

Virtual Mentor

American Medical Association Journal of Ethics
August 2008, Volume 10, Number 8: 521-523.

HEALTH LAW

The Legal Boundaries of Informed Consent

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Kimberly Randall was born on January 19, 1987. A seemingly healthy baby girl, she would later be diagnosed with juvenile laryngeal papillomatosis (JLP), a disease that causes warty growths from the nose to the lungs in the respiratory tracts of children and has an estimated mortality rate of 5 percent. The disease is managed by removing the warts from the throat using laser surgery, but they regrow immediately after removal. Throughout her pregnancy, Kimberly's mother complained of vaginal discomfort and of seeing tissue coming from her vaginal area. It would later be found that Kimberly had contracted JLP from her mother while in the birth canal because Ms. Randall was infected with the human papilloma virus (HPV). Ms. Randall's physicians were aware of the HPV, the risks associated with vaginal birth, and treatment for pregnant women with genital HPV, but they failed to warn her of the risks [1].

Ms. Randall sued Walter Reed Army Hospital for malpractice. The resulting case, *Randall v. United States*, explored how much patients must be told of their medical condition and treatment options and the extent of physicians' responsibility to inform their patients of the risks of medical procedures. Physicians have medical training, experience, and knowledge of their patients' medical history and current condition to draw upon when considering the risks and benefits of medical procedures, but they cannot know with precision how their patients will weigh that information. It is because of this uncertainty that the law requires physicians to fully inform patients of the risks associated with the medical procedures being considered so that patients can weigh the risks in light of their own values and goals.

The Legal Matter of Informed Consent

Informed consent, a relatively new concept to the legal profession, first arose in the context of assault and battery in civil tort procedures. The law recognizes an individual's right to have "complete immunity of his person from physical interference of others... . Any unlawful or unauthorized touching of the person of another...constitutes assault and battery" [2]. In other words, a patient's consent must be given, either expressly or implicitly, before a physician may legally "interfere" with the physical body of the patient. Hence, in past tort cases, physicians have been found guilty of assault and battery because they did not allow their patients to be the final decision makers about undergoing a medical procedure. Consent is also needed because the physician and the patient are entering into a contract in which the physician will employ skills and judgment to bring about desired results and, in

return, receive payment from the patient. Contracts demand consent of all parties, making a patient's knowledge of what he or she is consenting to essential [3].

Informed consent became a vital part of patients' rights in the 1970s, as illustrated in the landmark case of *Canterbury v. Spence* [4]. The court held in that case that "the patient's right of self-decision shapes the boundaries of the [physician's] duty to reveal" [5]. The court found that a patient must be fully informed by the physician or other health care provider so that he or she can make an intelligent choice as to which medical procedure, if any, to undergo. Physicians must communicate to their patients information that is "material" to the decision at hand, including all risks associated with the procedure that might sway the patient's decision. A risk is "material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy" [6]. In other words, if a physician fails to inform a patient of risks that he or she knows are important or that may have an impact on the patient's decision about the proposed therapy, then the physician is legally liable for not fully informing the patient.

There are two exceptions to this rule. The first exception comes into play when the patient is unconscious or otherwise incapable of consenting, and the possible harm from a failure to treat outweighs the harm from the proposed treatment [7]. The second exception, known as the therapeutic privilege principle, acknowledges that in some situations the disclosure of certain risks would not be in the patient's best medical interest. This principle must be exercised with great care and discretion and should not be used as an excuse to withhold bad news. It applies only when, in the physician's clinical judgment, disclosure would exacerbate the patient's condition [8].

The Case of Jacqueline Randall

Jacqueline Randall charged that her physicians' failure to inform her of the risks to her infant from a vaginal birth resulted in the medical need for 25 procedures over 7 years to treat her daughter's JLP. Her physicians were aware that she had irregular cells in her Pap smear before becoming pregnant and, Randall claimed, she should have been counseled to consider a caesarean section to eliminate the risk of JLP; a reasonable person, the case alleged, would have wanted this information.

The court found that the physicians at Walter Reed Army Hospital knew or should have known that Jacqueline Randall had HPV at the time of her daughter's birth. Her doctors conceded that there was an obligation to inform Ms. Randall of the risks associated with each mode of delivery and to provide her with options. The court further found that, despite the fact that there was no standard method of treatment or a procedure to counsel a patient with HPV, the physicians had an obligation to tell Ms. Randall of the risks associated with HPV and a vaginal delivery. Lastly the court decided that a reasonable, prudent person in Ms. Randall's position, having been made aware of the risks and severity of JLP in an infant, would have chosen to have a caesarean section [9].

A Path to Follow

By not informing her of the risks of having a vaginal delivery while suffering from HPV, Jacqueline Randall's physicians eliminated her ability to choose delivery by caesarean section. Physicians can avoid the repercussions that the Walter Reed physicians faced by communicating risks that their patients would find "material." The *Canterbury* court had concluded that not all information related to the proposed medical procedure must be disclosed, only the information that a reasonable person would find necessary when making an informed decision [10]. If physicians cannot discern what information is important, then disclosing all possible risks about the procedure would be prudent. Keeping patients informed has become legally and ethically imperative because patients base their decisions about whether to risk their lives or those of loved ones on what they are told by their physicians.

References

1. *Randall v United States*, 859 F Supp 22, 24 (DDC 1994).
2. *Mohr v Williams*, 95 Minn 261, 271 (Minn 1905).
3. Definition of offer. Restatement (Second) of Contracts, Section 24.
4. *Carr v Strode*, 79 Haw 475, 480 (Haw 1995).
5. *Canterbury v Spence*, 464 F 2d 772, 786 (DC Cir 1972)
6. *Canterbury* at 787-788.
7. *Canterbury* at 789.
8. *Carr* at 480.
9. *Randall* at 28-32.
10. *Canterbury* at 787.

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