The 2016 Annual University of Miami Bioethics Debate

Case Packet

(Adapted from the 2016 National Undergraduate Bioethics Conference Case Packet)

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Case 1
Bits and Pieces – Uterine Morcellation

In 1995, the Food and Drug Administration (FDA) approved the uterine morcellator through an expedited 510(k) process since similar devices were already being used in other surgical fields. Essentially, the morcellator allows for large tissue specimens (usually the uterus in gynecology) to be electrically cut into smaller segments and pulled out of the body through a much smaller incision. This allows for surgeries that would otherwise require large incisions and thus, increased intraoperative complications, post-operative recovery times, and overall increased morbidity to remain as minimally-invasive (laparoscopic or robotic) surgeries.

However, recently, the high-profiled case of the tragic morcellation of an occult malignant uterus (thus, potentially spreading the cancerous cells throughout the pelvis and decreasing prognosis), has resulted in a firestorm of impassioned responses via the media, physician groups, hospitals, and the FDA. The FDA has now put a warning on the use of the electric power morcellator in gynecologic surgery, urging physicians to be cautious about its use. Many device manufacturers have stopped production and several large hospital systems have altogether banned its use.

While at first glance this seems appropriate given the risk of upstaging cancer, many researchers and physician groups have argued the opposite point of view. For example, they have argued that the risks of laparotomy (using a big incision to remove the large specimen) far outweigh the risks of minimally-invasive surgery combined with the risks of the morcellator. Occult malignancy, or cancer that is unknown prior to surgery, is rare and occurs with a frequency of 1:3,000 by some estimates, although high quality data are lacking to pinpoint an exact rate. While it is unfortunate that one person in 3000 patients has a worse prognosis due to the use of the morcellator, some believe it is unfair to mandate the known increased risks of laparotomy on the other 2,999 who would not have had such an outcome.

Question: Should physicians and hospitals continue to use the morcellator for gynecologic surgery? If so, whose decision should it be – the patient's, the physician's, or the hospital's?

Resources:

American College of Obstetricians and Gynecologists. Power morcellation and occult malignancy in gynecologic surgery: a special report. Available at: http://www.acog.org/Resources_And_Publications/Task_Force_and_Work_Group_Repo rts/ Power_Morcellation_and_Occult_Malignancy_in_Gynecologic_Surgery.

American Association of Gynecologic Laparoscopists—Tissue Extraction Task Force. Morcellation during uterine tissue extraction. Available at: www.aagl.org/wp-content/uploads/2014/05/ Tissue_Extraction_TFR.pdf.

Levitz J. Doctors Eye Cancer Risk in Uterine Procedure. Wall Street Journal. 2013. Available at: http://www.wsj.com/articles/SB10001424052702304173704579264673929862850

Case 2
Doctor's Orders

Dr. Jones is a 60-year-old physician working at a medium sized for-profit hospital in a large city. His father had died twenty years previously from a cerebral stroke that had left him ventilator dependent and unable to speak or otherwise communicate. Prognosis was dismal. Dr. Jones, the oldest child, had been asked by the hospital staff whether he wanted the ventilator turned off for his father. Dr. Jones was tortured about the decision. His father had given no directions about what he would have wanted in this situation. He chose not to stop aggressive intervention. His father lived for four months without recovering his communicative abilities.

Dr. Jones was determined that he would never place himself and his family in the same position. He knew that strokes run in families. He filled out a living will stating clearly that if he ever had severe brain damage from a stroke and lost the ability to communicate with no chance of recovery, he would want all treatment stopped and be allowed to die with comfort care only.

Dr. Jones was a workaholic. He spent long hours at his office, frequently missing dinner and social events with his wife and two daughters. His wife complained and, after 35 years of marriage began threatening divorce. He also was unhappy with work. A younger physician had been given his administrative responsibilities as head of an important clinical unit. Dr. Jones was generally in good health.

One night, while working in his office next to the hospital, he wrote a DNAR on a series of Post It® notes and pasted them around his office. He then wrote a long suicide note telling his wife and daughters how much he loved them but that he had failed them as a husband and father and now was a "failure" at work. He explained how well he had provided for them financially for the future and explicitly how they could access the considerable amount in his estate. Next, at approximately 10pm, he took a large overdose of barbiturate medications. The cleaning staff found him comatose at 6am the next morning, called 911 and he was emergently resuscitated, including intubation, and admitted to the medical intensive care unit of his own hospital, deeply comatose.

Over the next two days the barbiturates cleared from his system, but he remained unresponsive. His wife brought in his advanced directive and told the physicians to stop the ventilator and all other life-sustaining measures. The physicians refused saying the prognosis was not yet clear. The wife was furious. Four days later, he began to wake up. Ten days later his thinking and speech seemed normal. He regained all motor function. While he was doing physical therapy, he had a major stroke and became aphasic and hemiplegic. His condition had not improved after one year.

Question:

Were the staff and physicians wrong to resuscitate Dr. Jones in the face of all the all the DNAR notes clearly visible to them?

Case 3
A PPACA Controversy

This election cycle, Republican presidential candidates have openly criticized the Patient Protection and Affordable Care Act (PPACA) both in entirety and specifically for including prenatal testing within the range of prenatal care services to be covered by health insurers. In some candidates' view, requiring insurance coverage for prenatal testing, and specifically amniocentesis, is problematic in that it would encourage abortion of pregnancies in which fetal anomalies are detected.

Historically, insurance coverage for abortion services has been restricted, and these candidates' concerns highlight the contentiousness between the increasing availability of prenatal genetic testing modalities with simultaneous limitations on abortion provision in the United States.

Question: **What are the ethical implications of federally mandating insurance coverage for prenatal genetic testing?**

Case 4
Limitless in the ER

Consider the following hypothetical. Drug A has been found to significantly enhance the performance of emergency room physicians. Clinical trials have demonstrated that physicians who have taken this drug 5 days a week (one dose a day at the beginning of their shift), 48 weeks per year for five years show no long-term ill effects. Transient effects while on the drug include mild headache in 10% of users. There is no addiction or withdrawal problem. There is no sleep problem.

Studies have shown definitively that the drug enhances cognitive skills such as ability to focus, process information more quickly, and multitask during 10 hours shifts. Studies have also demonstrated conclusively that the rate of medical error is reduced by 20% and the death rate by 5% when ER physicians take Drug A.

Questions:

Which of the following policies should a hospital adopt:

(a) Require any physician working in the ER to take Drug A while on duty;
(b) Suggest that ER physicians take Drug A but leave it up to them;
(c) Remain silent on the issue?

Are there any compelling ethical reasons to forbid physicians from using Drug A while working?

Case 5
Who's Listening?

Kelly and Mark are a thirty-something couple who have been together five years, but are not married. They recently found out that Kelly is pregnant. The fetus' biological paternal grandmother, Mary, is deaf and several of her brothers and sisters are deaf, although her parents were hearing. When the Kelly is 20-weeks pregnant, the couple, along with Mary, visits a genetic counselor to determine if deafness may be genetic. The genetic counselor, Dr. Cole, advises them that it's possible if there is a mutation with Connexin 26. Lisa also tells them that they would have to test the Mary to verify. Mary is willing, as she is very interested in knowing if the deafness in her family is genetic. Because Mary is the one that is tested, Dr. Cole gives her the results, which are positive for the mutation. Mary advises Dr. Cole that she has no intention of sharing the information with Kelly and Mark because she'll be thrilled if her grandchild is deaf.

Kelly has a normal pregnancy and a normal birth. Alexis, the newborn, subsequently passes a newborn hearing screening test. Because of this, Kelly and Mark never have her retested, although their pediatrician repeatedly expresses concern about her hearing. At 3 years of age, Alexis is diagnosed as completely deaf. Kelly and Mark revisit Dr. Cole to have Alexis tested to see if she is a good candidate for chochlear implants. If Alexis tests positive for the Connexin 26 mutation, then she'll be a good candidate. If she doesn't, then she will not be. Alexis tests positive for the mutation. During the follow-up visit, Dr. Cole learns that Kelly and Mark have a 1-year-old who also has passed a newborn hearing screening test. Dr. Cole suggests that Kelly and Mark also have her tested. Mark agrees, but Kelly declines.

At Kelly's insistence, she and Mark take Alexis to an otolaryngologist, Dr. Kim, to be evaluated for the implants. Dr. Kim advises that Alexis is a good candidate. Kelly is adamant that Alexis get the implants. Mark tells Dr. Kim that Alexis is fine without them and he is unsure as to whether they should go through with the surgery. Dr. Kim learns that Alexis is not getting any education in sign language, even though Mark and Mary both sign, as Kelly is adamant that Alexis not be considered deaf. Kelly has also banned Mary from the house and Alexis' life. Dr. Kim explains to Kelly and Mark that while the implants will be helpful to Alexis, they will not provide her with normal hearing. He advises that whether or not Alexis gets the surgery, she should be learning to sign and to read lips. Kelly states that she will not permit this until after the surgery, if at all, and asks what the next steps are to move forward with the surgery.

A few weeks later, Dr. Cole is surprised to see Mark on her schedule alone. However, when she enters the room, she finds him with his 1-year-old, Hayley. Mark asks Dr. Cole to test Hayley for the Connexin 26 mutation.

Question: Should Dr. Kim have assisted Kelly and Mark in moving forward with the surgery?

Case 6
Never Let You Go

Ms. Smith was a 45-year-old woman diagnosed with a type of lymphoma that carries a very bad prognosis. She was told that the most aggressive chemotherapy could keep her alive for two years at the most. Ms. Smith was a life-long Jehovah's Witness. She was unmarried, had no children and was very close to her loving parents. The aggressive therapy would almost certainly suppress her bone marrow to the point that transfusions would be necessary to preserve her life during treatment. She refused transfusions but requested that the physicians try the aggressive chemotherapy nonetheless. They refused, but offered her a less aggressive chemotherapy that would not suppress her bone marrow but would only provide a very small chance of surviving more than a couple months. She agreed to the weaker chemotherapy.

Things did not go well for Ms. Smith. The lymphoma rapidly spread throughout her body. Her organ systems began to fail and eventually she was admitted to the intensive care unit where she was intubated due to respiratory failure. Her liver, kidneys, intestines and heart also began to fail. Ms. Smith had consistently told her physicians that she wanted to "stay alive as long as possible." Her hematocrit and hemoglobin levels were barely compatible with life (not from the chemotherapy but rather from the lymphoma itself). The inability of her blood to deliver adequate oxygen was in large part responsible for her heart, gut, and brain failure. Her parents were distraught. Themselves Jehovah's Witnesses, Ms. Smith's parents surprisingly asked the physicians in the intensive care unit to give their daughter transfusions saying, "We don't want to lose her." The hospital record and conversations with previous physicians indicated that the patient had never swerved from her wish to refuse blood or blood products.

The physicians denied the family's request. Over the next few days, the patient hovered near death. The physicians recommended that a DNAR order be written. The parents insisted on full resuscitative efforts that, according to the physicians, had no chance of prolonging her life for more than a few minutes. The parents insisted. The physicians called for a clinical ethics consultation saying resuscitation in this case was futile and that they should be allowed to unilaterally refuse resuscitative efforts.

Question:

Is futility a viable concept that allows physicians to unilaterally refuse resuscitation or other potentially life-prolonging interventions?

Case 7
Anyone Need a Womb? – Uterus Transplantation

Doctors in Sweden have recently announced the first human livebirth after uterus transplantation after nearly fifteen years of research. Uterine factor infertility affects nearly 9.5 million women in the United States. Previously, there were only two potential treatments – surrogacy or adoption. Uterus transplantation represents a novel third option. Following this success in Sweden, the Cleveland Clinic recently announced it will begin enrolling research subjects for the first uterus transplant clinical research trial in the United States.

In the reported Swedish case, a 61 year-old close family friend donated her uterus to a 35 year-old woman who was born without a uterus. After a ten-hour surgery for the donor and an almost five-hour surgery for the recipient, the recipient was placed on immunosuppressive medication. After several months of waiting to ensure stabilization of the transplant, transfer of an embryo created through in-vitro fertilization previously using the recipient's eggs and her husband's sperm was placed into the transplanted uterus. Over the course of the next eight months, the recipient's pregnancy progressed. Due to medical complications arising from her baseline health and the superimposed risks of pregnancy, she delivered via cesarean section several weeks preterm. Both mom and baby recovered well and are healthy.

Uterus transplantation represents a medical first – both in the reproductive infertility world and the transplant world. It is the world's first ephemeral transplant, that is, intended only for a short time rather than for life-long benefit. After the recipient is done childbearing (she plans on having 2 children), a hysterectomy will be performed so that she does not need to be on immunosuppression for the rest of her life. It also allows for the experience of the gestational component of motherhood, unlike the current options of surrogacy and adoption. However, it is an incredibly costly treatment for infertility and represents an organ transplant done for quality-of-life and not life-saving reasons.

Question:

Uterus transplantation could be regulated either as an infertility treatment (currently through the free market in the United States) or as an organ transplant (governed by need as defined by the Uniform Network for Organ Sharing). What are the implications and limitations to each method of regulation?

Resource:

Brannström M, Johannesson L, Bokström H, Kvarnström N, Mölne J, Dahm-Kähler P, et al. Livebirth after uterus transplantation. *Lancet* 2015;385(9968):607-16.

Case 8
Mom's Genes

Jane is a 54-year-old divorced female who was diagnosed with ovarian cancer seven years ago. Her treatment included a hysterectomy followed by six cycles of chemotherapy. She has not had a recurrence of that cancer, but was recently diagnosed with stage 4 breast cancer. She has two daughters, 32-year-old Sarah who is her health care power of attorney and 30-year-old Jennifer who is the executor of her will. Sarah has two young daughters and Jennifer recently got married and is planning to start a family. Both Sarah and Jennifer have been very involved in Jane's care and have attended all of Jane's doctor's appointments with her.

Unfortunately, Jane suffered a medical complication, was rushed to the emergency department, and expired unexpectedly with both Sarah and Jennifer at her side.

Immediately after Jane's death, Sarah asks the nurse if Jane's blood can be drawn for genetic testing for a BRCA mutation. She claims that Jane had recently scheduled an appointment with a genetic counselor to get information on being tested for the sake of providing the results to her daughters and granddaughters (and future grandchildren). Jennifer, on the other hand, disagrees and does not think the blood should be drawn. She states that Jane had concerns that her genetic information would not be kept private and so was unsure that she wanted to be tested. According to Jennifer, the appointment with the genetic counselor was only to gain further information into the testing process before Jane made a decision. Jennifer explains that Jane was a very private person, and that although she wanted to help her children and grandchildren, she had serious concerns about leaving her genetic information behind. Sarah adamantly disagrees.

Given that blood must be drawn within hours of the death, the nurse quickly consults a genetic counselor, Dr. Choudhary, to determine how important it is test the deceased for a genetic mutation in this situation. Dr. Choudhary explains that it is very important because testing an affected individual is the best way of determining whether there is an inherited mutation. If Jane tests positive for a BRCA mutation, then her daughters have a 50% chance of testing positive. If either one, or both, tests positive, then they should seek proper medical management given their increased risk of getting cancer. If Jane tests positive, but her daughters test negative, then her daughters did not inherit the mutation and are not at an increased risk of getting cancer. Dr. Choudhary emphasizes that the problem arises if Jane tests negative or is not tested at all. If Jane and her daughters are all negative for the BRCA mutation, then Dr. Choudhary will ask for more family history in order to determine what other genetic tests to run on Jane to determine if there is another genetic mutation responsible for the cancer. If Jane is not tested and her daughters test negative, then they will not know whether Jane did have a genetic mutation other than a BRCA mutation responsible for her cancer and so they will not know what genetic mutation to look for in her daughters or granddaughters.

Question: **Should the blood be drawn? Is there any further information that would be helpful in determining whether to draw the blood or not? If so, what information would be helpful and why?**

Case 9
Sharing the Wealth

A patient (call him DF) is treated at Dana-Farber Cancer Institute for a rare cancer (Truog *et al*., 2012). His illness is progressing rapidly, and he is not doing well. He is admitted to the hospital due to increased shortness of breath. His doctors insert a pleural drainage catheter in order to help relieve his symptoms.

During this hospital admission, DF consents to his doctors' request to collect discarded fluid from the catheter so they can isolate a number of his tumor cells for research. Because DF has a rare cancer, these tumor cells, if they can be grown into a cell line in culture, could become a valuable resource for basic science research and for the development of new therapeutics. DF's doctors, who are also scientific investigators, believe that, in the future, DF's cell line could provide a steady revenue stream for Dana-Farber Cancer Institute, as well as provide additional personal income for themselves.

DF's cancer continues to progress, and he eventually dies. The physician-investigators who treated him wonder if they should arrange to have his family receive some financial benefits from any future commercial success of his cancer cell line. They are aware that they are not legally obligated to share down-stream revenues with the family. The U.S. courts have ruled in a number of legal cases that patients do not have property rights over their tissues after they have been removed during treatment, and that they do not have the right to demand royalties from profitable discoveries derived from the use of their discarded tissues. Nonetheless, nothing legally prevents DF's doctors from offering to share revenues with the family.

Question:

Are DF's doctors in this case ethically obligated, permitted, or forbidden from sharing future revenues with DF's family?

Resource:

Robert D. Truog, Aaron Kesselheim, Steven Joffe, "Paying Patients for Their Tissue: The Legacy of Henrietta Lacks," *Science* 337, 2012: 37-38.

Case 10
Please Don't Feed Him

The patient is an 84 year-old retired professor who has become progressively more and more demented over the past 7 years. He has now been living in a nursing facility for 4 years. He is nonambulatory, although the staff gets him up in a wheelchair daily. He is nonverbal, and although awake and alert, he does not seem to recognize his family any longer. He can no longer participate in any activities. The patient can no longer feed himself, and must be fed by the staff. He seems to have a good appetite, however, because when food is put up to his mouth he takes it.

The patient has a living will in which he said he would not want artificial nutrition or hydration at end of life. There is a DNAR in place. The family is distraught, because they see their father losing his dignity and he had always said that he wouldn't want to be kept alive in a condition where he could not think, interact, and care for himself. They say that he would be mortified if he "could see himself now." But despite the years of dementia, he is surprisingly strong. He is in a very good nursing facility and does not have bedsores or some of the other problems that come with poor care.

The family has approached the director of the facility and asked that the staff stop feeding their father. They should continue all other care, but not do the hand feedings. They say that if their father could speak, he would definitely ask the same.

The staff, who have grown quite attached to the patient, are horrified and cannot believe that the family would want to starve their father to death. They indicate that they would not follow such an order.

Question:**Does the nursing home staff have an ethically compelling argument to refuse the family's request?**