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New Challenges in Consent and Informed Consent in Society: Implantable Life-saving Medical Devices

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ABSTRACT

Because of the success of keeping people alive after a life-threatening arrhythmia, the implantable cardiac defibrillator (ICD) has become an invasive medical device posing unique challenges to patients, physicians, and healthcare personnel. This paper examines the unique societal challenges of the ICD in the context of consent and informed consent in the Great Britain, the United States, Canada, and Australia. The main societal issues in consent and informed consent regarding implantable life-saving medical devices involve the types of information (individual vs. societal) that are to drive the discussion between patient and his or her physician.

Keywords: New Challenges, Consent and Informed Consent, Implantable Life-saving Medical Devices

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Because of the success of keeping people alive after a life-threatening arrhythmia, the implantable cardiac defibrillator (ICD) has become an invasive medical device posing unique challenges to patients, physicians, and healthcare personnel. This paper examines the unique societal challenges of the ICD in the context of consent and informed consent in the Great Britain, the United States, Canada, and Australia. The main societal issues in consent and informed consent regarding implantable life-saving medical devices involve the types of information (individual vs. societal) that are to drive the discussion between patient and his or her physician.

The First Consent Case Involving a Medical Device: *Slater v. Baker and Stapleton* (1767)

The first consent case was heard in Great Britain in 1767, *Slater v. Baker and Stapleton.1* This case involved the use of "a mechanical device with teeth" to set of fracture of the femur, the long bone of the leg. Physicians called to court to testify, agreed that the securing of the patient's consent was a custom among physicians. Thus, the court established the use of a professional standard in consent, that is, consent cases were to be judged by the prevailing professional standard of physicians. I use the term "prevailing" because as medical science and clinical science both develop, change in each will mandate what is said to a patient in consent. The term "informed consent" entered the judicial lexicon in 1957 in a U.S. California appellate decision, *Salgo v. Leland Stanford Junior Board of Trustees.2* An amicus curiae brief submitted by the American College of Surgeon stated that surgeons secure the informed consent of their patient prior to performing a surgical procedure. Neither the amicus curiae brief nor the appellate opinion written by Justice Bray defined informed consent.

PARQ

Today, consent and informed consent as heard in the high courts of the United States focus on three types of information to be provided to a competent patient by a physician prior to a non-emergent medical intervention: (1) a description of the nature of the physician-recommended procedure (P), (2) reasonable alternatives (A) to the physician-recommended procedure, and (3) the risks (R) of both the physician-recommended physicians and its alternatives. The patient then has a right to ask the physician any questions (Q) which the physician is obligated to answer truthfully.

Reasonable Person in the Patient's Position Standard

In 1972, Judge Spottswood Robinson articulated a non-professional standard for informed consent in *Canterbury v. Spence*3 that was adopted by about half of the U.S. states, the Supreme Court of Canada (*Reibl v. Hughes*, 19804), the High Court of Australia (*Rogers v. Whitaker*, 19925), and, most recently, the UK Supreme Court (*Montgomery v. Lanarkshire Health* Board, 20156) also adopted the reasonable person in the patient's position standard. These U.S. state courts and these high courts hold that physicians should inform the patient of those risks that a reasonable person in the patient's position would want to be informed. All share the view that reasonable person would want to know the chance of severe adverse outcomes occurring no matter what their chance of occurrence.

Yet, new the development of new medical devices that save lives brings with them new information challenges, adding new forms (types) of information may need to be added to patient informedness related to the decision whether or not to accept these life-saving medical devices, in particular, the cardio-defibrillator. This device has expanded our understanding of informedness in the light of a patient's decision whether or not to accept the implantation of a cardio-defibrillator in his or her care. Typically, the decision will be one between choosing one type of cardio-defibrillator over another, or choosing a cardio-defibrillator or therapy with anti-arrhythmic medications.

Severe adverse outcomes

Severe adverse outcomes include loss of organ or organ function, risks of loss of limb, stroke, death, among others.

Uncertain risks in research on humans

During its research phases, there are uncertain risks related to the fact that the research intervention has not as yet been carried out in a

high number of patients, and, therefore, the full-range of risk is not as yet known. Most likely, the full-range of risks will not be known completely until 5-6 years after the intervention is being used in patient in the population.

Two Classic Examples of Medical Devices and the Nature of their Risks

Medical devices today carry with them a broad range of risks of varying types that are performed on a daily basis in each of the countries of our interest but which have not reached as yet consideration by the high courts under consideration. These two medical devices carry with them many more risks than typically considered in a high court case in consent and informed consent. We will now review these two medical devices: stent placement by an interventional radiologist and cardio-defibrillator placement by a cardiologist or a cardiac surgeon.

Example-1: The Decision to Stent

Combinatory risk-1: medical device-related risk vs. risk of patient's body habitus and device

A stent is a medical device . . . It is a known point that patients with particular body habituses have increased risks with the placement of particular stents. There are risks to implanting a stent, but there are also risks of a patient's body habitus regarding placement of a stent.

Combinatory risk-2: above example in Combinatory risk-1 plus the need to proceed with repeat imaging to visualize where the stent has migrated, e.g., the circulatory system

Once there are problems with the medical device not a\being an appropriate fit in the patient in question, there are the risks of imaging to localize where the stent has migrated within the circulatory system.

Example-2: The Decision to Implant a Cardio-Defibrillator

As the population ages, there will be an expansion of decision making related to devices that save lives. These devices do not change the course of underlying diseases, but they do bring people who would otherwise be dead due to an arrhythmia, back to life.

Risks to Self vs. Risks to Others

There are risks to self with the decision to implant a cardio-defibrillator, and there are risks to others. Physicians, researchers, medical institutions, and clinical and research review committees need to be prepared to evaluate the type of life-saving medical device should it be the object of a research study. One way to approach such a medical device evaluation starts off with a set of 6 questions:

1. Is the medical device to be implanted in the body of the person?

2. If to be implanted, can it be implanted in more than one location?

3. Who is going to implant the device?

4. How much training is needed to implant the device?

5. What are the risks of:

a. the medical device?

b. its implantation procedure?

6. What are the risks of each component of the medical device being studies?

We will illustrate the above research study of a medical device and its implantation procedure by examining a life-saving medical device which will be increasingly used and studied in new models over the next decade. This medical device is the implantable cardio-defibrillator.

Example: Life-Saving Medical Device: The Implantable Cardiac Defibrillator (ICD)

A life-saving device saves an individual who is about to die from dying. Such devices would include portable defibrillators that one finds in many public buildings, but also implantable cardiac defibrillators (ICDs). A life-sustaining device is a device that not only saves an individual at a particular time, e.g., in a cardiac arrest due to ventricular fibrillation, and may save that same individual many times during that individual's life.

Research review committees or IRB consider both types of devices when research studies are undertaken to on new models of such device or new approaches to mechanical aspects of the

device, or new approach to implanting the device into a research study participant. In any of these three situations, the IRB must be ready with a set of questions to evaluate the research study of the device in any of the three above forms of the research study.

The risks of implantable cardiac defibrillators are quite extensive, and the involve two unique aspects of risk: (1) risk borne by the individual over time as long as he or she has the device implanted during the course of the research study and (2) risks borne both others than the individual study participant.

Device Risks to Be Considered by the Individual Being Recruited Into the Research Study

The individual will bear the risks the following device risks.

- Risks of surgical implantation
- Risks of the device

Risks of Surgical Implantation

The surgical implantation procedure will need to be detailed as in any research study. However, the IRB must ask the following questions:

• Are there any new variations of the surgical implantation procedure being studied? If so, these risks of variation must be listed and compared to risks of current implantation procedures?

Risks of the Device

The risks of the device include the following:

- Risks of the device and each of its components. [7,8,9,10,11,12,13,14]
    - o ICD devices
    - o Device components include: leads, batteries, and the container in which the device sits.
        - How long will the battery last?
        - Who is responsible for device maintenance and check-ups over time?
        - Will the study participant be reminded of these check-up times? If so, how will he or she be reminded?
        - Will there be information about the device printed out so that if the study participant travels and something goes wrong, the physician evaluating the patient will know about the device, who on the research team to contact, what to do in case of emergency, unique aspects of the device?

Psychological Risks to the Study Participant

Psychological risks to the study participant include risks of the device failing to read rhythm strips accurately causing the device to fire when the rhythm is normal.15 Psychological risks include the device misfiring and the adverse outcomes that may occur should the device misfire in various circumstances, e.g., when the participant is in the shower. Will the individual be allowed to drive a car alone or accompanied with the device in place? Who will make that determination?

Psychological Risks to the Family, Partners, and Significant Others

The psychological risks to the study participant will also be shared by the participant's family members, partners, and significant others.[16,17]

Summary and Conclusions

Data is showing that Primary prevention ICDs are associated with lower mortality in patients regardless of race and ethnicity.18 Data about benefit and risk is accumulating.[19,20] Yet, three outstanding questions that need to be answered include the following: (1) Who will get the message out to all groups about the benefits and risks of ICD placement? (2) Who will inform not only the eligible patients, but all others who will be impacted by the patient's or participant's decision to have an ICD placed or not in consent and informed consent about the risks and benefits of ICD placement? And (3) in what level of detail will these be communicated to the others beyond the patient or participant? Research needs to be done on both questions

to aid the future development of consent and informed consent.

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