



Statistics, Not Memories: What Was the Standard of Care for Administering Antenatal Steroids to Women in Preterm Labor between 1985 and 2000?

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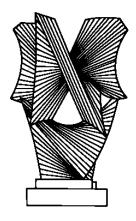
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Statistics, Not Memories: What Was the Standard of Care for Administering Antenatal Steroids to Women in Preterm Labor Between 1985 and 2000?

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We determined the frequency of antenatal corticosteroid use for mothers with threatened premature delivery in 1985, 1990, 1995, and 2000. We next compared published data to the surveyed recollections of 302 obstetricians who were practicing during these years. Two points emerged. First, published reports reveal that the use of antenatal corticosteroids increased steadily, from 8% in 1985 to 20% in 1990, 52% in 1995, and 75% in 2000 (P < .001). Second, "expert" opinions derived from the recollections of practicing obstetricians consistently overestimated the actual use of antenatal corticosteroids during the year in question-31% versus 8% for 1985, 56% versus 20% for 1990, 78% versus 52% for 1995, and 92% versus 72% for 2000 (all Ps < .001). The use of antenatal corticosteroids by obstetricians in the past 15 years reveals a phenomenon that is widely recognized elsewhere-retrospective memories are often wrong, and when they are wrong they are not randomly wrong. Rather, recollections are systematically skewed toward an outcome that, in hindsight, is considered desirable (the "Monday morning quarterback" phenomenon). We offer a simple proposal. In determining the "standard of medical care," the legal system should rely on statistical data about doctors' performance rather than the recollections of experts about doctors' performance. The fallible memories of isolated experts are a crude second-best, far inferior to the data that they approximate. Widespread adoption of this view by professional physician organizations would dramatically increase the rationality of expert testimony in medical malpractice tort law. (Obstet Gynecol 2003;102:356-62. © 2003 by The American College of Obstetricians and Gynecologists.)

Imagine this: In the early 1990s, a woman was admitted to an obstetric service in the early stages of labor at 28

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weeks' gestation. At the time of admission, her fetus was estimated to weigh 0.9 kg (2 lb). The likelihood of survival for an infant born at that gestation in the early 1990s was approximately 80%. However, the likelihood that the infant would exhibit respiratory distress syndrome (RDS) of prematurity after birth was also approximately 80%. There had been reports in the medical literature for more than a decade that administration of antenatal corticosteroids might reduce the incidence and severity of RDS in infants after birth. However, the indications and side effects of administering antenatal corticosteroids to mothers were not well understood. Some obstetricians used antenatal corticosteroids routinely in the early 1990s. Most did not. This woman's obstetrician did not.

The woman delivered the infant at 28 weeks' gestation, and it weighed 0.9 kg (2 lb). The infant was sick with RDS but did not die. It suffered long-term permanent morbidity related to the RDS. The obstetrician was sued for malpractice—specifically, for failing to administer antenatal corticosteroids to the mother before delivery.

At trial, the plaintiff's expert claimed that in the early 1990s it was the "standard of care" to administer antenatal corticosteroids, and that a failure to have administered them to this mother constituted medical negligence. This claim was based on the expert's experience and training in the field. A defense expert argued that only a minority of obstetricians were using antenatal corticosteroids in the early 1990s, and consequently the standard of care, which he took to be the use of "ordinary care in similar circumstances," did not require antenatal corticosteroids in this case. The defense expert buttressed his opinion by pointing to a large body of medical literature. Published articles described the experience of more than 30,000 women in the early 1990s who delivered comparably premature infants. The overall percentage receiving antenatal corticosteroids was 20%.

How should a juror decide which of these arguments is more persuasive? More precisely, how much weight should be given to statistical descriptions of medical practice versus anecdotal recollection of an expert's individual experience?

In most jurisdictions in the United States, jurors are instructed that a doctor must "use the skill and care that is ordinarily used by reasonably well-qualified doctors in similar cases.... A failure to do so is a form of negligence called malpractice." Moreover, except in unusually obvious circumstances (such as operating on the

wrong limb), lay jurors are not expected to understand what level of care physicians ordinarily provide and consequently are informed by the testimony of medical expert witnesses. Expert witnesses, in turn, are expected to describe the relevant standards of medical care by reflecting on their own professional experience.²

A problem immediately arises, although it is not usually recognized as such. No additional instructions are offered regarding the mechanism by which the expert is supposed to convert experience, knowledge, and training into an opinion. One might assume that the expert is being asked to recall what he or she and his or her reasonably well-qualified colleagues usually did in similar circumstances and testify accordingly. This seems obvious. However, there is much more to say. To begin with, a great deal of literature over several decades in many related areas of memory research suggests that anecdotal recollection of past experience is flawed.^{3,4} Moreover, anecdotal recall is not randomly wrongrather, it tends to be skewed in the direction that in hindsight would have been preferred. That is, once an outcome is known to have occurred, the predominant reaction is "I knew it all along." This is often called the "Monday morning quarterback" phenomenon. 5,6

Experts are not immune to such memory flaws. Even professional golfers misremember. In an extensive survey, golfers on average claimed that the percentage of 6-foot putts they made was 75%, but actual observation put the number significantly lower, at 55%. As another example, when emergency room physicians were asked how long it took them to diagnose and begin antibiotic treatment for children with suspected meningitis, they recalled 46 minutes. Actual observation found the number to be significantly longer, at 120 minutes.

These examples are not elicited to demonstrate that professional golfers or emergency room physicians are deliberately untruthful. Rather, selective skewed recall appears to be part of us all. We would all rewrite parts of history if we could, and in our minds, we cannot help doing it.

We have explored the Monday morning quarterback phenomenon in the context of administration of antenatal corticosteroids to women in preterm labor in the United States over the past 15 years. To do so, we first determined the actual use of antenatal corticosteroids at 5-year intervals between 1985 and 2000, as documented in reports from tens of thousands of patients in the medical literature. We then sampled the recollections of several hundred potential "expert witnesses": obstetricians who had been in clinical practice during the period in question. We compared the published data to the recollections of the obstetric specialists.

MATERIALS AND METHODS

Published Data on Antenatal Corticosteroid Use From 1985 Through 2000

To estimate the actual frequency of antenatal corticosteroid use, we searched MEDLINE and PubMed for the MeSH key word "antenatal corticosteroids." We then found and read each article that pertained to the incidence of antenatal corticosteroid use in human infants in 1985, 1990, 1995, and 2000 (Wright LL, Fanaroff AA, Poole WK, Carlo W, Vohr BR, Ehrenksang RA, Scott BJ, McDonald SA. Repeat courses of antenatal steroids: Risks and benefits [abstract]. Pediatr Res 2001;49:287A) (Narendran V, Donovan EF, Hoath SB, Warner BB, Steichen II, Jobe AH. Comparison between early bubble CPAP and conventional CPAP in reducing the incidence of chronic lung disease [abstract]. Pediatr Res 2002;51:337A). 9-24 In addition, a National Institutes of Health (NIH) conference on the use of antenatal corticosteroids convened in 1994 produced many articles that dealt directly and indirectly with antenatal corticosteroid use and contained numerous references to earlier studies. After 1994, several publications directly assessed the impact of the NIH consensus statement on increasing the use of antenatal corticosteroids. Finally, to assess recent antenatal corticosteroid use (around the year 2000) we could not rely on published literature, as much remains in press or under review. Consequently, we reviewed abstracts from pediatric academic societies and the Society of Maternal/Fetal Medicine.

We restricted our database to mothers for whom antenatal corticosteroids might appropriately have been prescribed. Consequently, we reviewed publications with one of two possible inclusion criteria: 1) prematurity or low birth weight—typically, very low birth weight (VLBW) infants (birth weight less than 1500 g)—where data were reported from population-based neonatal intensive care unit outcome studies, or 2) RDS—typically, mechanically ventilated infants—where data were derived from studies of the efficacy of surfactant administration.

"Expert Opinions" About Antenatal Corticosteroid Use From 1985 Through 2000

We had no way of determining which obstetricians had ever served as expert witnesses, nor were we interested in sampling just that subset. Rather, we were interested in demonstrating the phenomenon of hindsight bias for the field as a whole. Consequently, we obtained a list of all registered obstetricians in the United States from Ross Laboratories. The obstetricians were identified by city and state. We sent out two mailings of 500 surveys each to ten randomly selected obstetricians in each of the 50

Table 1. Publications Used to Document Antenatal Corticosteroid Use, 1985–2000

Documented year	No. of infants	% ACS	Inclusion criteria	Reference
1983–1985	3780	8.1	BW, RDS	14
1985	970	10	\mathbf{BW}	13
1989-1990	1533	34	BW, RDS	14-16
1988-1992	9949	19.2	$\mathbf{BW}^{'}$	17
1989-1990	3270	25.4	BW, RDS	14
1989-1990	11,077	13.9	RDŚ	12
1989-1991	915	19.7	BW, RDS	14
1990-1991	6425	22.4	BW	18-20
1989-1990	480	20	BW	13
1990-1991	356	27	BW	21
1994	3239	33	BW, RDS	22
1994-1995	279	46	BW	17
1994-1995	19,252	53.8	BW	24
1995	191	63	RDS	23
1999	26,007	72	BW	24
1998-2000	4047	74	BW	Wright*
1999-2001	399	78	RDS	Narendran [†]

ACS = antenatal corticosteroid; BW = birth weight 500–1500 g; RDS = respiratory distress syndrome requiring mechanical ventilation. A total of 92,169 infants were represented in these publications.

states. We received 153 responses from the first survey and 149 responses from the second survey.

The survey questionnaire described a hypothetic case of a woman presenting in early labor at approximately 28 weeks' gestation. The obstetricians were asked two questions regarding the use of antenatal corticosteroids for this woman:

- 1) What percentage of obstetricians do you think were using antenatal corticosteroids in such cases in 1985, 1990, 1995, and 2000?
- 2) Was it your personal practice to administer antenatal corticosteroids in such cases in 1985, 1990, 1995, and 2000?

Statistical Analyses

Two separate mailings were sent to obstetricians between July 2000 and June 2001. Responses regarding antenatal corticosteroid use from the first mailing were compared with those from the second mailing using both two-way analysis of variance, with year as the withingroup variable and mailing as the across-group variable, and comparison of proportions test, with correction for multiple comparisons. No significant differences were found comparing results from the first and second mailings. Consequently, data from the two mailings were combined.

Responses from the obstetricians regarding antenatal corticosteroids were then contrasted with data derived from the medical literature using two-way analysis of variance, z scores derived from the comparison of pro-

portions test, and χ^2 analysis.²⁵ Meta-analysis of the multiple published descriptions of antenatal corticosteroid use during each period was performed using the number of patients involved, not the number of hospitals or publications. For all tests, an α level of P < .01 was required to assume statistical significance.

RESULTS

Table 1 shows antenatal corticosteroid use in 1985, 1990, 1995, and 2000, as determined from case reports of 92,169 infants in the medical literature. Figure 1 contrasts the use of antenatal corticosteroids as reported in the medical literature with the compiled recollections of 302 "expert" obstetrician respondents to our questionnaire. Two points are readily apparent. First, published reports revealed that the use of antenatal corticosteroids increased steadily, from 8% in 1985 to 20% in 1990, 52% in 1995, and 75% in 2000 (P < .001). Second, expert opinions derived from the recollections of practicing obstetricians consistently overestimated the actual use of antenatal corticosteroids during every year in question: 31% versus 8% for 1985, 56% versus 20% for 1990, 78% versus 52% for 1995, and 92% versus 72% for 2000 (all $P_{\rm S} < .001$).

In addition to consistently overestimating their colleagues' use of antenatal corticosteroids from 1985 to 2000, the obstetrician respondents consistently ranked their personal use higher than their estimates of the average behavior at the time: 68% versus 31% in 1985,

^{*}Wright LL, Fanaroff AA, Poole WK, et al. Repeat courses of antenatal steroids: Risks and benefits [abstract]. Pediatr Res 2001;49:287A.

†Narendran V, Donovan EF, Hoath SB, Warner BB, Steichen JJ, Jobe AH. Comparison between early bubble CPAP and conventional CPAP in reducing the incidence of chronic lung disease [abstract]. Pediatr Res 2002;51:337A.

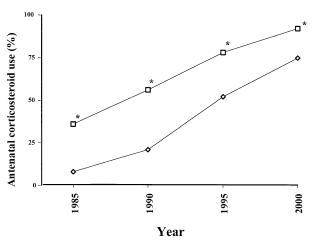


Figure 1. The use of antenatal corticosteroids (derived from cases reported in the medical literature) compared with expert opinions about the use of antenatal corticosteroids (derived from responses to our survey questionnaire) at 5-year intervals between 1985 and 2000. For 1985, 4750 reported infants and 235 responding obstetricians are compared. For 1990, 34,005 infants and 260 obstetricians are compared. For 1995, 22,961 infants and 274 obstetrician responses are compared. For 2000, 30,453 infants and 299 obstetricians are compared. The literature database is more fully elaborated in Table 1. "Expert" opinions derived from the recollections of practicing obstetricians consistently overestimated the actual use of antenatal corticosteroids during every year in question: 31% vs 8% for 1985, 56% vs 20% for 1990, 78% vs 52% for 1995, and 92% vs 72% for 2000 (*P < .001). Obstetricians recollections (squares); published data (diamonds) Meadow. Statistics, Not Memories. Obstet Gynecol 2003.

88% versus 56% in 1990, 99% versus 78% in 1995, and 100% versus 92% in 2000 (all Ps < .01).

DISCUSSION

We demonstrate a phenomenon that is widely recognized elsewhere: Retrospective memories are often wrong, and when they are wrong they are not randomly wrong. Rather, recollections are systematically skewed toward an outcome that, in hindsight, is considered desirable.

Over the past 15 years it has become widely accepted that antenatal corticosteroid administration to women in preterm labor significantly reduces complications in prematurely delivered infants. ^{9–12} Antenatal corticosteroid use has risen roughly ten-fold, from 8% to 75% for prematurely delivered infants during this period. Consequently, viewed retrospectively from the vantage point of 2001, antenatal corticosteroid use for women in preterm labor at 28 weeks' gestation has always been desir-

able. As we hypothesized, the recollections of 302 obstetricians surveyed in 2001 about the use of antenatal corticosteroids for preterm labor in the past 15 years were wrong and predictably skewed. Obstetricians recalled antenatal corticosteroid use to have been greater than it demonstrably was at each 5-year interval between 1985 and 2000.

To the extent that obstetricians like the ones in our survey might serve as expert witnesses in antenatal corticosteroid cases, testifying about ordinary care in similar circumstances based upon their recollection of their own personal experience, they are likely to be wrong. What do such discrepancies between recollections of expert practitioners and objective documentation of medical practice imply for expert testimony in cases of alleged medical negligence?

Personal Knowledge and Statistical Knowledge

A substantial body of evidence on the psychology of decision making documents systematic biases in the anecdotal recall of experience. People are excessively optimistic about what can happen or has happened; at the same time, they are overconfident about the accuracy of their memories. Medical experts are not immune from this phenomenon. Moreover, and perhaps most importantly from the standpoint of malpractice testimony, people reliably suffer from hindsight bias. Once an outcome is known to have occurred, the predominant reaction is "I knew it all along." Excessive optimism and skewed recall about past practices appear to be human nature. This point raises some serious problems for adjudication of negligence allegations.

A central purpose of medical malpractice law is to protect the general public by ensuring that physicians provide reasonable care. Reasonable care is determined, at least in part, by asking about ordinary practice. If descriptions of ordinary practice are important to the judicial process, why should jurors and judges rely on the fallible and anecdotedriven recollection of an individual expert's experience, especially if we know that this recollection is likely to be wrong? Instead, why not inform jurors and judges of the verified and reverifiable collective experience of dozens, hundreds, or even thousands of cases reported by comparably expert physicians? Citations of practice distributions derived from published medical literature could provide a necessary buffer for jurors specifically and the public more generally against the inevitable possibility that an individual expert's memory is faulty.

Methodological Concerns With Reliance on Databases

Several methodological concerns must be addressed directly. Most reflect difficulties traditionally associated with meta-analysis of the efficacy of medical procedures. Comparisons across and within studies of different size may be difficult to describe succinctly. How is one to balance a small study from a single center with a large study from multiple centers? As an example from the antenatal corticosteroid analysis, in 1990 14% of 11,077 infants reported from 446 centers in the Exosurf Neonatal Treatment Investigational New Drug Program received antenatal corticosteroids,12 compared with 20% of 480 infants reported from a single center by Teberg et al. 13 Should we consider the number of studies or the number of patients within studies? Further, single publications that report data from multiple centers often describe a wide spectrum of behavior around a mean value. As an example, the use of antenatal corticosteroids among the 30 reporting centers of the Vermont-Oxford Trials Network in 1990 ranged from 0% to 58%.¹⁸ Finally, inclusion criteria may differ across studies. Consider in the context of antenatal corticosteroids whether a hypothetic published article included or excluded mothers with premature rupture of membranes, pregnancies above 32 gestational weeks, pregnancies below 26 gestational weeks, or twins. Each of these conditions has, at times, been argued to be a contraindication for administration of antenatal corticosteroids.9-11

There are two related questions here, one narrow and one broad. Narrowly, how can we deal with published data in the context of the standard of care for antenatal corticosteroids? More generally, given the recognition that published studies will always have overlapping but nonidentical inclusion criteria and that they will inevitably invoke an interval of uncertainty around every point estimate, how can statistical analysis ever determine the standard of care for a single case?

In the specific instance of antenatal corticosteroids, one might proceed as follows: Our survey was deliberately designed to ask obstetricians about behavior in a single "idealized" case, analogous to the opinion an expert witness would be asked to provide in a single case of alleged negligence. Published data are, inevitably, more messy. Even when antenatal corticosteroid use is intended in all cases, we must assume there will be some "slippage," such as mothers who for one reason or another did not receive antenatal corticosteroids even though the doctors intended them to do so. Consequently, the actual use of antenatal corticosteroids will always be a bit lower than the intended use. How can we account for this slippage in our data-based formulation of standard medical care?

We might start by assuming that by the year 2000 almost all obstetricians wanted to use antenatal corticosteroids in idealized cases of women threatening preterm delivery. We then can look to see how close the obste-

tricians came to that ideal and note that the answer is "quite close." In 2000, approximately 75% of 30,000 mothers who delivered VLBW infants received antenatal corticosteroids (cf Figure 1 and Table 1). This, then, can be taken as a "ceiling" against which other comparisons can be measured. As an example, in 1990, 20% of all VLBW infants actually received antenatal corticosteroids, compared with a theoretic ceiling of 75% who might have received antenatal corticosteroids. Consequently, the "adjusted" antenatal corticosteroid use in idealized circumstances in 1990 was approximately 20 of 75 (27%). Even after adjustment for slippage, this value is significantly lower than the 56% that our obstetricians recalled for antenatal corticosteroid use in 1990. For every time interval studied, even after adjusting published reports of antenatal corticosteroid use to account for the potential of nonideal cases, "expert recollection" still significantly overestimated adjusted antenatal corticosteroid use.

There is a larger claim here. Meta-analysis has become widely accepted in modern medicine. Indeed, it has become essential to the growth of evidence-based medical care in obstetrics and elsewhere. However, meta-analysis is complicated. One possible response to these complexities might be to argue that statistical analysis is just too hard for judges, lawyers, and juries to understand. If this is true, then attempts to import data into the courtroom are doomed. In such a postmodern legal world, the scientific method would be abandoned and only anecdotal narrative would survive.

There is another response, which we favor. We welcome methodological complexities and encourage their elucidation enthusiastically. With this view, the more light shone upon the meaning of data and the difficulties of importing it the better, precisely because accuracy is what is most important. Whatever difficulties might arise in importing statistical methodology into the courtroom, these problems pale against the alternative: relying on the memories of individual experts, where none of the methodological rigor required for scientific analysis is applied, or even acknowledged, and where the recollections are almost certain to be inaccurate.

Ordinary Practice and the Standard of Medical Care

Is standard medical care always the standard of medical care? That is, are physicians obliged to administer the care that is "ordinarily provided in the same or similar circumstances," or are physicians obliged to conform to a more aspirational standard, "the care that *should* be provided in such circumstances"? In other words, does customary practice determine negligence?

There is a dispute about the weight to be given to ordinary practice in medical negligence cases. In some jurisdictions, custom defines reasonable conduct. 32-40 However, in other jurisdictions, both federal and state, 42-45 a more aspirational standard is applied (not what physicians ordinarily do, but what a reasonable physician should have done), and customary medical treatment is not decisive on the exercise of standard care. In these latter jurisdictions, do statistical compilations of normative practice become irrelevant to expert testimony regarding the standard of care?

The answer is "No." Even when ordinary practice is not controlling, it is always relevant, and when it is relevant, juries and judges should learn what it actually is. Moreover, in their attempts to influence judge and jury, experts ought to distinguish exhortation from normative description. As an example, consider expert testimony in the context of an allegation concerning whether use of antenatal corticosteroids for a woman in preterm labor in the early 1990s was part of the ordinary standard of care. One can envision an expert obstetric witness saying that one should have given antenatal corticosteroids to this woman or even that he or she would have given antenatal corticosteroids (although, intriguingly, our data suggest that even these memories are flawed). However, under no circumstances could an expert accurately claim that administration of antenatal corticosteroids in the early 1990s conformed to ordinary care in similar circumstances. That point is sufficient for our purposes here. If legal authorities want to depart from the standard of ordinary care, they should do so with an accurate rather than fanciful understanding of what ordinary care is (cf Meadow 46,47).

There can be no doubt that experts know a great deal about topics on which ordinary people lack information. But experts, no less than other people, are subject to predictable memory biases. As a specific example, we have shown that a majority of obstetricians "recalled" antenatal corticosteroid use to be common in the early 1990s, but the best available data suggest that only a small minority of obstetricians were actually using antenatal corticosteroids during this time.

We offer a simple proposal. In determining the standard of medical care, the legal system should rely, whenever it can and far more than it now does, on statistical data about doctors' performance rather than the opinions of experts about doctors' performance. The fallible memories of isolated experts would be seen as a kind of crude second-best, far inferior to the data that they approximate. Widespread adoption of this view by professional physician organizations, supplemented by anticipatory publication of practice distributions for potentially problematic clinical scenarios, would dramatically increase the sense and rationality of expert testimony in medical malpractice tort law.

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