Informed Consent: Disclosure of Risks

Question: Regarding physician liability arising from medication injuries, which of the following is most accurate?

A. Doctor is liable if drug was prescribed for unapproved off-label use.
B. Doctor is liable for failing to warn for risk of serious side effects.
C. Doctor is liable for failing to warn of all complications.
D. Patient did not ask about side effects and therefore was contributorily negligent.
E. Liability will attach to manufacturer for a “defective product.”

Answer: B. The informed consent doctrine requires that physicians discuss all material risks, including rare but serious risks. Choice A is incorrect because prescribing a drug for an “off-label” use may be an acceptable practice. However, it is prudent for the doctor to document the reasons for using the drug. Choice C is overly broad. A warning is required for all material risks, even if rare. Those risks are important to discuss when deciding to accept or reject the recommended treatment, but a warning is not necessary for all risks. Patients are assumed to have little or no knowledge of medications, and they have no legal duty to inquire about side effects. The doctor, on the other hand, has an affirmative duty to warn of these side effects. In a malpractice case alleging lack of informed consent due to failure to warn, the defense cannot plead contributory negligence, so choice D is incorrect. Finally, E is also incorrect. The “learned intermediary” doctrine stipulates that the doctor, not the pharmaceutical company, is liable for medication-related injuries as he/she is a learned professional who directly communicates with the patient and who does the actual prescribing. This puts the doctor in the hot seat for an adverse drug reaction, even though the doctor has frequently been negligent in identifying and/or communicating the risk.

Disclosure of Material Risks

In order for patients to meaningfully give their consent to treatment, they should have sufficient information regarding the doctor’s treatment plans. The consent must also be given voluntarily. The notion of patient autonomy is so entrenched that the law imposes upon the practitioner the duty to disclose these fundamental aspects of treatment, even reasonably remembered by the mnemonic PAR (P = procedure, R = risks). The patient should be informed of all serious risks, even if unusual or rare. However, in one court case, a 1% risk of hearing loss required disclosure (Scott v. Wilson, 396 S.W.2d 532 [Tex. Civ. App. 1965]), whereas in another, the court appeared to say that a 1.5% chance of visual loss did not (Yates v. Harms, 393 P.2d 982 [Kan. 1964]). The California Supreme Court has stated that “material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient’s position when deciding to accept or reject the recommended medical procedure,” that “a (material) fact must also be one which is reasonably appreciated,” and that the scope of disclosure may be expanded in patients with “unique concerns or lack of familiarity with medical procedures” (Truman v. Thomas, 27 Cal.3d 285 [1980]). There is, however, no legal requirement to deliver a “mini-course in medical science” (Cobb v. Grant, 8 Cal.3d 229 [1972]).

Inaccurate Methods Often Used for Physician Cost Profiling

BY MARY ANN MOON

Current methods for profiling individual physicians as to whether they provide low-cost or high-cost care are often inaccurate and produce misleading results, according to a report. Health plans use cost profiling to limit how many physicians get in-network contracts and to allot bonuses to the physicians whose “resource use” is lower than average. In each case, there must be a method for determining physicians’ costs, yet the accuracy of these methods has never been proved, according to John L. Adams, Ph.D., of RAND Corp., and his colleagues.

“To our knowledge, the reliability of physician cost profiling has not been previously addressed,” they noted.

Dr. Adams and his colleagues assessed the reliability of current methods of cost profiling using claims data from four Massachusetts insurance companies concerning 1.1 million adult patients treated during 2004-2005. A total of 12,789 physicians were included in the study. They were predominantly men who were board certified, had been trained in the United States, and had been in practice for more than 10 years. The physicians worked in 28 specialties, including cardiology, endocrinology, gastroenterology, and urology. Family physicians, general practitioners, and internal medicine physicians comprised approximately one-third of the sample.

The investigators estimated the reliability of cost profiles on a scale of 0-1, with 0 representing completely unreliable profiles and 1 representing completely reliable profiles. They then estimated the proportion of physicians in each specialty whose cost performance would be calculated inaccurately. Overall, only 41% of physicians across all specialties had cost profile scores of 0.70 or greater, a commonly used threshold of acceptable accuracy. Only approximately 47% of internists, 30% of cardiologists, 41% of family or general physicians, 57% of OB-GYNs, 59% of gastroenterologists, and 22% of endocrinologists were classified as “lower-cost” physicians when they were not.

Also, 22% of internists were misclassified as “higher-cost” when they were not in fact high-cost physicians. This same misclassification occurred for 14% of cardiologists, 16% of family or general physicians, 10% of OB-GYNs, 11% of gastroenterologists, and 19% of endocrinologists. These findings indicate that standard methods of cost profiling are highly unreliable, and that many individuals and groups are basing important decisions on inaccuracies. “Consumers, physicians, and purchasers are all at risk of being misled by the results produced by these tools,” the investigators concluded (N. Engl. J. Med. 2010;362:1014-21).

The study findings also suggest that using cost profiles that are based on these unreliable methods will not reduce health care spending, they added.

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Antidepressants increased the risk compared to placebo of clinically significant and clinically relevant (including triptans), with drugs that impair metabolism of serotonin (including MAOIs), or with new symptoms that include dizziness, nausea, or severe renal impairment or ESRD. The doses should not be escalated in patients with moderate or severe including the following: dysphoric mood, irritability, agitation, dizziness, further clinical studies, mania was reported for approximately 0.1% of patients treated with Pristiq. Activation manic symptoms, such as, psychic activation, hypomania, or other mania-related symptoms, or any detectable use conditions. Subsequently, the physician may continue decreasing the dose, but at a more gradual rate [see Dosage and Administration (2.4) and Warnings and Precautions (5.9) in full prescribing information]. Discontinuation of Pristiq should be considered in patients at risk for activation, such as those with history of bipolar disorder. Suicidality and Antidepressant Drugs–Adverse Reactions–Clinical Experience– In controlled trials of adults with major depressive disorder (MDD), greater than or equal to 16 years of age, treated with Pristiq who present with progressive dyspnea, cough, or chest discomfort. Such patients should be evaluated and considered for appropriate therapy and management. Reduced plasma desvenlafaxine levels were observed in patients taking monoamine oxidase inhibitors (MAOIs) concomitantly with Pristiq. The most common adverse reactions reported for patients with Pristiq who present with progressive dyspnea, cough, or chest discomfort. Such patients may be at increased risk of developing new symptoms that include dizziness, nausea, or severe renal impairment or ESRD. The doses should not be escalated in patients with moderate or severe

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complications. The jury found that Dr. Schecter did not disclose to Ms. Warren all the risks associated with the procedure and failed to enable her to make an informed decision regarding surgery and that a reasonably prudent person in her position would not have consented to surgery if adequately informed of all the significant risks.

Other Aspects of Disclosure

Besides risks associated with a surgery and a medication, courts have also looked at other aspects of disclosure in the doctor-patient relationship.

Some litigated examples include disclosing the limited expertise of a neurosurgeon (Johnson v. Kokemus, 543 N.W.2d 495 [Wisc. 1996]), failure to disclose the duty of fiduciary responsibility (Moore v. The Regents of the University of California, 792 P.2d 479 [Cal. 1990]), and a surgeon’s disclosure of his positive HIV status (State of Behringer v. The Medical Center at Princeton, 192 A.2d 1231 [N.J. Super. 1991]) or a cardiologist’s disclosure of his terminal illness (Kolb v. Avent, 1192 [La.App. 1991]). However, in Arato v. Avent, the California Supreme Court held that the law did not require physicians to inform their terminal ill patients of their prognosis and life expectancy (Arato v. Aven, 888 P2d 598 [Cal. 1993]). An example of statutory law regarding disclosure is found in states that have adopted the Uniform Health Care Disclosure Act (see States §671-3. Amended by the 2003 legislature, the statute mandates disclosure of “recognized material risks of serious complications or mortality” but does not define the word “material.” This amended language replaced the earlier version which advised “malpracticed, serious adverse drug reactions, risks, complications and anticipated benefits,” arguably lightening the doctor’s duty regarding risk disclosure. In reality, the new language is unlikely to have a significant practical effect. An earlier 1976 version of the law merely required the disclosure of “probable risks and effects.”

Dr. Tan is professor of medicine and former adjunct professor of law at the University of Hawaii, Honolulu. This article is meant to be educational and does not constitute medical, ethical, or legal advice. It is adapted from the author’s book, “Managing the Risk: A Guide to Disclosure in the Medical Office” (2006). For additional information, readers may contact the author at siang@hawaii.edu.