Legal Corner

Informed Consent and Chemotherapy

By Dina Michels and Maura Cahill

As a matter of law and medical ethics, an oncologist is required to obtain a patient's informed consent before administering chemotherapy, even if the oncologist strongly believes that chemotherapy is the best treatment option available to the patient. The informed consent requirements discussed here apply to patient care and are regulated by state law; consult a legal professional for particular requirements in your state. Different informed consent requirements apply to clinical research.

Elements of Informed Consent

U.S. courts have long recognized that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."¹ The common law doctrine of informed consent to medical treatment requires disclosure of the patient's diagnosis, the nature of the proposed intervention, intended benefits, associated risks and side effects, and medically reasonable alternatives (and their corresponding risks and side effects).²

Two standards have emerged among the states by which courts determine whether informed consent was adequately obtained. Historically, most states use a physician standard, whereby a physician is obligated to disclose that information which physicians customarily disclose in similar circumstances. The modern trend among states, however, has been to use a patient standard of materiality, which requires a physician to disclose information that a reasonable patient would deem material to making a treatment decision in similar circumstances. In the landmark decision *Canterbury v. Spence* the court expressed the patient standard of materiality, reasoning, "it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie."² Approximately half of the states have adopted the patient standard of materiality, including California, Maryland, Massachusetts, Michigan, and New Jersey.

Informed Consent Procedure

The informed consent doctrine does not prescribe a process for obtaining informed consent, so different procedures are acceptable provided that the basic elements of informed consent are covered. Many practices use consent forms to document a patient's informed consent, but generally the form should confirm, rather than replace, a face-to-face conversation. A consent form should include all elements of informed consent, as discussed beforehand with the patient, and once signed, it should be maintained with the patient's medical record. A nonphysician member of the care team may provide the information and obtain the patient's consent, but the physician generally bears legal responsibility if informed consent is not properly obtained.

Informed Consent in the Context of Chemotherapy

Several informed consent cases have involved cancer treatment. Whether the patient standard of materiality or physician standard applies, oncologists face challenges related to informed consent and chemotherapy.

Degree of Potential Harm. The toxic nature of chemotherapy introduces numerous risks and potential side effects, and oncologists have a legal duty to disclose these. Package inserts provide reliable and complete information on chemotherapeutic agents, but it may be impracticable to communicate each and every associated risk and side effect. The informed consent doctrine requires disclosure of those risks and side effects that are either material to the patient's decision or customarily disclosed by physicians (depending upon applicable state law). The more serious or likely the risk or side effect, the more material that information becomes to the patient's decision.

Level of Uncertainty. Since patients' medical decisions are made by weighing potential harms and intended benefits, it is important to be forthcoming about uncertainties inherent in chemotherapy. Informed consent laws generally require only a reasonable explanation of potential harms, so specific disclosures such as statistical data may not be legally necessary.³ However, when a proposed intervention is innovative, untested, or otherwise outside the standard of care, this probably constitutes a material fact and should generally be disclosed. If chemotherapy is truly experimental, then the federal Common Rule (45 C.F.R. Part 46) applies.

Alternatives and Personal Choices. An important element of informed consent is the discussion of reasonable alternatives. Where clinically appropriate, an oncologist should discuss the option of palliative care so that a patient is given the opportunity to make a meaningful and personal choice.

Conclusion

Before administering chemotherapy, oncologists must receive a patient's informed consent pursuant to disclosure of required information, including information about medical uncertainty and palliative care, when appropriate. Meeting these informed consent requirements protects patient autonomy and minimizes physician liability.

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References

1. *Schloendorff v. N.Y. Hospital*, 105 N.E. 92 (N.Y. 1914)
2. *Canterbury v. Spence*, 464 F.2d 722 (D.C. Cir. 1972)
3. *Arato v. Avedon*, 858 P.2d 598 (Cal. 1993)