



Bioethics Notes



a newsletter from the Bioethics Review & Advisory Committee

November 4, 2003

"Training is everything. The peach was once a bitter almond; cauliflower is nothing but cabbage with a college education."

Mark Twain

Consult Services

We would like to remind you that the Bioethics Review and Advisory Committee in Danville provides ethics consultation services. We have an alphanumeric pager (2229). Anyone can request an ethics consultation. Page directly by phone, or leave a text message using the Infoweb Phone Directory. Enter "2229" in the Directory Search and then click on the "Quick Page" button.

[Jump to Quick Page](#) to request an ethics consult.

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Case Study

The Bioethics Review and Advisory Committee believes the Geisinger community would benefit from increased communication and educational efforts dealing with current issues in bioethics. Our new [homepage](#) is dedicated to current news in the world of bioethics and is updated on a continuing basis. We also look forward to your participation in our annual ethics conference to be held March 12, 2004 at Susquehanna University on "Ethical Implications of the Medical Liability Crisis." In this issue, we introduce a discussion on informed consent that includes a simple case study.

If you have been following the Terri Schiavo case, you are learning many of the fundamental and extended concepts of the process of **informed consent**. In particular, the concept of **substituted judgment**, whereby a designated **surrogate decision maker** is making decisions for another individual is being analyzed in depth. The Schiavo case, however, is complicated, and I would like to begin our discussion about the process of informed consent with a brief history, and then a simple case study.

The concept of informed consent has become the major doctrine guiding medical decision-making in Western society, and helped establish the boundaries for doctor-patient relationships. The ethics of **respect for human persons** is the basic moral principle that guides informed consent, because it is considered wrong to force another person to act against their own will. Simply, every individual has a right of self-determination. This ethic is heavily weighted in the principle of **patient autonomy**. Historic documents that support this conception of informed consent include the [Nuremberg Code](#) (1949), The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979, also known as the [Belmont Report](#)), and the Protection of Human Subjects (1991), commonly referred to as [The Common Rule](#), which is a part of the federal code of regulations (45 CFR 46), the codification of the general and permanent rules enacted by our federal government. The primary focus of informed consent in these historic documents, however, governs protections for human subjects in medical research. In parallel with the ethics of according respect for human subjects in medical research, over the last thirty years informed consent has evolved as the major construct of contemporary physician-patient relationships, replacing the older concept of physician **paternalism**.

The legal basis for informed consent preceded the ethical analysis by many years, and centered upon a theory of battery or "unconsented touching." This legal history dates as far back as the 1905 case of *Mohr v. Williams*, where the Minnesota court ruled that "express" versus "implied" consent, is required, and valid consent should include the patient's knowledge about "dangers and risks." In [Schloendorff v. Society of NY Hospital](#) (1914), New York State Supreme Court Justice Joseph Cardozo opined the oft-quoted "every human being of adult years and sound mind has a right to determine what shall be done with his own body." The term "informed consent" was

Events

6th Annual Bioethics Conference

Friday, March 12, 2004
Susquehanna University

"Ethical Implications of the Medical
Liability Crisis"

7th Annual Palliative Medicine Conference

Thursday, March 18, 2004
Bucknell University

Tentative Topic

"Issues Discussed and Issues Never
Discussed"

Grand Rounds

Neil Ellison, MD

Director, Palliative and Supportive
Medicine Program

**To Tell The Truth?
An Overview Of Medical Prognosis**

Hemelright Auditorium
Friday, November 21st
2:30 PM

e-mail

**The Bioethics Review and Advisory
Committee's address is:**

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**The Bioethics Review and
Advisory Committee Homepage**



what shall be done with his own body." The term "informed consent" was first coined in [Salgo v. Leland Stanford etc. Bd. Trustees](#) (1957)... "that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent." The Salgo case affirmed a duty to disclose crucial information necessary for an individual to make a reasoned and informed decision. These early judicial decisions demonstrate the close association between a society's legal and ethical foundations.

For the moment, let us consider informed consent to include two major elements. First, an **information element**, whereby there must be disclosure of information and comprehension of what is disclosed, and second, a **consent element**, that includes voluntary, reasoned decision-making, and agreement. The process of informed consent includes the following five components: 1) competence of the patient, 2) disclosure of information including risks and benefits, 3) understanding by the patient, 4) voluntariness of the patient and 5) consent. Then let us consider the following case:

Mrs. D is a healthy, college educated mother of three. She is currently in pre-op, in preparation for a tubal ligation. Dr. A approaches and introduces himself as one of the members of the surgical team. He asks Mrs. D whether or not she would like to participate in a clinical research study to investigate the presence of certain chemical markers found in the blood before and after surgery. All that is required will be a simple finger prick before and after surgery. Dr. A informs Mrs. D that the study has very important ramifications. Mrs. D says she would be happy to participate.

We can make several observations concerning this case. First, there is no reason to suspect that Mrs. D is incompetent, and therefore she is fully capable of making her own health care decisions. However, Mrs. D's understanding of the potential risks and benefits may be hampered by her illness, medication or emotional distress. Minutes before an operation is not the appropriate time to consent a patient, no matter how minimal the risks. The abrogation of true informed consent is only acceptable in an emergency. True informed consent requires thoughtful deliberation, without constraint or duress. We can not expect Mrs. D, in this circumstance, to be capable of making a truly autonomous, voluntary choice. Furthermore, because of the authority differential, Mrs. D may be inhibited from asking questions or expressing concerns, and wrongfully feel obligated to participate, especially given the necessity for a prompt decision. Given these considerations, it is not difficult to conclude that the process of informed consent, in this very simplified case, is being violated.

We will continue our analysis of the process of informed consent in the future, and add additional discussion and analysis of all the individual components. We hope you continue to find Bioethics Notes a useful resource.

Respectfully submitted,
Robert Shabanowitz

The Bioethics Review and Advisory Committee gratefully acknowledges *The Degenstein Foundation*, whose funding helps support the educational activities of our committee.



Feel free to forward *Bioethics Notes* to anyone interested. They can join by using the link below. To join the list, send a blank email to List-Join: [<mailto:join-bioethics@ghslistnt1.geisinger.edu>](mailto:join-bioethics@ghslistnt1.geisinger.edu)