



Lack of Consent Is an Ethical Issue

This is the fourth of six case studies, prepared by the staff of CHA's Theology and Ethics Department, scheduled to appear in Health Progress in 2003.

In 1994 a genetic test became commercially available for familial adenomatous polyposis (FAP), an autosomal dominant disorder that causes colorectal cancer if preventive surgery is not performed. The test can identify the mutation in affected members of 80 percent of families with FAP; and, when the particular mutation is known to exist in a family, the test can differentiate affected from unaffected family members with virtually 100 percent accuracy. Appropriate use of the test can confirm a diagnosis of FAP, justify surveillance with regular colonoscopies, and aid in the surgical management of the disease. In addition, negative test results in families with an identified mutation can exclude some family members from invasive (and expensive) surveillance.

In March 1997, F. M. Giardiello and colleagues published research on a sample of 177 patients from 125 families who had undergone testing two years before (F. M. Giardiello, et al., "The Use and Interpretation of Commercial APC Gene Testing for Familial Adenomatous Polyposis," *New England Journal of Medicine*, March 20, 1997, pp. 823-827). The research assessed whether physicians had recognized indications for the test and ordered it appropriately; whether informed consent had been obtained for the test; whether genetic counseling had been offered; and whether test results were accurately interpreted.

What did the researchers find? A high number (83 percent) of those tested had valid indications for the test, which is not surprising since the tests were ordered by specialists in the disease. Still, 17 percent of the tests had been ordered for "unconventional indications," and, when so ordered, the positive test rate was low. More worrisome was

the finding that, although genetic counseling before the test and informed consent to the test are considered essential, neither had been done in about 80 percent of the cases. One-fifth of the presymptomatic patients had the test before the precise mutation was identified in an affected family member. This means that, for those patients, the test was useless. Finally, one-third of the physicians involved would have misinformed their patients about uninformative test results. If a mutation was not detected, the patients would have been told that they were mutation-free, rather than informed that they must continue surveillance. Since surveillance and early intervention are the keys to saving lives in persons with FAP, this mistake could have been deadly.

Let's say that you have read this research. As a person with "colon cancer in the family," you are somewhat concerned by it. A conversation with the hospital's management team reveals that your facility has a sizable gastrointestinal practice. You suspect what was found true in the research done by Giardiello, et al., (concerning informed consent for the test being ignored, etc.) might also be true in your hospital.

QUESTION FOR SPONSORS AND BOARD MEMBERS

How does the new science of genetics enter into the board's deliberations regarding credentialing?

QUESTIONS FOR EXECUTIVE MANAGEMENT

Which of your hospital's core values speak to the deficiencies that the Giardiello team found in its research?

Continued on page 53

■
The test identifies a genetic mutation that causes colorectal cancer.

CASES IN GENETICS

Continued from page 43

H

as the executive team considered hiring a geneticist or genetic counselor?

What mechanisms does management have in place to ensure the clinical quality of new offerings by physician collaborators? More specifically, how does management ensure that testing is appropriately ordered and that physicians are adequately prepared to interpret results?

Has the executive team considered creating a position for a geneticist or, at the very least, a genetic counselor? If genetic testing is occurring in your facility and you do not have a genetic counselor, who is doing the counseling? Is that person adequately prepared? Is there some testing being done without counseling?

QUESTIONS FOR THE ETHICS COMMITTEE

How much self-education has the ethics committee undertaken on ethical issues in genetic testing?

One of the most egregious findings of the Giardiello team was the lightness with which informed consent to testing seemed to have been taken, although informed consent was identified as important. How visible is the ethics committee in acting as an advocate for and educating about informed consent, particularly with regard to new challenges posed by genetic testing?

Is the facility's informed consent policy sufficient to address genetic testing?

GUIDING ETHICAL PRINCIPLES

The following principle and norms are intended to provide some moral guidance to discussions around the questions above. They are not exhaustive of those that might be relevant to the case and the questions raised. They should, however, be of some help.

Promote and Defend Human Dignity Because each person is created in the image of God, each one is sacred and possesses inalienable worth, and is social by nature and finds fulfillment in and through community. Catholic health care, therefore, treats individuals—and their families and various communities—with profound respect and utmost regard.

- **Beneficence** Our decisions and actions should contribute to the well-being of others.

- **Nonmaleficence** Our decisions and actions should not harm others.

- **Informed consent** When making decisions about diagnostic and/or therapeutic measures, individuals should have adequate information about the procedure, sufficient understanding of that information, and be able to freely choose to either accept or refuse the intervention.

- **Stewardship** Health care resources should be used prudently (appropriately, efficiently and effectively) and justly.

- **Justice** Justice requires that people be given what is due them. There must be equity in the exchange of goods and services (commutative justice).

CHA's Theology and Ethics Department would like to thank Carol Bayley, PhD, vice president, ethics and justice education, Catholic Healthcare West, San Francisco, for developing the case and questions used in this article.

RESOURCE

New York State Task Force on Life and Law, *Genetic Testing and Screening in the Age of Genomic Medicine*, Albany, NY. See the chapter on "Informed Consent."

LESSONS OF MISSION DISCERNMENT

Continued from page 42

that have escaped the attention of managers and executives.

- Clearly communicate the values operative in whatever decision or choice is arrived at. More than once I have heard leaders say, "We made the right choice and for the right reason. But our communications with the stakeholders were poor and we met with a lot of opposition or mistrust." Not many decisions will meet with unanimous approval; members of the organization understand that. What they want to know is *why* that particular course of action was taken. What justifies it? What end or need does it serve? What values does it advance?

People understand that priorities must be established, especially in cases that involve competing values. Why, they ask, was this value (stewardship of resources, for instance) chosen over that (compassion, say) in these particular circumstances? People understand a decision better if they can see the mission and values that were operative in the decision-making process. They are, by the same token, suspicious of a business decision that is "baptized" in mission language.

UNDERSTANDING AND COMMITMENT

Those who have used an ethical-discernment process will remember the awkwardness that often accompanied the process's introduction into the organization. They will recall that co-workers did not recognize the process's terminology and did not feel competent to do what was being asked of them. But the whole premise of such discernments is that the people in our organizations *do* have the professional skills, knowledge, and competencies, *as well as the values*, to provide a critical analysis of a proposed initiative from a mission perspective. They learn to trust both the process and their own contributions to it. And, through the process, they discover the meaning and value of their own work and its place in the organization's mission. □

JOURNAL OF THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES

www.chausa.org

HEALTH PROGRESS®

Reprinted from *Health Progress*, July-August 2003
Copyright © 2003 by The Catholic Health Association of the United States
