GENE 220

Reproductive Genetics

ANJALI NARAIN & ALVINA ADIMOELJA

Learning Objectives

- Understand the role of eugenics in the development of the prenatal genetic testing field
- Summarize the current landscape of prenatal genetic testing, carrier screening, embryo selection, and gene editing
- Extrapolate the current and future implications of the currently available technologies with a focus on reproductive choice and disability rights
- Evaluate how ethics can help guide society towards ethical application of these technologies

Ground Norms

Be respectful of conflicting opinions
Commit to learning and growing
Compassionate listening
No talking over anyone
Make space, take space
What is said in the room, stays in the room (confidentiality)
Use “I”statements for sensitive topics
Don’t equate people with stereotypes
Don’t rush to judge others

Class Outline

5. Activity: Examples of eugenics influencing prenatal testing
15. Didactic: Landscape of Prenatal Testing and Carrier Screening
20. Activity: Case Study: Ethical Implications of Prenatal Testing & Carrier Screening
10. Didactic: Landscape of Future Reproductive Technologies (Pre-implantation Genetic Testing and Gene Therapy)
20. Activity: Hypothetical Case Study: Pre-implantation Genetic Testing
10. Didactic: Landscape of Future Reproductive Technologies (Genetic Engineering)
20. Activity: Hypothetical Case Study: Genetic Engineering

Ethical Issues in Reproductive Genetics

Our focus

Prenatal screening & testing
Carrier Screening
Embryo selection
Gene therapy & gene editing

Eugenics influencing reproductive health

In our first class, we discussed how forced sterilizations were used for eugenic purposes throughout the past several centuries.

With a partner:

1. Recall what traits were considered sufficient for forced sterilizations.
2. Connect this to what you have learned over the past few sessions in regards to race, behavior, sexuality, disability, and more.

(5 minutes)

When do individuals have clinical genetic testing?

Embryo

Family or personal history of genetic condition

Fetus

Screening for aneuploidies (Down syndrome & others)
Abnormal ultrasound findings
Advanced maternal age

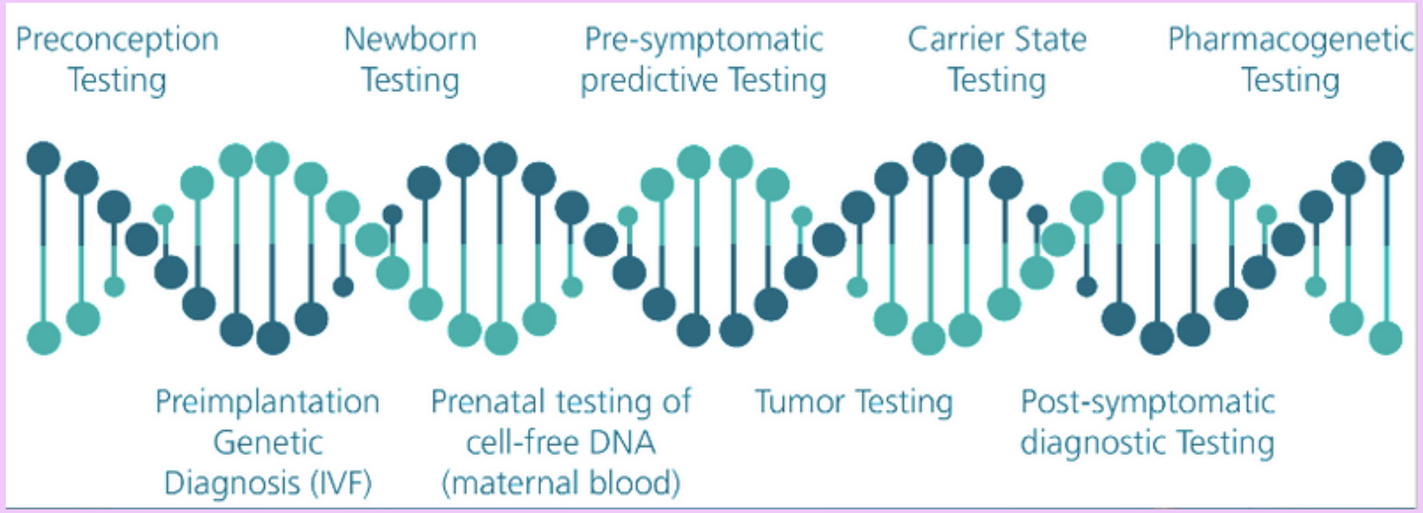
Child

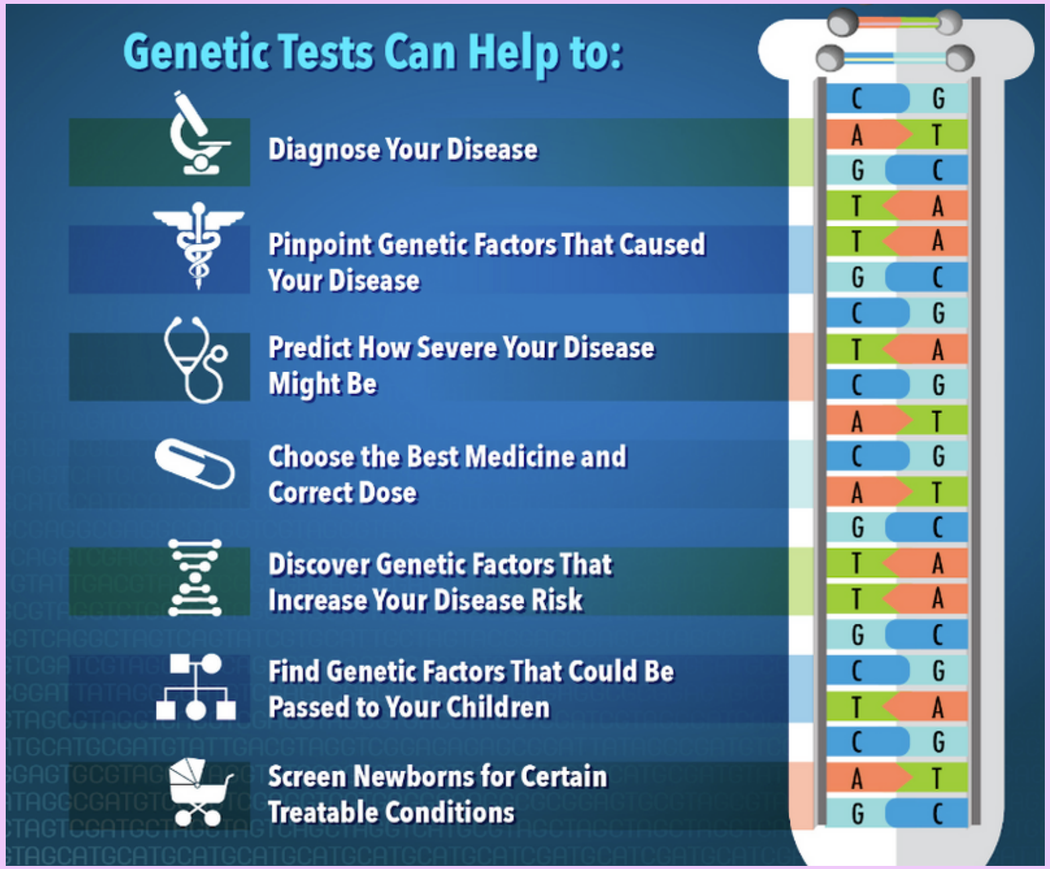
Presenting with medical issues, developmental delay, dysmorphic features

Adult

Presenting with medical issues
Known mutation in family
Curiosity

When do people have genetic testing?





When do people have reproductive testing?

Pre-conception

Carrier Screening
- **Autosomal recessive or X-linked conditions**

Embryo

Preimplantation genetic testing
- **Aneuploidies**
- **Mendelian**

Fetus

Prenatal Genetic Testing
- **Aneuploidies**
- **Mendelian**

Medical Decisions

For diagnosis / management
Medical benefit to individual

Value-Based Decisions

For personal planning
No medical benefit to individual, guided by personal values

CARRIER SCREENING & PRENATAL TESTING

Carrier Screening

Carrier: An individual who has one copy of a disease-causing gene for an autosomal recessive condition, and has none or mild symptoms.

Carrier Screening

- Identifies presumptuously healthy prospective couples in which both individuals are heterozygous for the same disorder, and are, therefore, at risk to have an affected child with a life-threatening, serious, or chronic disorder.
- Couples are screened for multiple genetic conditions (ranging from a ~150-500)
- All individuals are thought to be carriers of atleast one genetic condition

Why have carrier screening?

Can help plan ahead - if both parents are carriers, may consider various options:

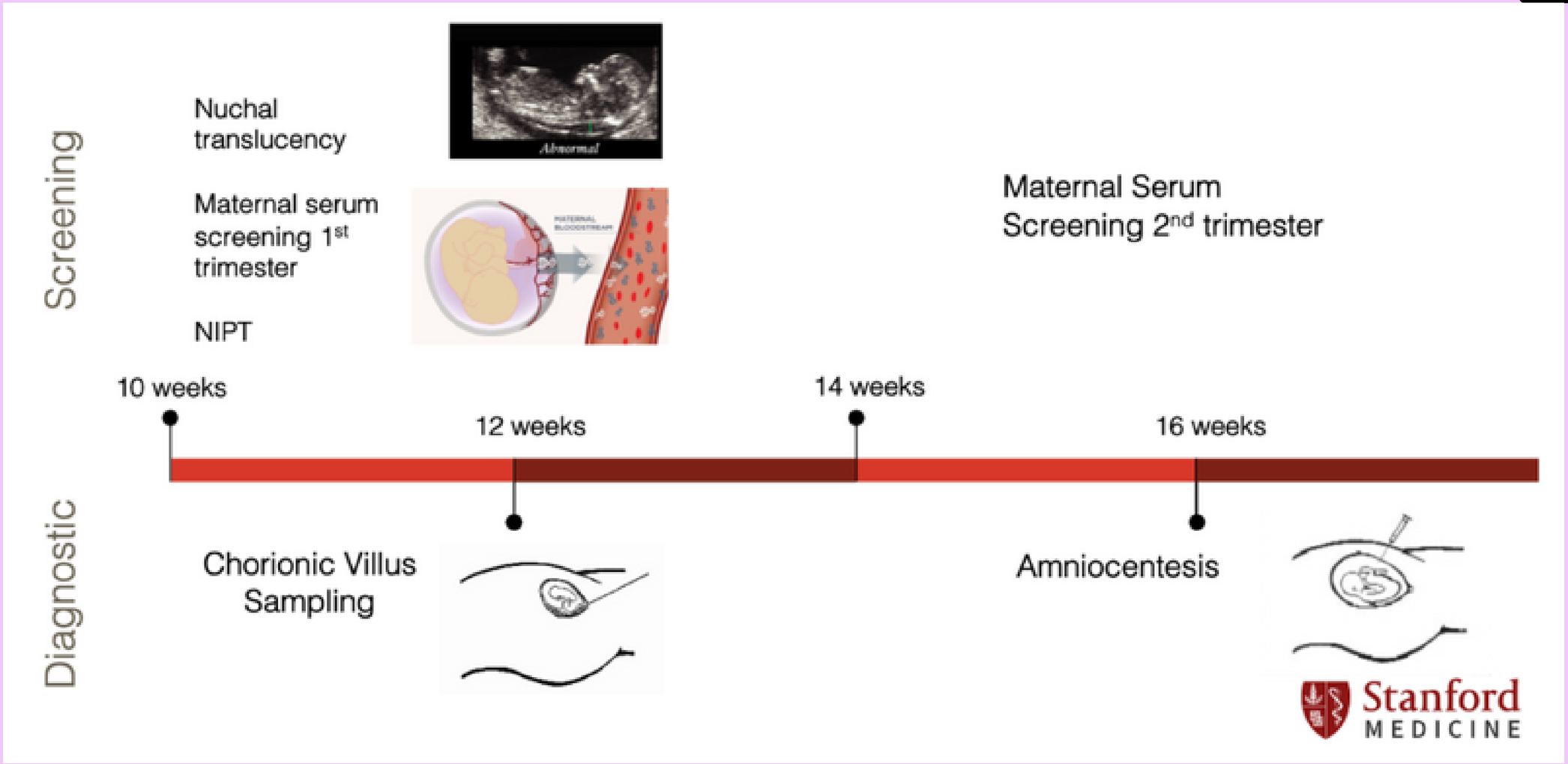
- Conceive naturally, test the fetus after conception
- Testing the embryo prior to implantation (with IVF)
- Sperm / egg donor
- Adopt, foster
- No genetic testing, but plan ahead for affected child

PRENATAL SCREENING & TESTING

Prenatal Screening vs. Testing

Screening	Testing
No suspected condition	Suspected condition
Not diagnostic; needs follow-up	Diagnostic
Blood tests (eg. NIPS), ultrasound measurements	CVS, Amniocentesis

Timeline of Prenatal Screening & Testing



(Chen, 2022)

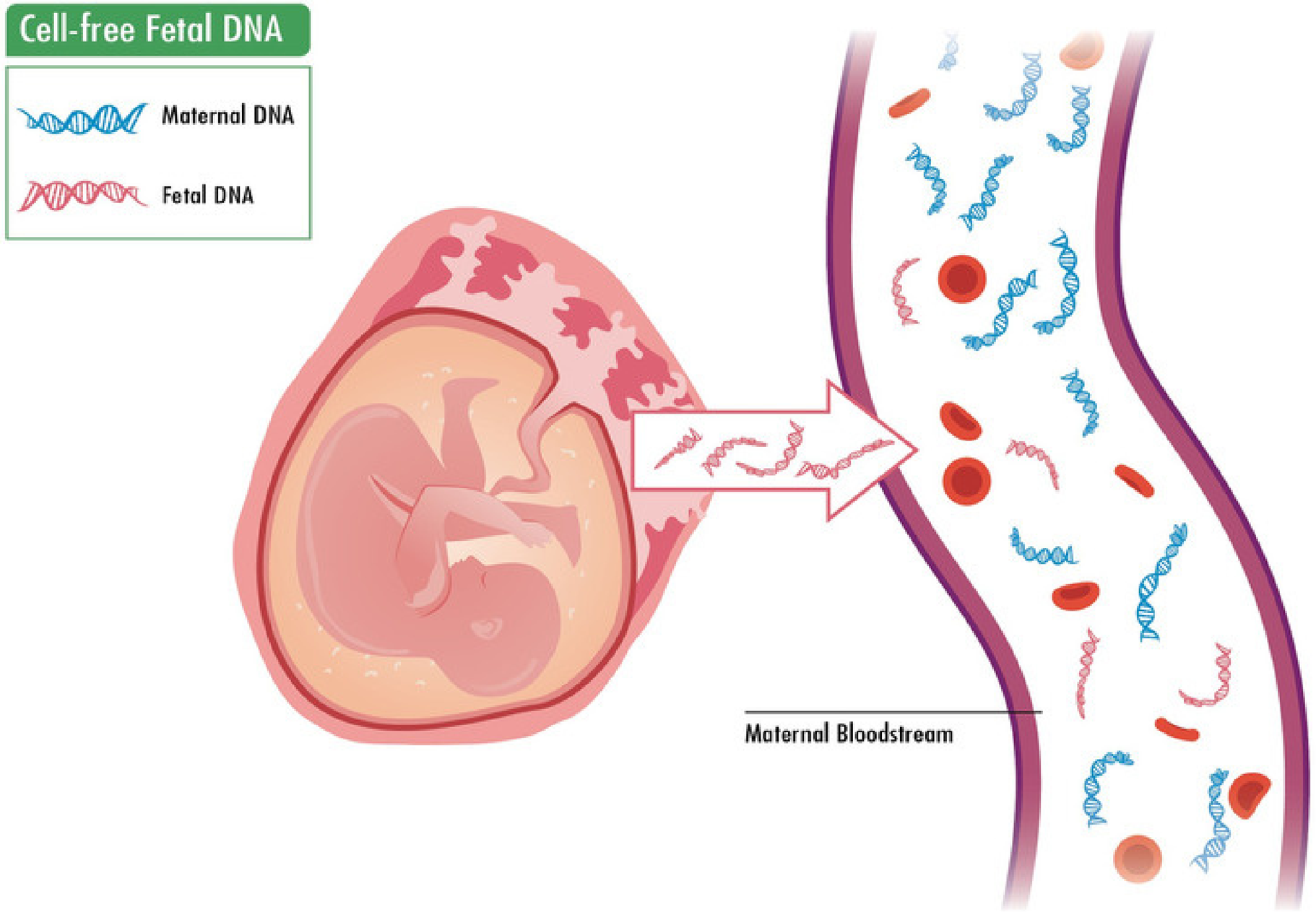
Prenatal Screening for Genetic Conditions

- Non-Invasive Prenatal Screening (NIPS)
- Ultrasound examinations
  - Aneuploidies
  - Neural Tube Defects (NTDs)
  - Certain birth defects

Non-Invasive Prenatal Screening (NIPS)

Extracting free-floating fetal DNA from the bloodstream of pregnant individual

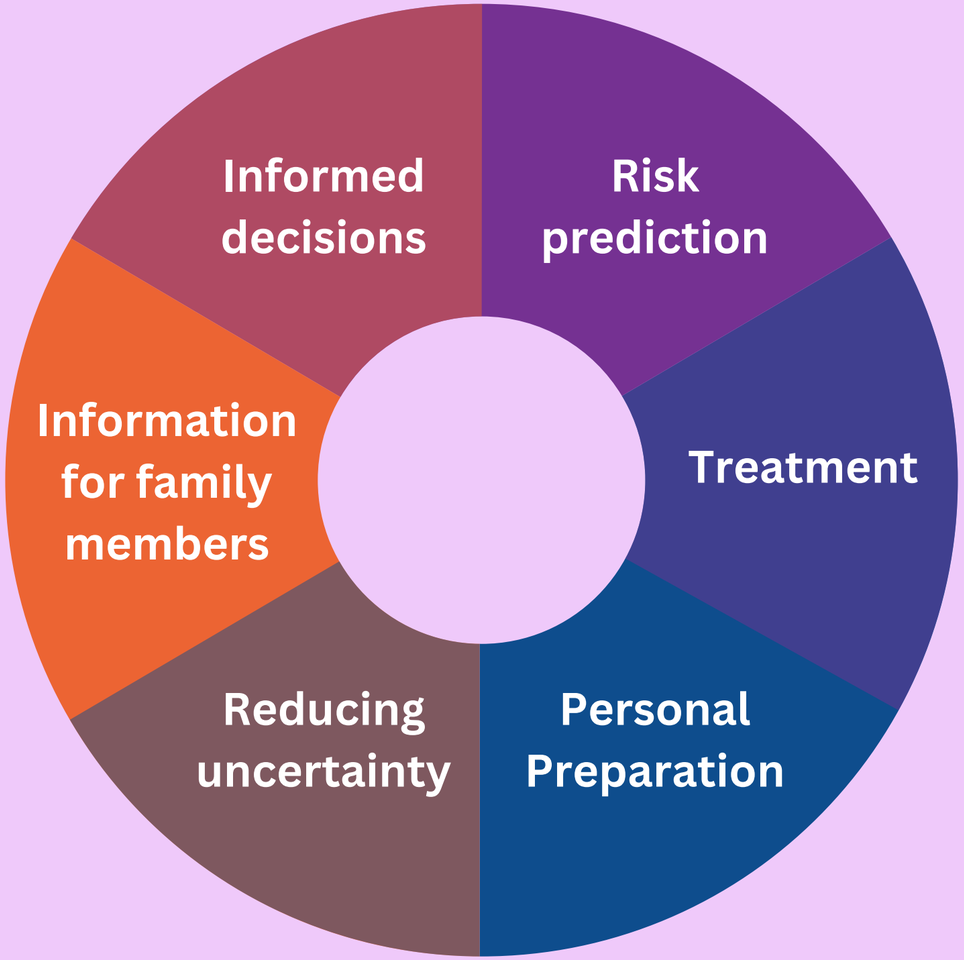
- Also called cell-free DNA screening


Cell-free Fetal DNA
Maternal DNA
Fetal DNA
Maternal Bloodstream

Prenatal Diagnostic Tests

- CVS
- Amniocentesis
- Karyotyping
- Fluorescent in-situ hybridization (FISH)
- Chromosome microarray
- DNA testing

Utility of Genetic Testing



Case Study: Carrier Screening

A couple are starting to plan a family together. They arrange carrier testing. They learn they are both carriers for a recessive form of blindness. They decide to conceive naturally and not pursue any testing of the pregnancy.

Discussion Points (5 mins):

1) What are some decision-making factors being considered by the parents?
2) What ethical considerations play a role here?

Case Study: Prenatal Screening & Testing

Discussion Points:

- Lived experience (exposure to / attitudes towards blindness)
- Prenatal testing: risk of miscarriage
- IVF with PGT: cost (financial, physical, emotional)

Case Study: Prenatal Screening & Testing

Ethical Considerations:

Whose role is it to ensure couples making reproductive decisions have context about what life could be like with that disability?

Case Study: Prenatal Screening & Testing

A pregnant 38 year old woman and her partner seek prenatal genetic testing for an autosomal dominant condition. 18 years earlier, they gave birth to a son who had this condition and he died 3 years ago. The couple also have a healthy 10 year old daughter.

Genetic testing confirms the pregnancy is affected by this condition, and the couple consider whether to terminate the pregnancy.

Discuss (5 mins):

1) What are some decision-making factors being considered by the parents?
2) What ethical considerations play a role here?

Case Study: Prenatal Screening & Testing

Group share (5 mins). Discussion Points:

- Lived experience (grief & loss)
- Feasibility of prolonged caregiver role
- Feelings about terminating a pregnancy
- Availability of support (financial, emotional, physical, other)
- Desire and likelihood of future opportunities to have children
- Whether it was an otherwise wanted pregnancy
- Impact on 10 year old daughter
- Whether different treatments for this condition are available since their late son was diagnosed

Case Study: Prenatal Screening & Testing

Ethical Considerations:

- Personal, cultural and/or religious beliefs re: termination
- A life worth living?
  - Treatment availability in future?
  - Part vs the whole
- Hereditary - message it sends to other relatives

CURRENT & FUTURE REPRODUCTIVE TECHNOLOGIES

Pre-implantation genetic testing (PGT)

- Definition: genetic testing of embryos prior to implantation
  - The embryo is created via in vitro fertilization (IVF)
  - Typically, a single cell is removed from the embryo at the 8-cell stage (3 days after fertilization)
  - Genetic testing is performed
  - The results of testing are used to decide which embryos, if any, to implant in the prospective mother's uterus

- Most commonly for aneuploidies or monogenic disorders, but have potential for other uses (e.g. structural rearrangements, **complex traits**)

Genetic testing to select embryos for certain traits was brought into the public eye in 2001 by the Nash family

Photo by Mark Engebretson, University of Minnesota

Feature

Almost two decades later, doctor reflects on using embryo selection to save young girl's life

June 21, 2018

From: https://twin-cities.umn.edu/news-events

Molly Nash was not expected to live to the age of 10. But her parents, and John Wagner, M.D., professor with the Department of Pediatrics in the Medical School, refused to let the genetics of her disease have the final word.

Molly was born with Fanconi anemia (FA), a severe, inherited blood disorder with high risk of cancer. Based on her genetics, she was predicted to have marrow failure by the age of 6 and myelodysplastic syndrome or leukemia by the age of 8. She wasn't expected to survive more than 10 years. The only proven treatment for the bone marrow failure, myelodysplasia and leukemia was a bone marrow transplant. Molly and her family sought help in the 1990s, a time when very few survived without a matched brother or sister marrow donor. Unfortunately, Molly had no siblings.

In 1994, after much ethical debate, Wagner offered a new option called embryo selection. Newly available technologies permitted rapid genetic testing on a single cell, allowing couples to obtain embryos after in vitro fertilization that were unaffected by FA and could also serve as HLA matched donors. The Nash family jumped at the idea knowing full well that this would be highly controversial. But, ultimately, they desired a healthy family and desperately wanted Molly to live.

On August 29, 2000, a day Wagner has memorized, Adam Nash was born. Several weeks later, Molly received her transplant.

"That's when it all started," Wagner remembers the headlines and criticism, "'Frankenstein', 'Crime against Humanity', 'Evolution is Dead' and 'Playing God.'" For a period of time, Wagner received both praise and threats.

The US public holds a range of opinions about the uses and limits of embryo screening via PGT

Data from Winkelman et al (**2015**)

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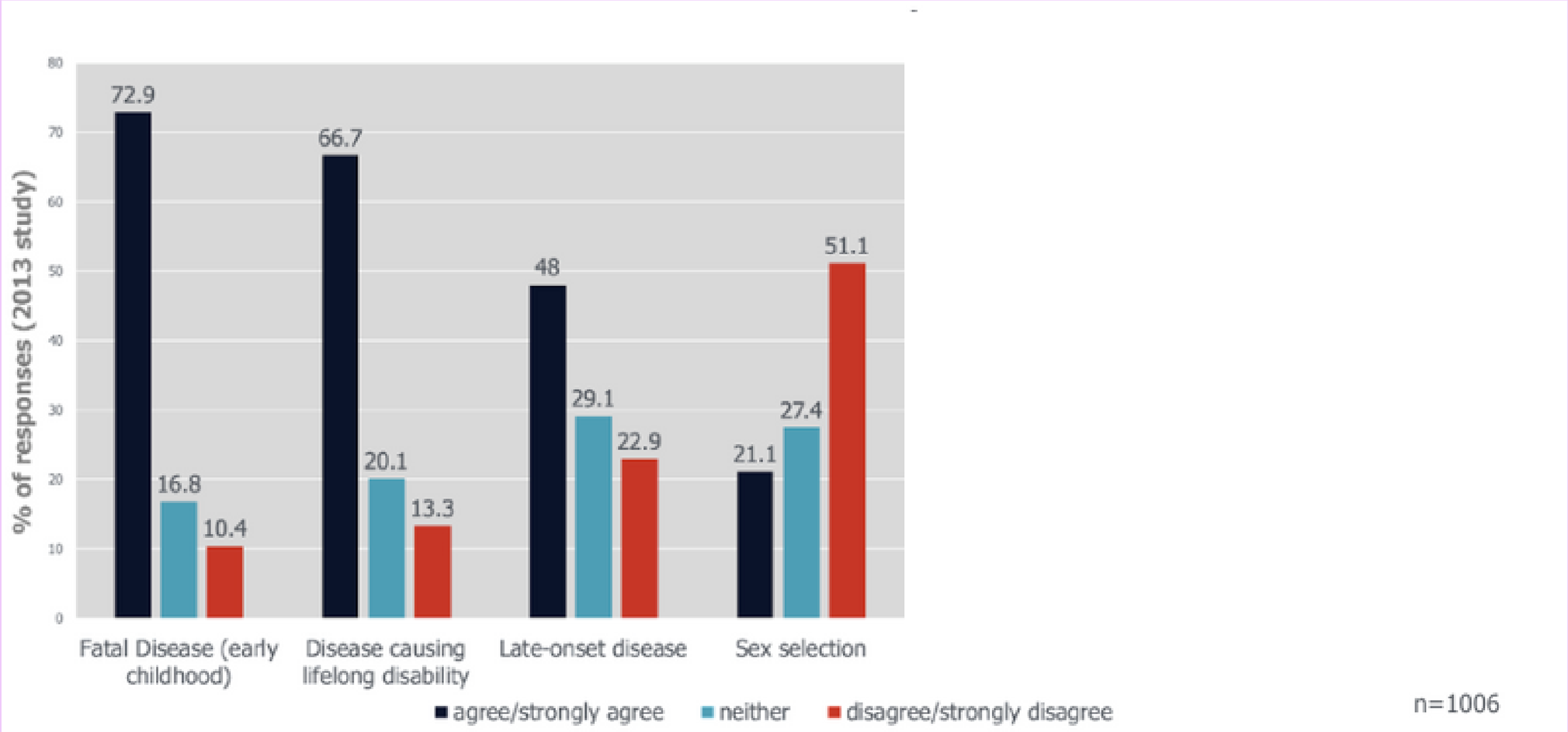

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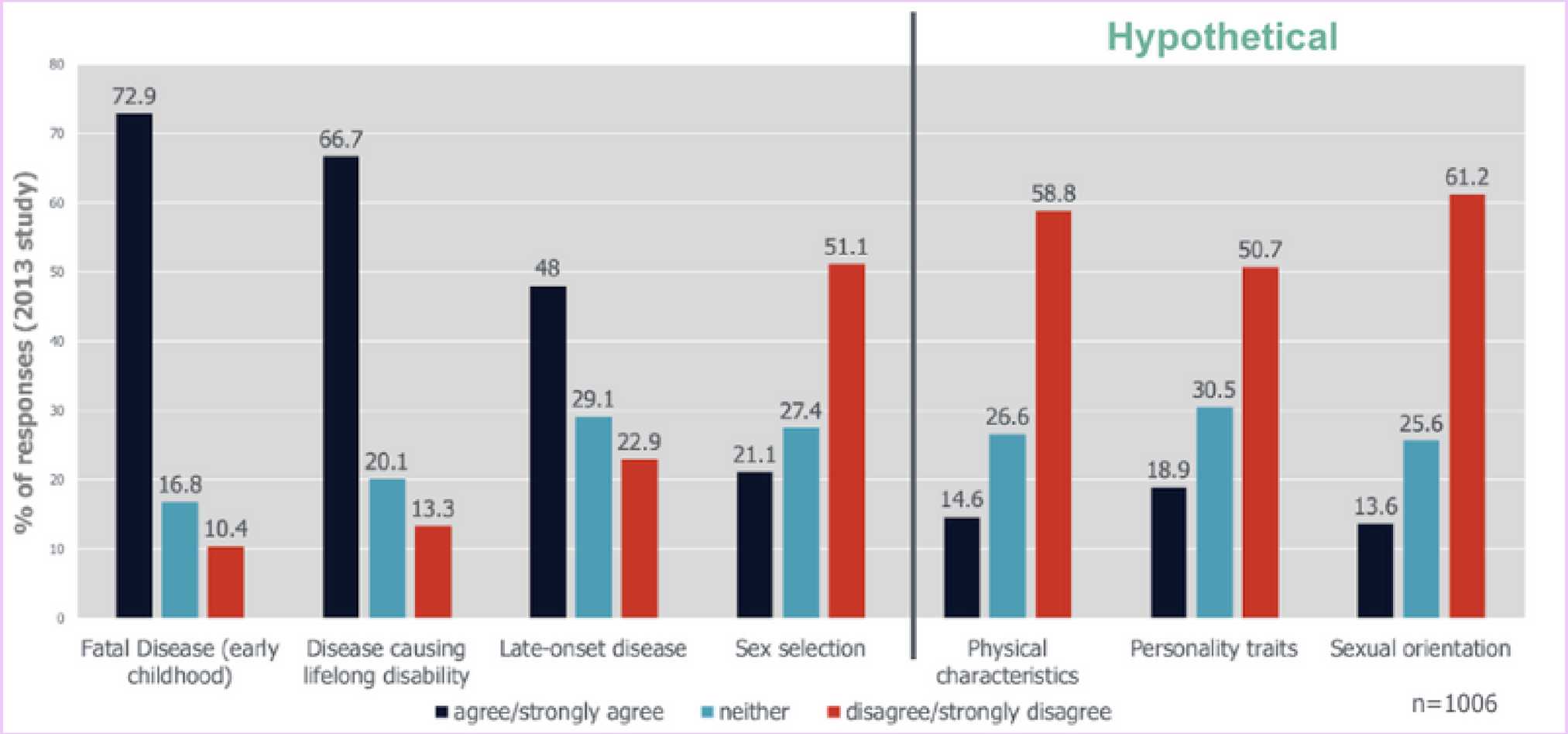

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Access to IVF (and thus PGT)

State laws to cover infertility-related treatments		
State	**IVF**	**Exemptions (not exhaustive)**
Arkansas	Yes	Life-time max of $15,000; Employers who self-insure
California	No	
Connecticut	Yes	Religious organizations; Employers who self-insure
Delaware	Yes	Companies <50 employees; Religious organizations
Hawaii	Yes	Only 1 cycle of IVF; Employers who self-insure
Illinois	Yes	Companies <25 employees; Religious organizations; Employers who self-insure
Louisiana	No	
Maryland	Yes	Companies <50 employees; Religious organizations; Employers who self-insure

State laws to cover infertility-related treatments		
State	**IVF**	**Exemptions (not exhaustive)**
Massachusetts	Yes	Employers who self-insure
Montana	No	
New Jersey	Yes	Companies <50 employees; Religious organizations; Employers who self-insure
New York	No	
Ohio	No	
Rhode Island	No	
Texas	Yes	Religious organizations; Employers who self-insure
West Virginia	No	

Data compiled by pgEd. Sources: https://resolve.org/what-are-my-options/insurance-coverage/infertility-coverage-state/ and https://www.reproductivefacts.org/resources/state-infertility-insurance-laws/ (accessed **June 11, 2019**).

PRE-IMPLANTATION GENETIC TESTING: POLYGENIC TRAITS

Polygenic traits and polygenic risk scores

Polygenic traits (and diseases)

Traits that are influenced by many genes. Many polygenic traits are also influenced by the environment. Examples of polygenic traits are: height, cardiovascular disease, diabetes.

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Traits that are influenced by many genes. Many polygenic traits are also influenced by the environment. Examples of polygenic traits are: height, cardiovascular disease, diabetes.

Polygenic risk score (PRS)

A score that quantifies an individual's relative risk for a certain trait. This score is based on numerous genetic variants, and a model that then translates that genetic data into relative risk.

PRS for embryo selection: issues to consider

- Relatively new approach; research and development is ongoing
- Generally optimized for people of European descent
- Relies on having enough genetic data for people with the condition of interest (not true for every condition)
- Lack of regulation for companies that want to apply this approach

Hurley et al., NEJM 2021

ORCHID

○ COUPLE REPORT ● EMBRYO REPORT GET ACCESS

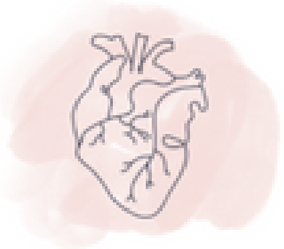
Protect your future child from genetic risks

Genetics influence the chance of developing disease later in life. Uncover risks and make an informed choice.

Orchid's advanced embryo screening measures:

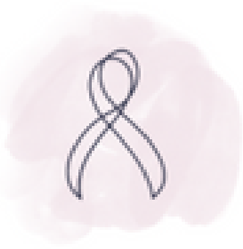
Brain Health

- Schizophrenia
- Alzheimer's Disease



Heart Health

- Heart Disease
- Atrial Fibrillation
- Stroke



Cancers

- Breast Cancer
- Prostate Cancer

General Health

- Inflammatory Bowel Disease
- Type 1 & Type 2 Diabetes

Offers a service to couples undergoing IVF

Uses PRS to calculate each embryo's risk of various diseases - then tells couple to choose

ORCHID

COUPLE REPORT EMBRYO REPORT GET ACCESS

Protect your future child from genetic risks

We help couples have healthy babies.

Brain Health

- Schizophrenia
- Alzheimer's Disease

Heart Health

- Heart Disease
- Atrial Fibrillation
- Stroke

Cancers

- Breast Cancer
- Prostate Cancer

Diseases that matter

Other tests look for disorders that impact less than 1% of babies. Orchid looks for the top chronic diseases.

ACTIVITY: DISCUSSION OF HYPOTHETICAL CASE STUDY

Discussion

(2 mins) Reading of hypothetical case study

(8 mins) Small group

- Applying one of the four bioethics principles that has been assigned to your group, what decision will you take?
  - Autonomy (respect for the individual; making informed choices in line with one's own beliefs and values)
  - Beneficence (promoting outcomes that are good for people)
  - Non-maleficence (doing no harm)
  - Justice (fairness; equity; access)
- Is it ethical for companies to offer such tests? What additional considerations do you have? Would your decision differ if it is for a complex disease e.g. coronary artery disease?

(10 mins) Class sharing

GENE THERAPY

Gene Therapy

- Gene therapy is broadly defined as the introduction of genetic material into a patient for the purpose of halting or reversing a pathological process.
- Package gene of interest in a vector or plasmid, then introduce into cells
- Methods of gene therapy: Gene replacement therapy, gene silencing therapy (siRNA), exon skipping etc.
- Gene therapy is currently approved for the treatment of select hematological malignancies, RPE65-mediated inherited retinal dystrophy, and spinal muscular atrophy.

Iavarone et al., 2022

CNN health | Life, But Better | Fitness | Food | Sleep | Mindfulness | Relationships

FDA approves $3.5 million treatment for hemophilia, now the most expensive drug in the world

By Deidre McPhillips, CNN

Published 4:26 PM EST, Wed November 23, 2022

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Gene Therapy with Etranacogene Dezaparvovec for Hemophilia B

S.W. Pipe, F.W.G. Leebeek, M. Recht, N.S. Key, G. Castaman, W. Miesbach, S. Lattimore, K. Peerlinck, P. Van der Valk, M. Coppens, P. Kampmann, K. Meijer, N. O'Connell, K.J. Pasi, D.P. Hart, R. Kazmi, J. Astermark, C.R.J.R. Hermans, R. Klamroth, R. Lemons, N. Visweshwar, A. von Drygalski, G. Young, S.E. Crary, M. Escobar, E. Gomez, R. Kruse-Jarres, D.V. Quon, E. Symington, M. Wang, A.P. Wheeler, R. Gut, Y.P. Liu, R.E. Dolmetsch, D.L. Cooper, Y. Li, B. Goldstein, and P.E. Monahan

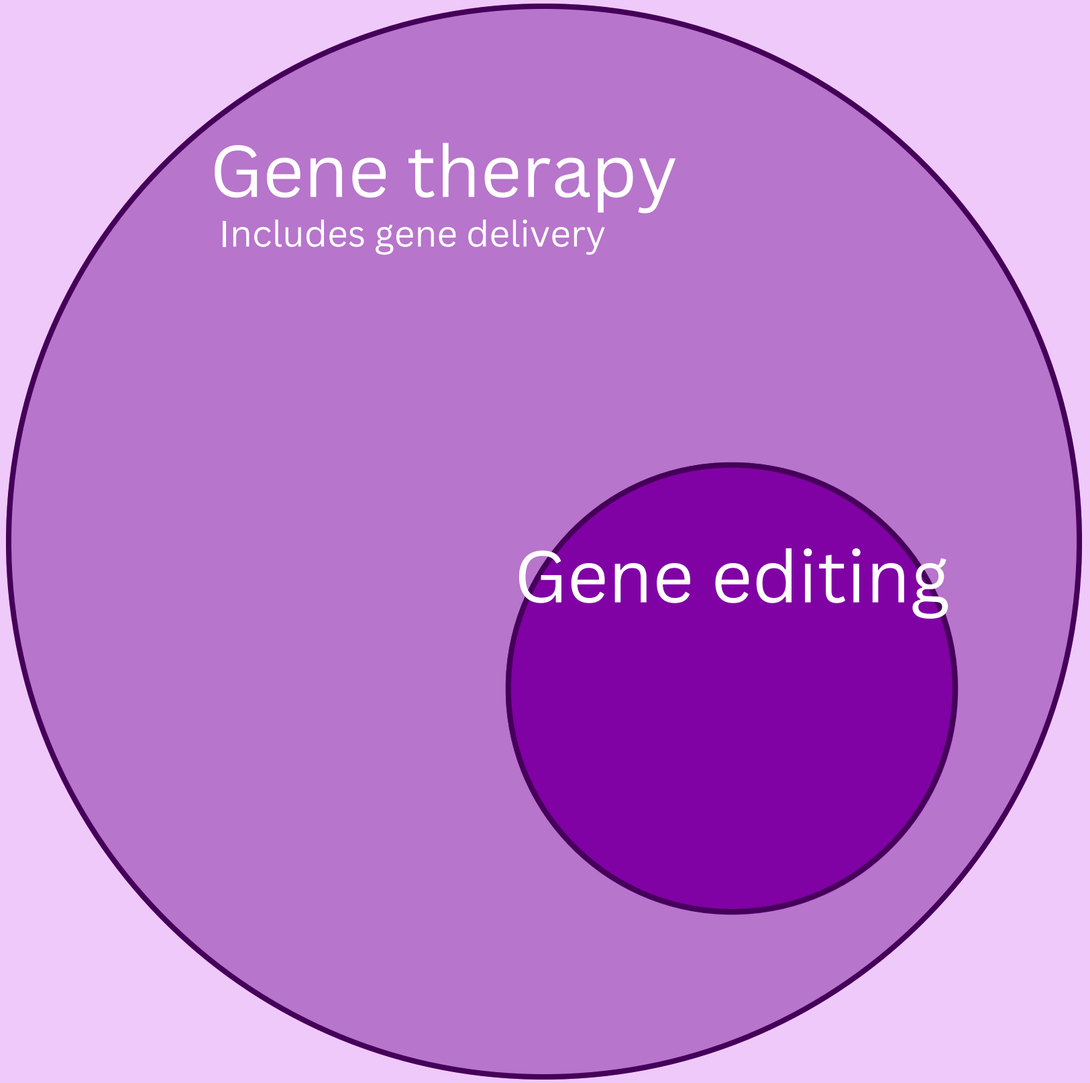
BACKGROUND

Moderate-to-severe hemophilia B is treated with lifelong, continuous coagulation factor IX replacement to prevent bleeding. Gene therapy for hemophilia B aims to establish sustained factor IX activity, thereby protecting against bleeding without burdensome factor IX replacement.

(≥6 months) of factor IX prophylaxis, we administered one infusion of adeno-associated virus 5 (AAV5) vector expressing the Padua factor IX variant (etranacogene dezaparvovec; 2×10^{13} genome copies per kilogram of body weight) to 54 men with hemophilia B (factor IX activity ≤2% of the normal value) regardless of preexisting AAV5 neutralizing antibodies. The primary

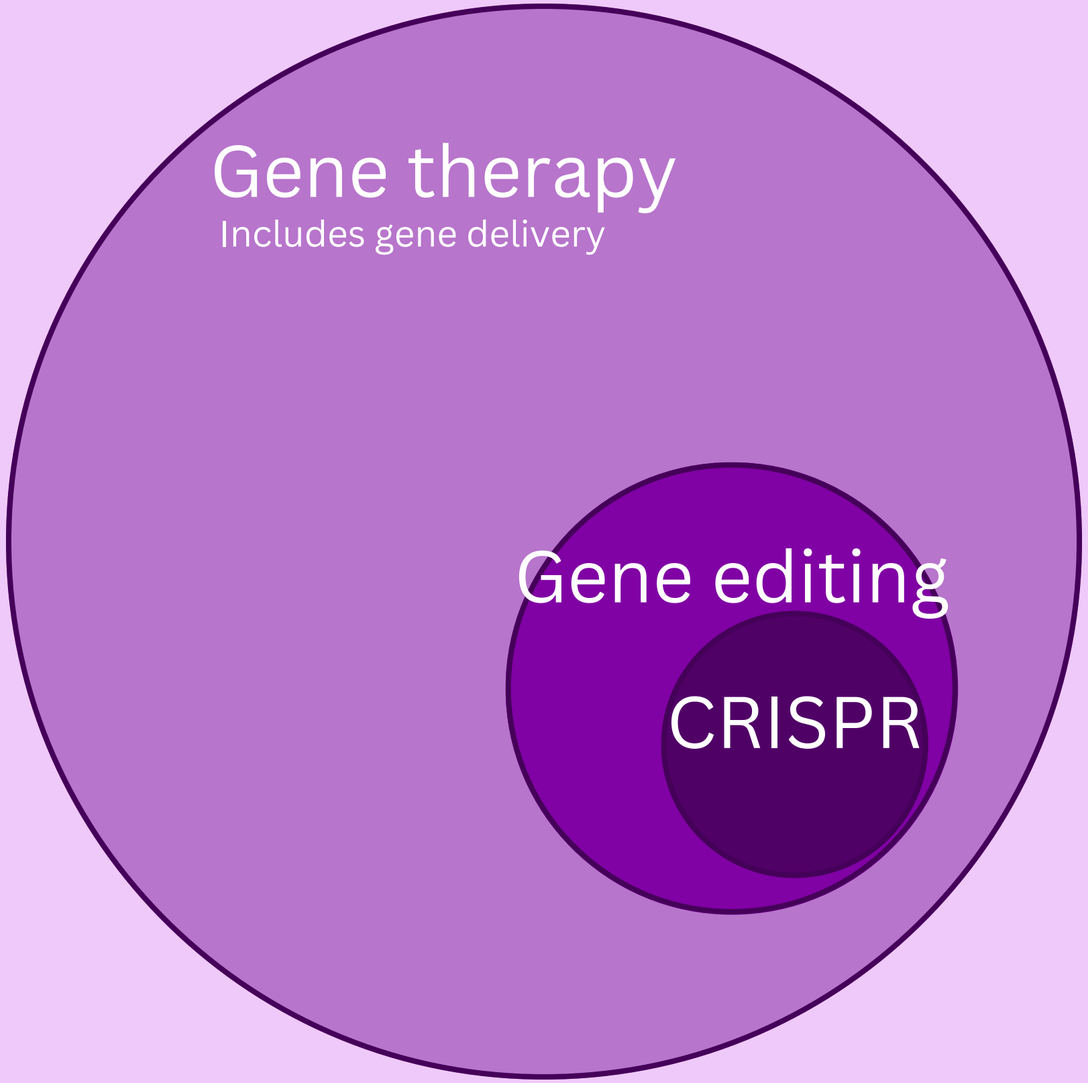
GERMLINE GENE EDITING

Gene therapy vs gene editing



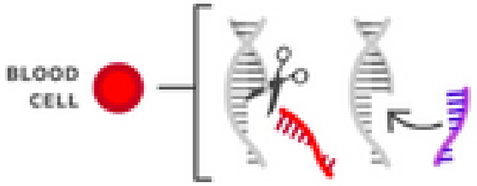
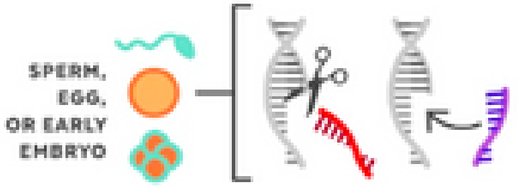
Conceptual Venn diagram (not drawn to scale!)

Gene therapy vs gene editing vs CRISPR



Conceptual Venn diagram (not drawn to scale!)

SOMATIC GENE EDITING VS. GERMLINE GENE EDITING

	SOMATIC GENE EDITING	GERMLINE GENE EDITING
EDIT	 Somatic therapies target genes in specific types of cells (blood cells, for example).	 Germline modifications are made so early in development that any change is copied into all of the new cells.

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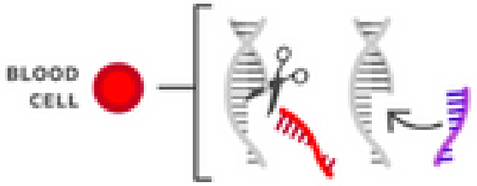
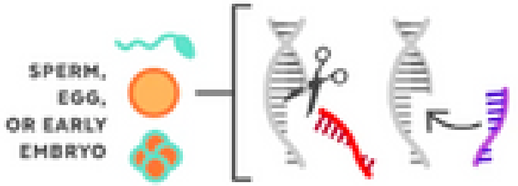
EDIT	 Somatic therapies target genes in specific types of cells (blood cells, for example).	 Germline modifications are made so early in development that any change is copied into all of the new cells.
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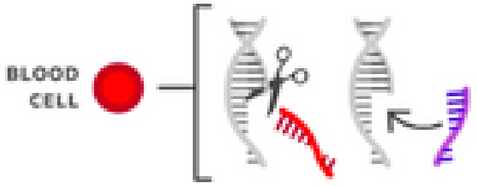
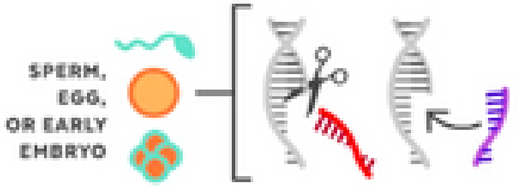
EDIT	 Somatic therapies target genes in specific types of cells (blood cells, for example).	 Germline modifications are made so early in development that any change is copied into all of the new cells.
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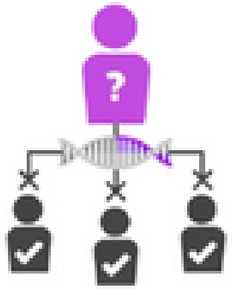
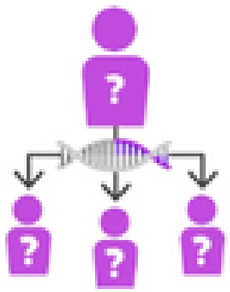
NEXT GENERATION	 The edited gene is not passed down to future generations.	

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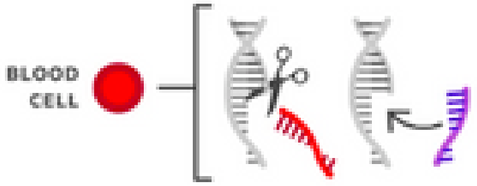
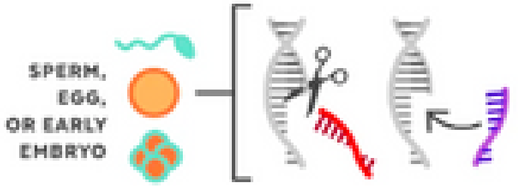
EDIT	 Somatic therapies target genes in specific types of cells (blood cells, for example).	 Germline modifications are made so early in development that any change is copied into all of the new cells.
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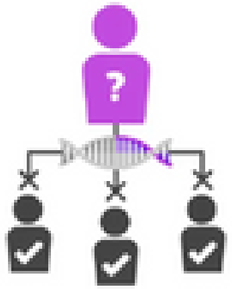
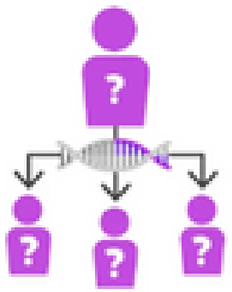
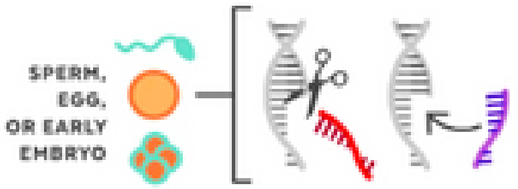
NEXT GENERATION	 The edited gene is not passed down to future generations.	
CONSENSUS	 Somatic cell therapies have been researched and tested for more than 20 years and are highly regulated.	 Human germline editing is new. Heritability of germline changes presents new legal and societal considerations.

From The Harvard Gazette: https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/

S. GERMLINE GENE EDITING



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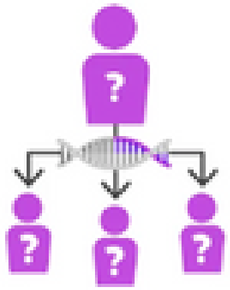
The edited gene is copied in every cell, including sperm or eggs.



If the person has children, the edited gene is passed on to future generations.

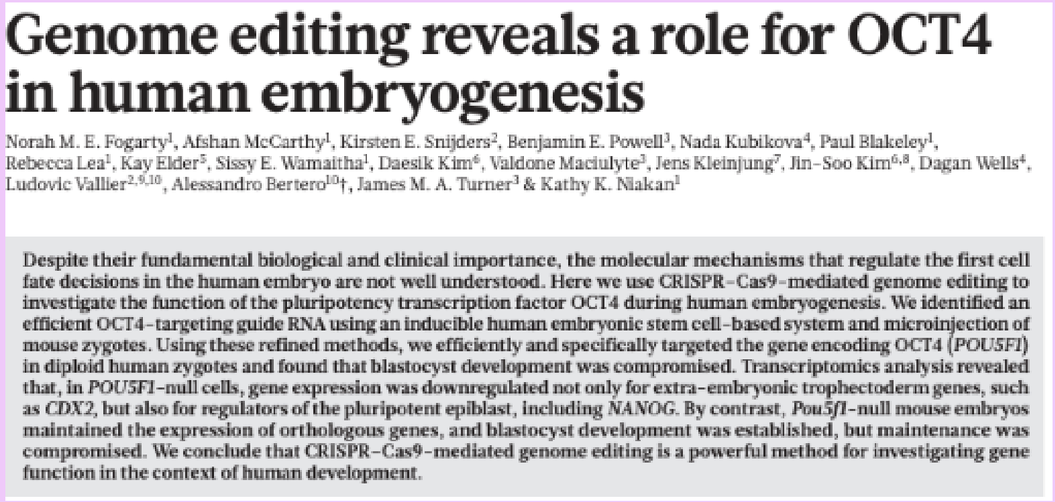
Human germline editing is new. Heritability of germline changes presents new legal and societal considerations.

edu/gazette/story/2019/01/perspectives-on-gene-editing/

CRISPR and germline editing

2015: A research group used CRISPR to make genetic changes in non-viable human embryos

2017: CRISPR used to make genetic changes in viable human embryos



Genome editing reveals a role for OCT4 in human embryogenesis

Norah M. E. Fogarty[1], Afshan McCarthy[1], Kirsten E. Snijders[2], Benjamin E. Powell[3], Nada Kubikova[4], Paul Blakeley[1], Rebecca Lea[1], Kay Elder[5], Sissy E. Wamaitha[1], Daesik Kim[6], Valdone Maciulyte[3], Jens Kleinjung[7], Jin-Soo Kim[6,8], Dagan Wells[4], Ludovic Vallier[2,9,10], Alessandro Bertero[10]†, James M. A. Turner[3] & Kathy K. Niakan[1]

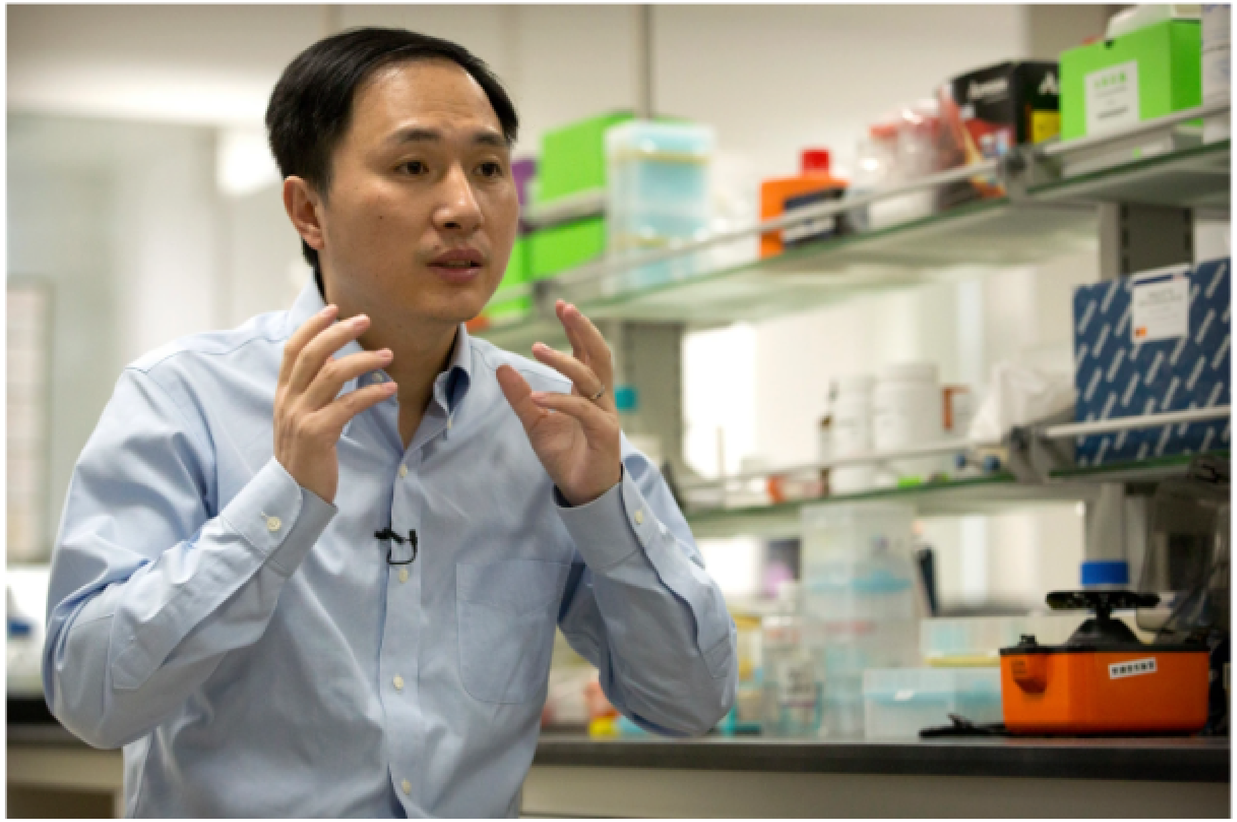
Despite their fundamental biological and clinical importance, the molecular mechanisms that regulate the first cell fate decisions in the human embryo are not well understood. Here we use CRISPR–Cas9–mediated genome editing to investigate the function of the pluripotency transcription factor OCT4 during human embryogenesis. We identified an efficient OCT4–targeting guide RNA using an inducible human embryonic stem cell–based system and microinjection of mouse zygotes. Using these refined methods, we efficiently and specifically targeted the gene encoding OCT4 (*POU5F1*) in diploid human zygotes and found that blastocyst development was compromised. Transcriptomics analysis revealed that, in *POU5F1*–null cells, gene expression was downregulated not only for extra–embryonic trophectoderm genes, such as *CDX2*, but also for regulators of the pluripotent epiblast, including *NANOG*. By contrast, *Pou5f1*–null mouse embryos maintained the expression of orthologous genes, and blastocyst development was established, but maintenance was compromised. We conclude that CRISPR–Cas9–mediated genome editing is a powerful method for investigating gene function in the context of human development.

CRISPR and germline editing

Currently: germline modification is illegal in countries, and federal funding in the US cannot be used for such work. Researchers have gotten approval to perform genome editing in human embryos for research purposes only.

Scientist at center of gene-editing controversy worked at Stanford

Chinese physicist discussed ethics with a Stanford bioethicist, revealed plans to a UC Berkeley geneticist



Oct. 10, 2018: He Jiankui speaks during an interview at a laboratory in Shenzhen in southern China's Guangdong province. (AP Photo/Mark Schiefelbein)

By LISA M. KRIEGER | lkrieger@bayareanewsgroup.com | Bay Area News Group

2018: CLAIMS OF CRISPR BEING USED TO EDIT GENOMES OF TWIN GIRLS

The Chinese physicist at the center of an ethical storm over what's believed to be the world's first gene-edited babies conducted his post-doctoral research at Stanford under one of the university's top bioengineers.

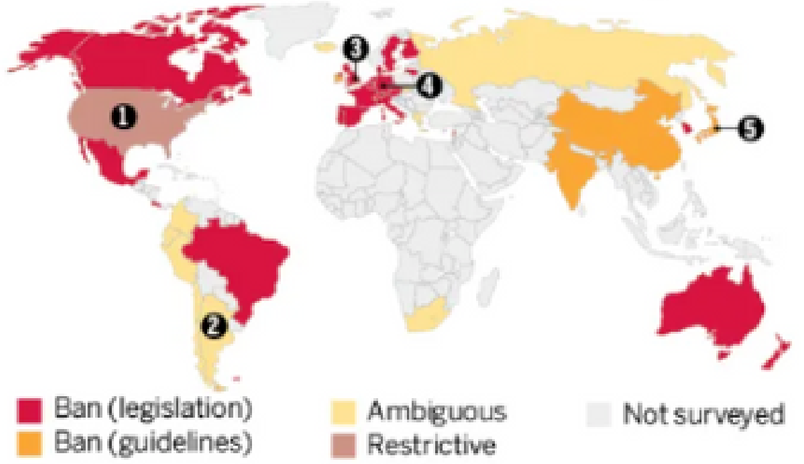
In the years that followed, He Jiankui discussed ethics with a Stanford bioethicist and even revealed his plans to a UC Berkeley geneticist, who urged him not to do it.

Now there's global controversy over He's brazen violation of a scientific taboo — using CRISPR-Cas 9, he claims, to edit the genomes of twin girls Nana and Lulu while they were embryos, violating a scientific taboo.

He says that he altered the genes with the goal of making the girls resistant to HIV. Announced on the eve of the Second International Summit on Human Genome Editing in Hong Kong, He has not provided evidence or data about his research and did not publish his findings in a journal. Outside scientists have not yet verified He's claims.

CRISPR EMBRYOS AND THE LAW

Regulations governing genetic modification in human embryos vary. Some countries ban the practice through legislation that carries criminal penalties; others have unenforceable guidelines.



❶ The United States does not allow the use of federal funds to modify human embryos, but there are no outright genome-editing bans. Clinical development may require approval.

❷ Argentina bans reproductive cloning but research applications of human-genome editing are not clearly regulated.

❸ The United Kingdom's independent Human Fertilization and Embryology Authority may permit human-genome editing for research, but the practice is banned in the clinic.

❹ Germany has strict laws on the use of embryos in assisted reproduction. It also limits research on human embryos, and violations could result in criminal charges.

❺ Japan, like China, India and Ireland, has unenforceable guidelines that restrict the editing of a human embryo's genome.

Source: M. Araki & T. Ishii Reprod. Biol. Endocrinol. 12, 108 (2014).

ACTIVITY: DISCUSSION OF CASE STUDY

Discussion

(10 mins) Reading of hypothetical case study & pair discussion

Discuss:

- Should this germline genetic engineering be approved or not? Why?
- What additional information would you like to have in order to make your recommendation?
- If you support approval, what path to approval do you see feasible?
- Do your considerations differ in the previous case study (on PGT)? How so and why?

(10 mins) Large group sharing

Stanford Events

SCIENTISTS SPEAK UP

Stanford Science Policy Group

ACLU Stanford

MEDICATION ABORTION AND THE FUTURE OF SCIENCE-BASED POLICY

Hank Greely
Professor of Law

Dr. Monica Saxena
Clinical Assistant Professor

Monthly Science Policy Series

May 25 | 12 PM PT | Bldg 420, Room 041 & Zoom

RSVP: https://tinyurl.com/ma-525

Roe v. Wade and IVF

- Roe v. Wade is the historic case that established a woman's right to have an abortion. With the reversal of Roe v. Wade (through Dobbs v Jackson), each state can now make laws about abortion. As a result, laws surrounding abortion will vary from state to state. This might also affect fertility services and genetic testing

Roe v. Wade and IVF

- Some abortion bans exempt IVF
  - Since 2010, states have introduced or passed 83 bills that mention both abortion and IVF. Of these, 45 bills explicitly exempt IVF and assisted reproductive technologies. None of these bills explicitly included IVF — or any reproductive technology — in banning abortion or defining legal personhood as beginning at conception.
    - The Louisiana legislature recently refused to pass an abortion ban bill that would have criminalized some aspects of IVF, instead moving forward a different abortion ban that explicitly exempted both contraception and IVF. More recently, Oklahoma passed a more expansive abortion ban that had no specific exemption for assisted reproductive technologies. However, the bill's sponsor later asserted that the law would not ban IVF, despite the bill's vague language (*Washington Post)*

- Fertility clinics, obstetricians, and gynecologists should consult with legal counsel to determine whether the states in which they are located have passed abortion restrictions that may impact their practices, and to ensure their services remain compliant with state law.

Next session: Identification & Privacy

Learning goals:

- **Analyze** the role that government, private and public databases play in the application of forensic genetics in the criminal justice system globally.
- **Examine** risks and benefits of identification and privacy from private and public entities.