Harvard Medical School Annual Bioethics Conference

The Ethics of "Making Babies"
Poster Abstracts • Friday, April 7, 2017

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# Poster Presentations At-a-Glance

**Friday, April 7**  
Martin Conference Center, 77 Ave. Louis Pasteur.

<table>
<thead>
<tr>
<th>Title</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shared Decision Making and Ethical Challenges in Fertility Preservation in Youth at Risk for Infertility</td>
<td>Bray Room</td>
</tr>
<tr>
<td>Attitudes of Pediatric Patients Regarding Fertility Preservation Options</td>
<td>Bray Room</td>
</tr>
<tr>
<td>The Role of Egg Donation Agencies in Defining the Moral Status of Eggs</td>
<td>214</td>
</tr>
<tr>
<td>Savior Siblings: Ethical Conundrums and Regulatory Void</td>
<td>214</td>
</tr>
<tr>
<td>Women’s Reproductive Autonomy and the Ethics of Baby Making: The Nigerian Case Study</td>
<td>217</td>
</tr>
<tr>
<td>Biological Ties and Right to Parenthood in Medically Assisted Reproduction: Ethical and Juridical Implication Among Lesbian Couples</td>
<td>217</td>
</tr>
</tbody>
</table>
Purpose
The purpose of this presentation is to present a series of cases of youth at risk for impaired fertility due to gonadotoxic treatment or genetic conditions and examine the ethical issues of shared decision making (SDM).

Shared Decision Making is a collaborative process that allows patients and providers to make healthcare decisions together. It takes into account the best clinical evidence available, as well as the patient’s values and preferences.

Approach
4 cases examine the:
• Evidence of SDM
• Parental decision challenges
• Clinician challenges
Using the Thompson and Thompson bioethical decision-making model (TBDM)

Case 1
• 14 yo transgender male beginning gender affirming hormones
• Fertility preservation offered, but declined
• Parents want it, but the pt does not want to consider “right now” and wants to start treatment

Case 2
• 16 yo with Klinefelter syndrome
• Has low IQ and behavioral problems
• Pt interested in getting testing and trying to bank sperm but parents not interested, state “he will not be able to care for a child”

Case 3
• 22 yo male GBM cancer pt with poor prognosis
• MD reluctant to discuss/make arrangements for fertility preservation
• Feels patient has < 3 months to live

Case 4
• 3 yo with Turner syndrome
• Pt is likely to experience POI- opportunity for ovarian tissue cryopreservation
• Single mother unsure if child should have invasive procedure

Significance
• In each case, there is high risk of permanent infertility
• Options exist to preserve fertility through standard and experimental assisted reproductive technologies (ART)
• Decisions ideally require input from the parents/caregivers, clinicians and the patient through shared decision making
• Current evidence contradictory on teen’s ability to make decisions about future reproductive goals
• Decision making in general can be compromised in an emergency situation
• In the case of ART there may be little empirical evidence on which to base decisions

Implications
• The field of ART is rapidly developing and offering options for fertility preservation, yet its growth is occurring at a greater speed than empirical evidence can be gathered or guidelines can be established
• Each of the cases reviewed presents a learning opportunity for those involved in reproductive decision making
• Future directions include developing tools and strategies for shared decision making in the context of fertility and preservation are essential to assist patients, parents and providers in reducing decisional regret and improving communication

Thompson and Thompson Bioethical Decision Making Model

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step One</td>
<td>Review situation to determine health problems, decision needed, ethical components and key individuals.</td>
</tr>
<tr>
<td>Step Two</td>
<td>Gather additional information to clarify situation.</td>
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<td>Step Three</td>
<td>Identify ethical issues in the situation.</td>
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<tr>
<td>Step Four</td>
<td>Define personal and professional moral positions.</td>
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<tr>
<td>Step Five</td>
<td>Identify moral positions of key individuals involved.</td>
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<tr>
<td>Step Six</td>
<td>Identify value conflicts, if any.</td>
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<td>Step Seven</td>
<td>Determine who should make the decision.</td>
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<td>Step Eight</td>
<td>Identify range of actions with anticipated outcomes.</td>
</tr>
<tr>
<td>Step Nine</td>
<td>Decide on a course of action and carry it out.</td>
</tr>
<tr>
<td>Step Ten</td>
<td>Evaluate/review results of decision/action.</td>
</tr>
</tbody>
</table>
How Subterranean Regulation Hinders Innovation in Assisted Reproductive Technology

Myrisha S. Lewis
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Background
Most scholars believe assisted reproductive technology is subject only to minimal regulation, especially by the federal government. This Article reveals why that belief is wrong.

Findings
The FDA has been targeting new forms of assisted reproductive technology that involve small genetic modifications ("advanced assisted reproductive technologies" or "AARTs") through regulatory actions that receive little public, media, or scholarly attention. I term this method of regulation "subterranean regulation."

Implications/Discussion/Conclusions
• It is likely that the FDA lacks jurisdiction over AARTs under applicable statutes, namely the Food, Drug and Cosmetic Act and the Public Health Service Act.
• FDA regulation has hindered the use of cytoplasmic transfer and mitochondrial transfer in the United States.
• A hidden, ad hoc regulatory practice is exactly the wrong kind of process to use when it comes to scientific innovations in fraught ethical areas, which includes not only assisted reproductive technology but also other DNA-modifying technologies (including CRISPR-Cas9).

References
3. See National Bioethics Advisory Committee, Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Committee, at 5 (noting that in 1981, the first baby was born in the United States as a result of in vitro fertilization).
Background, Ethical Problem

The act of procreating is an essential part of private life, allowing people to achieve and live specific roles in society. Everyone, including homosexuals and single individuals, may have, at some stage of their life, the desire to form a family with children.

Adoption and foster care are not always considered by couples as good alternatives. While homosexual couples tend to use ARTs to overtake the ontological inability to procreate, heterosexual people are used to accessing these technologies to cure a sterility/infertility status or other types of pathologies. By providing a broad technological portfolio, medical science is able to cure homosexual in the achievement of their biological parenthood. When last-born in an ART, a couple can have a baby: one of the partners may be entitled to have the baby only a social relationship. The choice of who will be biologically linked to the baby is a pivotal moment. In this situation, the need to take part to the procreation process may cause conflicts. Because some Western countries (such as Italy, France and Germany) do not allow homosexuals to access to ARTs, it is very common that they leave their country towards more open-minded places in order to circumvent domestic prohibitions. This phenomenon, called as “Reproductive Tourism”, may cause problems of Public Order and International Family Law, given that couples may have some children in more than one occasion, regardless of the sex and sexual orientation of the intended parents.

A critical analysis of the conceptual distinction between cases in which both the partners are biologically linked to the baby and cases in which one of the partners only maintains a social relationship with the baby has been made. An international bibliography research pertaining to the use of ARTs was performed using the *PubMed* database. The 2016 Eurobarometer survey about surrogate motherhood, adoption and marriage by LGBT were used also. The perception of Italian public opinion regarding the right to homo- sexual parenthood (Figure 3).

Materials and Methods

Local and EU legal sources (laws, judgments, orders of Institutions and national/scientific publications) have been examined, using official web-sites and electronic databases of national authorities and Institutions bodies, with the aim to define the law context about the use of ARTs.

The analysis of the conceptual distinction between cases in which both the partners are biologically linked to the baby and cases in which one of the partners only maintains a social relationship with the baby has been made. An international bibliography research pertaining to the use of ARTs was performed using the *PubMed* database. The 2016 Eurobarometer survey about surrogate motherhood, adoption and marriage by LGBT were used also. The perception of Italian public opinion regarding the right to homosexual parenthood (Figure 3).

Findings

- The well of homosexual couples to be recognized as parents of babies born abroad through ARTS is still a matter of debate.
- The fact that certain types of ARTs are prohibited under the laws of the countries may be relevant in the assessment of the legal parental rights.
- The tendency of heterosexual parents to access to ARTs is debated. The debate over the moral acceptability of ARTs among homosexual couples.

Discussion

The right to use ARTs by homosexuals depends on the governance model stated for the medically assisted reproduction framework. At international level, in the past, the European Convention on Human Rights (ECHR) settled the precedent given in the Paras and Campanelli case (21 January 2017). According to the Court of last resort, the absence of any biological ties between the child and the intended parents, the short duration of the relationship with the child and the lack of any ties from a legal perspective prevent to regulate the case under the article 8. As for homosexual people, in cases Foulon and Bouvet v France (2014) cases (nos. 9063/14 and no. 10410/14) – two cases focusing on French couples who decided to use traditional surrogacy in the United States – the ECHR accepted to record the foreign birth certificates. Because a familial relationship was grown between the couples and the babies, the judgments’ decision was in line with article 8 of the European Convention on Human Rights. In both cases, applicants were genetically related to the baby. The analysis of the EU cases shows, that in the European context, the absence of any ties from a legal perspective prevents the recognition of foreign birth certificates in cases where at least one of the partners is biologically linked with the baby.

The recognition of parental right in heterosexual couples requires a complex assessment in order to strike a balance between different legal interests. The decision of the ECHR, by acknowledging the respect for the private and family life of the applicants, found a solution to the problem, that allows the development of the harmonization of the legal frameworks on the rights of the children. In cases Paradiso v Italy (2001) and Menzies v United Kingdom (2013) the ECHR allowed the recording of the foreign birth certificates. Instead, in cases Foulon and Bouvet v France (2014) cases (nos. 9063/14 and no. 10410/14) – two cases focusing on French couples who decided to use traditional surrogacy in the United States – the ECHR accepted to record the foreign birth certificates. Because a familial relationship was grown between the couples and the babies, the judgments’ decision was in line with article 8 of the European Convention on Human Rights.

Conclusions and Follow-Up

- The widespread of ARTs among homosexuals increased the number of non-standard situations that do not fit with the Traditional model of family=BIOLOGICAL MOTHER, FATHER and CHILDREN [Figure 2].
- The legal model of family is changed as the needs of the children is more than one generation.
- Medical advances in the field of reproduction health technology may enlarge the spectrum of civil rights.
- Domestic bans to some types of ARTs and difficulties in meeting treatment eligibility criteria place same-sex families in situations of uncertainty, where they face social and legal obstacles, disheartening the harmony and the balance of the family. Along with the child’s best interest.
- The absence of the law, the resolution of cases is made at the discretion of the Courts, taking into account the child’s best interest.

What is the real value of biological ties? Should the biological ties be necessary to recognize the right to parenthood?
Background: The Patriarchal Ikwerre society of Rivers State, Nigeria and the culture of absolute respect for men have turned the average Ikwerre wife into baby making factory. Not just any baby but a male child. Hence a wife who is unable to produce children, especially male children for her husband is regarded as a worthless woman. She is either expected to marry a wife who will bear children for her husband or her husband marries another wife who will bear children for him. The implication for this is that the wife which her husband will marry will be her mate and the first wife will not have control over her. But if she marries a wife for her husband, she will be able to control the new wife.

Aim: To examine the ethical implications of using women as a baby making ‘factory’

Findings:
- Poverty and patriarchy were observed to be the major factors responsible for the use of women for making babies.
- Lack of education was also another reason women succumb to be used for baby production.
- Pressure from the family and the society on the wife to have male children is also a factor that make women allow themselves to be used as baby making factories.

Implications/Discussion: The use of a woman solely for the purposes of making babies does not only reduce her to a sex object but also harms her bodily integrity and psychology. Her self identification and personal identity are undermined. Also, her autonomy is greatly diminished because she is controlled and manipulated by her user.

Conclusion: The patriarchal Ikwerre society and the culture of absolute respect for men need to be addressed. Policies that protect women have to be implemented.

Methods: Using qualitative exploratory research design, 34 In-depth interviews (IDIs) and six focus group discussions (FGDs) were conducted with married women of various educational status, in either monogamous or polygynous marriages, aged 22-60 years. Questions such as educational status, type of marriage, age, religion, reason for marriage, and decision when to have children were asked. When necessary, prompts were asked to elicit further details to understand implicit meaning in the responses of the participants. Data were analyzed thematically with the aid of content and narrative analysis. Coding was done by using MAXQDA version 11 software.

Future Plans/Follow Up
- Legal framework and code of practice for proper surrogacy is needed.
- Cultural practices that exploit women should be addressed.
BACKGROUND

- Savior sibling: a sibling created for the purpose of providing biological material that can help treat or cure an existing terminally ill child.
- They are conceived through the sequential use of two reproductive technologies developed for other purposes: pre-implantation genetic diagnosis (PGD) and in-vitro fertilization (IVF).
- PGD is used to screen embryos prior to implantation in the uterus, in order to determine whether the embryo will be a tissue "match" to a sick child.
- Roughly 1% of PGD in the United States is used to create children that are tissue matches for their siblings.

AIM

To consider the regulatory and ethical frameworks concerning savior siblings.

METHODS

Considered the position of savior siblings, from an ethical and bioethical dimension:
- Examined stories, interviews, and case studies with actual families and savior siblings, to try and distill the landscape.
- Examined legislation and regulation concerning IVF, PGD, and specifically about savior siblings, both in the United States and the United Kingdom.
- Reached out and discussed savior siblings with several IVF clinics in the US and UK.

DEFINITIONS

- PGD: Pre-implantation genetic diagnosis
  - The genetic profiling of embryos
- IVF: In-Vitro Fertilization:
  - A procedure in which eggs (ova) from a woman's ovary are removed and fertilized with sperm in a laboratory procedure, and then the fertilized egg (embryo) is returned to the uterus

FINDINGS

REGULATION

United States:
- No governmental regulation or specific legal guidance.
- Uses of PGD, including creation of a savior sibling, left to the discretion of providers and patients.
- Sole governmental action/"regulation" is the ban on federal funding for embryo-related research.

United Kingdom:
- The Human Fertilization and Embryology Act (HFEA) of 1990 regulates PGD.
  - PGD can be performed in order to:
    - Test for severe genetic diseases.
    - Perform tissue type matching for savior siblings under strict criteria.
  - Clinics must obtain licenses before they can perform the procedures that create a savior sibling.
  - UK has fertility regulators in specialized courts.
  - 2004 RULING: HFEA allows parents to use modern reproductive techniques to create a savior sibling.
  - HFEA provides for enforcement: Required clinics to apply for NEW license for EACH GENETIC DISEASE.

Potential Harms:
- If the child believes that they were not wanted for themselves.
- If a child conceived for this reason enjoys a less close and loving relationship with parents.
- Could lead to feelings of depression and a lack of self-worth (malaise), as the child may not feel special in their own right, but rather that they are forever tied to their sibling.
- Is the savior sibling afforded the same level of autonomy that a normal individual is given when deciding to consent to a transplant of biological material?
- Will savior siblings face undue pressure from their family unit?
- Slippery Slope Arguments:
  - Today: savior children save sick siblings. Tomorrow: create a child to save a parent, elderly family member, or even someone outside the family unit.
  - IVF and PGD could be used to usher in a new age of eugenics, if parents can select certain traits/characteristics.

In Support:
- While some contend that the savior sibling is being used as a means, it is not merely a means to an end. In fact, savior siblings serve a more complicated role: that of a savior, a family member, and an individual person.
- Anecdotal interview data report high level of satisfaction for the savior sibling.
  - Many siblings report high levels of personal pride.
  - Unique feeling of connection with their sick, older siblings.
  - Clear therapeutic benefits for:
    - The existing sick child, who gets to continue living.
    - The family unit as a whole, who now does not have to bury a child, and shares in the happiness of two (hopefully healthy) children.

Ethanics

Parental Motives:
- Ultimate arbiter of medical and family planning decisions for their individual family unit.
- Process unlikely to be undertaken by parents who don’t care for their children.
- Acceptable motives for family planning are complex:
  - Create heir, continue legacy, provide playmate, strengthen/save marriage.
- Pandora’s Box: Questioning whether society/gov’t should have role in which birth motives are acceptable.
- Newer but not necessarily worse reason than traditionally selfish motives.

Need Monitoring and IN/FORMAL Regulation:
- Given the absence of the above:
  - Gathering of data regarding the prevalence of savior siblings is restricted.
  - Harm to savior children may go unreported.
  - No system exists for follow-up with savior families.
  - Limited data on long term emotional and physical health is collected.
  - Clinics performing PGD make their own decisions on moral and ethical issues.
  - Similarly situated individuals in different locations may have vastly different options.

FUTURE DIRECTIONS

US can learn from the UK regulatory framework:
- Efforts to advance a discussion are currently hampered by the lack of robust data.

Cord Banking:
- As a method to reduce the need for a living donor.

New Technological Advances:
- As medicine and medical technology advances, the hope is that living donors will become less important.
The Role of Egg Donation Agencies in Defining the Moral Status of Eggs
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Harvard Radiation Oncology, Harvard Dermatology

Introduction
• As long as there have been reproductive complications, there has been a demand for assisted reproductive strategies, including egg donation.
• While infertility is a medical diagnosis, services for egg donation are provided through private agencies.
• Egg donation agencies use both market-based approaches and a language of altruism, which results in morally ambiguous language.
• This ambiguity may potentiate widening discrepancies regarding the moral status of an oocyte, as biological tissue, as potential life, or as an economic good.
• Clarifying these definitions is at the heart of most ethical issues regarding egg donation.

Findings
• In the attempt of egg donation agencies to simultaneously defend the exchange of egg donation with language of altruism while promoting compensation using economic arguments, egg donation agencies help frame the exchange in such a way that contributes to moral ambiguities regarding the status of eggs.

Transaction of Egg Donation

Altruism

“Donation” “Gift”

Compensation for Time/Inconvenience

Market-Based

Exchange of Money

Price based on market forces

Aims of Research
• The objectives are to better describe the role of egg donation agencies as brokers of moral value for human oocytes and for the process of egg donation itself.

Method/Strategy
• Mixed methodologies, including media and content analysis, were used to explore the language used by egg donation agencies.
• The transition of egg donation from a medicine to the market is explored.
• Two differing views on the exchange of ova for money are examined:
  (1) the altruistic donation, rewarded with a monetary gift
  (2) a commercialized, market-based transaction of a good for money.

Conclusions
• Whether or not egg donation is framed as a transaction for services or as altruistic donation of biologic tissue may ultimately influence future decisions regarding parental rights, compensation limits, the use of eggs for medical research, and other emerging ethical issues regarding the moral status of a human oocyte.
Attitudes of Pediatric Cancer Patients Regarding Fertility Preservation Options
Divya Yerramilli, MD, MBE 1 Clarisa Gracia, MD, MSCE2

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Introduction
- Patients of reproductive age or with reproductive potential who receive treatment for cancer may be at risk for infertility.
- It is standard of care to discuss fertility preservation with all cancer patients if infertility is a risk of treatment, regardless of patient age, as it is part of their total cancer care.
- Cancer patients face many barriers to accessing fertility preservation, which include awareness of fertility preservation options.
- Pediatric patients may face additional barriers for many reasons, including: awareness of options, willingness of physicians to discuss these options, and prioritizing cure over survivorship.
- However, given the high rates of care and survivorship in pediatric patients, infertility must be discussed prior to initiating therapy.
- Studies have shown that youth diagnosed with cancer in fact desire future fertility at the time of cancer diagnosis.

Aims of Research
- The study aimed to describe the differences in knowledge of fertility preservation options between adult and pediatric female patients.

Method/Strategy
- A survey-based study was administered to female cancer patients referred to the Reproductive, Endocrinology, and Infertility Department at the University of Pennsylvania.
- The survey was designed to prospectively collect health, exposure, and demographic information of female patients as it related to ovarian reserve.
- 101 adult and 23 pediatric patients were asked if they had thought about various options for fertility preservation, and then asked if they had pursued any of these options.
- These survey results were then analyzed to characterize differences between pediatric and adult patients.

Fertility Preservation Options
- Pre-Puberty
  - Ovarian Tissue Banking
  - GnRH Agonist
  - Other/Not Asked
- Post-puberty
  - Ovarian Tissue Transposition
  - Embryo Cryopreservation
  - Oocyte Cryopreservation

Findings
- 101 adult patients and 23 pediatric patients were surveyed.
- 74% of adult vs. 30% of pediatric patients thought about fertility options (p=0.0004).
- Adults thought about embryo cryopreservation more often than pediatric patients (34% vs. 4%, p=0.004).
- Pediatric patients thought more frequently of not using any method for fertility preservation (61% versus 24%, p=0.008).
- More adults pursued fertility preservation, with 28% versus 0% (p=0.007) pursuing oocyte cryopreservation (17% versus 0%, p=0.0403).

Conclusions
- Pediatric cancer patients do not think about fertility options frequently.
- This may be due to age and reproductive goals at diagnosis.
- The difference in knowledge between adult and pediatric patients highlights the need for greater dissemination of information and referral for fertility preservation to all pediatric cancer patients.

Strategies To Improve Referral for Fertility Preservation
- Multi-disciplinary Care
- Consent/Assent
- Patient Comprehension
- Financial Barriers
- Insurance Coverage

References