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Disclosing Risks of New Technologies: Ethical Challenges for Physicians, Patients, and Companies

Dianne M. Bartels*

I. INTRODUCTION

The number of patient deaths linked to implanted cardiac defibrillators (ICDs) underscores the importance of balancing patient autonomy and risk disclosure, and raises a number of questions for both clinicians and medical device manufacturers. At what level of risk of death should patients be notified? What information should be provided to the patient prior to gaining consent for initiation of new therapies? Is there an ongoing responsibility to disclose new risk information? What do doctors need to know to meet their obligations? What role should manufacturers play in risk notification? I will attempt to answer these questions from a clinical practice perspective with a particular focus on obligations to patients faced with difficult medical decisions.

Questions about risk disclosure have not been definitively answered even for clinical trials.¹ However, ethical guidance developed for researchers could shed light on the physician's responsibilities related to risk notification, particularly where risks are life-threatening.

II. PHYSICIAN'S DUTY TO DISCLOSE RISKS AND BENEFITS

The Belmont Report describes an obligation to inform research participants of risks and benefits based on the principle of respecting individual autonomy.² Informed consent

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1. See Jonathan Kimmelman, *Valuing Risk: The Ethical Review of Clinical Trial Safety*, 14 KENNEDY INST. ETHICS J. 369 (2004).

2. See NATIONAL COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF

was developed to protect participants from undergoing undue risks. The duty for physicians to disclose risks and benefits as a part of consent to participate was defined as an expectation that would allow participants to determine, within the context of their own value system, whether to become part of a study. In *The Belmont Report*, failure to notify participants about relevant risks was described as tantamount to showing disrespect: "To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there is no compelling reason to do so."³

III. RESPECT FOR AUTONOMY IN CLINICAL PRACTICE

The principles that originally guided the conduct of research have become guiding principles for decisions about medical treatment as well. Consent was a major mechanism in the evolution of medical practice from paternalism, where doctors acted in the best interest of patients, to respect for autonomy, which supports patients' personal well-being and self-determination. Ideally, consent is a collaborative process in which the physician shares information about risks and benefits and patients determine where an intervention fits in the context of their own lives.

So, where does risk notification fit into informed consent? "Risk" refers to an adverse future event that is not certain, but probable.⁴ The duty to warn patients of risks of a proposed treatment is a facet of due care.⁵ The patient's right to self-determination shapes the boundaries of the physician's duty to reveal risks.⁶ In that context, a physician's communication is measured by a patient's need to know information that is material to a specific medical decision.⁷ A risk is material

BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 4 (1979).

3. *Id.*

4. Bettina Schöne-Seifert, *Risk*, in 4 ENCYCLOPEDIA OF BIOETHICS 2316, 2316 (Warren Thomas Reich ed., rev. ed. 1995).

5. *See Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972), *reprinted in* THOMAS A. MAPPES & DAVID DEGRAZIA, BIOMEDICAL ETHICS 93, 94 (5th ed. 2001).

6. *See id.* at 786, *reprinted in* THOMAS A. MAPPES & DAVID DEGRAZIA, BIOMEDICAL ETHICS 93, 94 (5th ed. 2001).

7. *See id.* at 786-87, *reprinted in* THOMAS A. MAPPES & DAVID DEGRAZIA,

when a reasonable person would be likely to attach significance to the risk in deciding whether or not to forego the proposed therapy.⁸ Because life-preservation is the purpose of new cardiac technologies, a risk of death would seem material to every patient offered ICD treatment. Therefore, one might say that if sudden death is even a miniscule risk, the patient should be apprised of that risk.

Of course there are challenges to total disclosure. First, it is impossible to cover all potential risks of any technology in relation to a specific individual's physiological response or unique value system. Therefore, physicians must select information that is relevant for each patient.⁹ Second, volumes have been written about the challenges in conveying probabilities in a way that is meaningful to a particular individual. Uncertainty about the likelihood of failure in an individual situation compounds that challenge. Third, if an emergency decision must be made in the context of a life-threatening event, the obligation to disclose may be set aside in order to save the patient from undue harm.¹⁰ Fourth, some patients do not want to hear about risks and ask that someone, in some cases their doctors, make decisions about what would be best for them. Finally, clinical practice has also shown that many patient decisions do not seem rational in terms of statistical risks. For instance, some people have ICDs removed because experiencing the electrical shocks is more worrisome than the risk of death without the defibrillator. Also, some patients, with their families, decide that survival is not their most important goal when the quality of their lives is severely diminished. Despite these challenges to "rational" decisionmaking, the physician's responsibility continues to be one of sharing information about the risks and benefits of each medical intervention proposed.

BIOMEDICAL ETHICS 93, 95 (5th ed. 2001).

8. See *id.* at 787, reprinted in THOMAS A. MAPPES & DAVID DEGRAZIA, BIOMEDICAL ETHICS 93, 95 (5th ed. 2001).

9. See Mack Lipkin, *On Lying to Patients*, NEWSWEEK, June 4, 1979, at 13, reprinted in THOMAS A. MAPPES & DAVID DEGRAZIA, BIOMEDICAL ETHICS 85 (5th ed. 2001).

10. See *Canterbury v. Spence*, 464 F.2d 772, 788-89 (D.C. Cir. 1972), cert. denied, 409 U.S. 1064 (1972), reprinted in THOMAS A. MAPPES & DAVID DEGRAZIA, BIOMEDICAL ETHICS 93, 96 (5th ed. 2001).

IV. COMPARING CONSENT IN CLINICAL TRIALS TO CONSENT IN TREATMENT

Many risks present in a clinical trial continue to be risks when an innovative technology has been approved for use as a medical treatment. Surprisingly, one often finds in a patient's medical record great disparity between the consent process during research and treatment phases. Consent to be involved in research usually involves a form of ten to twenty (or more) pages listing every possible risk: physical risks, psychological risks, commentary on lifestyle considerations, as well as the risks and consequences of technical malfunction. Once an intervention is approved for treatment, however, we often find a routine surgical consent in the patient's medical record, often with a very non-specific note from a physician indicating that the patient understands the risks and benefits of the proposed intervention.

Given the enormous discrepancy between consent in clinical trials and consent once approval for treatment is obtained, I would advocate for a more specific written consent process for new cardiac technologies. Each of the risks identified in a clinical trial could be reevaluated with trial data, and a consent form created to include actual known risks. Katrina Bramstedt, a former fellow in the Program in Biomedical and Research Ethics at the University of California–Los Angeles, has suggested that consent in clinical trials be maintained as a “living” document.¹¹ Likewise, consent forms for treatment would need to be continually updated to reflect the accrual of new risk data.

Physicians would still need to consider the individual patient to determine what risk information is most relevant for their conversation. They would also need to continue to evaluate the ability of the patient to understand and handle various levels of information and to make decisions. Patients eligible for treatment with ICDs are in a unique situation because they risk death with or without treatment. Therefore, a conversation about risks would in most cases address *relative* risk: How the risk of failure of a particular device compares with the risk of death without the intervention.

What about the responsibility of the physician to contact

11. See Katrina A. Bramstedt, *Failure Mode and Effects Analysis as an Informed Consent Tool for Investigational Cardiothoracic Devices*, 48 AM. SOC'Y ARTIFICIAL INTERNAL ORGANS J. 293, 295 (2002).

patients when a higher risk is determined or when a recall is announced? It seems that new risks *would be* material to many patients and that a physician who knows an individual patient—and the patient’s interest in knowing about risks—should determine when and how patients should be notified.

One Minnesota mother decided, after a device recall, to take her son back to surgery to replace an ICD with an ICD produced by another company.¹² As patients and families are deciding about replacing one device with another, device failure risks could be compared, factoring in the additional mortality risk of an added surgical procedure. Patient care has become an onerous responsibility in the age of new technological interventions, and the burden for physicians treating patients with innovative therapies has become heavier. Although it is challenging, I believe the physician responsible for initiating a particular therapy remains the best person to discuss relative risks over time.

V. ROLE OF MANUFACTURERS TO SHARE INFORMATION

Given that the physician needs to share all relevant information with patients, physicians should definitely be apprised of known risks and a revised likelihood of a death-inducing malfunction. It might be useful to provide physicians with information similar to that disclosed in the failure mode and effects analysis (FMEA), which is supplied to the FDA as a means of determining clinical risks.¹³ Information for physicians would also need to be updated as post-trial assessment reveals new risks or new probability of risk. The physician would then need to decide whether to contact patients to warn them of a risk of death and to discuss treatment options available. Because “first do no harm” is not possible, the next best step is acknowledging potential harms as honestly as possible during both research and treatment phases of new product trial and dissemination.

Some suggest direct notification of patients by manufacturers, similar to that of auto vehicle recalls.¹⁴ My sense is that increased risk and recall information should be given to physicians, who would then determine how such

12. See Maura Lerner, *Trusting Lives to Tiny Machines*, STAR TRIB., Aug. 28, 2005, at 1A.

13. See Bramstedt, *supra* note 11, at 293.

14. See *id.* at 295.

information should be given to individual patients based on what the physician knows about the patient's health, lifespan, risk averseness, and other factors. To support the physician's capability, a company could maintain a website that regularly posts current data about the likelihood of varying risks.¹⁵ That site could be made available to interested patients, the public, and to physicians who could share revised estimates as a part of the consent and continuing treatment process.

No system of notification is perfect. Hopefully, the challenges coming from these well-publicized "worst case" scenarios will lead to an industry standard of full and continuing disclosure. Otherwise companies acting ethically to disclose relevant risks may be disadvantaged in the marketplace.

15. According to the *British Medical Journal*, GlaxoSmithKline agreed to publish the results of all clinical trials on a website following a lawsuit for "repeated and persistent fraud" for concealing the results of clinical studies for its antidepressant paroxetine." Liza Gibson, *GlaxoSmithKline to Publish Clinical Trials After US Lawsuit*, 328 *BRITISH MED. J.* 1513, 1513 (2004).