Developing a Better Process for Informed Consent

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Goal of this talk

• Describe practical steps to improve the process of informed consent, in the effort to achieve ethical goals.

-Schenker & Meisel, JAMA, 2011
The Case of Mr. L

A 70-year-old man with end-stage heart failure, who is being evaluated for a destination left ventricular assist device (LVAD).
Destination Left Ventricular Assist Device
Patient-Centered Care
Documented Failures

- Poor understanding
- Medical errors
- Preference-discordant care

Can we do better?

- Schenker et al, Med Decis Making, 2010
Improving the Process

- When
- What
- How
- Who
Who

- Surgeon
- LVAD nurse coordinator
- Palliative care clinician

-CMS, Decision Memo for Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy, 2013
Team-based approach

- Clear roles
- Improved patient understanding
- Choice reflects values
- More efficient
Immediately before the procedure

- Patient too sick / surrogate consent required
- Psychologically committed
- “Medical Miranda Warning”

- Meisel & Kuczewski, Arch Int Med, 1996
In advance

- Patient not as sick
- Multiple information sessions possible
- More time to prepare, engage, ask questions
- Informed consent → informed choice
Timing Matters

- Schenker & Meisel, *JAMA*, 2011
Right-sided heart failure: If I have had a left ventricular VAD inserted there is a possibility that the right side of my heart could fail requiring the insertion of an additional pump. This can occur 10-25% of the time.

Other Common Risks include:

- The need for another operation for removal of fluid due to infection, repair or closure of a wound incision, tracheotomy (insertion of a tube in your neck to assist with breathing), the placement of a chest tube to drain fluid from around the lungs and the insertion of a tunneled (under the skin) long-term intravenous catheter.

- An increase or decrease in blood pressure that would require further treatment.

- Some other abnormality of the cardiovascular system such as, a rapid and/or irregular heartbeat that may require additional medical care.

Risks of Surgery

I understand that there are in certain circumstances a source of third party payment, and I will be personally responsible for such costs, including any applicable copays, coinsurances, and deductibles that are not covered. The procedures to be charged to my insurance provider constitute usual subject care, and are reasonable and medically necessary independent of this research study. Support equipment, including the LVAS pump, the controller or driver system, a backup driver system, rechargeable batteries, emergency power pack, battery clips, power base unit cable, battery holsters, pocket pack, night belt, travel case, power base unit and monitor will be billed to my insurance carrier. UPMC will obtain pre-certification for approval of payment from insurance carriers prior to LVAS implantation. If my insurance carrier refuses payment during this pre-certification process the ventricular assist device will be offered to you as a destination therapy, however, with an FDA approved ventricular assist device, I may have to pay personally for such device and care if the insurer again would refuse to pay. I have been advised that a financial counselor is available to talk to me about the costs associated with my surgery and to answer questions about sources of payment for those costs and costs that may not be covered by insurance and that I will need to pay myself. I understand that I am responsible to pay for the cost of dressings and supplies needed to change the dressings when I am discharged from the hospital.

Rash, fever, headache or shock exposure to blood borne virus Immunodeficiency Virus (HIV) hepatitis C is approximately in 200,000 per unit transfusion can affect a person’s ability to receive future organs. Pericardial effusion: The accumulation of fluid around the heart can decrease my heart’s ability to pump blood and may be required.

Pregnant and nursing women: The safety and effectiveness of an LVAD has not been demonstrated in pregnant or nursing women. If I am a woman in childbearing years, I understand that I will be required to use a reliable method of birth control. The use of an LVAD on a pregnant woman poses serious risks, including the death of the baby or myself.

Risks Involving Medical Costs and Insurance UPMC will bill my insurance carrier and/or any other available source of third-party payment for the cost of implantation of the LVAS and my hospital care. Charges for services such as hospitalization, laboratory test, diagnostic or evaluative procedures, or other services required for the appropriate treatment of your condition will be billed to my insurance carrier and/or any other available provider.
Focus on Risks

- Vague
  “The risks are bleeding and infection”
- Overwhelming
- Impersonal
Focus on Outcomes

- Best case scenario
- Worst case scenario
- Most likely scenario for individual patient

-Schwarze ML et al, JPM, 2013
Do patient goals and outcomes align?

LVAD

- Worst Case Scenario
- Most Likely Scenario
- Patient Goals
- Best Case Scenario

Palliative Medical Therapy

- Worst Case Scenario
- Most Likely Scenario
- Best Case Scenario

-Schwarze ML et al, JPM, 2013
Best communication practices

- Ask-tell-ask
- Show don’t tell
Ask-Tell-Ask

• “What have you heard about LVADs”
• Fill in the gaps/correct misconceptions
• “I want to be sure I have done a good job of explaining things today. Can you tell me . . . ”

-Back, Arnold & Tulsky, *Mastering Communication with Seriously Ill Patients*
-Bodenheimer et al, *Helping Patients Manage Their Chronic Conditions*, 2005
Surgery
I have been told that implantation of a LVAD will require a major operation, similar to open heart surgery. I will be put under general anesthesia, which means that I will be given drugs to put me to sleep, block pain and paralyze parts of my body. (The type of anesthesia and the risks of the anesthesia will be explained to me by a representative of the anesthesia department and I will be asked to sign a separate consent form.) The surgery will then make a cut vertically down my breastbone and extending into the upper abdomen as needed to allow for the implantation of the LVAD. I will also have a small catheter (a thin flexible tube) inserted into a vein in my arm, probably in the area of my wrist or groin, to monitor my blood pressure, and from which to draw blood. I will likely have another catheter inserted into one of the veins in my neck that will monitor pressures inside my heart. The catheter can be used to infuse medication into my blood stream as well as to draw blood for monitoring. The doctors will determine when these lines can be removed after surgery.

I will be placed on a heart lung machine that will circulate my blood and provide oxygen to my body. The surgeon will operate on my heart and insert the implantable components. The surgeon will create a pocket in my abdomen (belly) wall to support the pump. The inflow cannula (a tube that connects the pump to my body) will be sewn into my heart, while the outflow cannula (a tube that connects the artery to the pump) will be sewn into my aorta (the largest artery in my body). The driveline (the tube that comes through my skin) is inserted through my abdominal wall and under my skin. It will exit my body over the right or left side of my abdomen. The driveline (or percutaneous lead) will connect the pump inside my body to the controller and external power supply of the pump that sits outside my body. This tube (or driveline) contains the power cable. The power cable is connected to a small monitor (computer), and then to a special power supply. The power supply needs to be changed every 2-3 hours or 2 a power based unit, which is plugged into an AC wall socket. This power supply is connected to the driveline and can be used when the amount of fluid draining from them decreases. Special mechanical “boots” will be used to flow through my legs to try to prevent dangerous blood clots. The entire operation should take approximately four (4) to six (6) hours.

Post Surgical Recovery, Care and Conditions
After the surgery I will be transferred to an intensive care unit where I will stay until my physicians determine that I am medically stable enough for transfer to a monitored step-down (intermediate) unit. As long as the LVAD is in my body I may need to take blood thinners depending upon the type of VAD inserted. Should the physician determine that blood thinners are necessary I will require frequent monitoring including blood samples daily while I am in the hospital, and twice a week or as often as the doctor determines. It may be necessary to be discharged to a rehabilitation facility or skilled nursing facility before my doctors feel I have recovered enough to go home. I have been told that I must make a commitment to attend training sessions to learn how to manage the VAD in the out-of-hospital setting. There will be four (4) training sessions lasting for approximately 1 hour each. I have been told that I must take a written test and hands on test to demonstrate my ability to take care of the VAD while I am supported outside the hospital. I will be required to have one family member also trained in the care of the device and how to get help when needed. The artificial heart program team will evaluate when it is safe for me to leave the hospital. It may be necessary to be discharged to a rehabilitation facility or skilled nursing facility before my doctors feel I have recovered enough to go home. I have been told that if the artificial heart program team agrees that it is safe for me to leave the hospital and once I am home then I must make a commitment to return to the outpatient cardiology clinic every three (3) months and to have blood work drawn at least once a week or as needed.
Technology Can Help

• Enable patients to envision treatments and outcomes

• Engage patients in the consent process

• Connect patients through support groups

Volandes et al, BMJ 2009
http://www.acpdecisions.org/
https://www.prepareforyourcare.org/
http://decisionaid.ohri.ca/
Improving the process of informed consent

**Who**
- Team-based approach

**When**
- In advance

**What**
- Focus on outcomes

**How**
- Ask-tell-ask
  - Technology can help