LAW & MEDICINE

Informed Consent: Exceptions to Disclosure

Question: An unconscious man is brought to an emergency department in vascular collapse. He had been thrown off a motorcycle and ruptured his spleen. The surgeon recommended emergency surgery and blood transfusion, but no next of kin was readily available to give consent. An old wrinkled card in his wallet indicates the patient is a Jehovah's Witness and should never receive blood, but there is a diagonal line drawn across that part of the card. Which of the following is best?

BY S.Y. TAN, M.D., J.D.

A. All interventions require informed consent, so in this case the surgeon should not operate.

B. Because this is an emergency, no consent for operation or blood transfusion is necessary, as long as you get two supporting doctor signatures.

C. If the man's spouse can be located and she gives consent for transfusion, then it's okay.

D. Operate on the patient, but respect his disavowal of blood even if it means death.

E. If the patient desperately needs a lifesaving blood transfusion, it should be given, because his wishes are not entirely clear.

Answer: E. Some of the other choices have merit, but the best answer is E. This is because of the dire nature of the patient's condition, the critical and immediate need for blood, and most of all, the reasonable belief that the line across the wrinkled card represents a revocation of an earlier refusal of blood. Some may view D as the better option, and it is arguably the legally "safe" approach. However, a life hangs in the balance, and a doctor's first duty is to the patient.

Exceptions to Informed Consent

Under some circumstances, informed consent may be neither possible nor necessary. Statutory provisions that protect public health and safety may mandate quarantine, examination, treatment of a patient, or referral of a death to a coroner without requiring patient or family consent. The following are legitimate exceptions to the informed consent requirement:

► **Emergencies:** The guiding principle is whether delay in treatment in order to obtain consent would result in harm to the patient. The procedure need not be lifesaving, as long as the potential harm to the patient is significant. This exception is typically provided for in state statutes on informed consent, such as this one from Hawaii: "Nothing in this section shall require informed consent from a patient or a patient's guardian when emergency treatment or an emergency surgical procedure is rendered by a health care provider and the obtaining of consent is not reasonably feasible under the circumstances without adversely affecting the condition of the patient's health" (Hawaii Revised Statutes §671-3 [d]).

► **Unanticipated conditions during surgery:** This is a narrowly construed exception and comes into play when a surgeon encounters an unanticipated abnormality within the field of surgery. It is called the "extension doctrine," and it assumes that the surgeon is using reasonable judgment. Thus, a surgeon incurred no liability for draining some ovarian cysts during the course of an appendectomy (*Kennedy v. Parrott,* 90 S.E.2d 754 [N.C. 1956]). But in a case where the surgeon operated on the left ear despite consent only for the right ear, the court held his conduct actionable as the situation was not a true emergency (*Mohr v. Williams,* 104 N.W. 12 [Minn. 1905]). The condition must be one that was unforeseen, and the patient must not have expressly refused such an intervention. Most informed consent forms now incorporate an "unanticipated condition" clause.

► **Therapeutic privilege:** If a doctor believes that the patient's emotional and physical condition could be adversely affected by full disclosure of the treatment risks, disclosure may be legally withheld. This principle is called therapeutic privilege, which was clearly enunciated in *Nishi v. Hartwell,* Hawaii's first case on informed consent. The plaintiff-dentist, Dr. Nishi, sought damages for below-waist paralysis following thoracic aortography. This procedure-related risk was never discussed with him, purportedly because of his serious underlying cardiac status and extreme apprehension over his condition.

In addressing the therapeutic privilege defense raised by the defendant, the Hawaii Supreme Court held that "the doctrine recognizes that the primary duty of a physician is to do what is best for his patient, and that a physician may withhold disclosure of information regarding any untoward consequences of a treatment where full disclosure will be detrimental to the patient's total care and best interest" (*Nishi v. Hartwell,* 473 P.2d 116 [Haw. 1970]). This doctrine has subsequently been reaffirmed (*Carr v. Strode,* 79 Hawaii 475 [1995]).

In the well-known case of *Canterbury v. Spence,* the U.S. Court of Appeals in the District of Columbia also articulated the therapeutic privilege exception to informed consent, in order to enable the doctor to withhold risk information if such disclosure would pose a serious threat of psychological detriment to the patient. However, the physician is still required to disclose any information that will not prove harmful to the patient (*Canterbury v. Spence,* 464 F.2d 772 [D.C. Cir. 1972]).

► **Waiver or risks known to the patient:** Some patients expressly indicate that they do not wish to be informed of the treatment procedure and associated risks. This constitutes a waiver and is recognized as a legitimate exception. Waivers should be documented in writing. The health care provider is also not obligated to disclose risks that are commonly understood, obvious, or already known to the patient.

► **Informed consent not feasible:** The U.S. government was alleged to have used investigational drugs on military personnel during the Gulf War without their consent. In *Doe v. Sullivan,* a federal court refused to enforce the informed consent requirement because of the impracticality of obtaining consent under the circumstances (*Doe v. Sullivan,* 938 F.2d 1370 [D.C. Cir. 1991]). This exception to informed consent is obviously a very narrow one. ■

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Medical Societies Sign New Conflict of Interest Code

BY ALICIA AULT

Fourteen medical specialty societies have signed a voluntary pledge to be more transparent in dealings with pharmaceutical and medical device manufacturers and other for-profit companies in the health care field.

The pledge, issued by the Council of Medical Specialty Societies (CMSS), was the result of at least a year of negotiations, said Dr. Allen S. Lichter, who is chair of the CMSS Task Force on Professionalism and Conflict of Interest and the chief executive officer of the American Society of Clinical Oncology (ASCO).

"CMSS is committed to encouraging and supporting a culture of integrity, voluntary self-regulation, and transparency," said Dr. James H. Scully Jr., CMSS president and chief executive officer of the American Psychiatric Association. "This code provides a clear benchmark for maintaining integrity and independence."

The 14 societies adopting the CMSS Code for Interactions with Companies agree to establish and publish conflict of interest policies as well as policies and procedures to ensure separation of program development from sponsor influence. They also must disclose corporate contributions and board members' financial relationships with companies, and prohibit financial relationships for key association leaders.

The initial signers included the American College of Physicians (ACP), American Academy of Family Physicians (AAFP), American Academy of Neurology (AAN), American College of Cardiology (ACC), Accreditation Council for Continuing Medical Education (ACCME), American College of Emergency Physicians (ACEP), American College of Obstetricians and Gynecologists (ACOG), American College of Radiology (ACR), American Society for Radiation Oncology (ASTRO), and ASCO.

Dr. Daniel J. Ostergaard, the AAFP's vice president for professional activities, said that the CMSS code gives his organization a chance to see where it might improve its current policies on disclosure and ethical conflicts. He said that the AAFP has a long history of seeking to conduct itself ethically. "I feel very confident that my academy has always been addressing the issues pretty directly and with transparency," Dr. Ostergaard said in an interview.

The AAFP's board members and counsel will spend the next few months determining how to bring its policies into compliance with the CMSS code, he added.

Adoption of the code will not impact the controversial alliance the AAFP struck with Coca-Cola in the fall of 2009 to conduct a consumer awareness campaign about beverages and sweeteners. Dr. Ostergaard said that the code related specifically to health-related companies and that Coca-Cola did not purport to be health related.

Dr. Lichter called the code a "very important milestone" because it will create consistency where there has been none. Many previous efforts to reduce conflicts have been done in private, but this effort is very much a public undertaking, designed to reassure the public and regulators that professional societies are acting ethically, Dr. Lichter said.

It is also, however, just a first step, he said. The code is not meant to be the last word; it represents a minimum set of guidelines. Some organizations may choose to be more restrictive, Dr. Lichter said.

According to the CMSS, the code was developed by a 30-member task force. More of the 32 CMSS members plan to adopt the code in the next few months. ■

The 25-page code is available on the CMSS Web site at www.cmss.org/codeforinteractions.aspx.