS AND NON-EXPERTS

A common question is whether the standard of care differs for a nurse practitioner as compared to a physician. And, does it differ for a primary care physician versus a specialist or sub-specialist? The answer is that it depends on the circumstances.

Fundamentally, the standard of care is always defined in the same manner. It is whatever a reasonable, prudent and cautious clinician would do under the circumstances. The first part of the definition (i.e., reason, prudence and caution) mandates an unemotional, scholarly approach. This part of the definition never changes. Every clinician is held to this standard. And, if he cannot deliver an unemotional, diligent and scholarly approach, then he must ask for assistance. For, that is the "reasonable" thing to do.

While the first part of the definition applies equally to all clinicians, the second part of the definition, "under the circumstances," does not. For, "the circumstances" necessarily include the training and expertise of the clinician, just as it includes the patient's insurance coverage and personal preferences. As a result, the standard of care varies based upon the experience and training of the provider.

A primary care physician is often held to a different, but never a lesser, standard than is a specialist.

This does not mean that persons of lesser training are held to a "lesser" standard or allowed to be less scholarly or diligent. But, because the circumstances are different, the standard for a primary care physician is often different than the standard for a sub-specialist. The following case examines those differences.

Case #1

Mr. X presents to his family physician, Dr. A, with a chief complaint of acute abdominal pain.

<u>Analysis</u>

Acute abdominal pain can be associated with a wide range of disease states, some of which are serious surgical conditions and others which are mild and self-limited in nature. Regardless of Mr. X's underlying problem, Dr. A's obligation is always the same. He must deliver the standard of care. This will completely shield him from any and all medical malpractice related liability.

The standard of care mandates that Dr. A take a reasonable, prudent and cautious approach that weighs Mr. X's diagnostic and treatment alternatives in a scholarly and diligent manner. The first step in this process is for Dr. A to determine whether he is qualified to evaluate and possibly treat Mr. X's condition, or whether he should make an immediate referral.

> Clinicians must continuously evaluate whether they are qualified to care for the patient or if the standard of care mandates referral.

As a family physician, Dr. A feels qualified to evaluate Mr. X's abdominal pain initially. He performs a history and physical which lead him to believe that Mr. X may have acute appendicitis. He orders blood tests, notifies a surgeon, and sends Mr. X to the emergency room.

Upon arrival, the emergency room physician confirms Dr. A's findings and concurs with his working diagnosis. The emergency room physician also notifies the surgeon that Mr. X is in the emergency room. At this juncture, it appears that Dr. A has delivered the standard of care. He has a good working diagnosis and has made a timely referral both to the emergency room and the general surgeon. Under these circumstances, the approach appears to be careful, appropriate and scientifically sound. Nothing more can be expected.

Twenty minutes later, Dr. A arrives in the emergency room but finds that the surgeon is delayed in the operating room with a very difficult case. He will not be able to see Mr. X for three or four hours.

Under ideal circumstances, Mr. X would have been seen without delay by the surgeon. Assuming that he indeed had appendicitis, this would have given him the best opportunity for a good outcome.

However, as is often the case, the circumstances here are not ideal. But, this does not mean that all is lost from a medical-legal perspective. For, Dr. A is still able to deliver the standard of care.

Performing a procedure that is outside the field of one's expertise is rarely the standard of care.

The standard of care mandates that Dr. A take an approach which is "reasonable under the circumstances," so that he can deliver the best available combination of risk and benefit. Here, the treatment of choice for Mr. X seems to be an appendectomy. But, the desired surgeon is temporarily unavailable. As such, Dr. A should proceed with his next most viable option, which thus becomes the (new) standard of care.

Dr. A switches to Plan B and attempts to find another surgeon to see Mr. X. But, he is unsuccessful. He then changes to Plan C and attempts to transfer Mr. X to another nearby facility. Unfortunately, he encounters a number of obstacles with transportation which make timely transfer impossible.

Dr. A concludes that he cannot find a surgeon to see or operate on Mr. X in a timely manner. Without timely surgery, Dr. A believes that Mr. X's treatment will fall below the standard of care.

The standard of care is always available.

Plans A, B and C have all been negated and Mr. X will not have timely surgery by a qualified individual. But, the standard of care is still available. For, the standard of care, which rises and falls with the circumstances, is always available. In this situation, it is now Plan D. This is not as good as Plans A, B, or C; it would not be any clinician's first choice; and, it may not produce an ideal result. But, it has become the standard of care.

When Plan A is not available, Plan B becomes the standard of care.

In weighing the remaining options, Dr. A could try to perform the surgery himself. But, as a family physician who has not been in the operating room since he was a resident, it would be unreasonable for Dr. A to attempt an exploratory laparotomy. Although the procedure is needed, the benefits outweigh the risks only in the hands of a qualified surgeon. As such, Dr. A would probably violate the standard of care by attempting an appendectomy himself.

There are some cases where the standard of care permits a non-expert to attempt an invasive procedure (e.g., having a family physician relieve a tension pneumothorax in a decompensating patient), but the degree of urgency here does not warrant taking that level of risk. Accordingly, Dr. A is not expected to perform a laparotomy and cannot be faulted for the fact that he is not trained to do so. However, he must continue to care for Mr. X in a clinically sound manner.

Having exhausted all of his apparent options, Dr. A is uncertain what he should do next and lifts his hands in frustration.

When a clinician nears the limits of his knowledge and/or his patience, the standard of care mandates consultation.

This is a reliable sign that it is time to ask for consultation. When a clinician nears the limits of his knowledge and/or his patience, the standard of care mandates consultation. Here, Dr. A is unable to find a surgeon who can see Mr. X. But, he might be able to ask a surgeon what treatment (other than surgery) is most appropriate.

Such treatment might include antibiotics, lab tests or radiographic studies. As a family physician, Dr. A would certainly be able to accomplish these measures. If input from a surgeon were unavailable, he might consult infectious diseases (ID) or gastroenterology (GI). Either expert opinion might favorably affect Mr. X's treatment and ensure that Dr. A delivered the standard of care.

Every clinician must know when it is time to ask for assistance and then manage the patient to the best of his abilities until that assistance arrives.

In the end, the standard of care does not mandate that Dr. A, as a family physician, open Mr. X's abdomen. For, this would rarely be favorable from a risk-benefit perspective. However, it does mandate that Dr. A remain diligent and continuously search for the option which gives Mr. X the best opportunity for a good outcome.

Although sub-specialists often possess more expertise in their respective fields than do generalists, every clinician must know when it is time to ask for assistance and then manage the patient to the best of his abilities until that assistance arrives.

GEOGRAPHIC/COMMUNITY VARIATION

A generation ago, the standard of care was defined by the community in which a physician practiced. For example, if physicians in a given community always performed cardiac catheterization for patients who had an abnormal cardiac stress test, then that was the community standard of care.

If a physician evaluated chest pain in this community, he was expected to perform cardiac catheterization for any patient with an abnormal stress test. Doing otherwise would violate the community standard and, with it, the legal standard of care. This was true regardless of the medical literature, how or where the physician may have been trained, or what approach was being used in surrounding communities. As a result, there were often significant geographic variations in the standard of care.

The standard of care is a national standard, determined by whatever literature, ideas and options are applicable and available.

In a time when medical information was not as readily accessible and did not travel with great speed, the "community" standard of care best served the practice of medicine. But, in the modern era of information dissemination and accessibility, the community standard is no longer appropriate. Now, the standard of care is a national standard, determined by whatever literature, ideas and options are applicable and available.

As such, it is no longer a legally valid defense to state "we don't believe in that procedure around here." For, the literature is national, if not international, in nature. The effectiveness of heparin against a blood clot is not affected by where a patient lives. The goals for diabetes treatment do not vary based on latitude or longitude. And, *The New England Journal of Medicine* does not publish regional editions. We all receive the same edition of the *Journal*. Accordingly, we are all held to the same intellectual standard.

Although we are all held to the same intellectual stan-

dard, there are clearly regional differences in the way medicine is practiced. These differences can be explained in several ways.

First, regional differences often result from scenarios where the standard of care allows for more than one recognized approach. That is, in many situations, there are two or more viable approaches to a patient's problem. Assuming both approaches are supported by the literature and equally effective from a risk-benefit perspective, both are recognized as being within the standard of care. In the law, this is known as the "Two Schools of Thought" doctrine and is discussed further beginning on page 7.

Although the law no longer recognizes a "community standard of care," the community clearly affects the standard of care.

The second and more common reason for regional differences in the standard of care is variation in the circumstances under which care is delivered. Medical resources (e.g., available technology, number of sub-specialists) vary significantly from town to town. As these resources change from one community to another, the standard of care is altered accordingly. The following cases will explore how the community affects the standard of care.

Case #2

Mr. X is seriously injured in a motor vehicle accident. The accident occurs several blocks from a university hospital trauma center. Mr. X arrives in the trauma center within minutes of the accident.

<u>Analysis</u>

Mr. X has hit the jackpot from a standard of care perspective.

The standard which applies to his treating physicians is the same standard that applies to every clinician. Namely, they must be knowledgeable, attentive, and properly balance risk with benefit under the circumstances.

With respect to the first part of the definition, the intellectual component, the physicians must be familiar with the evaluation and stabilization of a trauma patient, order appropriate tests, and ask for timely consultation whenever needed. This aspect of the standard of care is the same everywhere.

The standard of care rises and falls with the circumstances.

The second part of the standard of care definition, "under the circumstances," incorporates the realities of the situation in which the care must be delivered. Here, the circumstances are nearly perfect. Although Mr. X has been seriously injured, he was fortunate enough to wreck his car on the doorstep of a trauma center. This is as good as it gets for a trauma victim. Every conceivable test, procedure and specialist is immediately available.

Because the circumstances are quite good, the standard of care is very "high." In an ideal setting like this one, we expect the involved physicians to deliver care at the highest possible level. Put another way, there is no excuse here. In an "ideal" situation, the standard of care is also "ideal."

Case #3

On the same day as the preceding case study, Mr. Y is also seriously injured in a different motor vehicle accident. Unlike the first accident, this one occurs on a desolate stretch of road in an isolated area of North Dakota. Mr. Y is taken to the nearest facility, a small community hospital. The nearest trauma center is 200 miles away.

Analysis

From a standard of care perspective, Mr. Y is in trouble.

The standard of care is always defined in the same way with the same two elements. With respect to the first element, the physicians at this small hospital must be knowledgeable, attentive and adept decision makers, just as the physicians at the trauma center. This part of the definition never changes. The mere fact that these physicians practice in a smaller facility does not lower the standard of care to account for the possibility that they may not stay abreast of the literature.

But, the circumstances here are not nearly as good as the above case. The small hospital is unlikely to match the medical resources of a trauma center. Under these less than ideal circumstances, the standard of care will also be less than ideal. This is true regardless of how diligent, knowledgeable and attentive the treating physicians may be.

Physicians must be reasonable, prudent and cautious regardless of the circumstances.

The emergency room physician quickly determines that Mr. Y has a hemothorax, abdominal injuries and a serious head injury. He inserts a chest tube, administers blood and fluids, and does his best to stabilize Mr. Y's condition. The hospital has only one general surgeon, who is unavailable, and the hospital does not have an intensive care unit.

Within minutes after Mr. Y's arrival, the emergency room physician determines that immediate transfer to a trauma center is Mr. Y's only chance for survival. A call is made for a life flight helicopter. During the hour long flight to the trauma center, Mr. Y dies.

The standard of care rises and falls with the circumstances in which the care is delivered. In simple terms, the standard of care mandates that physicians do the best that they can with what they have.

In this example, the standard of care for Mr. Y's injuries fell as his distance from the nearest trauma center increased. For physicians who attend to patients in even more desolate situations, the standard of care is sometimes next to nothing. However, it is still the standard of care. And, so long as it is delivered, the physician is never responsible for the consequences.

> The standard of care, in simple terms, is: Do the best that you can with what you have.

In this case, the emergency room physician decided to transfer Mr. Y and he died en route to the trauma center. It is commonly said that, from a medical-legal perspective, it never looks good when a patient dies during transfer to another facility. It is probably more accurate to state that it never looks good when a patient dies anywhere.

Of course, a patient should not be transferred unless the transfer is appropriate and the patient is sufficiently stabilized. And, there is certainly the potential for liability if this standard is not met.

In this case, the transfer was appropriate in that it was Mr. Y's only chance to live. And, he was stabilized as sufficiently as was practical given the emergent situation and limited resources. Although the risk of dying during transfer was high, the risk of dying without transfer was absolute. This meant that a high risk transfer was the standard of care, regardless of the fact that Mr. Y did not survive the flight.

THE STANDARD OF CARE IN NON-CLINICAL SETTINGS

Medical advice and treatment are sometimes provided in informal settings such as a hospital hallway or a social gathering. The situation is often as simple as writing a prescription for a colleague or offering some medical advice to a friend. Most of the time, the scenario results in a good outcome and is entirely uneventful.

Unfortunately, this is not always the case. The "informal" advice or casual prescription can sometimes produce an undesired outcome. In these situations, there is often a question about whether the standard of care applies and, if so, how it is defined.

Case #4

Dr. A happens to encounter Nurse B in the hospital elevator. Nurse B tells Dr. A that she is out of her blood pressure medicine and that her physician is out of town. She asks Dr. A if he could write a prescription for her that will last until her physician returns.

Dr. A has never seen Nurse B as a patient, but ascertains that she has been stable without issue on her medication for some time. In an effort to be helpful, Dr. A gives Nurse B the prescription that she requested.

Analysis

This is a common scenario in which every physician has participated at one time or another. Helping a friend or family member who is in need is often a simple affair. And, in and of itself, does not violate any law or medical principle.

However, any time a physician assumes the role of physician and a patient assumes the role of patient, they step into a doctor-patient relationship and the standard of care applies. There are no exceptions. The standard of care applies in an elevator, at the roadside, and at the bedside. The rule of law is very simple: Anytime doctor and patient come together, the standard of care applies.

> Anytime doctor and patient come together, the standard of care applies.

In addition, the standard of care is never "watered down" by the informal nature of an interaction. Here, it would be easy for Dr. A to think that he was "just helping out" and was "not really" Nurse B's physician. He could then conclude that the standard of care might not really apply either. Unfortunately for him, there is no such rule in law or medicine. The standard of care is an all-or-nothing phenomenon. Either it applies or it does not.

In this case, Dr. A and Nurse B assumed the roles of doctor and patient and this means that the standard of care therefore applies to their interaction. It mandates that Dr. A takes a scholarly, diligent approach that best balances benefit with risk. Here, Nurse B was out of her medicine and could not reach her physician. She knew the name and dose of her medication, had been stable, and had no complaints.

The standard of care is never watered down due to the fact that the patient is a family member, friend or colleague.

Although it could always be argued that Dr. A should have had Nurse B come to his office and submit to a full physical and a battery of labs before prescribing anything, that would be a waste of time and money.

In fact, when covering another physician's practice, we regularly refill medications in situations that are very similar to the one here. That is, we often do not know the patient's history other than the fact that they are being treated for hypertension and are out of their medication. In that the risks associated with a short-term refill are almost non-existent while the benefits are great, we are well within the standard of care to refill these prescriptions.

While Dr. A is not technically "covering" for Nurse B's physician, he might as well be. As such, his decision to refill her blood pressure medicine is most likely within the standard of care. Again, and importantly, this means that he is not responsible for any adverse consequences that may subsequently arise.

Although Dr. A chose to assist Nurse B, there are similar situations where physicians wish to avoid potential liability. This can be easily accomplished by simply avoiding the role of doctor. That is, the standard of care (and the accompanying liability) does not apply until a doctorpatient relationship is formed. And, formation of a doctor-patient relationship cannot occur until persons assume the roles of doctor and patient.

Regardless of the setting or situation, when a person asks for medical advice they are assuming the role of "patient." As such, any physician who wishes to avoid the formation of a doctor-patient relationship, must not assume the role of "doctor." This can be politely accomplished with one of the following:

- "Without being your doctor, it is really hard to know what to say."
- "It doesn't sound serious, but you need to talk to your doctor."
- In order to avoid confusion, I do not refill medication for anyone who is not my patient."

Properly applied, these words allow us to politely avoid liability from those who seek medical advice in a non-clinical setting.

STANDARD OF CARE CORNERSTONES

One of the frustrations that many physicians face with the standard of care is that, ultimately, it is determined by a jury. The disadvantages of this system are widely known in the medical community and will not be discussed herein, other than to state that the jury system is unlikely to change in the foreseeable future. Therefore, a legally astute clinician must be aware of the standard of care from a juror's perspective.

Major academy position statements are the cornerstones of the standard of care.

This is not to state that the proper practice of medicine should ever be compromised just to appeal to what a jury might believe. For, it should not. However, it does mean that when dealing with options that are equally viable from a clinical perspective, understanding how a jury views those options can be helpful.

And, all things being equal, juries are more likely to believe, in descending order:

- Major academy position statements (i.e., the American Academy of Pediatrics),
- National guidelines,
- Review articles,
- The results of solid clinical studies, and,
- Reputable editorials.

Accordingly, clinicians should view major academy position statements and national guidelines as cornerstones of the standard of care. This does not mean that a failure to follow a guideline is an automatic violation of the standard of care. But, significant deviation from a recognized guideline will require a solid explanation. And, from a jury credibility perspective, it is better to be quoting the American College of Cardiology (or Dermatology, Rheumatology, Surgery) than to be explaining why the College is wrong.

> Jurors generally believe the American College of Cardiology.

Two Schools of Thought

When everyone agrees on the proper approach, the standard of care is easy to define. But, this is often not the case. In many situations, reasonable clinicians differ as to the best approach, and both are able to cite credible literature to support their respective positions. In fact, sometimes even major academy position statements are not in agreement with one another. Defining a reliable standard of care in these situations appears to be impossible.

Case #5

Dr. A is a family physician who is seeing Mr. X as a new patient. Mr. X is 55 years old and has no significant medical or family history. Mr. X is open to whatever health maintenance and preventive medicine items Dr. A might propose.

Dr. A recently attended an educational seminar on prostate cancer screening. The speaker, who was a prominent urologist, recommended prostate cancer screening for all men over age 50, in accordance with the positions of the American College of Urology and the American Cancer Society.

But, on Dr. A's desk is a copy of the current American Academy of Family Physicians screening recommendations for prostate cancer. The guidelines recommend that for asymptomatic, low risk patients, screening is of no utility and merely exposes patients to unnecessary testing and procedures. As a family physician, Dr. A believes that the standard of care is most likely what his own Academy recommends. Accordingly, he informs Mr. X that he does not need screening for prostate cancer.

Although he believes his recommendation is the correct one, Dr. A is concerned that other academies have taken an opposing position. He worries that this sets him up to be second guessed. In addition, he knows neither which other academies or associations may have issued a guideline on this issue, nor what they might have recommended.

Finally, he is concerned that, even if there are only three guidelines, two are against him while only one is for him. This means that he would be in the minority, which he believes is legally undesirable.

<u>Analysis</u>

The standard of care is not determined by what a majority even a super-majority of physicians would do. Instead, it is determined by a scholarly, attentive and thorough approach to the problem. So long as this approach is followed, the result will always be the standard of care.

> A scholarly, attentive and thorough approach will always produce the standard of care.

In this case, Dr. A followed the current recommendation

of the American Academy of Family Physicians. Regardless of whether Dr. A himself is a family physician, the Academy's position is valuable. Viewing this recommendation from a standard of care perspective, it is scholarly, well-balanced, thorough, and literature based. It thus meets all of the criteria mandated by the standard of care and must be deemed to be within the standard of care. This is true regardless of what other opinions might exist and regardless of Dr. A's particular specialty.

The standard of care often permits more than one acceptable approach.

It does not matter whether all, most or only a few clinicians would choose to follow this approach. It is valid regardless. In many situations, the standard of care allows for multiple acceptable approaches. Courts recognize this as valid under the doctrine of "Two Schools of Thought" or "Respected Minority Opinion."

Regardless of its name, the principle is of enormous value to physicians. So long as an approach is recognized by respected persons and/or literature, it is within the standard of care and can be entertained as a viable treatment option by any physician, anywhere. Although the position of one's own specialty organization and literature is often most helpful, a family physician, or any physician, is not required to follow his own academy's position. Instead, he may choose to follow the American College of Urology's position if he believes it is more appropriate for his patients.

> A physician is not required to follow his own Academy's position statements.

In addition, when faced with a "two schools of thought" scenario, clinicians are not required to choose the same option every time. In other words, the standard of care does not mandate that physicians be internally consistent with how we approach a particular problem. If there is more than one viable approach, we may choose one, the other, or alternate between the two. Although consistency is often preferable from a practical perspective, it is not legally required.

In addition, the standard of care is not determined by what option the treating physician may have preferred yesterday, what he usually does in a given situation, nor with what articles he may have personally written. The only thing that matters is whether the approach is recognized as a viable option for this particular patient. If so, then the option is within the standard of care and the analysis ends. If there are two recognized therapeutic alternatives, the standard of care permits the choice to be determined by coin toss.

Viewed at its most basic level, if there are two recognized approaches to a patient's situation, then the treating physician can choose either option. The physician's specialty, geographic location, place of training, community practices, articles written, and past choices are all irrelevant. In fact, when dealing with two equally viable options, it would be legally acceptable for the physician to determine the course of treatment by flipping a coin (although I would not recommend actually doing so in front of the patient).

In order to sue a physician for malpractice successfully, the patient/plaintiff must first conclusively establish the applicable standard of care and then show that the physician failed to meet it (and also prove that this failure was the cause of his injuries). With this as a background, the following legal arguments (which are commonly attempted by the plaintiff) are insufficient to prove the physician was outside the standard of care:

- Demonstrating that an alternative approach was available (this is almost always the case);
- Demonstrating that the plaintiff's expert witness uses only an alternative approach in his personal practice (the expert witness' personal preferences are irrelevant in determining the standard of care);
- Demonstrating that the physicians at both Harvard and Johns Hopkins would have chosen an alternative approach (although important, neither institution defines the standard of care);
- Demonstrating that most physicians would have chosen an alternative approach (the standard of care is not determined by the democratic process);
- Demonstrating that every physician in the community would have chosen an alternative approach (the standard of care is national, not community);
- Demonstrating that a major academy endorses an alternative approach (there may be other position statements or literature that do not concur);
- Demonstrating that the defendant physician's own academy recommends an alternative approach (a physician is free to choose from any viable approach and is not bound by the position of his particular specialty society);

- Demonstrating that the defendant physician usually chooses an alternative approach but failed to do so on this occasion (the standard of care is determined by whether a reasonable, knowledgeable physician could have chosen the option, not by what the defendant physician may have done in the past);
- Demonstrating that the defendant physician recently authored an article recommending an alternative approach (the standard of care is not determined by the views of any one physician, even if he is the treating physician); or,
- Demonstrating that an alternative approach would have (in retrospect) produced a better result (the standard of care is determined prospectively).

If a reasonable physician could have taken the approach, then the approach is within the standard of care.

Instead, the standard of care is determined by what a hypothetical physician, well-versed, attentive and thorough might do under the circumstances. So long as this mythical creature **might** have chosen it, the option must be deemed as being within the standard of care.

This rule of law must be kept in mind when analyzing a plaintiff's argument and expert witness' assertions. Too many expert witnesses are allowed to testify as to what they would have done or about what most people would have done. All of which is irrelevant. The plaintiff and his expert witness must conclusively state that NO reasonable physician would have taken the approach used by the defendant physician. Unless he can definitively state this, his case is lost.

Unless the plaintiff's expert witness can state that NO reasonable physician would have taken the approach used by the defendant physician, his case is lost.

In this case, Dr. A's recommendation against PSA screening meets all of the required elements of being literature based, attentive, scholarly and thorough. It therefore must be deemed as being within the standard of care. This is the end of the analysis.

Dr. A sees Mr. X several times over the next year and he remains well. Then, Mr. X undergoes a prostate cancer screening test that is offered by his employer. His PSA is elevated at 9.0. He undergoes biopsy and is found to have prostate cancer.

When Dr. A learns of the situation, he is concerned that he may be sued for a delay in diagnosis. He realizes that a PSA ordered a year earlier could have detected the cancer at an earlier stage and potentially made a difference in Mr. X's treatment and/or outcome. Dr. A's worry is deepened by the fact that all of the urologists in his town have been recommending widespread use of PSA screening for at least several years.

Dr. A's response is a classic one. Physicians believe in the standard of care until something bad happens. Then, we lose all faith and second guess ourselves. Here, as with every case, the only thing Dr. A needs to worry about is the standard of care. Either he delivered it and is in the clear or he did not and is in trouble. Nothing else matters.

Either a physician delivers the standard of care and is in the clear or does not and is in trouble.

There is no doubt that if had Dr. A ordered a PSA a year earlier, the test would have detected the cancer. There is also little doubt that this could have made a difference in Mr. X's treatment and/or outcome. There is no question that all of this constitutes a delay in diagnosis. For, technically speaking, the diagnosis could have been made earlier. There is also no question that other well-trained physicians would have ordered the screening test and made the diagnosis a year earlier. But, none of this matters. It is all clinically and legally irrelevant.

Although we all share an ethical desire that the patient do well, the only thing that matters here is the standard of care. The standard of care is every clinician's primary duty and also his main defense. In this case, we previously determined that Dr. A delivered the standard of care. This determination is unaffected by the events that followed.

The standard of care always contains risks and they sometimes materialize.

It is unfortunate that the standard of care produced a less than ideal result for Mr. X, but this is the nature of the standard of care. Defined as the best available combination of risk and benefit, the standard of care necessarily contains risks. And, they sometimes materialize. But, whether the patient receives all benefit, all risk, or some combination of the two, the standard of care is the standard of care.

NO SCHOOLS OF THOUGHT

When there is one widely recognized approach, the standard of care is obvious. When there are several viable choices, the standard of care includes all or any one of them. But, many clinical decisions are made in situations where there is limited scientific information and no clear guidance from the literature. These cases raise medicallegal concerns because the treating physician often has very little in terms of literature directly supporting his decision.

Case #6

Mr. X has a seizure disorder which is treated by his neurologist, Dr. A. Over the past few years, Dr. A has tried all of the common approaches to Mr. X's seizures and twice referred him for consultation at the University. But, Mr. X's seizures are not adequately controlled.

Dr. A has searched the literature for a better option, but has found nothing that has been definitively proven. Eventually, Dr. A decides to try a combination of medications that have been shown to be effective in patients with a similar type of seizure disorder, although there is no literature showing efficacy with Mr. X's type of seizure.

Unfortunately, the medications cause Mr. X to have a serious skin reaction and he is hospitalized for several days.

<u>Analysis</u>

Anytime a patient has a bad outcome, the concern of being sued for medical malpractice arises. In each case, the issue comes down to the standard of care. Was it delivered or violated?

Many clinicians will look at this case and worry that Dr. A cannot provide enough literature to support his treatment decision. And, the concern is that unless he can sufficiently prove his position, he will be deemed to be outside the standard of care. This is a concern that many physicians face when the practice of medicine reaches the limits of the available literature.

Fortunately, Dr. A does not have to prove anything. In a medical malpractice lawsuit, the plaintiff/patient must do the proving. The plaintiff must definitively establish what the applicable standard of care was, and then show that the treating physician failed to meet it. If the plaintiff cannot do this, then he loses. The principle is similar to the "innocent until proven guilty" standard used in criminal cases.

The plaintiff must prove that the defendant physician was wrong. The physician does not have to prove anything.

Here, this is a significant problem for Mr. X. If there is no good literature and no clear guidance, then it is difficult to establish the standard of care definitively. If the standard is grey, murky and unclear, then he faces a great challenge showing that Dr. A has violated it. Of course, there is another way for Mr. X to make his argument. Rather than defining the standard and then showing that Dr. A failed to meet it, he could choose to declare that, although the standard of care was not well established, it was certainly not what Dr. A chose to do. In other words, even with the uncertainly, no reasonable physician would have done what Dr. A did.

In analyzing this argument, Mr. X had been unresponsive to every conventional treatment. He continued to seize despite all of the things which ordinarily work. The options were to have him continue to seize or to try something that was proven only in patients with a slightly different type of seizure disorder. At that point, the riskbenefit analysis was as follows:

- Without treatment, Mr. X suffered the substantial risks associated with continued seizures and had no real chance of improvement;
- By trying the treatment, Mr. X stood to reap the benefit of seizure control. But, he would have to face the inherent risks of the medications (although the combination had been shown to be safe in another group of seizure patients);
- The actual risks and benefits of the proposed treatment were not known with certainty; and,
- There were no other options which were more viable.

Under these circumstances, a reasonable, prudent and cautious physician could certainly have given the medication combination a try. A plaintiff attorney's potential argument that it was unreasonable even to try the medications carries little credibility.

This is not to imply that, in cases where there is little scientific guidance, the clinician can do whatever he pleases. For, the standards of reason, prudence and caution always apply. If the facts were different, and the only available treatment options carried substantial risk with limited benefit, the standard of care might have been to allow Mr. X to continue to seize, while taking measures to limit the possibility of injury to him or another.

EVOLVING STANDARD OF CARE

The standard of care is in constant evolution. It moves forward by incorporating new science and molding it to the changing circumstances. In most cases, the progression is gradual, allowing new and old practices to coexist within the recognized standard of care. Aside from dramatic events like product recalls, the standard of care rarely moves very far in a single day. And, it is a rare situation where the standard of care hinges on a single study or article. In most situations, well-established approaches tend to be stable over extended periods of time.

The surgical techniques used during the American Civil War were the standard of care.

Most importantly, the standard of care is determined at the instant at which the decision is made. It is based on what was known and/or knowable at that point. It does not matter what is later learned or discovered. The standard of care stands as the standard of care. Although we view the surgical care provided to soldiers during the American Civil War as barbaric, that was the standard of care in the 1860's. And, as terrible as the care was, it did not represent malpractice.

Case #7

Dr. A recently attended a seminar where a new treatment for diabetic retinopathy was presented. Based upon two recently published studies, the procedure reduced retinal neovascularization by 25% compared to standard treatment. Dr. A has a large number of diabetic patients in his practice.

Analysis

A 25% reduction in neovascularization certainly sounds promising. But, it is doubtful that Dr. A is now required to offer this treatment to all of his patients. First, the availability, safety and cost of the treatment have not been discussed. These are key elements. The standard of care includes a balancing of risk and benefit and also incorporates the element of availability.

We must be cautious in abandoning the proven for the promising.

Second, the standard of care mandates the application of caution. This means that we must be slow to completely abandon the proven for the promising. This is not to say that the new treatment is not an acceptable option. For, it may well be a good choice for some of Dr. A's patients. However, it is unlikely at this point that the standard of care mandates that all diabetics immediately switch over to the new treatment.

INSURANCE COVERAGE

Sometimes, access to the treatment of choice is impeded due to a denial of payment by the patient's healthcare insurance company. These situations create standard of care questions and raise the issue of potential liability in the event that the patient cannot receive the treatment of choice.

Case #8

Mrs. X has been suffering from intermittent headaches. Due to the nature of her complaint, Dr. A believes that an MRI is needed to rule out a brain tumor. Mrs. X has healthcare insurance, but the insurer requires preauthorization for all MRIs. The preauthorization process involves faxing a one page form or making a brief telephone call. Dr. A is not paid any additional money for the time involved in obtaining a preauthorization.

<u>Analysis</u>

Dr. A's obligation to Mrs. X in this situation is the same as his obligation to any patient in any situation. Namely, he must deliver the standard of care. The standard of care has been defined in two ways. Both definitions are helpful here. The first definition is that Dr. A must be reasonable, prudent and cautious under the circumstances. The second definition is that he must deliver the best available combination of risk and benefit.

Insurance company coverage decisions can lower the standard of care by making certain treatments "unavailable."

In this case, the treatment of choice based on the available literature and good clinical judgment is an MRI. For, that test offers the best combination of risk and benefit. But, the standard of care is not defined as the best combination of risk and benefit. Rather, it is defined as the best **available** combination of risk and benefit. The question, then, is whether the MRI is "available." If so, then it is the standard of care and anything less would be unacceptable.

The issue of "availability" has several components:

- The technology must exist in a geographically accessible location;
- The patient must be willing to undergo the test; and,
- Any required payment must be in place. (As a general rule of law, there is no obligation to perform an elective/non-emergent test or procedure if the patient is unable to make payment.)

In this case, the technology exists in a geographically accessible location and Mrs. X is willing to undergo the test.

So, the first two components are satisfied. But, payment for the MRI has not been secured. If Mrs. X was an inpatient or being seen in an emergency room, payment would not be part of the analysis. But, neither is the case. As such, unless there is a means of payment, the MRI must be deemed "unavailable," and therefore not required by the standard of care.

Payment for medical care may come from the patient, their insurer or some other third party. Any source will suffice. Most times, payment is first sought from the patient's insurer.

Here, Mrs. X's insurer will not automatically pay for an MRI. Instead, it requires preauthorization, a process for which Dr. A is not separately compensated. The first question, then, is whether Dr. A is required under the standard of care to make the request for preauthorization.

Once an administrative burden becomes unreasonable, it is no longer required of the physician.

The fact that Dr. A is not separately paid for the preauthorization process is not relevant. Neither is he separately paid for writing a prescription for a medication or for calling the hospital to order a blood test. Although no one enjoys doing added administrative work without additional compensation, the standard of care includes an obligation to perform those administrative tasks which are needed to obtain the requested care. Otherwise, most care could not be delivered.

However, the standard of care limits the obligation to those tasks which are "reasonable under the circumstances." Once an administrative burden becomes unreasonable, it is no longer required of the physician. With respect to preauthorizations, it is reasonable to make a phone call or fax a request. But, preparing multiple page documents or personally appearing at an appeal board is unreasonable (and therefore not required).

Dr. A calls for MRI preauthorization, but the request is denied. The insurer states that the decision can be appealed by filing a letter of justification along with the patient's medical record and supporting medical literature.

Dr. A has fulfilled his duty with respect to obtaining insurance coverage. He is not legally required to pursue the matter any further. Although he is free to file the appeal, the amount of work involved is unreasonable in the context of the daily practice of medicine.

However, this does not automatically mean that the MRI is "unavailable." For, Mrs. X may be willing to pay for the MRI herself or file her own appeal with her insurance

company.

Dr. A explains the options to Mrs. X. She is not willing/able to pay for the MRI, and she does not want to waste her time with an appeal. Dr. A is unaware of any means by which the MRI could be obtained for free.

From a standard of care perspective, the MRI is "unavailable." Although the machine is in operation just down the street, it cannot be procured for Mrs. X by any reasonable method. Dr. A should write a note in the chart stating "neither the insurer nor the patient willing to pay for MRI." He should then move to the next best option, which is probably a CT scan. Although this option is "second rate" medical care and may well miss a tumor that would have been seen with MRI, it is the standard of care nonetheless.

The standard of care rises and falls with insurer coverage just as it does with every other complicating circumstance.

The standard of care is not defined as the "best" option. It is defined as the "best available" option. This means that the standard of care is often second and third tier medical care. But, from a legal perspective, the standard of care is always a compete defense to an allegation of malpractice. It is frustrating when insurer coverage rules degrade the practice of medicine. However, the standard of care rises and falls with insurer coverage just as it does with every other complicating circumstance.

NONCOMPLIANCE

Patient noncompliance lowers the standard of care. But, it does not in any way relieve the physician of his responsibility to deliver the standard of care.

Case #9

Mr. X is overweight, smokes and has diabetes. Dr. A recommends diet, exercise, weight loss, smoking cessation and regular blood glucose monitoring. Although these are excellent recommendations, Mr. X does very little. Dr. A repeatedly encourages Mr. X to follow his recommendation and warns him of the serious consequences of not doing so.

Eventually, Dr. A realizes that Mr. X has a major motivation problem. Dr. A works with Mr. X to find something that he is willing to do. Dr. A believes that if he makes the tasks easier, there is a chance Mr. X will begin caring for himself. Realizing that Mr. X will not make an immediate and complete lifestyle change, Dr. A asks him to consider checking his sugars or stopping smoking as a first step.

<u>Analysis</u>

Ideal diabetic care includes a number of measures. But, those are not possible under these circumstances. As such, Dr. A has decided to try a gradual, "baby steps" approach. Given the circumstances, this seems to be within the standard of care. Assuming he documents the basis for his limited approach, Dr. A has little reason for legal concern.

Mr. X ignores all of Dr. A's suggestions. He tells Dr. A that the only reason he even comes to the doctor is because his wife nags him. Dr. A gradually loses his enthusiasm with respect to Mr. X's care. Although he continues to see him as a patient, Dr. A makes minimal effort and considers the entire venture to be a waste of time.

Dr. A has just fallen victim to the largest standard of care trap, the one of frustration. Patient noncompliance is an inevitable part of the practice of medicine. From a standard of care perspective it is a part of the "circumstances," and it often prevents us from delivering optimal care. Put another way, noncompliance makes the best treatment option "unavailable" and forces us to practice in an alternative, less effective manner. Despite its prevalence, noncompliance never relieves the physician of his obligation to deliver the standard of care.

Frustration awaits every physician as the largest standard of care trap.

Specifically, the legal obligation to be attentive, thorough, diligent, scientific, and objective applies no matter what the circumstances may be. It does not matter how disinterested the patient may be, the physician must maintain his interest.

Here, Dr. A is headed for legal trouble. He has a patient who is not caring for himself and is certain to encounter serious diabetic consequences. In addition, Dr. A's frustration now makes it impossible for him to be attentive and diligent. There is no worse medical-legal situation than a patient who is headed for a bad outcome being cared for by a doctor who has lost interest.

When the patient's lack of motivation begins to "rub-off" on the physician, the time has come to end the doctor-patient relationship.

The time has come for Dr. A to end his doctor-patient relationship with Mr. X. Although most patients with noncompliance can remain part of our practices, the noncompliance crosses a threshold when it becomes an emotional burden for the physician. At that point, our ability to deliver the standard of care is attenuated, com-promising both the patient's care and our legal position. Despite our reluctance to admit defeat, there is almost no reason to remain in this type of doctor-patient relationship.

Termination of a doctor-patient relationship is an underutilized and excellent medical-legal tool. As a general rule, physicians are permitted to end a doctor-patient relationship for just about any reason, including patient noncompliance.

CONCLUSION

The standard of care is surprisingly accommodating to every nuance and uncertainty that physicians face. When confronted with "second guessing," the best defense is simply to state, "I did the best I could with what I had." This simple phrase is readily understood by every clinician, family member and juror. And, it is the embodiment of the standard of care. LAW AND MEDICINE REPRESENTS THE AUTHOR'S OPIN-ION ON A VARIETY OF MEDICAL-LEGAL ISSUES. BECAUSE THE MATERIAL MUST BE INTERPRETED IN THE CONTEXT OF EACH PHYSICIAN'S INDIVIDUAL SITUATION, AS WELL AS WITHIN AN EVER-CHANGING ARRAY OF FEDERAL AND STATE LEGISLATION, LAW AND MEDICINE SHOULD NOT BE CONSIDERED TO BE A SOURCE OF LEGAL ADVICE, EITHER IN GENERAL, OR WITH RESPECT TO ANY PARTICULAR SITUATION, UPON WHICH THE READER SHOULD RELY. IF YOU HAVE ANY QUESTIONS RELATED TO THE ISSUES RAISED IN LAW AND MEDICINE, YOU SHOULD CONSULT YOUR ATTOR-NEY.

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