Ethics in Reproductive Medicine

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Disclosure Slide

- I do not have any relevant financial relationships with any commercial interest
What Isn’t Ethics?

- Intuition
- A naïve sense of right or wrong
- An algorithm for solving problem cases
What Is Ethics?

• “Moral principles that govern a person or groups behavior”
  • Oxford Dictionaries

• “A set of concepts and principles that guide us in determining what behavior helps or harms”
  • Richard William Paul and Linda Elder
Principles of Medical Ethics

- **Beneficence**
  - A commitment to the welfare of the patient
- **Nonmaleficence**
  - Avoid nonintentional harm to patients
- **Autonomy**
  - Respect for the right of individual patients to make their own choices about their healthcare
- **Justice**
  - Fairness, avoidance of discrimination
Reproductive Medicine

Helping Achieve Pregnancy

Avoiding Unwanted Pregnancy

Limitations

Possibilities

Informational Level

Moral feelings

World Out-Look

Perception of What a Human Being Is

Altruism

Virtues

Personal Interest
The Biggest Concern...

What is sought to be permitted

What is sought to be avoided
The Designer Baby
"Congratulations, it's a Versace!"

WE CHOSE YOUR SPERM FROM A GENIUS SPERM BANK!
WE CHOSE YOUR EGG FROM A FASHION MODEL WEBSITE!

WHY WOULD I WANT TO HAVE ANYTHING TO DO WITH YOU TWO STUPID UGLY PEOPLE?

AND WE GOT JUST WHAT WE ASKED FOR!
Case #1

- 34 y/o G3P1021 trying to conceive with 32 y/o partner for 6 months
  - Partner, healthy, fathered all 3 pregnancies
  - PMH: Healthy
  - PSH: None
  - FH: Non-contributory
Case #1

- **Gyn History**
  - Regular 29 day cycles, +OPK CD 14-15. No h/o STI/PID, dysmenorrhea.

- **OB History**
  - 9/2011 – Uncomplicated term SVD, daughter
  - 12/2011 – Unplanned pregnancy, medical AB
  - 7/2015 – TAB 12 wga, following cfDNA testing that confirmed female fetus

- Couple would like IVF/PGS for male fetus
Use of ART for Sex Selection For Non-Medical Reasons

• Treatment Options
  ▫ Sperm Separation/Sorting
    • Sperm containing X chromosome more dense
    • 2.8% more DNA
    • Centrifugation or Flow Cytometry
    • Accuracy = 75-90%
    • Not FDA approved
  ▫ IVF with Preimplantation Genetic Screening (PGS)
    • Cleavage stage/Blastocyst biopsy
    • Aneuploidy screening to identify sex chromosomes
American Society For Reproductive Medicine

• 1999
  ▫ Approves PGD to avoid X-linked disorders
  ▫ Use of PGD for patients undergoing IVF should “not be encouraged”
  ▫ Use of IVF/PGD solely for gender selection discouraged
    • gender bias/social harm
• 2001
  ▫ Approves sex selection for those wanting a child of opposite gender than what they already have
    • Sex selection aimed at increasing gender variety may not increase risk of harm to children, women, society
• 2015
  ▫ No consensus
Use of ART for Sex Selection For Non-Medical Reasons

<table>
<thead>
<tr>
<th>For</th>
<th>Against</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient Autonomy</td>
<td>• Harm to women, men and offspring</td>
</tr>
<tr>
<td>• Reproductive Liberty</td>
<td>▫ Long term risks unknown</td>
</tr>
<tr>
<td>▫ May be a constitutionally protected concept</td>
<td>▫ Diagnostic errors</td>
</tr>
<tr>
<td>• Experience of raising a child of given gender important</td>
<td>• Discrimination</td>
</tr>
<tr>
<td>▫ May have several children of one sex, unwilling to attempt pregnancy</td>
<td>▫ Embryos</td>
</tr>
<tr>
<td>• Doesn’t necessarily reflect discrimination</td>
<td>▫ Imposes inappropriate gender norms on children</td>
</tr>
<tr>
<td>• May help avoid pregnancy termintation</td>
<td>• Psychologic harm</td>
</tr>
<tr>
<td></td>
<td>• Slippery slope</td>
</tr>
<tr>
<td></td>
<td>▫ Selection of other traits</td>
</tr>
<tr>
<td></td>
<td>• Social injustice</td>
</tr>
<tr>
<td></td>
<td>▫ Gender imbalance</td>
</tr>
<tr>
<td></td>
<td>▫ Utilizes resources otherwise available for infertility</td>
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Long term risks unknown
Diagnostic errors
Embryos
Imposes inappropriate gender norms on children
Psychologic harm
Selection of other traits
Gender imbalance
Utilizes resources otherwise available for infertility
Use of ART for Sex Selection For Non-Medical Reasons - Legal Aspects

- **United States**
  - **State law**
    - No states prohibit the practice
- **Prohibited in Canada and several European countries**
  - Regulations vary widely throughout Europe
- **Israel**
  - Permitted by approval in rare cases
Gender Bias/Discrimination

- **Social Context**
  - Societal preference for one gender increases risk
    - India/China
      - Infanticide, abortion, preconception sex selection
    - United States
      - No preference for one gender over another

![Pie chart showing gender preference distribution]

- Boys = Girls: 27%
- Boys > Girls: 51%
- Boys < Girls: 7%
- Only Boys: 6%
- Only Girls: 4%
- No Preference: 5%
Provider Responsibilities

• Provide appropriate consent/counseling
  ▫ Risks of procedure
  ▫ Ensure patients not subject to coercion
• Ensure provider/clinics decision to offer service does not adversely affect access to service for medical reasons to others
• Service applied without discrimination
• Clinics encouraged to establish written policies
  ▫ Availability of service
  ▫ Under what circumstances
• Clinic employees with objection to the service permitted to recuse themselves
Case #1 Follow-Up

• Patient has received appropriate counseling
  ▫ MD
  ▫ Genetic Counselor
  ▫ Psychologist

• Moving forward with IVF/CCS
  ▫ What if all euploid embryos female?
    • Will transfer female embryo
Case #2

- 39 y/o G2P2002 trying to conceive for 6 months
- 40 y/o partner, 2 sons from previous relationship
- OB History
  - 2000 – Term SVD, daughter. Previous relationship
  - 2002 – Term SVD, daughter. Previous relationship
- GYN History
  - Regular, 28 day cycles with +OPK CD 14.
- PMH: Healthy
- PSH: None
Case #2

• Family History
  ▫ Father with early onset familial Alzheimer’s disease
    • Presenilin-1 gene mutation
    • Died at 48 y/o

• Social History
  ▫ Marketing director, lives in Portland
  ▫ Basketball Coach, lives in New York

• Treatment Plan
  ▫ IVF with CCS
Case #2

“I don’t want to know if I am a carrier or not. But I would like to ensure that the embryos transferred are not carriers. Can I do this?”
Preimplantation Genetic Diagnosis for Adult Onset Conditions

• Designed to identify embryos that carried genetic mutations linked to serious childhood onset diseases
• Increasingly used for adult onset diseases
  ▫ Huntington’s chorea
  ▫ Early-onset familial Alzheimer’s
  ▫ Cancer predisposition genes
    • BRCA
  ▫ Non-fatal conditions
    • Cleft palate
• Post-conception diagnosis
  ▫ Pregnancy termination
Things To Consider...

- Genetics are complicated!!!
- Age of onset is variable
- Presence of the gene does not mean disease will occur
- Not all diseases are universally fatal
- IVF is not without risk
- Diagnostic testing is not perfect
Preimplantation Genetic Diagnosis for Adult Onset Conditions

<table>
<thead>
<tr>
<th>In Favor Of</th>
<th>Against</th>
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</thead>
<tbody>
<tr>
<td>• Reproductive Liberty</td>
<td>• Some genes have variable expressivity</td>
</tr>
<tr>
<td>• Avoid worry associated with uncertainty</td>
<td>• Effective treatment modalities may be available in the future</td>
</tr>
<tr>
<td>▫ AAP recommendation</td>
<td>• Has potential to devalue certain lives</td>
</tr>
<tr>
<td>▫ Genetic testing inappropriate until adulthood</td>
<td>• Slippery slope</td>
</tr>
<tr>
<td>▫ Controversial</td>
<td>• Diagnostic error</td>
</tr>
<tr>
<td>• Avoid stress of medical management in childhood</td>
<td>• Economic impact</td>
</tr>
<tr>
<td>▫ Cancer screening</td>
<td>▫ Cost of IVF</td>
</tr>
<tr>
<td>• Effective intervention to avoid disease</td>
<td>▫ No certainty of live birth</td>
</tr>
<tr>
<td>• Economic impact</td>
<td>• Psychologic impact</td>
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<tr>
<td>• Psychologic impact</td>
<td>• Economic impact</td>
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</table>

Cost of IVF

No certainty of live birth
ASRM Recommendation

“PGD for adult-onset conditions is ethically justified when the condition is serious and no safe, effective interventions are available”

“The Committee strongly recommends that an experienced genetic counselor play a major role in counseling patients”
Case #2 Follow-up

• After appropriate medical and genetic counseling couple decided against further testing
• IVF with CCS for aneuploidy screening
Case #3

• 47 y/o single male with no h/o paternity
  ▫ Donor egg IVF and a gestational surrogate
  ▫ Normal semen analysis
• PMH: Healthy
• PSH: Ortho
• Social History
  ▫ MD
  ▫ Lives in Seattle
Case #3 - His Plan

- Known donor living on East Coast
  - 32 y/o G3P3003
    - She has 1 child
    - Traditional surrogate x’s 2
    - AMH <1, AFC 9-10
- Complete IVF, cryopreserve embryos, send them to an outside clinic to be transferred back to the known donors uterus

The Traditional Surrogacy Loophole
Definitions

- **Traditional Surrogate**
  - Gestational carrier provides oocytes and uterus
- **Gestational Carrier/Surrogate**
  - Gestational carrier only provides uterus, not oocytes
  - Requires IVF
- **Intended Parent**
  - Individuals contracting with the gestational carrier
  - Plan to be social and legal parents
- **Gamete providers**
  - Source of sperm/oocytes
  - May or may not be IP
Traditional Surrogacy....

• Not a new concept
  ▫ Old Testament
    • Sarai, Abram and Hagar
• History repeats itself
  ▫ 1980’s
    • The case of Baby M
      • Supreme Court of NJ invalidated surrogacy contracts
        ▫ “illegal, perhaps criminal, and potentially degrading to women”
        ▫ Custody awarded to IP
        ▫ Visitation rights to GC
Commercial Surrogacy

• Controversial since its inception
  ▫ Feminist theory
    • Commodification of the GCs body
  ▫ Conflicts with interests of the child
  ▫ Supporters of traditional family structures/reproduction

• Safeguards for GC and IP needed for process to be ethically justifiable
  ▫ Economic compensation
  ▫ Access to medical treatment
  ▫ Psychologic support
  ▫ Informed consent
Legal Protections

• Matter of state law
  ▫ Laws vary dramatically
• GCs have a right to independent legal counsel
• GC should be free to choose own counsel
• Costs of legal counsel should be the responsibility of the IP
Who is a good GC?

- > 21 years-old
- Healthy
- Stable social environment
- At least 1 pregnancy resulting in a live birth
GCs Should Receive Reasonable Economic Compensation

**In Favor**

- Pregnancy is a demanding process
  - Time
  - Inconvenience
  - Risk
  - Discomfort
- Consistent with ASRM guidelines regarding oocyte donation
- Consistent with compensation for medical research

**Against**

- May encourage women to expose themselves to physical/emotional risk
  - May not consider risks
- May encourage dishonesty about health/family hx
- May entice economically disadvantaged women
- Socioeconomic differences between IP and GC
- Commodification of GC
- Commodification of child
  - Baby selling
Economic Compensation

• Needs to take into account burden of pregnancy without increasing risk of exploitation or dishonesty
• Interests of both parties need to be protected
  ▫ Compensation held in an escrow account
    • Ensures compensation covered to GC
    • Keeps financial negotiations separate from ongoing relationship
    • Removes immediate burden of financial issues between IP and GC
Medical Considerations and Informed Consent

- Need to be fully informed about risk of process and pregnancy prior to cycle start
  - *Multiple gestation*
    - GC makes final decision
  - *Infectious disease risk*
- Have right to appropriate medical care
- Receive counseling regarding impact on partners and children
  - No data to suggest GC’s children have negative sequelae associated with experience
Psychological Considerations

- IP and GC should receive counseling
  - Review expectations
    - Consequences of not having expectations met
  - Specific issues
    - Emotional attachments
    - Antenatal testing
    - Pregnancy termination
    - Multiple gestation
    - Selective reduction
- GC has ultimate authority over procedures on her body
Legal Agreement is Essential

- Document roles and responsibilities of IP/GC
- In the event of a dispute
  - Contract should direct resolution
  - Intentionality should be documented
Case #3 Follow-Up

- Patient counseled regarding complexities of traditional surrogacy
  - Not a service line that we provide
- Elected to proceed with individual as a known oocyte donor
  - Gestational carrier through local surrogacy agency
Case #4

- 32 y/o G3P0120 (sister A) accompanied by 36 y/o sister (sister B)
  - Sister A is single
  - Sister B is a Go in SSR
- OB History Sister A
  - 2008 early 2\textsuperscript{nd} trimester SAB
  - 2010 early 2\textsuperscript{nd} trimester SAB
  - 2014 Severe pre-eclampsia/HELLP at 23 wga, delivery, infant death day of life #2
Case #4 - Her Plan

- Sister B to undergo anonymous donor insemination
- Following delivery, baby to be adopted by Sister A
## Using Family Members As Surrogates

<table>
<thead>
<tr>
<th>Donation Type</th>
<th>Arrangement</th>
<th>Genetic/Social Relationship</th>
<th>Thoughts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traditional Surrogacy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sister for Sister</td>
<td>Social aunt is genetic mother</td>
<td>Consider relationship with sister’s partner</td>
<td></td>
</tr>
<tr>
<td>Sister for Brother</td>
<td>Social aunt is genetic mother</td>
<td>Prohibited</td>
<td></td>
</tr>
<tr>
<td>Daughter for Mother</td>
<td>IP is genetic GM</td>
<td>Concerns re. coercion</td>
<td></td>
</tr>
<tr>
<td>Mother for Daughter</td>
<td>Social GM is genetic mother</td>
<td>Not reported, age</td>
<td></td>
</tr>
<tr>
<td><strong>Gestational Surrogacy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(genetic relationships unchanged)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sister for Sister</td>
<td>Social aunt is gestational mother</td>
<td>One of 1st reported cases</td>
<td></td>
</tr>
<tr>
<td>Sister for Brother</td>
<td>Same as above</td>
<td>Impression of incest</td>
<td></td>
</tr>
<tr>
<td>Mother for Daughter</td>
<td>Social GM is gest. mother</td>
<td>Mother’s health</td>
<td></td>
</tr>
<tr>
<td>Daughter for Mother</td>
<td>Social ½ sister is gest. mother</td>
<td>Unlikely, age</td>
<td></td>
</tr>
<tr>
<td>Daughter for Father</td>
<td>Same as above</td>
<td>Impression of incest</td>
<td></td>
</tr>
</tbody>
</table>
Unique Concerns

- Incest/Consanguinity
- Undue influence to participate
- Confused parentage for offspring
# Using Family Members As Surrogates

## In Support
- Some IP’s prefer familial connection
- Efficiency
- Cost reduction
- Paid surrogacy prohibited in many states
- Intra-familial organ donation widely accepted

## Concerns
- Can GC make a free and informed decision?
- Consequences of resulting relationships
- Consequences of creation of new genetic relationships

Very little data available addressing these concerns
Impermissible Collaborations

Fertility practices should not participate in surrogacy in which child would have same genetic relationship to IP/GC as they would in a consanguineous or incestuous relationship.
Protecting Autonomy

• Some suggest that a truly free decision is impossible
  ▫ Child-to-parent donation generally prohibited
• Manipulation from family members who would benefit from participation of the GC
  ▫ Risk greater with intergenerational arrangement
• Contributing factors
  ▫ Closeness of GC to IP
  ▫ Maturity of involved parties
  ▫ Financial dependency/coercion
Potential For Emotional Harm

• Exposed to emotional/physical risk
• Negative feelings projected on GC
  ▫ Family members
  ▫ General public
• Treatment not always successful
  ▫ Anger towards GC
• Child born with a birth defect
  ▫ GC may blame herself
  ▫ Blame directed towards GC
• Difficulty with detachment from child
• Conflicts may result in limited visitation/contact with child
Impact on Offspring and Family Relationships

- Children unable to consent to details of their conception
  - Ensure protection of child’s welfare
- Societal concerns
  - May create new genetic relationships previously not possible
  - Can become confusing
  - Impact is likely minimal
    - Add complexities to a small number of families
    - Increasingly complex concept of family
ASRM Recommendations

• Use of familial surrogates is ethically acceptable
  ▫ Special care taken to ensure interests protected
    • Increased screening
    • Multidisciplinary
    • Increased counseling
  ▫ Informed consent
    • IP and GC
    • Potential risk to all parties, including offspring
    • Confirm decision to participate is voluntary
  ▫ Financial compensation should not be so great that it leads participant to discount risk
  ▫ Legal counsel provided
Case #4 Follow-Up

• Discussed the complexities of traditional surrogacy
  ▫ Not a service line that we provide
• Referred to local provider who provides this service
  ▫ Recently delivered
Case #5

• 34 y/o Go trying to conceive with her 36 y/o partner for 12 months.
  ▫ No h/o paternity
  ▫ Normal semen analysis
• PMH: Healthy
• PSH: None
• Evaluation
  ▫ Normal FSH, AMH, AFC, HSG
Case #5

- Social History
  - 2nd grade teacher
  - Separated from her husband
Summary

• Biomedical ethics, particularly in reproductive medicine is complex
  ▫ Follow the basic principles
• Each case needs to be considered on an individual basis
• Clinics need to clearly define policies regarding ethically challenging situations
• Utilize resources (ASRM guidelines, ethical review boards) to determine best course of action when faced with ethical dilemma
Thank You For Your Time!

QUESTIONS?