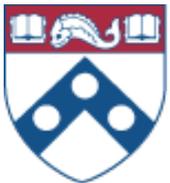


Megan L Shinal and Robert J
Shinal v. Steven A Toms, M.D.

A Discussion of the Recent PA
Supreme Court Decision
regarding Informed Consent

IRB Member Training
August, 2017



Overview

- ◆ The duty to obtain a patient's informed consent is a non-delegable duty of the physician performing the procedures/providing the treatment
- ◆ A physician may not rely upon a subordinate (i.e., resident, advanced practice provider, nurse, etc.) to disclose information required to obtain consent
- ◆ Applies to research when study involves the administering of an experimental medication, using an experimental device, or using an approved medication or device in an experimental manner



Agenda

- ◆ Overview of relevant prior cases and legislation
- ◆ Description of the Shinal v. Toms case
- ◆ Summary of the Court's Ruling
- ◆ Discussion



Legislative requirement to obtain informed consent

The Medical Care Availability and Reduction of Error (MCARE) Act of 2002

- ◆ **Duty of physicians.** Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:
 1. Performing surgery, including the related administration of anesthesia
 2. Administering radiation or chemotherapy
 3. Administering a blood transfusion
 4. Inserting a surgical device or appliance
 5. Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner



Case Law on Informed Consent Requirements

- ◆ Bulman v. Myers (Pa Super. 1983)
 - The court rejected an argument that “a patient cannot formulate a valid, informed consent to a surgical procedure when disclosure of the risks of surgery are made by a nurse assistant and not by the operating surgeon.”
 - Court found that “the primary interest of Pennsylvania jurisprudence in regard to informed consent is that of having the patient informed of all the material facts from which he can make an intelligent choice as to his course of treatment.”
- ◆ Foflygen v. Allegheny General Hosp. (PA Super. 1999)
 - The court held that “the validity of a surgical patients informed consent depends upon the pretreatment information relayed to the patient, regardless of whether the disclosures are made by the treating physician or another qualified person such as a nurse or other assistant.”



Case Law on Informed Consent Requirements

- ◆ Valles v. Albert Einstein Medical Center (Pa. 2002)
 - Court decided that the duty to obtain informed consent belongs solely to the physician and that it is non-delegable.
 - Describes consent as a process flowing from the discussion each patient has with his or her physician.
 - Found that the duty to obtain informed consent rests solely upon the healthcare provider performing a medical procedure, and not upon a hospital.



Shinal v. Toms

- ◆ Medical malpractice action premised upon lack of informed consent
- ◆ Megan L Shinal – patient with a recurrent, non-malignant tumor in the pituitary region of her brain
- ◆ Stephen A Toms, M.D. – Neurosurgeon and Director of the Department of Neurosurgery at Geisinger Medical Center in Danville, Montour County



Shinal v. Toms

- ◆ November 2007 - Megan Shinal met with Dr. Toms to discuss total versus subtotal surgical resection of her tumor. Dr. Toms advised that total surgical resection offered the highest chance for long term-survival.
- ◆ December 2007 - Mrs. Shinal had a conversation with Dr. Toms' physician assistant about the surgery and the craniotomy incision.
- ◆ January 2008 - Mrs. Shinal met with the physician assistant who obtained medical history, conducted, a physical, and provided her with information related to the surgery. Mrs. Shinal signed the surgical consent form.
- ◆ Mrs. Shinal underwent open craniotomy total resection. During the operation, Dr. Toms perforated her carotid artery, which resulted in hemorrhage, stroke, brain injury and partial blindness.
- ◆ Mrs. Shinal filed a medical malpractice claim that Dr. Toms failed to explain the risks of the surgery or to offer her the lower risk surgical alternative of subtotal resection of the tumor followed by radiation.



Shinal v. Toms

- ◆ Geisinger Medical Center and Dr. Toms were both named as defendants. The liability phase of the trial solely addressed whether Dr. Toms obtained Mrs. Shinal's informed consent
- ◆ During the trial, the trial court judge instructed the jury that "in considering whether [Dr. Toms] provided consent to [Mrs. Shinal], you may consider any relevant information you find was communicated to [Mrs. Shinal] by any qualified person acting as an assistant to [Dr. Toms]."
- ◆ The jury returned a verdict in favor of Dr. Toms.
- ◆ Case was appealed to the Superior Court – Mrs. Shinal argued that the jury instructions were erroneous and prejudicial.
- ◆ The Superior Court rejected this argument and cited two prior cases – *Foflygen v. Allegheny General Hosp* and *Bulman v. Myers*
- ◆ Case was appealed to the Supreme Court



Supreme Court Decision - 6/20/2017

- ◆ Court considered whether the trial court misapplied common law and the MCARE act
- ◆ Court determined that the Bulman and Foflygen decision pre-date Valles and the MCARE Act.
- ◆ Supreme Court concluded: “that the trial court committed an error of law when it instructed the jury to consider information provided by the defendant surgeon’s qualified staff in deciding the merits of the informed consent claim. Because a physician’s duty to provide information to a patient sufficient to obtain her informed consent is non-delegable”
- ◆ The court determined that a physician cannot rely upon a subordinate to disclose the information required to obtain informed consent.
- ◆ Court instructed that a new trial take place



Quotes from Supreme Court Decision

- ◆ “Thus, we hold that a physician may not delegate to others his or her obligation to provide sufficient information in order to obtain a patient’s informed consent. Informed consent requires direct communication between physician and patient, and contemplates a back-and forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent.”
- ◆ “Without direct dialogue and a two-way exchange between the physician and patient, the physician cannot be confident that the patient comprehends the risks, benefits, likelihood of success, and alternatives....Informed consent is a product of the physician-patient relationship.”
- ◆ “Nothing in the plain language of the Act suggests that conversations between the patient and others can control the informed consent analysis or can satisfy the physician’s legal burden.”



Discussion

- ◆ Decision applies when obtaining consent for any of the procedures discussed in the MCARE act
 1. Performing surgery, including the related administration of anesthesia
 2. Administering radiation or chemotherapy
 3. Administering a blood transfusion
 4. Inserting a surgical device or appliance
 5. Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner
- ◆ Most common research application will be clinical trials involving drugs and devices



Discussion

- ◆ How does the IRB apply this decision to the review of the consent process?
- ◆ Should the IRB encourage the use of screening consents for clinical trials in light of this ruling?
- ◆ Are there other practical ways to alter the consent process to ensure a sufficient consent process that is in line with this ruling?
- ◆ What should occur if the PI is not the treating physician?

