The Potential Role of Diabetes Guidelines in the Reduction of Medical Injury and Malpractice Claims Involving Diabetes

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Little is known about the nature of the medical injuries that give rise to malpractice claims. Also little is known about the degree to which clinical practice guidelines would apply to the medical conditions and associated medical treatment in malpractice claims.

As a first step in getting a better understanding of the epidemiology of malpractice with respect to diabetes and the potential relationship between medical injury and guidelines, we examined all Indiana medical malpractice claims involving plaintiffs with a primary or secondary diagnosis of diabetes. These claims were filed and closed in Indiana between July 1975 and December 31, 1988.

Data for this study came from the Indiana Malpractice Claims Data Base obtained from all Indiana malpractice claims filed with the Indiana Department of Insurance from 1975 through 1988 (1). Data on allegations of negligence and severity of injury were coded according to national scales (2–3). Diagnoses and injuries, derived from hospital records to the extent available in the claim file, were coded by a medical records administrator according to the International Classification of Disease (9th Revision) classification scheme (4). Data on physicians came from published data of the American Medical Association (5).

We compared the medical injuries in those claims to conditions that gave rise to one set of guidelines to see the extent to which, if at all, the guidelines would have applied to the medical situations and, if so, whether following the guidelines could have potentially influenced the outcome in the case by avoiding the medical injury that gave rise to the claim.

We selected the *Guide to the Prevention and Treatment of the Five Complications of Diabetes* (6) published by the National Diabetes Advisory Board in 1983. We selected this guide as a means of organizing our analysis because it is the oldest set of guidelines that is specifically directed to primary-care practitioners who care for most patients with diabetes. Thus, this guide might have been available for some of the practitioners involved in the Indiana claims. We have no information about whether this guide or any other guideline was used by the practitioners in providing the care or in the adjudication of malpractice liability. We suspect that, given the guide's 1983 publication date, it was not used in this manner. The only question we asked was whether these guidelines, had they been in place and within knowledge of the defendants, could have influenced the outcome of the treatment episode that gave rise to the claim.

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Epidemiology of claims involving diabetes

The most interesting finding about the character of malpractice claims involving diabetes in the relevant period is that the number of such claims is surprisingly small, particularly when compared with the number of encounters between physicians and diabetes patients each year. Of the 2,074 closed claims filed in the 12-year period from after July 1975 and closed before 31 December 1988, only 35 involved claimants who had diabetes as either a primary or secondary diagnosis (Table 1).

The number of physician-patient encounters in which malpractice claims involving diabetes arose is infinitesimal compared with the total number of physician-patient encounters for the treatment of diabetes in Indiana between 1975 and December 1988. There were 33 million outpatient encounters and 28.4 million hospital days for the 5.5 million individuals with diabetes in the U.S. during 1980, the last year of available data (7). Because Indiana's population comprises 2.5% of the national population, it can be estimated that there were 825,000 annual outpatient visits and 710,000 annual inpatient days in Indiana during the study period.

Guide-related claims

Of the 35 diabetes-related claims, 14 involved the five complications of diabetes covered by the medical practice guidelines in the guide (40%). Of these 14 claims, 8 were paid. These 14 claims involved 8 physicians (2 osteopathic and 6 allopathic) and 2 nonphysician health professionals. Most claims were settled

Table 1—*Analysis and disposition of closed Indiana malpractice claims involving diabetes 1975–1988*

Claim number	Claimant Age	Claimant Sex	Date of injury	Date claim closed	Allegation of negligence	Initial injury	Final injury
Guide-related claims							
Amputations to lower extremities							
1	60–64	F	1984	1986	Improper trimming of callus	Infection	Below knee amputation
2	50–59	M	1978	1981	Failure to treat	Infection	Amputation
3	—	M	1981	1982	Negligent Rx	Infection	Below knee amputation
4	65+	M	1981	1982	Negligent Rx	Infection	Toe amputation
5	65+	F	1978	1982	Negligent Rx (swollen toe)	Infection	Below knee amputation
Blindness							
6	50–59	F	1984	1985	Negligent laser Rx	Destroyed macular: eye	Blindness
7	18–29	M	1984	1987	Failure to Dx diabetic retinopathy	Blindness	Blindness
8	—	M	1978	1982	Failure to Dx glaucoma	Unspecified visual field	Blindness
9	—	M	1978	1981	Negligent surgery of retinal bleed	Blindness in one eye	Blindness
10	—	F	1977	1988	Failure to Dx diabetic retinopathy	Retinopathy	Blindness
11	—	M	1980	1987	Failure to Dx diabetes	Retinopathy	Blindness
Fetal death							
12	Birth	F	1983	1988	Failure to Dx gestational diabetes	Fetal death	Fetal death
Diabetic ketoacidosis							
13	30–39	F	1977	1982	Failure to Dx	Ketoacidosis	Death
14	1–17	F	1980	1983	Failure to Dx	Ketoacidosis	Renal failure
Kidney disease							
No claims							
Non-guide-related claims							
Medical treatment caused diabetes							
15	—	F	1984	1988	Failure to remove tampon	Toxic Shock Syndrome	IDDM
16	30–39	M	1975	1983	Steroids for disc disease	Diabetes	Diabetes
34	—	M	1983	1978	Negligent care of unconscious patient	Death	Death
35	—	F	1985	1987	Negligent care	Fall	Trauma to multiple areas

From the Indiana Malpractice Claims Data Base, The Center for Law and Health, Indiana University School of Law, Indianapolis, Indiana.

Table 1—*Continued*

Severity of injury	Payment ($)	Defendant specialty	Claim paid	Panel decision
6	257,500	Podiatry	Yes	None
		Family practice	Yes	None
6	10,000	General practice	Yes	None
6	40,000	General practice	Yes	None
5	None	Podiatry	No	None
6	5,950	General practice	Yest	None
		Emergency medicine	Yes	None
		Hospital	Yes	None
6	310,000	Ophthalmology	Yes	None
7	500,000	Internal medicine	Yes	Malpractice
		Hospital	No	None
5	4,500	Optometry	Yes	None
6	None	Ophthalmology	No	None
7	None	Optometry	No	None
6	None	Osteopathy	No	No Malpractice
		Osteopathy	No	No Malpractice
		Osteopathy	No	No Malpractice
		Corporation	No	No Malpractice
9	None	General practice	No	None
9	None	Other surgery	No	None
5	18,000	General surgery	Yes	None
		Hospital	Yes	None
6	205,585	Hospital	Yes	Malpractice
5	2,000	Orthopedic surgery	Yes	None
		Hospital	Yes	None
		Hospital	Yes	None
9	None	General practice	No	None
		Hospital	No	None
4	18,500	Hospital	Yes	None

without adjudication by either a medical review panel or a court. When panels of physician peers adjudicated liability, their decisions were, with one exception, observed in the final disposition of the claim.

The allegations of negligence in the paid claims were that basic errors in diagnosis or treatment occurred. In each amputation claim, a primary-care practitioner was involved who allegedly neglected to take the basic care of feet at risk, and the lack of such care then resulted in infection and subsequent loss of a limb (Table 1). It could be reasonably argued that following the basic standards in the guide might have prevented both the medical injuries and lawsuits in these 5 claims.

In the 6 cases involving blindness, the allegations of negligence again were errors of a basic nature (Table 1). The one paid claim involving an ophthalmologist was a misadventure with laser therapy. In the 3 claims involving the missed diagnosis of diabetic retinopathy, the blindness and subsequent suit might have been prevented by following the screening standards in the guide. In the claim involving the missed diagnosis of diabetic retinopathy by an internist, a medical review panel concluded that the resulting injury was caused by malpractice. Yet, the claims involving a missed diagnosis of diabetic retinopathy by the optometrist and osteopath were not paid, which suggested a different standard was applied to these practitioners. Nevertheless, in all claims, presumably the injury, e.g., blindness, may well have been avoided by adherence to the guide irrespective of the professional specialty of the defendant or the facts of the individual cases. The final blindness claim involved an optometrist's missing a case of glaucoma. Whereas this situation falls outside the standards in the guide, several publications have recommended screening for glaucoma as part of a routine physical examination that, if followed, might have prevented this case (e.g., 16).

The standards presented in the guide are most detailed for the detection and treatment of diabetes and pregnancy. In spite of specific recommendations that all patients be screened for gestational diabetes mellitus, the one case alleging fetal death because of a missed diagnosis of gestational diabetes mellitus was surprisingly not paid (Table 1). One could again argue that had the standards been followed, fetal death and the malpractice suit both might have been prevented.

The failure to diagnose diabetes resulted in 2 claims, only one of which was paid even though the unpaid case resulted in the patient's death (Table 1). Application of the standards to the claims might have resulted in both claims being paid because the standard recommends that all patients in emergency room settings with symptoms that could be related to a diabetic coma be screened for diabetes.

Non-guide-related claims

Of the 35 diabetes-related claims, 21 did not involve complications of diabetes covered by the medical practice guidelines in the guide (60%) or medical practice guidelines developed subsequently (8–14). These cases generally involved allegations of negligent care in which diabetes was only incidental, e.g., falls or failure to diagnose the underlying condition. In 3 cases the injury was the result of hypoglycemia that contributed to the patients' deaths. These cases suggest that closer in-hospital bedside glucose monitoring of blood glucose, which has become routine in most hospitals, has the potential to reduce these injuries.

Taken together, the data presented suggest that basic errors in diagnosis and treatment resulting in significant disability or death underlie malpractice suits. Indeed, the basic nature of the errors and injuries alleged in the claims suggest that developing more rudimentary guidelines addressed at avoiding basic errors of care might be desirable. Such guidelines would be along the lines of those developed by Harvard University Medical Center for the administration of anesthesia during surgery, made specifically to reduce malpractice liability (15).

The data presented also suggest that following the standards for screening and treatment for eye or pregnancy complications and those for diagnosis and aggressive treatment of foot lesions contained in the guide would have reduced both the medical injury to patients and the number of suits. In 12 of 14 guide-related claims, failure to adhere to the standards in the guide would appear to have been involved in the resultant injury. In 1 of the 2 remaining claims, failure to screen for glaucoma was involved. In only one guide-related case, a medical misadventure resulted in the primary injury. The findings appear to have particular relevance to the primary-care practitioners who made up the great majority of both defendants and contributors to payment in the guide-related claims.

Finally, the data presented suggest that, in addition to the quality of care issues raised previously, virtually all malpractice claims related to the five complications contained in the guide resulted from an alleged failure by primary-care practitioners to comport with these published standards in screening and treatment of diabetes and its complications. Research showing that practitioners do not universally adhere to standards of care for their patients with diabetes and other conditions has caused concern in the medical community as it relates to the quality of medical care (17–21).

Conclusions

In our judgment, the data presented argue for continued development and promulgation of medical practice guidelines and standards of care. The small number of claims involving diabetes suggest that the risk of increased exposure to malpractice liability for physicians with the promulgation of medical practice guide-

lines for the care and treatment of diabetes is not serious and certainly does not justify the discontinuation of standard setting endeavors (22).

The data also suggest that explicit standards such as those contained in the guide, which are directed toward primary-care practitioners and focus on screening and treatment of common complications of diabetes, have considerable potential for reducing injury and malpractice claims. Of the 35 claims involving diabetes, 40% (14 cases) involved complications included in the guide. Of these 14 cases, 12 appear to involve injuries that were potentially preventable by adherence to the recommendations included in the guide.

The non-guide-related claims also present an opportunity where guidelines might be developed to improve bedside monitoring of blood glucose. As noted above, the promulgation of simple, minimalist standards for the administration of anesthesia during surgery has worked to reduce malpractice liability and malpractice insurance premiums among anesthesiologists (16).

In summary, we conclude that the medical community's widespread adoption of simple preventive standards has great potential for the reduction of patient injury and malpractice litigation, and the fear that such standards may increase malpractice litigation or be used inappropriately in the adjudication of malpractice claims is not supported by these data.

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