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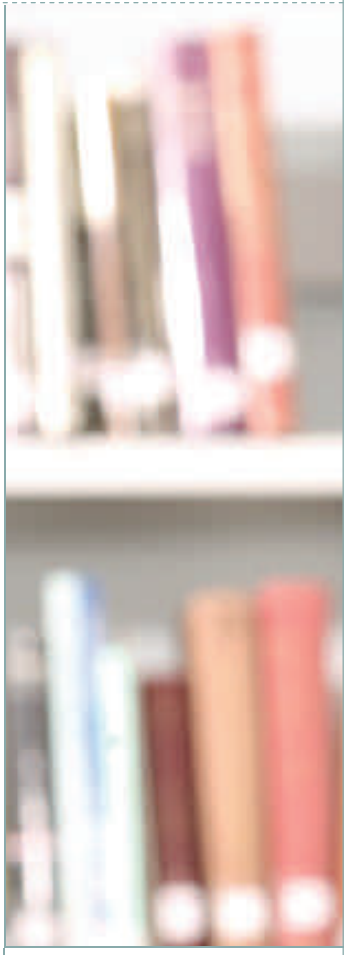
Insights
INTO RISK MANAGEMENT



@RISK: INFORMED CONSENT: YOU GOT THIS

By Jenny Williford, J.D.

This article is an enduring activity approved for *AMA PRA 1 Credit(s)™* and category 1 credit in Risk Management Study. *(See link on p. 3)*

The following is an account of the author's introduction and journey into the subject of informed consent, resulting in a law career and current position within the Claims Division of Lifespan Risk Services. Ms. Williford authored or contributed to information contained throughout this newsletter.

"Does she know that her baby is not getting the medicine?" "Does he understand that he is the only one in his family getting treatment?" As I processed blood samples for the HAART clinical trials for the treatment of HIV/AIDS, these types of questions haunted me. This job in the research lab at a large, well known Massachusetts hospital was intended to be my first step towards working for the Centers for Disease Control and Prevention. What it actually became was my first step into the practice of law.

I questioned the process of how human subjects were recruited and chosen for clinical trials. What information was given? How was it given? Did the person understand the information before agreeing to participate? Were they *able* to understand the information? She has a right to understand, doesn't she? Complete understanding is legally required isn't it? I was dissatisfied with the answers. My motivation to go to law school was my respect for medical research and my appreciation that proper informed consent was essential to preserving the integrity of the research itself. I naturally gravitated to healthcare law and medical malpractice defense where I realized that informed consent was equally critical to maintaining the integrity of medical care.

It was in law school when I truly appreciated the human subject atrocities like Nuremberg and Tuskegee. The discovery and prosecution of these and other unethical research horrors motivated the development and regulation of informed consent processes, not only in human subject research but also in the clinical setting. *(continued on following pages)*

INSIDE THIS ISSUE

TAKE NOTE

- Look for links throughout the publication that provide additional information and tools
- See page 3 for the 2017 *@Risk Live Lecture Series* schedule, as well as the Survey Monkey CME link for this edition

THE PATIENT'S RIGHT TO KNOW—AN HISTORICAL ACCOUNT

Bang v. Charles T. Miller Hospital, 1955: Surgeons were liable for failing to inform that surgery would likely result in sterility, establishing patients' right **to know probable risks/results of surgery**.

Corn v. Frech, 1955: Patient advised to undergo test for possible breast cancer, signing a consent for 'mastectomy' without explanation of procedure, and with assurance physician had no intention of removing breast. Physician found liable for an **unauthorized procedure**.

Natanson v. Kline, 1960: Court stated "…each man is considered to be master of his own body, and may, if of sound mind, expressly prohibit the performance of life-saving surgery, or other medical treatment. A doctor might well believe that an operation or form of treatment is desirable or necessary but the law does not permit him to substitute his own judgment for that of the patient by any form of artifice or deception." Court found **patient is final decision maker in his care**.

Reif v. Weinberger, 1974: Patient on welfare told that failing to undergo tubal ligation procedure would significantly reduce her welfare benefits. Court found **consent obtained under physical or mental duress is invalid** and surgeon found liable for **assault and battery.**

Truman v. Thomas, 1980: Family physician found liable for failing to advise patient of risks of her repeated refusal to have a pap smear. California Supreme Court established **physician's duty to inform patients of risks of refusal** of proposed treatment.

RESEARCH AUTROCITIES PRIOR TO INFORMED CONSENT

In 1947, twenty physicians were tried for their alleged involvement in Nazi human experimentation on prisoners, including children, held in concentration camps during World War II and the Holocaust. The prisoners were subjected to medical torture when forced to participate in horrendous experiments that resulted in permanent trauma, disfigurement, disability and death.

Known as the "Doctors' Trial," this was the first of twelve 'Subsequent 'Nuremberg Trials' held by US military courts in the United States occupation zone in Nuremberg, Germany for charges of war crimes and crimes against humanity.

This trial established the Nuremberg Code, ten ethics principles for human subject research. The first principle of the Code is the requirement of voluntary, well-informed consent from the human subject with legal capacity to understand. The Code became one of the foundations for the Code of Federal Regulations governing federally-funded human subject research in the United States.

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For 40 years beginning in 1932, the United States-sponsored Tuskegee Syphilis Study was an experiment conducted on misinformed, poor African-American men who were led to believe that they were getting free health care from their government. Unknown to the 600 subjects in this rural Alabama population, the experiment studied the progression of untreated syphilis.

Researchers knowingly opted against treating these men, even after penicillin was confirmed to be a cure for the disease. In addition to the numerous men who died without ever being told they had syphilis, many wives and children fell victim to this unethical human experiment.

The Office of Human Research Protections, a subdivision of the US Department of Health and Human Services, was created in the aftermath of this study and is tasked with implementing the federal regulations designed to protect human subjects.

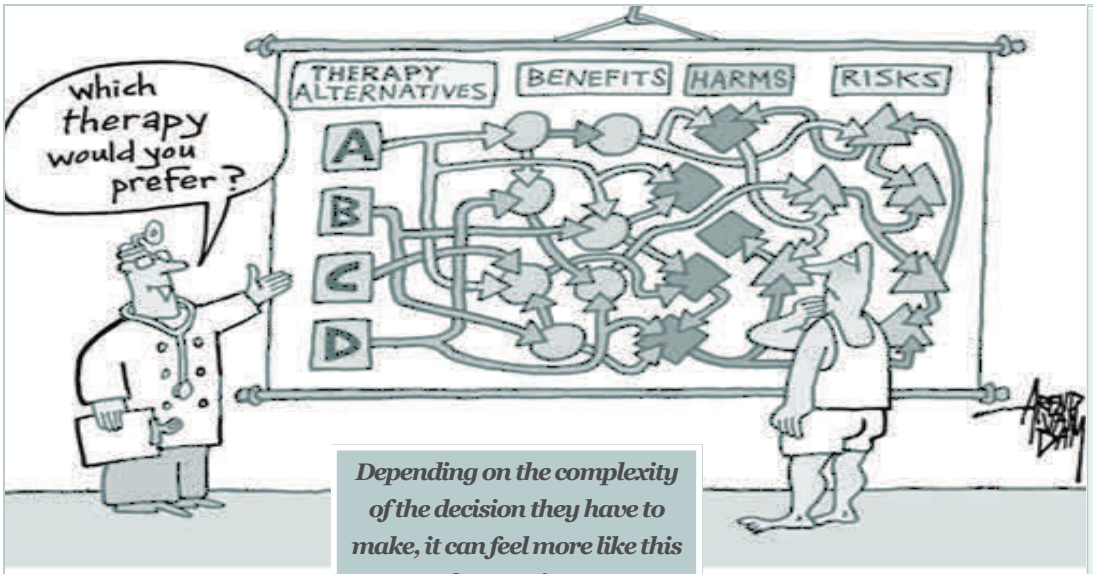
THE EVOLUTION OF INFORMED CONSENT IN THE CLINICAL SETTING

Ancient practitioners of medicine utilized a paternalistic attitude towards patient care, rarely involving the patient in the decision-making process. The English Common Law concept of assault and battery was established in the 18th and 19th century with the idea that a physician would be liable for a breach of duty to their patient for failure to obtain authorization from the patient before performing surgery or other invasive procedure. In the 20th century, many court decisions transformed the paternalistic approach of health care to more patient-centered medicine.

In 1914, Justice Benjamin Cardozo first established a patient's right of self-determination in *Schloendorff v. Society of New York Hospital*. Justice Cardozo stated:

"…every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained."

In the clinical setting, informed consent comprises a physician's duty to inform and a patient's right to choose. Born in an environment where the physician held nearly exclusive control over their patients' healthcare choices, with virtually no input from the patient, the concept of informed consent today has transformed to better respect and reflection of the patient's autonomy.



Depending on the complexity of the decision they have to make, it can feel more like this for a patient.

Barriers to the Process of Obtaining Informed Consent

Patient Factors:

- ◊ Low health literacy
- ◊ Limited English proficiency and cultural issues
- ◊ Cognitive impairments
- ◊ Confusion about the purpose of consent process
- ◊ Misunderstanding of information on the informed consent form or related educational information
- ◊ Feeling of intimidation and stress or time pressure

Provider Factors:

- ◊ Lack of time for up-front patient education
- ◊ Confusion among clinicians about when informed consent is needed
- ◊ Too complex or overly broad written materials
- ◊ Poor quality of consent form and related educational materials
- ◊ Physician concerns about giving too much information
- ◊ Lack of support with interpreters
- ◊ Wrong assumptions about patient comprehension
- ◊ Clinician inability to detect patient's lack of comprehension

The degree to which these barriers affect physicians certainly varies from practice to practice and situation to situation, but each of them should be meaningfully considered in assessing the effectiveness of your informed consent process.

Today's Challenges to Achieving Informed Consent

America has always been a wonderful melting pot. The country's makeup today, however, is drastically more diverse then it has ever been. In addition to the ever-growing diverse ethnicity and culture of our citizens, additional factors such as a decrease in health literacy, an increase in poverty and associated decrease in access to healthcare, and the rapid advancement of digital technology now contribute to the challenges you as physicians face when treating your patients.

Accompanying the development of the internet and sophistication of digital technology is the greater expectations of patients for instant information, more choices and quick results. This greater access to information has also resulted in a more litigious society and more financial and performance pressure on physicians.

Every single one of these factors poses a challenge for you to meet your professional and ethical obligation to obtain proper informed consent.

PY 2017 *@Risk Live Lecture Series
Presented by Lifespan Risk Services, Inc. - Loss Prevention
Rhode Island Hospital - George Auditorium

Informed Consent	Transgender Health Issues	Medical Ethics	De-escalation and Self-Protection in the Medical Setting
11/17/16 12 - 1pm	12/16/2016 12 - 1pm	02/1/2017 12 - 1pm	01/19/2017 12 - 1pm
04/14/2017 12 - 1pm	03/16/2017 12 - 1pm	06/16/2017 12 - 1pm	05/18/2017 12 - 1pm

To earn CME credit for reading information on Informed Consent in this issue, go to:

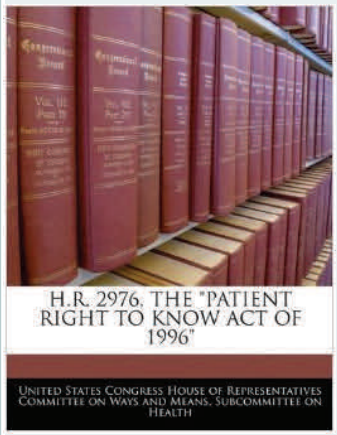
https://www.surveymonkey.com/r/SHCKBXB

*We are pleased to announce the 2017 curriculum for the *@Risk Live Lecture Series,* a program of nine (9) Risk CME certified presentations that tackle interesting and complex issues in professional liability and risk mitigation. To enhance the learning experience, attendees are encouraged to actively participate in these dynamic, innovative sessions through role playing, panel discussions and more. We hope to see you there!

Inadequate consent adds to the cost of surgery cases

$470,000: Average indemnity paid in cases with adequate informed consent process

$845,000: Average indemnity paid in cases with inadequate informed consent process*



Did you know?

The single best method to improve informed consent involves "teach back," in which patients or their representative are asked to repeat, or "teach back" in their own words all the information they were given during the informed consent. Studies have found that teach back, also called the 'show me' technique, greatly improves recall and retention of information by patients.

**CRICO - Owned by and serving the Harvard Medical Community. Found at: http://www.rmf.harvard.edu/Clinician-Resources/Topic-Tag/Informed-Consent on January 3, 2013*

INFORMED CONSENT IN LITIGATION: Case Studies

In medical malpractice lawsuits, 'counts' or allegations regarding informed consent typically accompany the underlying negligence claim. Although rarely the main focus in a case, informed consent allegations can certainly drive the value up if substantiated.

Informed consent can play a more significant role in a lawsuit if there is a question as to whether the patient consented to the entirety of a procedure or treatment or accepted certain risks associated with the consented to procedure.

The following are illustrative examples of informed consent issues that the author defended or has been involved with:

Case 1

Ms. A, a 17 year old student , and her mother, Mrs. A, presented to Dr. B to discuss the need for a meniscal repair following a sport-related injury.

A detailed conversation covered the procedure, preparation, day-of expectations, surgical technique to be utilized, post-op recovery, results expectations, and anticipated future care.

Mother and daughter asked Dr. B many questions which were addressed until all were satisfied with Mrs. A's and Ms. A's understanding.

Mrs. A agreed to the procedure on behalf of her daughter and signed the informed consent form.

During the surgery, a suspicious mass was noted behind Ms. A's knee, which was biopsied to avoid having a second procedure. The final pathology revealed the mass was a liposarcoma.

In the PACU post-op, Ms. A complained of severe pain behind the knee, and was found to have bleeding as a result of a nicked popliteal artery.

Due to multiple complications that ensued, Ms. A had an above-the-knee amputation.

Mrs. A sued Dr. B on her own and her daughter's behalf for medical malpractice regarding the surgery and failure to obtain informed consent for the biopsy.

1. **What issues do you see in these examples?**
2. **How adequate were the informed consent processes?**
3. **How legitimate are the allegations and claims?**
4. **What could be done differently?**

(see page 5 for improvement opportunities)

Case 2

Five years after a bowel resection for Crohn's Disease, Mrs. C's symptoms returned. Needing a second procedure, she consulted with Dr. D, who performed her prior surgery.

Once again, Mrs. C and her husband had a detailed discussion with Dr. D about the proposed surgery, risks and benefits. Particular attention was again given to the risk of wound dehiscence, as Mrs. C was obese, had diabetes and had taken corticosteroids for many years to treat her Crohn's Disease.

She had few questions stating, "I already know the drill," and quickly signed the comprehensive informed consent form.

On post-op day 3, Mrs. C's suture line was red, swollen, warm to touch and draining yellow exudate. Despite appropriate measures, the wound eventually dehisced.

A stormy, protracted hospital course ensued followed by a lengthy rehabilitation. Mrs. C was subsequently determined to be permanently and totally disabled.

Mrs. and Mrs. C sued Dr. D for failure to obtain informed consent, including a failure to warn of the risk of this condition.

Dr. D insisted the risk of wound dehiscence was specifically discussed although a separate note about the informed consent discussion with Mrs. C was not created.

Mrs. C also denied the signature on the informed consent document was hers.

Informed Consent Case Studies: *Opportunity for Improvement?*

Issues related to informed consent in litigation often revolve around *the consent form*. Regardless of whether the information contained on the consent form is too lengthy and alleged to be incomprehensible, or too sparse to memorialize any meaningful understanding of the patient, the consent form standing alone is always alleged to be insufficient.

* *Often, the defendant physician insists that a proper informed consent discussion was done and more details were discussed than what is reflected in the consent form.*

As defense counsel for these doctors, the author always recommended memorializing the discussion in a separate note in the chart. The note acts as proof that a discussion occurred and documents unique aspects of the conversation with the particular patient that may differ from information on the boiler plate form. An effective note, if done contemporaneously with the discussion, will memorialize the demeanor of the patient, his or her questions and concerns and any other unique aspects of the conversation that you may deem noteworthy.

* *The note is much more difficult for the patient to deny and the plaintiff's attorney to challenge.*

In *Rhode Island*, before proper consent can be obtained, a physician must advise her patient of the proposed procedure or treatment, the associated risks, alternative treatments reasonably available and the option of no procedure or treatment, if appropriate. In *Wilkinson v. Vesey*, the Rhode Island Supreme Court set forth a five-part test that must be met to succeed on a failure to obtain informed consent claim. The *Wilkinson* test is as follows:

(1) the physician's disclosure to the patient regarding a particular risk was *unreasonably* inadequate;

(2) the undisclosed risk was a *known* material risk;

(3) the undisclosed known material risk *did in fact occur*;

(4) the patient *would not have undergone the procedure* if advised of that risk; and

(5) the specific injury or harm of which the patient complains was the proximate *result of the occurrence* of that risk.

These elements, with vague terms such as 'unreasonably inadequate,' and subjective nature of the patient's intent to undergo the procedure if told about the risk, make pre-trial dismissal of the informed consent claim nearly impossible. If not voluntarily dismissed before trial, the question will go to the jury.

* *Because these are the factors that drive lack of informed consent claims in Rhode Island, it is important for physicians to document their discussions in addition to the informed consent form, focus on the textbook risks of each proposed procedure and also consider what risks may be 'material' to the particular patient.*

IMPROVING THE CONSENT PROCESS

Temple University endorses the following "best practices" for obtaining informed consent:

◊ Recognize differences in education or literacy levels; provide additional help accordingly

◊ Have extended discussions with patients; provide further explanation through other staff (e.g. RN's)

◊ Ensure thoroughness in content, consistency in language; employ a consistent outline or template

◊ Use lower reading levels, better formatting, graphics, shorter lengths, remove unnecessary material

◊ Ensure key information (risks, benefits, alternatives) is presented; use form as discussion outline

◊ Provide information or fact sheets to take home

◊ Bolster understanding; consider use of multimedia formats (e.g. webcasts, podcasts, DVDs)

◊ Use a "teach back" method; ask patients to repeat back the information presented

◊ Provide patients an opportunity to decline procedures; ensure their awareness of right to refusal

The Record is Your Black Box

◊ ***Jurors consider*** **the medical record to be a more reliable account of the patient's healthcare during the hospitalization than any other source.**

◊ ***Plaintiff's attorney*** **may not take case where they cannot fill holes in documentation with doubt and speculation.**

◊ ***Early settlement*** **typically means lower costs, payment & stress to parties**

◊ ***More reliable*** **than personal recollection the medical record is an admissible tool to refresh memory**

Temple University Health Resources Toolkit:

http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage1.html

IT'S NOT JUST ABOUT THE FORM

Obtaining informed consent is a process, not a piece of paper. The informed consent form is certainly an important tool in this process but, it should be utilized as just that, an aid. An effort to evaluate informed consent that is focused on the content of the form alone will come short of achieving proper informed consent. The form is most effective as an outline used during the informed consent process and to ultimately, when signed, memorialize the completion of the process, the understanding of the patient and his or her consent to the proposed procedure or treatment.

The purpose and focus of informed consent is to ensure the patient's understanding of the treatment or procedure they are about to undergo. Such assurance is best obtained by the face-to-face, deliberate and informative dialog between you and your patient. Questions should not only be encouraged, but purposely elicited from your patients. Questions you pose to your patients should require more than a yes or no response.

Establishing understanding may be best evaluated if it is asked for after each phase of the informed consent process. For example, you may break down the conversation by the various phases of the proposed treatment and conduct a Q&A after each: pre-op, day-of, surgery/treatment itself, risks, benefits, post-op side effects and future care expectation. Breaking down the discussion into bite-sized pieces may allow your patient to better comprehend the treatment and pose a question as soon as it formulates in his or her head.

Patients should also be encouraged to come to their informed consent discussion with pre-formulated questions. When they don't, a prepared patient questionnaire may provoke discussion.* These questions can provide you with some insight about what this particular patient's concerns are and tailor the discussion to those specific points. This can bring incredible comfort to your patients and allow them to feel in control of their health care decisions.

Informed consent remains an essential aspect of your relationship with your patients. Therefore, give it the due attention it deserves and focus on maintaining the trust your patients have in you. Allow this informed consent process to accurately reflect the excellent care you provide to each and every one of your patients.

***Consider use of a patient checklist to elicit questions and dialogue; you may tailor the following document from Temple Health to suit your practice needs.**
http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage21.html

Capacity vs. Competency: *What is the Difference?*

The terms *capacity* and *competency* are frequently mistaken for one another and are therefore erroneously often used interchangeably; however, under Rhode Island law and specifically in the context of one's right to make decisions, there is an important difference.

Capacity: An individual's ability to understand the nature and effect of one's acts and to make an informed decision. Any licensed physician may make a determination of capacity. Capacity is a fluid concept; an individual may have the requisite capacity in one moment and lack capacity in another. *The determination to be made is whether an individual has the ability to understand the nature and effect of his or her acts in a specific moment in time.*

Capacity to consent to medical procedures is determined by the criteria of informed consent. Does the patient have the ability to:

- ◊ Understand the medical procedure and specifically understand a description of the procedure, its risks, benefits, and alternatives?
- ◊ Voluntarily consent?
- ◊ Give consent because he/she is competent (meaning, he/she does not have a guardian)?

Competency: A legal finding, not a medical one. Competency proceedings, including guardianship and conservatorship hearings, are conducted to allow the court to determine the individual's mental capacity.

Incompetency: The lack of ability to discharge or understand either health care or financial management decisions. An individual is incompetent when *declared by the court* to be in need of a guardian or conservator. This determination is made only after the individual meets the proper legal standards.**

Common law dictates that individuals possess autonomy and self-determination, which encompass the right to accept or refuse medical treatment. When the ability of the patient to make reasonable decisions is called into question, management of medical treatment can be complicated. Our legal system endorses the principle that all persons are competent to make reasoned decisions unless demonstrated to be otherwise. ****For a landmark RI case on informed consent, see more @**
http://law.justia.com/cases/rhode-island/supreme-court/1993/625-a-2d-778.html

Insights is published by Lifespan's Department of Risk Management Loss Prevention division.
Submissions and ideas are welcome and may be submitted to the department or faxed to **401-444-8963.**