A Proactive, Data-based Determination of the Standard of Medical Care in Pediatrics

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ABSTRACT. A 3-week-old infant awoke with a fever. He was taken to the doctor who noted that the child was irritable. The doctor took him to the hospital where a resident performed a spinal tap, started an intravenous (IV) line, and ordered antibiotics. The entire drama, from entering the doctor's office to infusion of ampicillin, took 2 hours.

The doctor was sued for malpractice. Expert witnesses for the plaintiff testified that he had deviated from the standard of medical care by taking too long to administer antibiotics, which, in their view, ought to have been given within 30 minutes. Expert witnesses for the defense testified that 2 hours to administer antibiotics in this case was within the standard of care.

What ought to be the response of the pediatric community to discrepant expert testimony such as this?

One possible response is nothing. Lawyers from both sides will find expert medical witnesses who articulate positions favorable to their clients (as they did in this case), and the truth will emerge after vigorous cross-examination.

This, we suggest, is inadequate. We believe that some expert opinions can be viewed as better than others. That is, some opinions describe the standard of medical care correctly while other expert opinions are (to put it charitably) idiosyncratic, failing to depict accurately the skill and care ordinarily administered in comparable situations.

Currently, jurors are informed about the standard of care by expert witnesses, who rely on their own medical knowledge and experience. However, a huge body of literature demonstrates that recollections of individual experience are inevitably flawed, and flawed in a nonrandom direction (the Monday morning quarterback phenomenon).

Consider the infant with meningitis. When experts in pediatric emergency medicine and pediatric infectious diseases (ID) were asked about the median time from emergency room (ER) presentation to administration of antibiotics in a child with suspected meningitis, their opinions were wrong and slanted toward the outcome known to be desired (namely, a shorter elapsed time). ER physicians (median estimated time to antibiotic administration [AB-TIME] = 46 minutes) and ID physicians (median estimated AB-TIME = 80 minutes) consistently underestimated the actual median value of AB-TIME determined by chart review (120 minutes).

From the judicial perspective such potential flaws in expert testimony are assumed to be equally distributed among experts. All admissible evidence is a priori of equal weight until a jury decides otherwise. The standard of medical care is created anew by expert testimony in each individual case, disappearing, like Brigadoon, upon resolution of the dispute.

However, to anyone but a lawyer, the standard of medical care must exist as something outside the courtroom testimony of experts, and if it does exist, it should be easily described so that expert testimony can be judged more (or less) accurate in depicting it.

We contend that medical care is not a single behavior that conforms to or deviates from an idiosyncratic and retrospectively determined standard, but rather a distribution of behaviors in response to a variety of medical circumstances. For a given scenario, each of several possible responses can be ascribed a relative frequency based on empirical data, and the consequent normal curve depicts the totality of medical care. Substandard care then falls out neatly as behaviors lying outside the large majority of cases. Juries would be empowered (as they are currently) to determine exactly where on this curve substandard care lies, but at least the debate would share the same description of reality.

Recent US Supreme Court guidelines regarding expert testimony provide an opportunity to expand the use of databases in medical negligence cases. The Court restricted expert testimony to "scientific knowledge . . . based on generating hypotheses and testing them to see if they can be falsified . . . " The testable/falsifiable hypothesis in negligence cases is almost always the same—did the behavior in question fall within or outside the distribution of medical care that is ordinarily used in similar cases? We propose a simple two-part answer. First, determine the data-based distribution of standard medical care in similar circumstances. Next, superimpose this distribution upon the care actually provided.

Why is this so hard? Why haven't people done this before?

First, lawyers hate it. Not just plaintiff's lawyers—defense lawyers as well. Most lawyers are suspicious of all data sets. At the heart of this scepticism is a fundamental conflict. The legal profession can scarcely afford to embrace a theoretical vision of a data-based standard of care in advance of a particular case. What if the next client's behavior falls well outside the standard of care distribution?

Second, doctors hate it. More precisely, doctors distrust standards of any kind—imposed by third parties, inevitably distorting the doctor-patient relationship as it is romantically conceived. As one eminent pediatrician recently articulated, "Each infant or child . . . is an individual problem and one which cannot be measured against others . . . there can be no standard care or standard of care that can cover all cases."

Nevertheless, most pediatricians will be sued during their professional lifetime, most expert testimony will be woefully inadequate, and most jury judgments will be

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based on whimsy and debilitation, not negligence. It behooves us as a profession, and as professionals, to face this problem more directly. To this end, we recommend the following:

The American Academy of Pediatrics should organize a database of the issues involved in pediatric malpractice lawsuits. Members should be encouraged to report their experience with alleged deviations to the Academy. Some issues would likely recur—such as lawsuits dealing with meningitis alleging a delay in therapy, or lawsuits in which extremely premature infants were not treated in the delivery room or were sent home without apnea monitors. When common themes were identified, the Academy could survey members, or better yet develop databases reflecting actual practice (as opposed to reports of practice). These data, when published, would then presumptively define the spectrum of standard medical care to be applied, wherever possible, against the specific facts of an alleged instance of medical negligence.

We welcome constructive comments. ***Pediatrics*** **1998; 101(4). URL: http://www.pediatrics.org/cgi/content/full/101/4/e6;** ***malpractice, negligence, standard of care, expert testimony.***

ABBREVIATIONS. IV, intravenous; ER, emergency room; ABTIME, time to antibiotic administration; ID, infectious disease.

Let's start with a case—one that actually happened.

A 3-week-old male infant awoke with a fever and was taken by his mother to the doctor's office. The infant was first seen by the office nurse, who immediately moved him to the examining room. The doctor elicited a brief, unremarkable history from the mother and examined the child, who was irritable and febrile. The doctor informed the mother that he was concerned about meningitis and wanted to admit the child to the hospital for therapy. The mother agreed.

The doctor then walked the child across the street to the hospital and brought him directly to the pediatric floor, where he summoned the resident on-call. The resident examined the child, performed a spinal tap and blood culture, started an intravenous (IV) line, and ordered antibiotics that were administered by a nurse. The entire drama, from entering the doctor's office to infusion of ampicillin, took 2 hours.

The doctor was sued for malpractice. Expert witnesses for the plaintiff testified that he had deviated from the standard of medical care by taking too long to administer antibiotics, which, in their view, ought to have been given within 30 minutes. Expert witnesses for the defense testified that in their view the 2 hours taken to administer antibiotics in this case was within the standard of care.

The question we address in the rest of this article is what, if anything, ought to be the response of the pediatric medical community to discrepant expert testimony such as this.

One possible response is nothing. On this view, it is the province of the legal system to deal with such allegations. Lawyers from both sides have a fiduciary responsibility to find expert medical witnesses who will articulate positions favorable to their clients (as they did in this case), and the truth will emerge after vigorous cross-examination, presentation of contrary evidence, and careful instruction of the burden of proof.[4] Although the current adjudication system may be imperfect and may allow or encourage misleading or inaccurate testimony by experts, it is better than any alternative.

This response, we believe, is inadequate. There is considerable empirical evidence that the current system for adjudicating medical malpractice fails on a number of levels. In a landmark study of 31 000 medical records of adult patients in New York in the 1980s, Brennan and colleagues[10] used independent reviewers to assess the relationship of malpractice allegations to true medical negligence. These researchers determined that the fit was approximately one in six either way—that is, only one in six allegations of malpractice was justified but, conversely, only one in six episodes of true malpractice was actually sued. Recently, this skeptical view was further buttressed when these authors followed a subset of cases through discovery and trial proceedings and determined that the likelihood of pay-out (not the extent of pay-out, but the likelihood) bore no relation to any identifiable negligent behavior and correlated only with the degree of disability of the plaintiff.[2]

Further, a recent survey of neonatologists revealed widespread disillusionment regarding both the quality of expert witnesses and the testimony they provided.[14] Almost as many expert witnesses were viewed as charlatans as well as true experts, and there was considerable dismay that the expert testimony itself was unaccountable to any demonstrable standard. These views were expressed equally by physicians who themselves had been sued and those who had not.

Our purpose in writing this article was to assert that the medical profession should adopt standards to promote higher quality expert testimony. It is important to emphasize at the outset that we are not attempting to settle issues of admissibility of expert testimony here. We cannot and do not speak to the issue of who should be an expert witness, or what testimony should or should not be admissible at trial. Admissibility issues may be current and controversial, but, in our view, are beyond the power of organized medicine to influence.

Nevertheless, we believe that some expert opinions can be viewed as better than others. That is, some opinions describe the standard of medical care correctly while other expert opinions are (to put it charitably) idiosyncratic, and fail to accurately depict the skill and care ordinarily administered in comparable situations. To most doctors this claim seems so obvious that they cannot conceive of it as a question. To most lawyers, however, this claim makes no sense at all; to them there is no such thing as better or worse expert testimony (except, of course, along the dimension of more or less persuasive). On this view, once testimony is admissible it is up to the jury to determine the dimension along which better or worse should be decided. Are these views irretrievably divergent?

First, let us recall how medical malpractice is defined and determined by the legal profession. Malpractice requires the existence of four separate aspects: 1) contract; 2) deviation (or negligence as it is sometimes referred); 3) injury; and 4) causality. Our emphasis here is entirely on the second requirement—what constitutes a deviation from the standard of medical care?

Although medical malpractice is defined on a state-by-state basis, in almost all jurisdictions a physician is obliged to use the skill and care ordinarily used in similar circumstances.[8,11] Further, except in rare instances (eg, leaving a sponge behind during an operation) lay juries are assumed to be unfamiliar with how physicians actually practice in similar (or not so similar) circumstances. Consequently, jurors must rely on the testimony of expert medical witnesses, who, in turn, are charged with describing the standard of medical care on the basis of their own knowledge and experience.

So far, it would appear, so good. But a huge body of literature from psychology and the social sciences suggests that recollections of individual experience are inevitably flawed, and flawed in a nonrandom direction. When asked about events in the past, people consistently underestimate large numbers, overestimate small numbers, and skew responses in favor of outcomes deemed, in retrospect, more appropriate or desirable (the Monday morning quarterback phenomenon).[6,7,9,17] Physicians are not immune to these memory flaws.[1]

As an example, consider expert opinions regarding the infant with meningitis. We surveyed potential experts in pediatric emergency medicine and pediatric infectious diseases regarding their own experiences with meningitis.[12] Specifically we asked what do you think is the median time from initial presentation in the emergency room (ER) to administration of IV antibiotics to a child with suspected meningitis? We then compared these expert opinions to reality—that is, we determined the actual distribution of times from ER presentation to antibiotic administration (AB-TIME) in 93 cases at two pediatric medical centers.

To the surprise of no psychologist, the opinions offered were wrong—that is, they did not conform to the available data. Moreover, the opinions were wrong in a predictable direction, slanted toward the outcome known to be desired (namely, a shorter elapsed time). Both the ER physicians (median estimated AB-TIME = 46 minutes) and the infectious disease (ID) physicians (median estimated AB-TIME = 80 minutes) significantly underestimated the actual median value of AB-TIME determined in our study population (120 minutes). The available literature on this question supplemented our empirical findings for 178 children in two previous studies where the median values of AB-TIME were 2.1 and 1.9 hours, respectively.[3,16]

As we have previously pointed out, from the judicial perspective potential flaws in expert testimony are assumed to be equally distributed among experts, and will be outed in the give and take of cross-examination. All admissible evidence is a priori of equal weight until a jury decides otherwise. The standard of medical care is created anew by expert testimony in each individual case, disappearing, like Brigadoon, upon resolution of the dispute.

But to a scientist (or, we suggest, to anyone with more than a modicum of common sense), this seems disturbing and irrational. To anyone but a lawyer, the standard of medical care must exist as something outside the courtroom testimony of experts, and if it does exist it should be easily described so that expert testimony can be more (or less) accurate in depicting it.

We contend that medical care is not a single behavior that conforms to or deviates from an idiosyncratic and retrospectively determined standard, but rather a distribution of behaviors in response to a variety of medical circumstances. For a given scenario, each of several possible responses can be ascribed a relative frequency based on empirical data, and the consequent normal curve can be taken to depict the totality of medical care. Substandard care then falls out neatly as a subset of behaviors lying outside the large majority of cases (The 5th percentile? The 1st percentile? Certainly not the 50th percentile). Juries would be empowered (as they are currently) to determine exactly where on this curve substandard care lies but at least the debate would share the same description of reality.

What problems might arise from adopting such a proactive definition of the standard of medical care? We can think of three. Some have objected on theoretical grounds that the problem is insoluble—that there is no single standard appropriate to all cases.[5] Whoever said there was? If, as might be claimed, university tertiary care emergency rooms set too high a standard (that is, too short an AB-TIME) for community hospitals to be held to, then gather a new set of data from community hospitals. Surely, we must admit that there are some standards to hold doctors to.

Next, admissibility of standard of care data is a real concern. Traditionally, only two kinds of facts are admitted into evidence in medical malpractice trials—the specific details of the allegation at hand (eg, the elapsed time from doctor visit to antibiotics was 2 hours for this child), and case-law precedents (eg, in Illinois care need not be excellent nor even average to be above the level of negligence). An intermediate level of facts (eg, data about time-to-administration of antibiotics in a series of similar, or even not so similar, cases) is usually admissible only insofar as expert witnesses import it (otherwise it is viewed as hearsay and consequently barred). Monahan and colleagues have recently invoked the construct of a social paradigm to argue for increased acceptance of this middle-level of fact.[15] Nevertheless, the prevailing view has been that verifiable data carry no special cachet as more or less reliable than idiosyncratic recollections by countervailing experts.

Recently, however, the US Supreme Court provided new guidelines regarding expert testimony. In *Daubert et ux v Merrell Dow*,[4] the Court restricted expert testimony to "scientific knowledge, and explicitly noted that scientific knowledge is based on

generating hypotheses and testing them to see if they can be falsified . . . " In this regard the Court declared that "the criterion of the scientific status of a theory is its falsifiability, or refutability, or testability."

We suggest that the Daubert decision provides a remarkable opportunity to expand the use of databases to resolve allegations of deviation from the standard of medical care. The testable/refutable hypothesis in negligence cases is almost always the same—did the behavior in question fall within or outside the distribution of medical care that is ordinarily used in similar cases? To answer this question, we propose a simple two-part test. First, determine the data-based distribution of standard medical care in similar circumstances. Next, superimpose this normative distribution on the care actually provided in the case at hand. The scientific method underlying this procedure is readily derived from any introductory primer of population statistics, and stands in stark contrast to the ad hoc methodology invariably associated with applications of undocumented, unreliable anecdotal recall of an individual expert's experience to the facts of a particular case.

A third possible objection to our formulation is methodologic—how many suits really turn on the kind of questions that a data-based standard of care can describe? Obviously, many quantifiable concepts are litigated – both time (eg, to antibiotic administration, to blood gas determination, to transport, etc) and number (eg, bilirubin value requiring exchange transfusion, P_{CO_2} requiring intubation, etc). However, in addition to numerical quantities, many behaviors also lend themselves to a data-based description of medical care (eg, use of home apnea monitoring after discharge from the neonatal intensive care unit, requirement to resuscitate extremely premature infants in the delivery room, obligation to perform lumbar puncture in febrile children without neurologic symptoms). For completeness, we note that not all malpractice disputes are resolvable by data-based standards—failure to diagnose and causality disputes remain, as best we can tell, beyond the power of this formulation.[13]

We close with one final, and to us puzzling, question. Why is this so hard? Why haven't people done this before? We offer two possible reasons that may account for some of the past reluctance to embrace our formulation of a proactive determination of a data-based standard of medical care.

First, lawyers hate it. Not just plaintiff's lawyers—defense lawyers as well. Indeed, it is a truism that defense lawyers are much more like plaintiff's lawyers than they are like doctors. Most lawyers have little to no training in data analysis, and are suspicious of the origin of all data sets (they are incredulous, almost postmodern in their skepticism that objective data are determinable in any, let alone most, situations). At the heart of this skepticism, we suggest, is a more fundamental conflict. The legal profession can scarcely afford to embrace a theoretical vision of a data-based standard of care in advance of a particular case. What if the next client's behavior falls well outside the standard of care distribution? Fiduciary responsibility to the client would then run squarely afoul of their theory.

Second, doctors hate it. More precisely, doctors distrust standards of any kind—imposed by third parties, inevitably distorting the doctor-patient dyad as it is romantically conceived. As one eminent pediatrician recently articulated, "each infant or child . . . is an individual problem and one which cannot be measured against others . . . there can be no standard care or standard of care that can cover all cases."[5] Nevertheless, if one thing is certain about the future (besides death, taxes, and more malpractice suits), it is that external standards are coming. There may not be one standard that covers all cases (indeed, it is naive to think there would be), but all cases will be (and, we believe, should be) covered by some standard—practice guidelines, critical paths, utilization reviews, and quality assurance committees all demand accountability to a database of empirically determined physician behaviors.

In sum, most pediatricians will be sued during their professional lifetime, most expert testimony will be woefully inadequate, and most jury judgments will be based on whimsy and debilitation, not negligence.[2,14] It behooves us as a profession, and as professionals, to face this problem more directly. To this end, we recommend the following:

The American Academy of Pediatrics should organize a database of the issues involved in pediatric malpractice lawsuits. Members should be encouraged to report their experience with alleged deviations to the Academy. Some issues would likely recur—such as lawsuits dealing with meningitis alleging a delay in therapy, or lawsuits in which extremely premature infants were not treated in the delivery room or were sent home without apnea monitors. When common themes were identified, the Academy could survey members, or better yet develop databases reflecting actual practice (as opposed to reports of practice). These data, when published, would then presumptively define the spectrum of standard medical care to be applied, wherever possible, against the specific facts of an alleged instance of medical negligence.

We recognize that this may be a challenge to and for the Academy. It is possible that the dominant view of the membership reflects the position that each case is unique and cannot be held accountable to some preemptively determined database. We view this position as hopeless. At present, in virtually all jurisdictions in the United States, jurors **are** instructed to evaluate claims of medical deviations against the standard of skill and care ordinarily used in similar cases.[11] The only difference is that the current standard is inevitably retrospective, anecdotal, and distorted. It is already true that behaviors that deviate greatly from the norm are vulnerable to allegations of negligence. We are simply proposing that the Academy take the lead and adopt a procedure to protect mainstream behaviors from being characterized as outliers.

We welcome comments and constructive criticisms.

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