Ethics of Fetal Medicine
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Deirdre Fearon, MD, MA
Pediatric Emergency Medicine
Hasbro Children’s Hospital
KEEP CALM AND SING KUMBAYA
The Plan

• Bioethics 101
• Present cases
• Small group discussions
• Small group ANSWERS
• Summary/wrap up
Approaches to Ethics

• Duty-Based Ethics (Kant)
  - We all have duties, says Kant:
    to tell the truth, not kill, etc…
Approaches to Ethics

• Duty-Based Ethics (Kant)
  - Providers: duty to care for patients, save lives, reduce suffering
  - With duties come rights – to well-being, to act freely, to information
  - No easy solution when conflicting rights and duties exist
Duty-Based Ethics

• Right to your education vs. patients’ right to informed consent
Approaches to Ethics

• Utilitarianism (Mill)
  - Greatest good to the greatest number
  - Relies on predicting probable outcomes
  - Difficult to quantify happiness and calculate totals
  - Justifies seemingly unethical acts
Utility

• Greatest good to greatest number
Approaches to Ethics

- Principal-Based Ethics

  (Beauchamp and Childress)
  - Autonomy - decision-making capacity
  - Beneficence - provide benefits
  - Nonmaleficence - avoiding causing harm
  - Justice - fairness in the distribution of benefits and risks
Approaches to Ethics

- Principal-Based Ethics
  - Concrete way to evaluate difficult situations
  - Principals often conflict
Approaches to Ethics

• Virtue-Based Ethics (Aristotle)
  - Providers should possess: compassion, honesty, integrity etc.
  - Tough to apply clinically.
Approaches to Ethics

• Feminist Ethics
  - Focuses on context
  - Emphasis on caring
  - Attention to power differentials
  - Rejects paternalism
Approaches to Ethics

• Case-Based
  - Ethical reasoning based on precedents.
  - Start with something you KNOW to be right (or wrong) and look for similarities to the present case.
Approaches to Ethics

• John Rawls
  - “Veil of ignorance”
  - You don’t yet exist
  - Don’t know who you’ll be when you do
  - Capitalizes on self-interest
  - You split, I choose
Approaches to Ethics

• The Golden Rule
  - “Do unto others…”
  - Treat your patients as you would want your family treated
Phew! That’s a lot.

- Kant – duties/rights (rules)
- Utility – greatest good to greatest #
- Principles – do good, don’t harm, respect decision-making, be fair
- Be virtuous (especially caring)
- Start from what you know to be right
- You split/I choose
- Do unto others
When is a fetus a person?

1. Very young fetus
2. Viability
3. Newborn
4. When the parents say it is??
When is a fetus a patient?

Practically speaking, a fetus is a patient when a woman presents it for care.
When is a fetus a patient?

1. Fetuses presented for care are patients
2. Patients are people (?)
3. Fetuses presented for care are people

4. Fetal patients $\approx$ child patients?
Nobody likes premies: the relative value of patients’ lives

- A Janvier, I Leblanc and KJ Barrington, McGill University
- Various ages, predicted survival, some previously disabled
Who did they save?

- 2 mo old
- 7 yo
- 14 yo
- FT baby
- 50 yo
- 35 yo
- Preemie
- 80 yo
Who did they save?

- Order of resuscitation was not closely related to the predicted survival, impairment or potential life years gained.
- Kids valued over adults (unless you were a baby, esp preemie)
The cases
Case #1

• An experienced, talented pediatric surgeon feels she has the technical skills necessary to perform fetal surgery for Twin-Twin Transfusion Syndrome and has read all the literature available on the subject.

• [In TTTS blood can be transfused disproportionately from one twin to the other twin. Without treatment, most would not survive.]
Case # 1

• The surgeon receives a call from an OB/GYN about a case of twin-twin transfusion syndrome that might benefit from surgery.
• Should the surgeon perform the procedure?
Case # 2

• A fetus is diagnosed with a severe diaphragmatic hernia and lung hypoplasia.

• A mother knows about tracheal occlusion and wants to have it done for her fetus.
Tracheal Occlusion
Case # 2

• There was no study or FDA approval for the use of a balloon device for this procedure.

• Should a fetal surgeon with animal experience and extensive experience with other types of fetal surgery perform the procedure?
Case # 3

- A study is being performed on the efficacy of maternal-fetal surgery to repair encephaloceles prior to delivery.
Case # 3

• A pregnant woman was randomized to standard therapy (repair after delivery).
• She insists on getting the surgery.
• Should the surgery be done?
Case # 4

• Parents approach a fetal surgeon about performing a cleft lip and palate repair.
• They’ve heard that their child could be born without any scars.
• Should the surgery be done?
Case # 5

• A pregnant woman with HIV refuses to take AZT.
• [AZT reduces the rate of transmission of HIV to the fetus from 25-30% to 2-5%.
• The intern suggests she be put in custody until the baby is born so she can be forced to take the medicine.
• Should you call the police?
Case # 6

• A woman is pregnant with twins.
• One twin is sick and would benefit from early delivery.
• The other is healthy and would be better off if the pregnancy went to term.
• When should they be delivered?
Groups
Case #1

• An experienced, talented pediatric surgeon feels she has the technical skills necessary to perform fetal surgery for Twin-Twin Transfusion Syndrome and has read all the literature available on the subject.

• The surgeon receives a call from an OB/GYN about a case of twin-twin transfusion syndrome that might benefit from surgery.

• Should the surgeon perform the procedure?
Where should MFS be done?

- Major Centers exist.
- At those centers, procedures have been practiced on many patients.
- The learning curve for new centers puts patients at higher risk.
- Most innovations have not yet proved effective at major centers.
- Too many centers make research difficult.
Where should MFS be done?

• BUT!

• Each center started new at some point.

• How many major centers are enough?

• Who is to say that a talented surgeon should not be allowed to learn a new skill?

• Shouldn’t as many centers as possible be available so pregnant women can be close to home/support systems?
Case # 2

- A fetus is diagnosed with a severe diaphragmatic hernia and lung hypoplasia.
- A mother knows about tracheal occlusion and wants to have it done for her fetus.
- She is randomized to standard therapy, but insists on being in the occlusion group.
How is experimental medicine justified?

- Evolution of fetal surgery
  - A great idea
  - Extensive animal testing
  - New therapy is tried on a few humans
  - Equipoise is reached
  - Clinical trials are performed
  - It’s determined whether new therapy works
  - The new therapy is offered routinely (or not)
How is experimental medicine justified?

• What is equipoise?
  – When it is truly unclear which course of therapy carries the greatest risk to an individual patient.
  – Tricky because while there may be equipoise for the fetus, it’s usually better for the woman for the pregnancy to go to term.
How is experimental medicine justified?

- Fewer shunts
- More development
- More walking
- Less hind brain herniation
Case #3

- A study is being performed on the efficacy of maternal-fetal surgery to repair encephaloceles prior to delivery.
- A pregnant woman was randomized to standard therapy (repair after delivery).
- She insists on getting the surgery.
- Should the surgery be done?
Care outside study protocol

- A surgeon does not have an obligation to provide unproven therapy.
- A surgeon does have an obligation to promote responsible use of therapy, including supporting formal studies.
- Offering MFS off protocol reinforces the therapeutic misconception.
Case # 4

• Parents approach a fetal surgeon about performing a cleft lip and palate repair.

• They’ve heard that their child could be born without any scars.

• Should the surgery be done?
Non-lethal MFS

- It’s difficult to justify both maternal and fetal risks for non-lethal conditions.
- Attitudes toward people with disabilities should be examined.
- Until MFS can be performed safely, cosmetics currently being postponed.
Case # 5

- A pregnant woman with HIV refuses to take AZT.
- [AZT reduces the rate of transmission of HIV to the fetus from 25-30% to 2-5%.
- The intern suggests she be put in custody until the baby is born so she can be forced to take the medicine.
- Should you call the police?
Maternal-Fetal Conflict

• Recommendations must be understandable by the patient.
• Medical knowledge is fallible.
• Physicians have obligations to the pregnant woman as well as the fetus.
• Abiding by the woman’s wishes is generally best for the pregnant woman and the fetus.
• Generally okay to persuade, not coerce.
Maternal-Fetal Conflict

• Should pregnant women ever be taken to court to protect a fetus?
  – High likelihood of serious injury to the fetus
  – High likelihood intervening will prevent harm
  – Minimal risk and some benefit to woman
  – Benefits to fetus and woman outweigh harm done by violating woman’s autonomy, including loss of trust in the system by her and others.
Case # 6

- A woman is pregnant with twins.
- One twin is sick and would benefit from early delivery.
- The other is healthy and would be better off if the pregnancy went to term.
- When should they be delivered?
The Question

How much risk, *IF ANY*, should the healthy fetus be exposed to in order to improve the chance of a good outcome for the sick twin?
A graph of risk

TIME (weeks)

GOOD OUTCOME

26 40
What is minimally acceptable?
What is minimally acceptable?

26 40

TIME (weeks)
What is minimally acceptable?
Does a window of overlap exist?
The answer

• Deliver the twins at 30 & 2/7 weeks
• Thanks for having me
• The End
Get a consult

• “Wait a *teeny* bit longer, then poop them out. That way the healthy baby can get a little bigger, and then the doctors can take care of the sick one.”
What is *your* answer?

A) no risk
B) minimal risk
C) more than minimal risk
D) moderate risk
E) great risk (but with *some* chance of doing okay)
Why is that your answer?

- Utility (quality of life)
- Principles
- Cases with common features
Quality of Life

• Freedom from suffering, capacity to engage in social interactions
• Difficult to predict what disabilities people feel are worth living with
• Difficult to quantify
Quality of Life

100

-10

80

60
Quality of Life

• Can the net quality of life for the twins be increased?
• If so, should it?
Principles

• Autonomy
  - Relevant only in that mom’s input must be considered
Principles

• Beneficence
  - Want to do what is best for each fetus
  - These are competing in this case
  - Can strive to maximize the benefits
Principles

• Nonmaleficence

  - Suggests not harming the healthy fetus with early delivery.
  - Are you harming the sick fetus by not intervening? (i.e. Does “harm” require action?)
Principles

• Justice
  - Brings us back to our graph
  - How can the risks and benefits be distributed fairly?
Similar Cases

- Conjoined Twins
  - If left together, both will die.
  - Separated, one might live.
  - A choice of evils
  - Similar to our case in that if one twin makes a sacrifice the other will benefit
Doctorine of Double Effect

• A tool to help with decision making
• Developed by Catholic theologians as a part of “just war” theory
• Effects that would be morally wrong if intentional are permissible if foreseen and not intended
Doctorine of Double Effect

• The distinction between respiratory depression as a side effect of pain control and euthanasia is *intent*
Similar Cases

• Skydivers
  - Two skydivers jump from plane, but only one chute opens.
  - Rather than plummet to his death, one guy grabs onto the legs of the guy with the chute.
  - Together, both will die.
  - Can the one with the parachute kick the other guy off?
  - One is designated for life, the other - death
Similar Cases

• Twin-to-Twin Transplantation
  – Decisions for the donor are made on best interest and substituted judgment standards
  – Saving the life of a twin directly benefits the donor (psychosocially)
  – The risk is minimal
Similar Cases

• Children as Research Subjects
  - Nuremberg Code and Federal Regulation on Protection of Human Subjects
  - Laws were designed to protect those unable to give informed consent
  - Even if the experiment directly benefits the child, risk must be minimal.
Similar Cases

- Both organ donation and research require parental consent for participation.
- By law, this can only be granted if there is a direct benefit to the child with minimal risk.
- Is the healthy fetus directly benefiting from helping his sib?
- What is minimal risk prematurity?
What is your answer?

A) no risk
B) minimal risk
C) more than minimal risk
D) moderate risk
E) great risk (but with *some* chance of doing okay)
Summary

• MFS should ideally be approached as research in places with skilled teams until proven effective.
• Experimental medicine should be approached within studies (with equipoise).
• Don’t offer care outside the study protocol.
• MFS should be reserved for lethal (or at least non-cosmetic) conditions.
Summary

• Respecting the pregnant woman’s (and FOB’s) decisions is generally best for her and her fetus.

• Apply standards for handling children in research and as living donors when deciding about twin fetus risk.
Ethical Issues in Maternal-Fetal Medicine

Edited by Donna L. Dickenson