



From Fetal Surgery to Gene Editing

The Current and Potential Impact of Prenatal Interventions on People with Disabilities



National Council on Disability

June 5, 2024

National Council on Disability (NCD)
1331 F Street NW, Suite 850
Washington, DC 20004

From Fetal Surgery to Gene Editing: The Current and Potential Impact of Prenatal Interventions on People with Disabilities

(Part of the Bioethics and Disability Series)

National Council on Disability, June 5, 2024
Celebrating 40 years as an independent federal agency.

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National Council on Disability

An independent federal agency making recommendations to the President and Congress to enhance the quality of life for all Americans with disabilities and their families.

Letter of Transmittal

June 5, 2024

President Joseph R. Biden, Jr.
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear Mr. President,

Prenatal interventions can include a host of technologies and applications, ranging from fetal surgery to repair a lesion in utero for a baby with Spina Bifida, to pre-implantation genetic diagnosis screening out embryos with certain conditions, to human heritable genome editing to alter the DNA of an embryo to modify a genetic trait. All prenatal interventions, ranging from fetal surgery to prenatal genetic screening to heritable genome editing, carry unique practical, ethical, and disability rights implications. These technologies require guidance from policy experts, scientists, medical providers, disability and social justice advocates, researchers, bioethicists, and other experts. On behalf of the National Council on Disability (NCD), I hereby transmit NCD's report titled *From Fetal Surgery to Gene Editing: The Current and Potential Impact of Prenatal Interventions on People with Disabilities*. This report is part of NCD's Bioethics and Disability Series, which can be found on NCD's website at www.ncd.gov

This report identifies the possible impact of these technologies on the disability community; gathers input about recommended policies and practices to assure that any prenatal technologies developed and utilized are determined by including people with disabilities as decision-makers who have experience living with various prenatally diagnosed conditions; and aims to provide recommendations to ensure any prenatal interventions do not disproportionately harm people with disabilities as a historically marginalized population.

The disability rights critique of human heritable genome editing cautions against a repeat of the eugenic practices of the early twentieth century which sought to eliminate people with disabilities through "better breeding" and ultimately led to the euthanasia of people with disabilities in Nazi Germany (S. S. Garland-Thomson Rosemarie 2021). Assumptions about the lives of people with disabilities have been historically biased and discriminatory; therefore, people with disabilities stand to face even greater health disparities, if not the complete eradication of their populations, without their consent or approval if heritable human genome editing is given free rein in a commercial market. Moreover, disability advocates describe valuing their disability as a meaningful part of their cultural identity that brings them community and is a source of pride. Policymakers stand in a unique position

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to assure the ethical inclusion of marginalized voices and health equity in the development of heritable genome editing policies and parameters.

Mr. President, NCD stands ready to coordinate with you, Congress and federal agencies to ensure heritable gene editing technology reflects current progressive disability policy in this country.

Respectfully submitted,

Claudia Gordon

Claudia Gordon
Chair

(The same letter of transmittal was sent to the President Pro Tempore of the U.S. Senate and the Speaker of the U.S. House of Representatives.)

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3. Marcy Darnovsky, PhD, Center for Genetics and Society Executive Director
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5. Silvia Yee, JD, Disability Rights Education and Defense Fund (DREDF) Senior Staff Attorney

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<i>such as the Genetics Society of America; American College</i>	
<i>of Medical Genetics and Genomics; American Board</i>	
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Acknowledgments

This report is part of a series of reports on bioethics and people with disabilities. It was developed by Stephanie Meredith as part of an Applied Practice Experience through the Department of Public Health at Georgia State University. We thank her for her extraordinary work. We also thank those who participated in the public comment session, listening sessions, and key informant interviews, whose knowledge and willingness to share information helped make this next report in the series possible.

Dedication

This report is dedicated to NCD's late Chairman Andrés Gallegos for his fearless leadership in advocating for health equity for people with disabilities.

Executive Summary

Purpose

Prenatal interventions can include a host of technologies and applications, ranging from fetal surgery to repair of a lesion in utero for a baby with spina bifida, to preimplantation genetic diagnosis screening out embryos with certain conditions, to human heritable genome editing to alter the DNA of an embryo to modify a genetic trait. Pregnancy is a particularly vulnerable period in human development and carries special rules for ethical consideration in research and medical practice (National Commission 2010). Some of these technologies, like fetal surgery for spina bifida and early prenatal tests to identify early-stage fetuses with Down syndrome, are being used in clinic right now. However, other technologies, such as heritable genome editing, are currently prohibited in most countries (Baylis et al. 2020). Some view heritable human genome editing as a slippery slope toward the creation of “designer babies,” while others view that technology as a possible future clinical treatment or nonmedical intervention.

The purpose of this report is to do the following:

1. Identify the possible impact of these technologies on the disability community.

2. Gather input about recommended policies and practices concerning developed and utilized prenatal technologies to assure they are determined by including as decision-makers people with disabilities who have experience living with various prenatally diagnosed conditions.
3. Ensure that any prenatal interventions do not disproportionately harm people with disabilities as a historically marginalized population.

Background

All prenatal interventions, ranging from fetal surgery to prenatal genetic screening to heritable genome editing, carry unique practical, ethical, and disability rights implications. These technologies require guidance from policy experts, scientists, medical providers, disability and social justice advocates, researchers, bioethicists, and other experts. Notably, people with the conditions that would be targeted, along with their families, can offer vital insight due to their lived experience. However, despite their firsthand experience, they have been historically excluded from determining research and funding priorities and from crafting policies and guidelines for prenatal technologies.

Prenatal genetic screening/testing is widely used in the majority of pregnancies in the United States, and preimplantation screening is largely utilized during in vitro fertilization (IVF).

The National Council on Disability (NCD) produced a thorough report on the prevailing issues with prenatal genetic testing, which continue to be problematic, in *Genetic Testing and the Rush to Perfection* (2019). That report focused on technologies in pregnancy that **screen or test the fetus**, while this report focuses on technologies in pregnancy that **change the fetus**.

Some prenatal interventions like fetal surgery are already being used to treat fetuses with spina bifida and carry known benefits and risks that have been evaluated by scientists, medical providers, and disability advocacy organizations. The Management of Myelomeningocele Study (MOMS) was conducted between 2003 and 2010 and enrolled 183 participants in a randomized controlled clinical trial funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development to determine the effectiveness of repairing the spinal opening in utero for fetuses with spina bifida (Moldenhauer and Adzick 2017). The study was conducted at multiple hospital sites and found that some benefits include a reduced need for shunts to remove fluid from the brain and an increased ability to walk, but risks included potential pregnancy loss, preterm birth, and low risk of

mortality and difficulty with future pregnancies for the parent. These interventions offer much promise, but bioethicists and patient advocates emphasize that risks and benefits can and should

be clearly communicated to the patient who can then decide whether to utilize the surgery or not. Additionally, disability advocates reinforce that any conversations about risks should avoid making ableist assumptions about life with disability that can influence patient decisions.

The discovery in 2012 that CRISPR-Cas9 technology can be used to edit the DNA of humans opened up another option for treating different conditions at the cellular level (Markus 2020). For example, somatic gene editing, or gene therapy of certain

[NCD] produced a thorough report on the prevailing issues with prenatal genetic testing . . . in Genetic Testing and the Rush to Perfection (2019). That report focused on technologies in pregnancy that screen or test the fetus, while this report focuses on technologies in pregnancy that change the fetus.

Cost Impact on Availability of Some Interventions

Currently, both fetal surgery and somatic gene editing are very expensive treatments offered only in specialty medical centers and not universally covered by insurance. This means that the most vulnerable people with these conditions, often those whose incomes are below the federal poverty threshold or those from racially diverse populations, do not usually have access to these types of treatments.

cells in the body, started to be used in 2020 to alter the sickle-shaped blood cells of people with sickle cell anemia so that they do not experience the pain crises that are often part of that condition (Stein 2023b).

Both fetal surgery and somatic gene editing are similar in that a patient or parent can give consent by weighing known risks and benefits, and the decisions they make impact only the one person being treated.

Additionally, CRISPR-Cas9 has opened the door to heritable human genome editing, a powerful technology that could completely change the fabric and diversity of humanity. Heritable human genome editing is the modification of the genetic code of an embryo, including reproductive cells, so that the genetic change is passed down to future generations. Developers of the technology have called for moratoria and global regulations on the potential uses of CRISPR to edit embryos due to the profound ethical and practical concerns regarding that technology (Markus 2020). This concern became particularly acute after a rogue scientist in China edited the embryos that became twin baby girls in 2018, for which he was broadly condemned by the science community for human experimentation

and faced imprisonment in China (Normile 2018).

The disability rights critique of human heritable genome editing cautions against a repeat of the eugenic practices of the early twentieth century which sought to eliminate people with disabilities through “better breeding” and ultimately led to the euthanasia of people with disabilities in

Nazi Germany (Garland-Thomson and Sufian 2021). Assumptions about the lives of people with disabilities have been historically biased and discriminatory; therefore, people with disabilities stand to face even greater health disparities, if not the complete eradication

of their populations, without their consent or approval if heritable human genome editing is given free rein in a commercial market. Moreover, disability advocates describe valuing their disability as a meaningful part of their cultural identity that brings them community and is a source of pride.

Therefore, policymakers are in a unique position to assure the ethical inclusion of marginalized voices and health equity in the development of heritable genome editing policies and parameters.

Heritable human genome editing is the modification of the genetic code of an embryo, including reproductive cells, so that the genetic change is passed down to future generations.

The disability rights critique of human heritable genome editing cautions against a repeat of the eugenic practices of the early twentieth century which sought to eliminate people with disabilities through “better breeding” and ultimately led to the euthanasia of people with disabilities in Nazi Germany.

Table 1. Prenatal interventions

Technology	Description	Current status	Extent of use	Site of use	Modifies fetus or person	Modifies DNA of future generations
Fetal surgery	Surgery to repair a health issue for the fetus	Accepted	Available but limited by cost	Inpatient care	Yes	No
Prenatal genetic screening/testing	Screening for genetic traits in a growing fetus	Accepted	Used in about 75% of pregnancies (about three million pregnancies/year)	Routine prenatal care	No	No
Preimplantation screening	Screening for genetic traits before implanting a fertilized egg in a uterus	Accepted	Used in about a third of in vitro fertilization [IVF] pregnancies (about 54,442 pregnancies)	Only IVF clinics	No	No
Somatic gene editing	Gene therapy of certain cells in the body	Accepted	Available for people outside the womb but limited by cost (not available yet during pregnancy)	Inpatient or outpatient care	Yes	No
Heritable gene editing	Gene editing to change all cells in a growing fetus, including egg and sperm cells	Not accepted	Two babies known	Unauthorized experimentation	Yes	Yes

Key Findings

The NCD 2019 report *Genetic Testing and the Rush to Perfection* highlighted profound problems in the implementation of prenatal technologies, including the lack of training for clinicians on how to sensitively discuss disabilities; the lackluster dissemination of accurate, up-to-date and balanced patient education information about disabilities; and the continued outsized influence of unregulated labs selling prenatal screening tests (NCD 2019). Over the past four years, these issues have largely remained unaddressed, and researchers, advocacy organizations, and news outlets have continued to show that we still have problems with how disability is discussed and portrayed in the prenatal setting. Recent research by Iezzoni et al. and Meredith et al. has demonstrated that a majority of medical professionals are biased against people with intellectual and developmental disabilities and convey that bias during prenatal conversations. These providers continue to need training about how to eliminate that bias (Iezzoni et al. 2021; Meredith et al. 2023). Research also continues to show that the majority of patients are not receiving accurate, up-to-date information at the moment of diagnosis, and the way the information is presented often causes lasting trauma (May, Dein, and Ford 2020). Moreover, we continue to have problems in regulation of testing and fertility clinics driven by for-profit industries. An article prominently featured in *The New York Times* in 2022 showed that the lack of regulation of commercial prenatal testing labs has led to widespread confusion about the accuracy of the tests among patients and providers (Kliff and Bhatia 2022). In addition, professional genetics organizations have been compelled to weigh

in on the accuracy of claims about polygenic risk score assessments for embryo selection when used as part of preimplantation genetic diagnosis and IVF in fertility treatment. These organizations have been urging fertility labs and fertility clinics to stop offering the polygenic risk scoring of embryos as a financially lucrative service that lacks clinical validity (Novembre et al. 2022). Furthermore, the marketing incentives for adopting these technologies are often steeped in the perpetuation of stereotypes and fears about disability so that expectant parents are encouraged to leap at any opportunity for a “healthy baby”—as determined by marketing executives—even though research shows that many people with disabilities lead meaningful lives (Estreich 2019).

Fundamentally, the competitive market offers every financial incentive to continue pushing forward with new prenatal interventions like fetal surgery and genome editing without taking the time and money to engage in public conversations about ethics, education, guidelines, and policies, but we can see where this lack of foresight and planning leads us. After 30 years of calls from disability and patient advocates, we still do not have the infrastructure of patient education and provider training to support prenatal testing and interventions or the regulations, policies, or systemic inclusion of people with disabilities to ethically administer them. This phenomenon where technology continues to surge forward without the scaffolding of education, ethics, and governance is causing a public health dilemma that is currently traumatizing patients, fostering bias against people with disabilities, and creating systemic inequities.

Our central hope as prenatal interventions expand from prenatal testing to prenatal interventions is for state and federal policymakers and organizations to work with professional medical, genetic, and scientific organizations and also nonprofits focusing on disability rights and women’s health. Together, they could take an active role in developing policies and funding initiatives that actively address these issues and include the input of people with disabilities.

Key Recommendations

Congress

- Continue to expressly prohibit the use of human germline gene editing in reproduction, as has been done by the 29 countries that have ratified the Council of Europe’s *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (the Oviedo Convention). Exceptions should not be considered unless and until the medical and scientific communities determine parameters through broad social debate that includes the disability community at every stage of the process.

The Consolidated Appropriations Act, 2023, indicates that none of the funds available in the Act may be used for “the creation of a human embryo or embryos for research purposes” or “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR

46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))” (Rep. Connolly 2022).

- Create legislation that would develop a sustainable disability equity funding pool derived from excise taxes on companies that benefit from prenatal genetic testing and interventions. This disability equity funding pool could be modeled on the excise tax funding mechanism for the Patient-Centered Outcomes Research Institute (PCORI) through an excise tax on health insurance plans and TTY (telecommunication technology for those who are hard of hearing) through an excise tax on telephone services. However, this disability equity funding pool would be distinct and separate from PCORI with funds derived from an excise tax on companies that benefit from prenatal genetic testing and interventions and funds extramurally directed toward the development of an ombudsman who would advocate for disability perspectives at medical and scientific meetings; training clinicians/genetics professionals on disability rights; developing and disseminating accurate, up-to-date and balanced information about genetic conditions; developing and maintaining relationships with disability advocacy organizations; and promoting disability education and social initiatives.
- Fund education initiatives and social forums for educating about controversial fetal intervention technologies and debating them before adopting them into practice, including all the interested parties, to

determine parameters for if or when these technologies might be utilized and under what circumstances.

Funding options for education initiatives include the following:

- making public service announcements (plain language) in newspapers, online, TV, news programs, virtual public spaces, flyers
- creating an app to facilitate discussions
- developing presentations and online learning modules
- communicating via websites, Twitter, email

Funding priorities for forums include the following:

- town halls
- policy leaders seeking input from people with disabilities in accessible locations: centers for independent living, postsecondary programs for people with disabilities, high-rise buildings for seniors and people with disabilities, nursing homes
- public comment sessions
- universities
- disability organizations
- other human rights and social change organizations
- Fund the Prenatally and Postnatally Diagnosed Conditions Awareness Act, Pub. L. No. 110-374, 122 Stat. 4051 (2008) (NCD 2019).
- Incentivize and fund the development of educational units on disability civil rights

and eugenics for public education and the education of medical providers and scientific researchers.

- Provide funding to collect data on the current impact of prenatal interventions accuracy, outcomes, and impact on disability community.
- Develop enforceable sunshine and conflict-of-interest laws that will bring transparency to any financial relationships among medical providers, researchers, and commercial laboratories (NCD 2019).
- Protect and establish laws such as the Genetic Information Nondiscrimination Act to prohibit health insurers and other entities from discriminating against families for choices regarding prenatal interventions.
- Expand the appropriation of funding for disability support services such as Medicaid, Individuals with Disabilities Education Act, and Americans with Disabilities Act so that individuals and families do not experience discrimination if they choose to parent people with disabilities.
- Lead and participate in global discussions and treaties to establish accountability for heritable genome editing research and implementation. Include the Global South and other countries historically excluded where research can be performed without oversight—medical tourism.
- Pass the Access to Genetic Counselor Services Act H.R. 3876 to expand access to genetic counseling services by providing for coverage under Medicare for genetic

counseling services that are furnished by genetic counselors.

- Pass the HEADS UP Act H.R. 3380 to designate people with disabilities as a Medically Underserved Population so that people with disabilities can be included in NIH funding for research and diversity training initiatives to benefit underserved populations.
- Pass the VALID Act to increase FDA regulatory oversight of laboratory-developed tests (LDTs; commercial prenatal screening tests such as cfDNA screening) due to the widespread misunderstanding of the tests due to variable marketing and reporting claims. Require the collection of data on the accuracy of the tests.
- Provide funding for educational and career development training opportunities for people with disabilities and family members with lived experience to enter the medical/science workforce.
- Protect and expand policies that support comprehensive health coverage during pregnancy.
- Consider prohibiting the commercialization of prenatal interventions.

Office of Management and Budget

- Require that any cost justifications for research funding allocations also include calculations that weigh the cost/benefit analysis per person of technology development **with estimates for equitable dissemination** versus strengthening corresponding social determinants of health for people with disabilities.

Department of Health and Human Services (HHS)

- Establish standing relationships with disability advocacy organizations and include individuals from them on genetic advisory panels (NCD 2019).
- Encourage the attendance of advocates and representatives from disability communities at science and biomedical conferences by offering scholarships that reduce or cover fees and expenses. Invite advocates and representatives from disability communities to serve in leadership positions (NCD 2019).
- Using the principles of patient-centered outcomes research, establish policies so that all research pertaining to prenatal interventions, including heritable genome editing, is informed by patient advocacy group stakeholders. Establish ethical accountability for research and clinical trials.
- Organize a national-level policymaking committee to advise federal regulatory and funding agencies and include people with disabilities, disability scholars, other advocates and scholars grounded in social justice perspectives, and bioethicists to evaluate and provide feedback on prenatal interventions (Michie 2023). This committee would be responsible for reviewing and supporting scientists and researchers at the individual IRB level to determine who should review certain proposals, what kind of expertise is required, and what kinds of issues are important to understand. This committee would provide support and guidance for

regulatory bodies including checklists and guidance about who should be at the table, what kind of expertise they need to have in order to review these kinds of studies, and what has been shown to be the best practice for stepwise implementation in prenatal technologies.

Additionally, as noted previously and as described in the Directors Statement linked earlier, “NIH will not fund any use of gene-editing technologies in human embryos.” In addition, “NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)).”

HHS, Food and Drug Administration

- Regulate genome editing research labs, fertility clinics, and other prenatal testing commercial entities to establish and enforce standards for the accuracy of any claims and how disability is portrayed, and proactively work with the Federal Trade Commission to oversee marketing being done by labs and commercial entities.
- Regulate ART by requiring clinical trial validation for procedures, a translational pipeline, and implementation guidelines.
- End enforcement discretion and regulate LDTs, specifically, NIPS, to establish and enforce standards for the accuracy of any claims made by prenatal genetic testing entities, and proactively work with the Federal

Trade Commission to oversee marketing by genetic testing entities. Provide disability advocacy and medically informed regulatory guidance for LDTs and ART, including the manipulation of gametes and embryos.

HHS, Centers for Medicare and Medicaid Services

- Recognize genetic counselors as health professionals who can receive reimbursement through Medicare and incentivize Medicaid payments for genetic counseling as an independent health care service rather than only reimbursing genetic testing to create an infrastructure of professionals who can discuss complex genetic technology and prenatal interventions (NCD 2019).
- Develop funding mechanisms to ensure that all people who want to pursue fetal interventions, which have been ethically affirmed and clinically validated, have access to those technologies regardless of socioeconomic status, proximity to a specialty center, or race.

Federal Trade Commission

- Actively oversee the marketing claims and practices of for-profit companies developing prenatal tests, embryo screening and selection, genome editing technology, and other prenatal interventions.

Department of Education

- Develop and encourage curricula and units about the history of disability rights and eugenics for broader public understanding in public education, informed by disability advocates with lived experience.

Equal Employment Opportunity Commission

- Leave wellness rules as they are now (May 2019) or, if the Equal Employment Opportunity Commission does revise them, the agency should clarify that no financial incentives or penalties are permitted to induce employees to disclose health and genetic information (NCD 2019).

State Legislatures

- If prenatal interventions are funded as a Medicaid service, the state should also ensure Medicaid funding for neutral genetic counseling by independent professionals *before* and after prenatal interventions are utilized (NCD 2019).
- If prenatal interventions are funded as a Medicaid service, the state should also fully fund Medicaid waiver waiting lists for people with disabilities to ensure that people are not choosing risky prenatal interventions because they lack access to proper supports and services to live with disability.
- Where state Medicaid programs cover prenatal genetic testing, the state should ensure that it collects voluntarily provided information on patient demographics, including disability status, outcomes, and the quality of genetic counseling received before the testing, if any. This information will allow states and researchers to assess the use and results of prenatal genetic testing as a publicly insured service over time (NCD 2019).

- Provide funding for health care and critical social determinants of health that can prevent disabilities such as expanded Medicaid coverage for pregnant persons and babies, folic acid supplementation, nutrition and food vouchers, and transportation to medical appointments. Provide comprehensive and easy-to-access health care coverage for pregnancies to ensure the health of pregnant persons and babies, particularly for those at risk for health complications, so they can access validated prenatal interventions like fetal surgery.
- Assess laws about reproduction to ensure they do not penalize providers and patients if a loss accidentally occurs for parents who want to pursue validated prenatal interventions such as fetal surgery.

Professional Organizations and Training Accreditation Bodies of Health Care Providers Engaged in Obstetrics such as Council on Resident Education in Obstetrics and Gynecology; Maternal-Fetal Medicine; Genetic Counseling such as the Genetics Society of America; American College of Medical Genetics and Genomics; American Board of Medical Genetics and Genomics; American Board of Genetic Counseling; and the Association of Professors of Human and Medical Genetic

- Clarify that disability education and cultural awareness extend beyond examining best practices for effectively communicating with patients with disabilities and include a social and civil rights context for understanding disability (NCD 2019).

- Ensure that the materials used for provider and patient education are passed through a consensus group of reimbursed stakeholders, including representatives from affected disability communities (NCD 2019).
- Professional standards of care for offering prenatal interventions should be established through consensus negotiations that include genetic counselors, obstetrics and gynecology care providers, and representatives from affected disability communities. Commercial entities should not be allowed to market or provide prenatal interventions that have not been vetted through a professional organization using a consensus process (NCD 2019).
- Ensure that online and printed materials used for provider and patient education are fully communication accessible to people with a range of disabilities and diverse linguistic and cultural backgrounds (NCD 2019).
- Accreditation organizations must make disability education and cultural awareness mandatory and more consistent among medical and genetics education programs, within a reasonable range of time and resources. The same holds true of professional ongoing education (NCD 2019).
- Establish certification or licensure requirements to indicate clinicians are qualified to offer complex fetal surgeries.

Prenatal Intervention Researchers and Research Funders

- Require that the development of research priorities and projects for prenatal interventions include individuals with lived

experience and families, and advocates or scholars grounded in disability perspectives, as consultants and decision-makers.

- Expand data collection on the current impact of prenatal intervention accuracy, outcomes, and impact on disability community.

State and Federal Public Health Officials

- Engage in the active dissemination of information about prenatally diagnosed conditions to improve patient and provider understanding of the conditions that might be identified.
- Host public forums using Health in All Policies approach to assess the potential societal impact of controversial prenatal interventions by including a range of stakeholders including people with disabilities and their families, medical and genetics professionals, disability scholars, bioethicists, and others (Rudolph et al. 2012).

National Academy of Science

- Require and fund robust inclusion of experts with disabilities as decision-makers and leaders in the development of guidelines, presentations at summits, and any other forums/publications where policies are recommended or standards are set forth for technologies that impact people with disabilities.

Health Care Corporate Governance Organizations and Health Consumer Advocates

- Establish professional guidelines and social norms requiring that the genetics and health corporations have rigorous conflict-

of-interest policies, social justice informed marketing, and regular consultation from people with disabilities.

Institutional Review Boards

- Recruit people knowledgeable in maternal-fetal medicine to review pregnancy-related

research proposals. Include people with the patient and family perspective and/or disability community perspective to review research proposals that would affect people with disabilities or that could exacerbate disability stigmatization or discrimination.

Methodology

The methodology for this paper includes a literature review using multiple academic sources including policy analyses, disability studies articles, and science, medical, and social science journals and books. Key terms for searches included “heritable, germline, or reproductive human genome editing”; “fetal surgery”; “prenatal”; and “disability.” Nonacademic sources were also reviewed, including articles and analyses published in popular newspapers and magazines, as well as blog posts, documentaries, podcasts, and symposia featuring scientists, scholars focused on disability studies, bioethicists, and social justice advocates.

In addition, NCD held a public comment session on May 4, 2023, where participants were asked to address the following questions in three minutes or less:

1. What impacts do advances in the gene-editing and fetal medicine technologies have for the future of the disability community?
2. Which of these technologies do you think are completely out of bounds, should be used with parameters, or should be used regularly?
3. What legal and ethical parameters should be put in place to make sure the use of the technology is equitable toward people with disabilities?

NCD received comments from about 20 participants ranging from prominent bioethicists with disabilities including Rosemarie Garland-Thomson and Joseph Stramondo to advocacy organization leaders from the National Down Syndrome Congress and Little People of America to the President of the American College of Medical Genetics and Genomics.

On June 14, 2023, NCD conducted a half-day listening session focusing on the same questions with more robust policy discussions using the World Café format. The 25 attendees reflected broad representation from advocates with different types of conditions (e.g., Down syndrome, autism, achondroplasia, hemophilia, and spina bifida); different fields of medicine (e.g., genetics, genetic counseling, obstetrics, and pediatrics), and people from diverse racial backgrounds. Attendees divided into four breakout groups—with a moderator selected from each group and a notetaker from the NCD staff—for the three different sessions. Each session lasted 30 minutes with 15 minutes for all the groups to report out afterward. Each interdisciplinary group included a disability policy leader, a medical professional, bioethicists, academics, and advocacy leaders, and they rotated each session to get different perspectives.

Literature research, public comments, and the listening session were further supplemented by phone interviews of the following key stakeholders:

- a masters'-level genetic counselor with over a decade of professional experience who runs a national nonprofit providing genetic counseling services and genetic education
- a social science researcher/anthropologist investigating the impact of heritable human genome editing on the disability community
- a social justice nonprofit director and policy expert focusing on heritable human genome editing and disability
- a bioethicist and disability advocate with lived experience and expertise in health equity
- a policy and legal expert focusing on heritable human genome editing and disability

Glossary

Assisted reproduction technology (ART): uses technology like in vitro fertilization, preimplantation screening, and so on

Cell-free fetal DNA (cfDNA): used for prenatal testing; is obtained from a blood draw of a pregnant person

Chorionic villus sampling (CVS or CV): a prenatal diagnostic test that examines material from the placenta

CRISPR-Cas9: a technology that can be used to edit parts of the genome by altering sections of DNA

DNA (deoxyribonucleic acid): an extremely long molecular element that is the primary component of chromosomes and carries information for the genetic characteristics of life-forms

Fetal surgery: surgery performed while a fetus is developing in the womb

Gene: “segments of DNA that contain instructions for building the molecules that make the body work” (National Institute of General Medical Sciences 2017)

Genome: “all of the genetic material in an organism. It is made of DNA (or RNA in some viruses) and includes genes and other elements that control the activity of those genes” (National Institute of General Medical Sciences 2017)

Genome editing: method for making specific changes to the DNA of an organism

Germline: egg and sperm cells

Heritable genome editing (human heritable genome editing, also called germline genome editing and reproductive genome editing): making changes in germinal (reproductive) cells so that those changes will be passed on to future generations through reproduction

In vitro fertilization (IVF): A medical procedure where an egg is fertilized outside the body in a laboratory setting

Laboratory-developed tests (LDTs): a new genetic test usually comes to the market as an LDT where a single laboratory develops and performs the test and client- or provider-gathered specimen samples are sent to that laboratory to be tested (National Council on Disability 2019)

Noninvasive prenatal screening (or testing) (NIPS [or NIPT]): analyzes cell-free fetal DNA (cffDNA) or cell-free DNA (cfDNA) obtained from a simple blood draw from a pregnant person to determine the likelihood that a fetus carries particular genetic conditions; analyzes multiple regions of DNA at once to derive a fetus or person's likelihood of having or developing a certain trait or condition (National Council on Disability 2019)

Polygenic risk scores: provide a measure of your disease risk due to your genes (Centers for Disease Control and Prevention 2022)

Preimplantation genetic diagnosis (PGD): A lab procedure where an embryo created via IVF is tested for genetic conditions before implantation.

Preimplantation genetic testing for aneuploidy (PGT-A): Preimplantation genetic testing for aneuploidy where embryos created via IVF are screened for certain chromosome conditions before implantation.

Preimplantation selection (PIS): Selecting certain embryos based on their genetic characteristics to be implanted in the womb.

Prenatally and Postnatally Diagnosed Conditions Awareness Act (PPDCAA): U.S. P.L. 110-374, § 2(1)-(3), 122 Stat. 4051, 4051 (2008); federal law aimed at ensuring that pregnant persons undergoing genetic testing receive up-to-date information about raising children living with Down syndrome and other genetic conditions and evidence-based information about the accuracy of genetic testing

Somatic genome editing: editing cells in a body that are not reproductive cells

University Centers for Excellence in Developmental Disabilities (UCEDD): part of the Association of University Centers on Disabilities; administered by the Administration on Intellectual and Developmental Disabilities (AIDD)

List of Abbreviations

ABGC	American Board of Genetic Counseling
ABMGG	American Board of Medical Genetics and Genomics
ACA	Affordable Care Act
ACGC	Accreditation Council for Genetic Counselling
ACMG	American College of Medical Genetics and Genomics
ACOG	American College of Obstetricians and Gynecologists
ADA	Americans with Disabilities Act of 1990
APHMG	Association of Professors of Human and Medical Genetics
ART	Assisted reproduction technology
cfDNA	Cell-free DNA
CMS	U.S. Centers for Medicare and Medicaid Services
CRISPR	Clustered regularly interspaced short palindromic repeats
CVS or CV	Chorionic villus sampling
DNA	Deoxyribonucleic acid
DS	Down syndrome
EEOC	U.S. Equal Employment Opportunity Commission
FDA	U.S. Food and Drug Administration
FTC	U.S. Federal Trade Commission GINA: Genetic Information Nondiscrimination Act HHS: U.S. Department of Health and Human Services IVF: In vitro fertilization LDT: Laboratory-developed test MOMS: Management of Myelomeningocele Study
NCD	National Council on Disability
NDSC	National Down Syndrome Congress
NDSS	National Down Syndrome Society NIH: National Institutes of Health
NIPS (or NIPT)	Noninvasive prenatal screening (or testing)
NLM	National Library of Medicine
OI	Osteogenesis imperfecta PCORI: Patient-Centered Outcomes Research Institute

PGD	Preimplantation genetic diagnosis
PPDCAA	Prenatally and Postnatally Diagnosed Conditions Awareness Act
SB	Spina bifida
SBA	Spina Bifida Association
SCA	Sex chromosome aneuploidy
UCEDD	University Centers for Excellence in Developmental Disabilities



Scientists who use CRISPR could see editing genes such as ours out of the gene pool as entirely uncontroversial. But our genetic conditions are not simply entities that can be clipped away from us as if they were some kind of a misspelled word or an awkward sentence in a document. We are whole beings, with our genetic conditions forming a fundamental part of who we are. (Garland-Thomson and Sufian 2021)

Introduction

While some prenatal interventions, such as fetal surgery, carry more traditional ethical concerns such as informed consent about risks and benefits and lack of universal access, the ethics of heritable genome editing delve into much more controversial territory. CRISPR technology and heritable genome editing have dominated headlines since unauthorized genomic editing was performed on embryos by a Chinese researcher in 2018 (Normile 2018). The stated purpose of researcher He Jiankui's experiment was to modify the DNA of embryos that were used to initiate pregnancies, that then developed into twin baby girls, in order to make them genetically resistant to HIV. As many have pointed out, this justification was dubious. His unauthorized human experimentation was broadly condemned by the scientific community and resulted in a three-year prison sentence. Even though no country currently permits the practice of heritable genome editing for reproduction (Baylis et al. 2020), the United States and some other

Even though no country currently permits the practice of heritable genome editing for reproduction, the United States and some other countries do allow for private experimental germline gene editing on embryos (not intended for reproduction).

countries do allow for private experimental germline gene editing on embryos (not intended for reproduction). In addition, the National Academies of Science and Medicine published a report in 2020 arguing for a beneficence/utilitarian approach where "heritable genome editing could represent an important option for prospective parents with a known risk of transmitting a genetic disease to have a genetically related child without that disease and its associated morbidity and mortality" (International Commission on the Clinical Use of Human Germline Genome Editing et al. 2020). However, the National Institutes of Health (NIH) does not support government-funded research per the NIH Director's Statement of April 28, 2015, that indicated "NIH will not fund any use of gene-editing technologies in human embryos" (NIH n.d.). In addition, "NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than

that allowed for research on fetuses in utero under 45 CFR Part 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)).”

At the recent Third International Summit on Human Genome Editing in 2023, sponsored by the British Royal Society, the U.K. Academy of Medical Sciences, the U.S. National Academies of Sciences and Medicine, and The World Academy of Sciences, 400 scientists, doctors, bioethicists, patients, and others spent three days debating the use

of human genome editing. At this first meeting after the controversial experimentation by He Jiankui, the organizing committee summarized a response. “Heritable human genome editing remains unacceptable at this time,” the committee said in the summit’s closing statement. “Heritable human genome editing should not be used unless, at a minimum, it meets reasonable standards for safety and efficacy, is legally sanctioned, and has been developed and tested under a system of rigorous oversight that is subject to responsible governance. At this time, these conditions have not been met” (Stein 2023a).

While the summit organizers concluded that “a broad societal debate about the implications for humanity would be necessary before moving forward,” critics were still concerned that the

summit consensus discussed parameters without including the option that the science could be prohibited altogether (Stein 2023a). “There are a bevy of serious objections to reproductive genome modification,” argued

Tina Rulli, a bioethicist at the University of California, Davis. “They include: Concerns about the safety of the modification: . . . the risk of dangerous modifications let loose in the human gene pool, a slippery slope to using the technology to make

designer babies, unethical eugenic uses of the technology that harm disability communities, and unequal unfair access to the technology that only advantages the wealthy” (Stein 2023a).

Additionally, disability advocates and bioethicists argue against the beneficence argument as a valid justification to proceed with heritable genome editing. Bioethicist Tom

Shakespeare writes, “To ‘fix’ a genetic variation that causes a rare disease may seem an obvious act of beneficence. But such intervention assumes that there is robust consensus about the boundaries between normal variation and

disability. Contrary to the prevailing assumption, most people with disabilities report a quality of life that is equivalent to that of non-disabled people” (Shakespeare 2015).

400 scientists, doctors, bioethicists, patients, and others spent three days debating the use of human genome editing “Heritable human genome editing remains unacceptable at this time,” the committee said in the summit’s closing statement.

These stories demonstrate over and over again how easily biomedical research and practice can mask atrocity with benevolence and injustice with progress. Which leads me to ask: What, precisely, are we editing for?

Key Quotes

The following are key quotes on the reason why the general public might assume that heritable genome technology is benevolent:

Many people make the assumption that life with Down syndrome or life with Spina Bifida or life with autism or life with dwarfism is a horrible tragedy to be avoided. And therefore, yes, of course we would support [heritable genome editing]. But if you sit and think about it, if you think about these questions of human variability that we ought to be valuing rather than

I want a world accessible and habitable for people—full stop—not just the people we design. (Reynolds 2018)

winnowing away and eliminating and questions of identity and questions of solidarity and support for each other, then they become a whole different conversation. (Darnovsky 2023)

These stories demonstrate over and over again how easily biomedical research and practice can mask atrocity with benevolence and injustice with progress. Which leads me to ask: What, precisely, are we editing for?

I want a world accessible and habitable for people—full stop—not just the people we design. (Reynolds 2018)



Indeed, disability advocates and bioethicists like Rosemarie Garland-Thomson and Sandy Sufian warn of a “velvet Eugenics” movement that would edit people with disability identities out of human diversity—and thus inequitably impact the population of people with disabilities (Garland-Thomson and Sufian 2021). Moreover, they object to the exclusion of people with disabilities from the development of these scientific reports, arguing that their self-determination and human rights are being violated by policies that could eliminate the existence of people with disabilities without input from those with lived experience (Stanford Medicine X 2017). This situation presents a public health dilemma as policymakers will be called upon to (1) implement policies, plans, and laws to govern the use or prohibition of heritable genome editing and (2) advocate for systemic health equity for people with disabilities as part of a historically marginalized population that has notably been subject to state-sanctioned reproductive

discrimination, such as forced sterilization to prevent genetic disease during the eugenics era (Rutherford 2023).

Darnovsky posits, “Who do we welcome into the world? What kind of people? Those are serious ethical questions we have to confront. They’re big questions for all of us. They affect our future, the future of social justice, but they’re

“Who do we welcome into the world? What kind of people? Those are serious ethical questions we have to confront. They’re big questions for all of us. They affect our future, the future of social justice, but they’re questions and issues that are raised to the nth degree by heritable genome editing”

questions and issues that are raised to the nth degree by heritable genome editing” (Darnovsky 2023).

To address these critical issues and the potential impact of prenatal interventions on the disability community, this paper outlines the current landscape in Chapter 1; the potential impact of different prenatal interventions in Chapter 2; the medical, ethical, and disability rights perspectives regarding different prenatal interventions in Chapter 3; and legal and policy considerations in Chapter 4, with a list of Key Recommendations for policymakers and organizations at the end.

Chapter 1: Landscape of Prenatal Interventions

Prenatal and Preimplantation Genetic Screening/Testing

People with disabilities, disability scholars, and disability organizations have expressed concerns about prenatal selection technology for decades. The most widely adopted technology is prenatal screening which is used in about 72 percent of four million pregnancies in the United States each year (Palomaki et al. 2013). Prenatal screening involves blood tests, such as cell-free DNA (cfDNA) screening and the traditional quad screen, that indicate if a fetus has a higher chance of having a disability. Prenatal selection technology also includes diagnostic prenatal testing (amniocentesis and chorionic villus sampling) that can provide confirmation if a baby has a genetic condition. To a lesser extent, this prenatal selection also takes place in fertility clinics through the use of preimplantation technology, which largely seeks to detect and implant fertilized eggs that do not have disabilities.

[P]regnant patients are often asked to make reproductive decisions about whether or not to continue a pregnancy in an environment where expectant parents frequently receive little or no information about the condition, and the conversations are often steeped in biases against people with disabilities as a historically marginalized population.

Notably, in their seminal work *Prenatal Testing and Disability Rights*, Adrienne Asch, Erik Parens, and other participants in Hastings Center discussions raised concerns in 2000 about the implications for people with disabilities when pregnant patients find out their baby is likely to have a disability. They assert that pregnant patients are often asked to make reproductive decisions about whether or not to continue a pregnancy in an environment where expectant parents frequently receive little or no information about the condition, and the conversations are often steeped in biases against people with disabilities as a historically marginalized population (Parens and Asch 2000). Notably, these concerns have still not been sufficiently addressed as disability bias continues to pervade those conversations and as market forces continue to push screening without the accompanying support and educational infrastructure for patients and providers (Meredith et al. 2023).

The problems and potential solutions were the subject of a detailed 2019 NCD report, *Genetic Testing and the Rush to Perfection* (NCD 2019). That report focused on the use of prenatal technology to **select** which fetuses are born, whereas this report focuses on the use of prenatal technology to **modify** fetuses. What is notably different between selecting and modifying fetuses is that selection involves screening/testing and then deciding whether to continue the pregnancy. Because the use of prenatal technology for the purposes of selection involves abortion, the politics are fraught as disability advocates and reproductive rights advocates try to navigate whether a woman's right to choose ethically includes the right to choose what kind of baby; whether informed consent can be obtained when expectant parents are provided biased or inaccurate information about disabilities; and how to navigate an increasingly messy reproductive rights landscape following the *Dobbs v. Jackson Women's Health Organization* Supreme Court decision. The issues also differ significantly in the widespread use of prenatal screening and the unregulated market economies of laboratory-developed tests (LDTs) as compared to the more limited, if not prohibited, use of prenatal modification of fetuses and the more heavily regulated use of these technologies that are much less market driven, even though a market influence is present.

However, many of the concerns overlap for these different prenatal interventions as expectant parents are asked to make choices regarding their pregnancy, which can impact the broader landscape of people with disabilities, and they often receive little information about the lives of people with disabilities to make these monumental decisions. Additionally,

they frequently experience bias in the communications about disabilities and an overt emphasis on the medical issues and negative aspects of disability. Further, clinicians often do not receive the training and support they need to navigate these complicated decisions about prenatal interventions. Moreover, medical curricula, as well as federal and organizational policies, fall woefully short in preparing clinicians and patients to engage in sensitive and ethically complex discussions about prenatal interventions and disability.

Fetal Surgery

Fetal surgeries repair the medical issues of a fetus during pregnancy, and this technology is currently used to repair specific medical issues associated with conditions like spina bifida

Concerns with Use of Fetal Surgery

The primary concerns regarding the use of fetal surgeries are as follows:

- ensuring that fetal surgery priorities are determined with input from the individuals and families living with those conditions
- evaluating the safety and effectiveness of those fetal surgeries through research and peer-reviewed publications
- counseling expectant parents about the immediate and long-term benefits and risks of fetal surgeries for baby and pregnant patient (Fry et al. 2021)
- ensuring that fetal surgeries determined to be beneficial by professionals and patients are accessible to all families

and diaphragmatic hernias. These surgeries have undergone significant scientific scrutiny published in peer-reviewed research and carry largely known benefits and risks that parents can weigh with a medical team before making those decisions (Adzick et al. 2011; Jani et al. 2009). Some of these surgeries have been available for over a decade. The surgery repairs a specific and serious medical issue and does not alter the genetics of the fetus.

Genome Editing

Genome editing is changing the DNA in someone's cells using technology such as CRISPR-Cas9. There are different types of genome editing. Heritable human genome editing is distinct from somatic genome editing or gene therapy. Somatic gene editing or gene therapy, which is changing the DNA of a living person in certain cells, is available for a relatively small number of patients with conditions like sickle cell anemia (Stein 2023b). The technology is used to repair the blood cells in people with sickle cell anemia but is not yet widely used due to the high cost. In contrast, heritable genome editing involves changing the DNA of embryos or gametes used in in vitro fertilization (IVF). In this case, parents would make the decision for their future child. Heritable genome editing also changes the DNA of the reproductive cells in the fetus so that the DNA change will be carried into future generations. Emerging technology

may also allow for gene editing in utero that can be heritable or somatic. "In utero gene editing, similar to augmentation gene therapy, can be directed to specific organs and/or cell types by various modes of delivery and viral vectors while preimplantation embryonic gene editing has the potential to affect all cells of the body" (Peranteau and Flake 2020).

Heritable human genome editing is also called human germline genome editing or reproductive genome editing. Germline genome editing can happen in a lab without being used in a person, but our report primarily focuses on germline

genome editing used for reproduction. Although the phrase "genome editing" is commonly used, this terminology has received pushback because the term "editing" suggests that the original is flawed and needs to be fixed when many people in the disability community perceive their difference

as a natural part of human diversity (Coller 2019). Additionally, the term "editing" suggests a scientific precision that is not accurate.

Although the phrase "genome editing" is commonly used, this terminology has received pushback because the term "editing" suggests that the original is flawed and needs to be fixed when many people in the disability community perceive their difference as a natural part of human diversity.

It sounds like word processing, you think about cut-and-paste and you don't think about things like you're going to make a genetic edit in one place in the cell, and that is going to pop up in different places in the genome, or it's going to pop up down the line in a day or a week or a month or a year. That's not what you think about when you think about word processing, and the term

“editing” obscures that, and makes it just sound too easy and friendly and cut and dry. (Darnovsky 2023)

In fact, at the 39th annual meeting of the European Society of Human Reproduction and Embryology (ESHRE), Nada Kubikova from the University of Oxford reported study results demonstrating that “the use of CRISPR-Cas9 in early human embryos carries significant risks” and that even though the DNA of embryo cells can be targeted with high efficiency, this rarely leads to the sort of changes needed to effectively edit a gene. Consequently, the strand of DNA is permanently broken, which can potentially lead to other genetic issues (Mayer 2023). Additionally, off-target changes can contribute to the altered embryo becoming nonviable. Even if the embryo survives after the human heritable genome editing is complete, CRISPR can cause off-target gene mutations that can be passed to future generations as outlined in the article, “CRISPR Gene Editing in Human Embryos Wreaks Chromosomal Mayhem” (Ledford 2020).

Heritable genome editing is not explicitly permitted in any country at the present, and 75 countries expressly prohibit heritable genome editing according to a global policy landscape analysis done

by Françoise Baylis, Marcy Darnovsky, Katie Hasson, and Timothy M. Krahn (Baylis et al. 2020). Notably, 29 countries have ratified the Council of Europe’s *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of*

Biology and Medicine: Convention on Human Rights and Biomedicine (the Oviedo Convention) that expressly prohibits heritable genome editing, and the treaty was reaffirmed in

2017 by the Council of Europe’s Parliamentary Assembly (Baylis et al. 2020).

As knowledge of human genetics grew during the decades around the turn of the millennium, policymakers in dozens of countries came to agree that developing safe, effective gene therapies for sick people should be strongly supported, and that “germline” or “heritable” genetic modification, which would threaten

fundamental human rights and equality, should be put off limits. The clearest and most forceful expression of that view was the Council

of Europe’s 1997 Convention on Human Rights and Biomedicine (the Oviedo Convention), which prohibited germline interventions. (Hasson and Darnovsky 2018)

Even if the embryo survives after the human heritable genome editing is complete, CRISPR can cause off-target gene mutations that can be passed to future generations . . .

75 countries expressly prohibit heritable genome editing . . .

[T]he United States is one of 11 countries that permits human germline genome editing (not for reproduction) by private funders.

According to Baylis et al., the United States is one of 11 countries that permits human germline genome editing (not for reproduction) by private funders. However, the Further Consolidated Appropriations Act of 2020, an omnibus spending bill, “contains one provision that restricts federal funding of human embryo research (widely known as the Dickey-Wicker

Amendment) and another that prohibits the Food and Drug Administration (FDA) from considering applications for clinical trials involving heritable human genome editing. Several U.S. states ban specific research activities involving human embryos (e.g., for cloning or for stem cell research)” (Baylis et al. 2020). A more recent appropriations law, the Consolidated

Concerns with Heritable Genome Editing

In summary, the primary concerns about heritable genome editing are as follows:

1. The accuracy of the technology. Heritable genome editing can produce off-target effects (editing at sites in the genome other than those intended) and on-target errors (unintended changes at the intended site). It can also produce mosaicism in embryos, where some cells are edited and others are not (Nuffield Council on Bioethics 2016).
2. Limited knowledge of “gene functions and interconnected, complex genetics, biology, and environment (not necessarily single gene or Mendellian)” (Nuffield Council on Bioethics 2016). We do not know how changes to DNA might have unintended consequences given the complexity of genetics, biology, and environment.
3. Significant risks for human embryos. A study by Kubikova et al. “shows that homology-directed repair is infrequent in early human embryos and that, in the first few days of life, the cells of human embryos struggle to repair broken DNA strands” (Mayer 2023). Indeed, only 9 percent of targeted sites could be properly repaired.
4. Danger of market incentives and globalization. Katie Stoll and Marsha Michie warned of companies seeking profit and nations pursuing global advantage that could mischaracterize the accuracy of genetic tests and ignore ethical concerns in their pursuit of money and power.
5. Assumptions about life with disability. Key informants Silvia Yee and Anita Cameron expressed concern about scientists and medical providers determining priorities for research and clinical care based on biased and discriminatory assumptions about life with disability (Iezzoni et al. 2021).
6. Impact on future generations. Disability advocates and bioethicists Marcy Darnovsky and Katie Stoll caution against the potential for heritable genome editing to impact future generations without their consent and potentially eradicate certain disabilities that reflect human diversity and not disease or pain.

Appropriations Act, 2023, indicates that none of the funds available in the Act may be used for “the creation of a human embryo or embryos for research purposes” or “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))” (Connolly 2022).

Prenatally Diagnosed Conditions

When broadly discussing medical interventions, “disease,” “disability,” “defects,” and “pain” are often used as interchangeable terms. However, people living with these conditions may consider these concepts to be quite different. Deaf and hard-of-hearing people or Little People often consider themselves identity groups that do not want to be “fixed” by medical interventions and would prefer accommodations and social supports instead. However, people with some conditions like Down syndrome may view themselves as an identity group while

also having associated heart and respiratory conditions that they would consider as medical issues to be addressed. People with other conditions like sickle cell anemia or beta thalassemia may strongly consider those conditions diseases with symptoms they want to be cured.

Disability is different from disease, and some of the researchers in this area don't make that distinction. So, for example, I think it's much less problematic to think that interventions that would prevent the development of sickle cell, which most people might think is fine if we could take care of because of the way that operates, is very different from saying let's address a single gene entity like Down syndrome or cystic fibrosis. For some conditions, the elements of it that are inherent in the condition might be worth thinking about whether somebody wants to make those kinds of choices. (Robert Dinerstein, “NCD Public Comment Session” 2023a)

Examples of Prenatally Diagnosed Conditions

Following are some examples of different conditions that can be prenatally diagnosed and some very basic descriptions of those conditions that we refer to periodically throughout this document. Note: These are not comprehensive definitions that include the full range of outcomes for these conditions but are just simple references based on the descriptions provided by the National Library of Medicine (NLM).

Achondroplasia: According to the NLM, achondroplasia is a genetic condition and is the most common form of dwarfism. People with achondroplasia usually have normal intelligence and may experience health conditions such as back pain, ear infections, or

Examples of Prenatally Diagnosed Conditions: *continued*

obesity. Some may experience more serious spinal stenosis, which is a pinching of the spinal cord that can make walking difficult.

(MedlinePlus n.d.a).

Deaf/Deafness: NLM states that people who are Deaf experience hearing loss. Hearing loss can be caused by genetic or environmental factors (MedlinePlus n.d.b).

Down syndrome: According to NLM, Down syndrome is a condition where a person has an extra copy of the 21st chromosome, which usually causes mild to moderate intellectual disability and increases the risk for some health conditions, such as heart defects and gastrointestinal issues (MedlinePlus n.d.a)

Hemophilia: NLM indicates that hemophilia is a “rare bleeding disorder in which the blood does not clot properly” and can cause excessive bleeding during surgery or internally (MedlinePlus n.d.a).

Huntington’s disease: According to NLM, Huntington’s disease is an inherited disease that causes certain nerve cells in the brain to deteriorate with symptoms that usually do not appear until middle age. The later stages of this condition can ultimately cause people to lose the ability to walk, talk, and swallow (MedlinePlus n.d.a).

Osteogenesis imperfecta: According to NLM, osteogenesis imperfecta is a genetic condition in which bones break easily (MedlinePlus n.d.a).

Spina bifida: NLM indicates that spina bifida is a birth defect where the “spinal column of the fetus doesn’t close completely during the first month of pregnancy. . . . The symptoms of spina bifida vary from person to person. Most people with spina bifida are of normal intelligence. Some people need assistive devices such as braces, crutches, or wheelchairs. They may have learning difficulties, urinary and bowel problems, or hydrocephalus, a buildup of fluid in the brain” (MedlinePlus n.d.a).

Sickle cell anemia: According to NLM, sickle cell disease causes red blood cells to be a different shape (crescent instead of disk shaped). The sickle-shaped cells do not last as long and do not pass normally through blood vessels. This can cause exhaustion and pain crises (MedlinePlus n.d.a).

Tay-Sachs disease: NLM states that Tay-Sachs disease is a rare, inherited disease where children have no symptoms the first few months of life and then mental and physical abilities decline due to a lipid metabolism disorder. The children become blind and deaf before experiencing paralysis and usually die by age four years (MedlinePlus n.d.a).

Advocacy Positions

Some disability advocacy organizations, like the Autistic Self Advocacy Network (ASAN), have published their policy positions on these issues. They have said they oppose human germline genome editing because of the potential social and ethical impact for people with disabilities due to the potential editing out of people with disabilities as part of human diversity as well as the impact on future generations. ASAN does not endorse or condemn the use of gene therapy or nonheritable genome editing for people who are able to make those decisions after birth (Autistic Self Advocacy Network 2019). Additionally, prominent individual bioethicists and disability

advocates such as Rosemarie Garland-Thomson, Rebecca Cokley, Teresa Blankmeyer Burke, Alice Wong, Anita Cameron, and Sandy Sufian have published and commented at length on the issue. Specifically, they have raised concerns about “Stigmatization of Disability” (discussed on page 45); “Eradication of People with Disabilities and Loss of Cultural Identity and Diversity” (discussed on page 46); “Pitting Reproductive Rights and Disability Rights Against Each Other” (discussed on page 48); and “Health Equity Issues” (discussed on page 50). Other entities such as the National Down Syndrome Congress and National Down Syndrome Society have yet to release formal statements on human genome editing.

Disability Rights Models and Critiques

Disability Rights Models and Critiques

Because this report will be important for scientists, researchers, and medical providers who may or may not have training in disability studies, we also need to define some core concepts in the disability rights movement:

Ableism: Discrimination against people with disabilities because of their condition. Systemic ableism is discrimination against people with disabilities built into systems such as health care or education.

Ableism [according to Alice Wong]: form of oppression that systematically devalues disabled people—who are considered non-normative. (Stanford Medicine X 2017)

Audist: Discrimination against people who are deaf or hard of hearing.

Hierarchy of Disability: Assumptions that some disabilities are worse than others.

Policymakers must be careful when looking at different conditions to avoid the disability hierarchy and also to avoid casting people with disabilities as a monolithic entity. It is critical to gather input from people with disabilities who have lived experience across the range of different disabilities and their families to avoid making assumptions when considering any interventions.

Disability Rights Models and Critiques: *continued*

Identity Model of Disability: Disability is defined as a cultural and historical identity.

Many people with disabilities who have published about heritable genome editing perceive their conditions as meaningful identities. Notably, Jackie Leach Scully and Teresa Blankmeyer Burke caution against ableist and audist messages hidden in heritable genome editing:

Not all deaf people think they are disabled. Many consider themselves to be simply members of a cultural group that uses signed language to communicate. Those who identify strongly with a thriving signing Deaf community can often express a preference for having deaf children and find attempts to prevent the transmission of heritable deafness offensive and horrific. It is wildly premature for any scientist to suggest moving forward now, and particularly irresponsible to do so with a condition that at least some affected people consider to be not a "serious condition," but just a normal variation of human being. (Scully and Blankmeyer Burke 2019)

Indeed, many Deaf or hard-of-hearing advocates and disability advocacy groups echoed this point about disability identity, including Little People of America and ASAN.

Implicit bias: Biases, such as stereotypes, that are unconsciously held against groups of people.

Medical Model of Disability: Disability is defined as a collection of impairments that need to be fixed.

Disability rights scholar Alice Wong described that an exclusive focus on the medical model of disability can be manifested in heritable genome editing when scientists and medical providers "look only at a person's functional limitations, impairments, or deficits and make assumptions about quality of life for people with disabilities" (Stanford Medicine X 2017).

Social Model of Disability: Disability is defined as a social construct where the built environment and social attitudes create the most significant barriers.

Germline editing invariably name drops specific conditions and then abstractly emphasizes doing good, reducing pain, and increasing choice. But those discussions of disability occur without nuance. No distinction is made between having a disability and living a short, lonely, unproductive life of unending pain and zero joy. This does not match with the lives of millions of people with disabilities around the world. People with disabilities do endure hardships, and while some may be directly attributable to the fact of a disability, many more are attributable to social stigma, physical barriers, unequal access to social drivers of health like education and housing, and a general failure to recognize a disabled person's right to be in the world. (Silvia Yee, "NCD Public Comment Session" 2023b)

The Shadow of Eugenics

A dominant theme in the presentations and literature about heritable genome editing produced by the disability community is a real caution about the technology potentially being used like the pseudoscience of eugenics. In the early twentieth century, a primary objective was to weed out what were perceived as undesirable traits and even whole races and ethnicities. Importantly, eugenics was perceived as advanced scientific understanding in the early twentieth century in the mainstream of policy, culture, and science in the United States and many other countries—not as a fringe phenomenon. The practice was espoused by titans of industry like Henry Ford and John Harvey Kellogg and Supreme Court Justice Oliver Wendell Holmes, Jr. Eugenics is acknowledged as a pseudoscience now after increasing scientific knowledge disproved many of the earlier assumptions, but it was widely accepted in its time. There was significant ableism and racism in the eugenics movement which led to the forced sterilization of people with disabilities in the United States and policies that prevented the immigration of people from certain countries and ethnicities deemed as unfit (including Jewish people during the Holocaust) (Rutherford 2023). This ideology eventually led to the mass murder of people with disabilities in Nazi Germany under the Aktion T4 program and the subsequent horrors that ensued, at which point eugenics was broadly condemned (Rutherford 2023).

“It’s like we’re talking about making some groups of people who would be considered biologically superior, and some groups of people who would be considered biologically inferior. To me, that’s the core of what eugenics is about. And it hasn’t gone away.”

biologically inferior. To me, that’s the core of what eugenics is about. And it hasn’t gone away” (Darnovsky 2023).

*Rebecca Cokley
[who was born with achondroplasia and works as the Disability Rights Program Officer*

at the Ford Foundation in New York] has specifically spoken about this perspective saying, “It’s eugenics.” While Cokley was in labor with her third child, who is of typical height, she overheard a doctor in the room suggest that Cokley be sterilized. “They want to edit people like us out,” she says. That’s one reason why Cokley views CRISPR . . . as an “existential menace.” (Cokley 2023)

However, the ideology was popular for decades among scientists and intellectuals and profoundly influenced policy and practice, even though the science was deeply flawed and the ethics were dubious.

As decision-makers without disabilities lead the charge in the research and advocate for the clinical implementation of heritable genome editing, they run the risk of undervaluing the lives of people with disabilities. Key informant Marcy Darnovsky explained, “It’s like we’re talking about making some groups of people who would be considered biologically superior, and some groups of people who would be considered

Almost all key informants emphasized that the most important component of preventing these mistakes of the past is to include people

Key Informant Perspectives

Key informants and public commenters similarly cautioned about the potential for repeating mistakes of the eugenics era where the lives of people with disabilities were devalued by those perceived as scientific experts at the time. These “experts,” who came from privileged backgrounds, made policies based on discriminatory presumptions about disability, race, ethnicity, morality, and poverty. Yet, most of the key informants explained that eugenics would look different in practice now but still have the same impact and underlying ideology. Jessica Cussins wrote in an article, “These technologies threaten to bring about a new era of eugenics, guided by individual choices, but within a framework of particular social expectations” (Cussins 2013).

So can you see that there’s a path where maybe it’s not forcible sterilization, but maybe it’s more subtle than that. (Stoll 2023)

Heritable genome editing could be presented as “We’re just getting rid of sickness,” but that was the same rationale behind eugenics. Sometimes it’s about getting rid of people. But there’s often this assumption that we’re bettering humanity. So I think the thing I would want the people to understand is that there’s a rosy ideal that’s put on top and then there’s what it really means underneath. (Yee 2023)

I saw a report from 2021 from Harvard that says 82.7% of doctors think that disabled people have a poorer quality of life than non-disabled, or only 54% of doctors will accept a disabled person into their practice because 70% of doctors are uncomfortable about having a disabled person as a patient. And I’ve seen that myself. So as long as we have medical practitioners devaluing people’s lives and saying you need to be fixed, we’re going to have that. They’re going to be real smart about targeting groups of people.

I feel that the same thing’s going to happen, but it’s not going to be like it was in the earlier 20th century because people got more creative. It’s going to be in a more benevolent form. It’ll be like they’re selling assisted suicide. This is your bodily autonomy. This is only for if you’re terminal with six months left to live, this has nothing to do with disabled people where it has everything to do with disabled people. So, you know the next time around, they’re going to make it so that you want it.

They’ll put it out there so that you will want it. And not only will you want it, you’ll feel like you need it. And you know, you got that money. You’re going to do it.

(continued)

Key Informant Perspectives: *continued*

I almost figured that if they really want it to get rid of disabled people or certain subset, they'll make it available to you even if you're poor and convince you or your parents to line up to do this. And I think it's only going to be the ones with a healthy suspicion and who know history to say, hold up. I'm just not going to fall for this. I'm going to do my own research. They're going to be a whole lot more creative in how they deal with this than before. That's my thought. It's still going to be genocide.

It's still going to be eugenics. But they are going to spin it in a way that people want to do this. They'll make it into something that you want, or you need, or you feel that you want or need, or that you'll be a bad or unworthy person if you don't do this for yourself or your child. (Cameron 2023)

with disabilities who have lived experience in every single stage of the process ranging from the determination of research priorities to the possibility of clinical application. Contributors to this report exhorted scientists, medical professionals, and researchers to be mindful about including the voices of people with disabilities from diverse backgrounds in meaningful ways when debating the potential use of heritable genome editing.

In these conversations, preventing the births of people with disabilities is routinely used as an argument for moving forward with germline editing. And there is very little recognition of disability as distinct from illness, and disability voices are often

In these conversations, preventing the births of people with disabilities is routinely used as an argument for moving forward with germline editing. And there is very little recognition of disability as distinct from illness, and disability voices are often lacking completely.

lacking completely. So, for one example, in the most recent report from the National Academies focused on germline editing, which runs over 200 pages, the words "disability" or "disabilities" appeared only 13 times, and of those, 85% were part of the phrase "disease and disability," or a variant like that. And just this past March at the third international Summit on Human Genome Editing, the 3-day program included not a single voice representing disability rights or disability communities.

So, when these concerns and voices are not at the center, the conversations will continue to be shaped by false assumptions, by ableism, and by eugenic legacies. The need for these voices is greater than ever.

(Marcy Darnovsky, “NCD Public Comment Session” 2023c)

Foreshadowing from Other Technologies

The adoption and implementation of current technologies, such as polygenic embryo testing and noninvasive prenatal screening (NIPS), can provide foreshadowing for how the adoption of heritable human genome editing might proceed if policymakers do not preemptively establish standards for evaluation and civil discourse.

Lack of Disability Inclusion

Among the medical and genetics guidelines for cfDNA screening, for example, only the guidelines from the National Society of Genetic Counselors were created with input from the disability community. Other guidelines by the American College of Obstetricians and Gynecologists and American College of Medical Genetics and Genomics were created exclusively by medical and science advisors (Sheets et al. 2011; American College of Obstetricians and Gynecologists’ Committee on Practice Bulletins—Obstetrics, Committee on Genetics, and Society for Maternal-Fetal Medicine 2020; Dungan et al. 2023). Interdisciplinary experts recommend that guidelines for prenatal interventions meaningfully include people with disabilities as participants in the process so that they can emphasize what

type of information is important to families and what ethical issues might be important to that population, but that has not yet been established as the standard of practice (Meredith et al. 2022).

Lack of Patient and Provider Education

Additionally, prenatal screening for conditions like Down syndrome and spina bifida was broadly implemented, including the newer cfDNA screening, without the educational infrastructure to support families. Patient education resources

[P]renatal screening . . . was broadly implemented . . . without the educational infrastructure to support families. Patient education resources were never broadly disseminated to clinicians, and providers were never universally provided training on how to deliver a diagnosis because the Prenatally and Postnatally Diagnosed Conditions Awareness Act was never funded.

were never broadly disseminated to clinicians, and providers were never universally provided training on how to deliver a diagnosis because the Prenatally and Postnatally Diagnosed Conditions Awareness Act was never funded (Knight and Miller 2021). Research has subsequently shown that the majority of parents whose children received a prenatal diagnosis of Down

syndrome in the last 10 years have not received accurate, balanced, and up-to-date information, and this lack of patient and provider education has led to trauma for patients and bias against disabilities (May, Dein, and Ford 2020; Meredith et al. 2023).

During the listening session, Genetic Counselor Laura Hercher observed that “the sort of controls that exist now for prenatal selection involve trying to get out better information, but they haven’t been funded. We know that. And

they rely on medical advice and medical advice is often not very hospitable to disability or disability points of view” (“NCD Public Listening Session” 2023a).

Lack of Genetic Counselors

The lack of genetic counseling services further contributes to the absence of infrastructure to support patients and provide accurate, balanced information about disabilities. At least one-third of patients do not get the opportunity to visit with a genetic counselor following prenatal screening results that suggest a diagnosis of Down syndrome (Meredith et al. 2023), and Medicare/Medicaid do not universally provide reimbursement for genetic counseling services, which also impacts the number of other insurers willing to cover those services.

Supersized Influence of Commercial Companies and Lack of Regulation

When medical and genetic technology is driven by for-profit interests, investors have a strong financial incentive to make sure the technology is adopted and disseminated as broadly as possible without the necessary consideration of the full spectrum of patient needs and bigger societal implications. We have already seen this come to fruition with prenatal interventions in the cases of cfDNA screening and preimplantation genetic testing for aneuploidy. These tests have been brought to market without the patient or

provider education infrastructure about genetic conditions; rely on marketing with ableist subtext about “healthy babies”; and often use marketing messages that exaggerate the accuracy of the technology (Estreich 2019).

So, the commercial interest is always going to be towards increasing fear and anxiety set to make the testing seem useful. And then to make the testing seem as simple and straightforward and easy and reliable as possible, even though that’s not really what

it is. But there’s no real incentive for the companies to highlight the complexity of it.
(Stoll 2023)

Indeed, companies that offer cfDNA screening and preimplantation genetic testing for aneuploidy have increasingly come under media scrutiny

in the past few years in high-profile articles in *The New York Times* for the ways in which patients and providers are misled about the tests (Kliff and Bhatia 2022; Ghorayshi 2022). The increased media attention has motivated genetics organizations to offer more cautions against the use of preimplantation genetic testing for aneuploidy and prompted the FDA to again consider the regulation of LDTs.

There is every reason to expect that the commercialization of genome editing would cause similar problems with the absence of patient and provider education and marketing

When medical and genetic technology is driven by for-profit interests, investors have a strong financial incentive to make sure the technology is adopted and disseminated as broadly as possible without the necessary consideration of the full spectrum of patient needs and bigger societal implications.

incentives to increase fear and anxiety so that the companies can offer to provide the solution.

Lack of Equity

Furthermore, we have already seen that when a technology is found to offer health benefits, people of low socioeconomic status struggle to get access and coverage for care, so this would likely continue. For example, Sarah Struwe repeatedly explained in the listening session that patients with less financial means and who live in rural areas are often unable to get access and coverage for fetal surgery. The same is true for even the most basic technology for people with disabilities like hearing aids, which are generally not covered by health insurance and are very costly. Existing disparities illustrate what could similarly be expected with the implementation of future technologies.

Lack of Data

The implementation of current technology also highlights wide gaps in the collection of data to demonstrate the actual clinical validity and value of prenatal interventions. The type of data that needs to be collected includes the accuracy of detection for prenatal screening, patient and clinician attitudes about disability and prenatal interventions, patient experiences with prenatal testing and interventions, comparison of benefits and harms for different prenatal interventions, and other priorities determined by patient interests.

Because of the overlap in concerns raised by different prenatal intervention technologies and because of problems that have remained

Need for Objective Study of Benefits, Harms of Prenatal Testing

I think oftentimes patients are being advised by people who have a financial interest in advising them to adopt those technologies by saying, "This new technology is the best chance for you to have a good outcome." Oftentimes commercialized labs roll out these procedures and use them for years even when the data are pretty poor or nonexistent at the time, as has happened with reproductive endocrinology clinics.

We really need more objective studies that weigh the potential benefits versus the harms of expanded prenatal testing. I think that we shouldn't be having screening for everything and anything that can be tested for without really knowing how well we can call variance and whether or not they cause the conditions that we're telling expectant parents about . . . People are participating in a big experiment right now that actually isn't being tracked very well to even know what the potential benefits and harms are. It's just really the commercialization of these tests and procedures that are driving all of it. (Stoll 2023)

unaddressed with previous prenatal intervention technologies, a number of recommendations in this report reiterate content included in NCD's *Genetic Testing and the Rush to Perfection*.

Chapter 2: Impact of Prenatal Interventions on Individuals with Disabilities and on Disability Communities

Experts identified a host of potential impacts of prenatal interventions on individuals with disabilities and disability communities during the public comment session, during the listening session, during key informant interviews, and in the published literature and popular media. Their insights are synthesized in the thematic sections that follow.

Potential for Improved Health

Participants in the listening session agreed that prenatal interventions, specifically fetal surgeries, can have a positive impact for improving health when they change the lived experience for people with disabilities by addressing certain

undesirable attributes such as heart defects in people with Down syndrome, cancer, or spinal openings for babies with spina bifida.

Indeed, the NIH Management of Myelomeningocele Study (MOMS) study demonstrated that the fetal surgery to repair the opening of the spine in embryos with spina bifida usually lessens the need for hydrocephalus

treatment, such as shunts (Adzick et al. 2011). It can also improve leg strength. However, most babies who undergo fetal surgery to repair the lesion in spina bifida in utero will be born preterm and may have complications related to their early birth. Hence, it is not appropriate for everyone, so informed consent about the spectrum of health risks and benefits is important (Moldenhauer and Adzick 2017).

Listening session participants recommended that more time and funding be devoted to determine the distinction between disease, disability, and pain and to identify what attributes are considered undesirable by people with disabilities as compared to part of a cultural identity.

Listening session participants recommended that more time and funding be devoted to determine the distinction between disease, disability, and pain and to identify what attributes are considered undesirable by people with disabilities as compared to part of a cultural identity.

In an interview, Marsha Michie posited that the development of prenatal interventions should focus on “conditions that that are physically devastating, that result almost always in fetal loss or early infant loss that we now have amazing hope for.” Michie added, “I think that focusing on those rather than on conditions where people live long and fulfilling lives with lots of

accommodations and support is absolutely where we need to focus our attention” (Michie 2023).

In a public comment, David Wasserman theorized that prenatal interventions could also potentially give parents an alternative to abortion when he shared, “For prospective parents ambivalent about continuing their pregnancies in the face of a diagnosis of disability and for disability advocates disturbed by high rates of selective termination, fetal medicine may offer an alternative to the stark choice between bearing a child with a severe disability and aborting” (“NCD Public Comment Session” 2023d).

There are no current health benefits validated for heritable human genome editing and substantial risks given off-target edits that can occur. The technology could conceivably be used to treat fatal conditions like Tay-Sachs disease, but heritable genome editing also carries other ethical issues that would need to be debated and considered before implementation.

Potential for Parenting Genetically Related Children

Another potential benefit identified in the media is that heritable genome editing could help couples who both have the same recessive genetic conditions, such as sickle cell disease and cystic fibrosis, to have genetically related children (Stein 2023a). However, this is a rare scenario given that many of these conditions cause challenges with pregnancy and/or childbirth. Normally, they would need to seek sperm and egg donors or adopt children in order

to become parents while also avoiding the disease. In contrast, Katie Stoll points out that people with a condition like Tay-Sachs disease do not survive to adulthood to bear children. Carriers of that disease, who bear the trait but do not have the condition themselves, have a 25 percent chance that their baby will not have Tay-Sachs disease at all, a 50 percent chance that the baby will be a carrier without the disease like the parents, and a 25 percent chance that the baby will have Tay-Sachs disease. If carriers of a recessive condition want to have genetically related children and avoid the condition, they can already utilize assisted reproduction technology (ART) to select embryos that do not have the disease, which is much less invasive

and carries fewer risks than human genome editing.

Potential for Health Harms to Baby

A key thread of concern was the potential for health harms to the baby for any prenatal interventions. Any fetal surgeries must be evaluated comprehensively through research and multistakeholder input to determine whether the potential benefits outweigh the potential risks for infant mortality and preterm birth. In fact, the current use of fetal surgery for spina bifida did undergo rigorous scrutiny and was validated through clinical trials with ongoing assessments (Moldenhauer and Adzick 2017).

Bioethicist David Wasserman warns of any prenatal intervention where, “Prospective parents reluctant to abort but averse to having a child with a significant disability may be willing to subject the fetus to a high risk of

There are no current health benefits validated for heritable human genome editing and substantial risks given off-target edits that can occur.

Who is Driving the Technology?

People ask, “What about the couples who both have the same recessive condition, and they want to have a genetically related child that does not have that same recessive condition? Well, what about that situation? There’s no alternative, right?” You’re not going to be able to select embryos [for pre-implantation selection], because every embryo will have that recessive genetic condition. But I’ve yet to hear the voices of those couples that are asking for this technology. . . . I don’t think it’s patients or the public that would be driving this forward. (Stoll 2023)

death to prevent or mitigate disability” (“NCD Public Comment Session” 2023d) Therefore, all technology proposed as a prenatal intervention must be assessed for ableist assumptions that any level of risk that could harm the baby is acceptable to avoid disability.

Potential Harms to the Pregnant Patient

Prenatal interventions also carry some level of risk to the pregnant patient. Listening session participants cautioned against a culture where pregnant people feel pressure to pursue prenatal interventions that put them at risk. David Wasserman further commented that “Pregnant people may also feel pressured to assume

unreasonable risks to their own health to prevent or mitigate disability” (“NCD Public Comment Session” 2023d). Experts discussed that it was essential to preserve autonomy for pregnant people to choose whether they want to pursue prenatal interventions. This also means they need to be provided an overview of the risks and benefits to provide truly informed consent.

Regarding heritable genome editing, Marsha Michie added that the genetically modified cells of a baby could remain in the pregnant patient’s body for a lifetime with unintended consequences.

You literally carry a tiny part of your children with you for the rest of your life. Whether they ended up making it to term or not. And if those cells are genetically modified, then that could change something about you. That could have implications for you if there are off target effects that could affect your future offspring. They could affect you, and that’s a big deal. Not to mention that doing these various kinds of interventions during

pregnancy always involves risk, because it’s always going to involve messing around with a very, very delicate and dynamic process of pregnancy.

Certainly, we know fetal surgery has gotten better because they’ve been able to make certain parts of it less invasive. But it’s still quite risky for the pregnant person. Most of the time it’s not fatal, but it could very much impact your

[A]ll technology proposed as a prenatal intervention must be assessed for ableist assumptions that any level of risk that could harm the baby is acceptable to avoid disability.

Considerations Before Clinical Application

Limitations such as off target effects must be addressed prior to the clinical application. This requires the ability to demonstrate that desired changes can be made without introduction of abhorrent genetic variations. This is especially concerning when it comes to germline editing, as potential adverse effects could have consequences that take years or decades to recognize and impact future generations. Further, the consequences of editing a pathogenic variant may have other effects that may alter other patterns of gene expression in some tissues. We also must recognize the wide array of pathologies and the health and well-being of individuals. A decision to which specific genetic variants should be subject to genome editing needs further discussions at a societal level including adequate representation from the disability community. (Susan Klugman, "NCD Public Comment Session" 2023e)

ability to have kids in the future and those kinds of things. So, that's a similarity, but the extra part about genomic interventions is that it could actually change your genome in ways that that you might not have anticipated if you're the pregnant person, and it's never ever possible to just talk about fetal interventions without talking about the person in whose body that fetus is. It's just not possible. (Michie 2023)

Stigmatization of Disability

An often repeated concern was that if heritable genome editing were to become a regular practice, and disability were to be seen as an optional choice, then society might further stigmatize people with disabilities. This stigma could lead to less empathy for people with disabilities perceived as "preventable" problems and fewer resources allocated to an already vulnerable population. In addition, parents who do not choose to pursue certain treatments could be perceived as medically or socially neglectful and face negative consequences.

Barry S. Collier writes in the *Annual Review of Medicine*,

Public accommodations and public education have dramatically improved conditions for individuals with genetic disorders that compromise ordinary function, both in schools and in the workplace. Nonetheless, residual stigmatization remains, and given people's innate fear of those who are different from themselves, the advances are fragile. Thus, the emphasis that human genome editing places on "correcting" mutations has the potential for the unintended consequence of stigmatizing and marginalizing individuals with genetic disorders. It is vital, therefore, to redouble our efforts to protect against such stigmatization. (Collier 2019)

Catalina Devandas further expounds that, "People with disabilities are genuinely concerned that these developments could result in new eugenic practices and further undermine social

acceptance and solidarity towards disability—and more broadly, towards human diversity” (“New

Eugenics: UN Disability Expert Warns Against ‘Ableism’ in Medical Practice” 2020).

Key Quotes

Re: Disability Stigmatization

We need to confront the potential for genetic editing to exacerbate existing social inequalities. Policies will need to be put in place to avoid creating a divide that will further marginalize disabled people, who face new and different stigmas as their disability is perceived by the public as entirely preventable had their parents had access to genetic editing. (Kara Ayers Public Comment)

Should human germline editing be permitted, stigmatization of people living with disability and genetic conditions will only grow. Even if the technology itself does not significantly reduce the instance of genetic conditions, the commercialization and marketing of the technology will rely on framing disability and genetic conditions negatively as a human condition that should be avoided at great cost and unknown risk. (Stoll 2023)

If prospective parents have the option to prevent or mitigate disability, those who choose to take the fetus as is may come to be regarded as guilty of medical neglect, like parents who refuse safe and effective medical interventions for their born children. (David Wasserman Public Comment)

Eradication of People with Disabilities and Loss of Cultural Identity and Diversity

The most dominant concern of the disability community in the literature and the sessions we conducted was the potential eradication of people with disabilities and the loss of their cultural identity that could be caused by heritable genome editing. Many people with disabilities perceive their conditions as a core part of their identity from which they draw pride. Moreover, many see that they have developed strengths from their experiences and feel society would lose that crucial insight and diversity if people

with disabilities were to be eradicated through genetic engineering.

The participants also worried that heritable genome editing could exacerbate ableism based on who has access to technology and what technology is even adopted. They feared the technology could create divisions between people with disabilities based on access to resources and economics, social perception of disability, and the technology adopted. Listening session participants emphasized that they would prefer for society to focus on improving health and creating a more welcoming society instead of eliminating disabilities.

Key Quotes

Eradication of People with Disabilities

My biggest worry is the eradication of disabled people. I'm real queasy about that whole disease eradication because you're talking about groups of disabled people, and society already has a "better dead than disabled" mentality, or always assumes that if you're disabled that you're incompetent, you're worthless, you're useless. (Cameron 2023)

As the technology is further developed, the National Council on Independent Living (NCIL) is concerned about the slippery slope of society's beliefs and practices aimed at controlling reproduction to specify the population and the subtle message that people with disabilities' lives are not worth living so therefore let's reduce and eliminate them. We acknowledge the pros and cons of these technological advancements and will continue to monitor this technology and how it is used. (Jessica Podesva, "NCD Public Comment Session" 2023f)

"That has spawned fear among some disability rights activists. To them, dwarfism, deafness, or Down syndrome aren't so much disabilities as they are human differences. CRISPR theoretically could stamp out those conditions from the human gene pool for good. It also could usher in an era of 'designer babies' selected for a particular eye color, dimples, fast-twitch muscles, and other chosen traits. Where does it stop? Is autism next?" says Cokley, Disability Rights Program Officer at the Ford Foundation in New York. "What if they discover a gay gene?"

"I wouldn't be the person that I am today if I didn't have achondroplasia," she says, adding that disabilities teach people new ways to think about the world. (Rebecca Cokley in Marshall 2021)

As disability studies scholars and women with genetic differences who are experts in thinking about the consequences this technology will have for actual human beings, we have grave worries that the use of these "genetic scissors" will, in the future, cut people like us out of existence without others even noticing. Scientists who use CRISPR could see editing genes such as ours out of the gene pool as entirely uncontroversial. But our genetic conditions are not simply entities that can be clipped away from us as if they were some kind of a misspelled word or an awkward sentence in a document. We are whole beings, with our genetic conditions forming a fundamental part of who we are. Still, many Americans—including medical providers and even some people with genetic differences—consider lives such as ours as not worth living as they are. (Garland-Thomson and Sufian 2021)

Eradication of People with Disabilities: *continued*

It is crucial that we recognize the value and contributions of disabled individuals in our society. We must promote the social model of disability, which emphasizes that disability is not an inherent flaw but rather a result of societal barriers and prejudices (3). By adopting this perspective, we can foster a more inclusive environment that empowers individuals with disabilities and discourages the misuse of genetic editing as a tool to “normalize” them. Ableism, or the idea that the nondisabled life is ideal, harms everyone. Our society is made better, stronger, and more diverse through its inclusion of disabled members. (Kara Ayers, “NCD Public Comment Session” 2023g)

People with disabilities are the unexpected made flesh. The challenges of living in a world not built for us are occasions for resourcefulness and adaptability, especially for those of us who start out disabled early in life. . . .

We don’t know which human variations will be advantages and which will be disadvantages in the long arc of our struggle to prevail in an ever-changing environment. (Garland-Thomson 2017)

Yeah, let’s deal with the folks who are more and more marginalized, mental health disabilities, people with intellectual disabilities, people with developmental delays. The more marginalized amongst us are going to be the ones that they want to eradicate. So, I feel like as long as that possibility exists, to even one group of people or one person, it shouldn’t be used. It’s too dangerous and we are too much of an inequitable society to be messing around with technology like that. (Cameron 2023)

As an analogy to the potential eradication of people with disabilities as a form of human diversity, Silvia Yee describes a Bank of Life that exists to preserve plant forms that do not exist anymore and that are close to extinction. She describes that people with disabilities could be similarly threatened and need preservation. “The image of that for human beings, it’s kind of horrifying, isn’t it?” (Yee 2023).

Pitting Reproductive Rights and Disability Rights Against Each Other

Another complex concern discussed in the listening session was about the potential for reproductive rights and disability rights to be pitted against each other when establishing ethical

guidelines for prenatal interventions. Participants brought up particular concerns and also potential solutions for navigating thorny topics.

One unique concern raised by Marsha Michie was that certain prenatal interventions, such as fetal surgery, aimed at preserving the health of

a fetus with a disability do pose some degree of risk for pregnancy loss. Consequently, parents and practitioners seeking to improve the health of a baby using validated clinical procedures could face criminal charges if the surgery is not successful.

In fact, I'm mostly unsure that it's ethical to do these kinds of interventions in states where abortion is not legal because, you know, things go wrong. You might actually lose a pregnancy in

the process of doing these things, even if it's a desperately desired pregnancy and everybody's doing their very, very best to save that pregnancy. You could lose it, and that means that not only the pregnant person could be legally liable, but the doctor, the researcher.

There's huge, huge legal liability and problems with doing this in a state where the right to terminate the pregnancy is prohibited. (Michie 2023)

From a research perspective, another question given strict abortion laws in certain states, would be whether genetically altering an embryo in such a way that causes its demise constitutes termination.

Additionally, Kara Ayers brought up a concern about the potential risks of mortality or morbidity

to disabled pregnant people, or pregnant people managing complex pregnancies, and the importance of giving them options for managing those risky pregnancies.

The most dominant concern of the disability community in the literature and the sessions we conducted was the potential eradication of people with disabilities and the loss of their cultural identity that could be caused by heritable genome editing.

From a research perspective, another question given strict abortion laws in certain states, would be whether genetically altering an embryo in such a way that causes its demise constitutes termination.

Regulations set by an international body must supersede current restrictions on access to reproductive healthcare, including abortion services, across much of the United States. We cannot overlook these politically embedded barriers to healthcare

as we discuss the emergence of new technologies, which may bring their own health risks to pregnant people who, due to the current legal landscape, would be at greater risk of mortality or morbidity from pregnancy complications. ("NCD Public

Comment Session" 2023h)

Silvia Yee, from Disability Rights and Education Defense Fund, brought up another concern that abortion laws make it difficult to talk about

discrimination in the prenatal setting because of the politicization of that space where the primary concern for policymakers becomes preserving or eradicating abortion. Those overriding concerns make it difficult to address other important issues like bias against people with disabilities in health



care because the assumption is that any issue is being used to influence reproductive rights one way or the other (Yee 2023).

Liz Bowen and Marcy Darnovsky offer some potential strategies for navigating the tension between reproductive and disability rights:

Disability rights and reproductive rights are both grounded in respect for persons and should not be pitted against one another. The unparalleled erosion of reproductive rights in the U.S. is having dire consequences for millions of people, including disabled people who lack access to reproductive healthcare. We must insist on the rights of all persons to make informed decisions while also challenging notions of who should or should not be

a parent or who should or should not be born. Disabled people are not monolithic in their views toward prenatal technologies and should be supported to make free and informed decisions, consistent with their values and what is right for them and their families. (Liz Bowen, “NCD Public Comment Session” 2023h)

I think the principle is that there’s a vast difference between choosing to continue or terminate a pregnancy and choosing the particular traits and characteristics and genetic makeup of your children. And then understanding in political policy settings how to not back down in any way on reproductive rights while helping people really understand the full range of choices that they do have. (Darnovsky 2023)

Health Equity Issues

Once technology is developed, tested, and determined to be important by a consensus among researchers, medical professionals, and people with disabilities, participants universally emphasized the

importance of evaluating access and health equity. Participants were concerned that people with disabilities whose incomes are below the federal poverty threshold or who experience racial disparities would have limited access to advanced fetal surgery and genomic treatments when our current health care system already has so many disparities. Moreover, listening session participants were concerned about disparities in access to technology also causing disparities in the social supports and services for children who are born with disabilities and their families, further dividing people with disabilities into “haves” and “have-nots.”

Listening session participants also brought up a concern about how resources are allocated for prenatal technologies and how to determine return on investment which benefits the most people with disabilities. They discussed how shiny, new technologies can seem exciting and flashy, and they bring in substantial research and investor dollars.

Participants were concerned that people with disabilities whose incomes are below the federal poverty threshold or who experience racial disparities would have limited access to advanced fetal surgery and genomic treatments when our current health care system already has so many disparities.

They expressed concern about very specialized sorts of fixes taking away from broader solutions that help more people live and function well in the community as independently as possible.

However, at the end of the day, the funding may only benefit very few people who already have the means to improve their quality of life. They discussed past efforts to develop exoskeletons for paraplegics and quadriplegics to walk again

when a less expensive and more viable priority for those dollars would be to provide resources so those individuals are better supported in their community to make independent life choices. They expressed concern about very specialized sorts of fixes taking away from broader solutions that help more people live and function

well in the community as independently as possible.

And the truth is that a lot of scientists and a lot of policymakers are really, really

attracted by the shiny objects. This is huge, huge money. It's a big splash. It makes you famous. It makes your career, and you make a lot of money off of it, but what are you really doing for families

that are experiencing disability? It's easy to say "Oh, we're saving babies." But which babies? All the babies, just the rich babies? Whose babies are you saving? (Michie 2023)

Ensuring Equitable Access to New Prenatal Technologies

There's this assumption with all these brand-new technologies that the equity will just trickle down later and that it is voodoo economics. But the idea that you could just make these really expensive treatments and worry later about how everybody is going to get them is just absolute hogwash. You cannot do that. You have to think about it from the very, very beginning and think about how we're going to maybe use the profits from some people to support other people.

So, I think that the international gene editing summit, the most recent one, was trying to respond to [criticism about excluding people with disabilities] by bringing in the sickle cell community to this most recent summit. And I will say that I think that their intention probably got subverted a little bit by the people who showed up to talk about sickle cell, which is great, and I would love to see more of that. Sickle cell, is this amazing success story for gene editing, right? I think that they sort of thought like we're going to bring in patients, but they're going to talk about how amazing this is and how we need to make sure everybody gets access. But in fact, the folks that showed up said, look, people who have sickle cell all over the world aren't even getting standard of care right now.

What makes you think that these \$1,000,000 treatments are going to reach them, and they really questioned the entire basis of that conversation. I don't think anyone questions that the gene editing interventions for sickle cell that have been tried seemed to be really, really awesome. And if they were equitably available, everybody would be really excited about them.

But we're seeing this with postnatal gene therapies for Spinal Muscular Atrophy (SMA), for example, that they're tremendously expensive interventions, \$1,000,000 interventions. In the beginning, for the first couple of years, the company subsidized them so that they could get a lot of success stories.

Those programs have largely run out now, and there are hundreds, literally hundreds of GoFundMe's and Kickstarters for people to get these for their kids because they're completely out of reach. And I think for SMA postnatal, yeah, makes sense that that it could be a very, very good thing for kids. Once the disability community decides that a particular kind of intervention prenatally makes a lot of sense for them, then you have to also think about equity from the get-go, not like, later, how are we going to figure this out once the rich people get access to it? How are we going to make it equitable from the very, very beginning? (Michie 2023)

Another potential impact discussed is inequitable access to health care and genetic technology for historically marginalized people. People of color and people who experience low socioeconomic status are the most likely to feel the most profound impacts from disability discrimination and lack of access to prenatal interventions that are deemed useful by the disability community. When people have multiple identities that are more prone to discrimination, they feel the impacts exponentially. These people are also the least likely to be included in

conversations determining policies governing these interventions.

Disability Activist Anita Cameron writes, “Even if there are positive aspects to human genetic engineering, due to the ableist and racist nature of health care, Black people, people of color, and people with disabilities will not reap the benefits, if there are any. Instead, they’ll be more likely to suffer from the negative effects, including increased discrimination, that are sure to come from this” (Cameron 2017).

Key Quotes

Health Equity Concerns

We must ask and answer questions like, will Black, Indigenous, People of Color (BIPOC) disabled people have access to fetal medicine with the potential to cure deadly diseases in utero, so that the technology might reduce the infant mortality rate in this multiply marginalized group? And will BIPOC, working class, LGBTQ disabled people have a voice in deciding what kinds of disabilities are prioritized by those developing somatic gene editing? Or will decisions be made based on the technologies’ potential to make a return on investment?

People with disabilities are not monolithic. Impact can be different or more profound for people from multiply marginalized identities. In addition, impact is different for people with different types of disabilities. (Leah Smith, “NCD Public Comment Session” 2023i)

Racist Eugenics may be backdoor escalated by coercive means such as via promoting enhancing “human genetics for the benefit of people with disabilities” and to “adapt/modify human beings for the worsening Climate Catastrophe.” This likely would do even more harm to oppressed communities/ecosystems—particularly to BIPOC—and would embolden an ever-growing White Supremacist (and other Fascist) threats. Society must enact safeguards & consistently strengthen/update these in the years/decades ahead to mitigate harmful outcomes for our world and for humanity as much as possible. (Ravi Valleti, “NCD Public Comment Session” 2023g)

Because you know that technology and treatments like this are going to be expensive, which means that it’s going to be out of the reach of people who are poor, certainly communities of color who tend to be poor, are not even going to be able to access that anyway.

Health Equity Concerns: *continued*

I experience it and so that's why I feel like as long as human beings exist, we're going to find a way to be biased towards each other, to hate on each other. And it doesn't have to be hurling epithets or anything like that. It could be the way our health care system is run right now. Racial discrimination is built into that system. (Cameron 2023)

We need to think about how these technologies shape society, power, relationships, people's life chances, and not just whether they can access it. It would really be some children are superior, and they get all the advantages, and they're treated differently, and that's not the kind of society that I think we want to aspire to. So, the technologies and techniques and procedures that we support, absolutely, they have to be accessible to all, same with gene therapies. If it costs \$2,000,000 to get a treatment, that's not good, but there are other kinds of decisions that don't have to do with access. So, we have to look further than access and distributive justice. You have to look about whether this helps build the society—that it will be fair, that will be equal, that will be welcoming. (Darnovsky 2023)

Those folks who are already wealthy and beautiful will be able to use the technologies to help sustain the kind of social economic and political superiority, while those who do not have access, which are often people of color, lower income individuals, people who are disabled and so forth, will not have access. They'll also be less resilient to climate change, to pollution, to all kinds of less educational opportunities, and so forth . . . more likely to have disabilities that affect their learning capacity, lifespan, pain levels, and so forth. I see the potential to completely subvert the so-called American dream. Where one's social standing and one's educational and economic standing is further solidified by a technology that is available to a few. (Yee 2023)

In vitro fertilization and testing embryos, selection of embryos—that's not an option for people who have Medicaid. Medicaid doesn't cover these technologies. So I'm not advocating that they should or shouldn't be done, but they're not available for everybody. (Katie Stoll, "NCD Public Comment Session" 2023j)

Other Prenatal Interventions

Participants also raised the concern that heritable genome editing requires investment in a technology to address issues that are already being addressed by other less invasive prenatal interventions like embryo selection and IVF. While

these technologies already raise their own ethical issues regarding discarding embryos, selecting out disabilities, excessive cost, outsized influence of for-profit motives, and inequitable access, all of these issues would carry over to heritable genome editing and would add the additional

problems of human experimentation and genetic alterations that carry forward through future generations.

Key Quotes

Although those advocating for germline gene editing suggest that this will reduce the prevalence of genetic conditions and disability, in actuality, that is unrealistic beyond what is already possible through assistive reproductive technologies with embryo selection. (Katie Stoll, "NCD Public Comment Session" 2023j)

And in that conversation, we have found that all the issues addressed in the "Rush to Perfection" report come up in a big way, because the promise of heritable genome editing, or the justification for it, is that you're going to be able to prevent the births of children with heritable diseases. Then we run into the situation where there are very serious grave conditions that most people

would agree it would be better to be born without, and we'd be better to have a child without. Tay Sachs Disease is often the one that's used. And if you are convinced that's a goal that you're trying to achieve, you're trying to avoid passing on a deleterious genetic variation to your offspring, you can already do that by using these select screening and selection techniques on IVF embryos. And you'd have to use IVF if you were doing heritable genome editing, so that's not an issue. (Darnovsky 2023)

I don't see the Tay Sachs argument really playing out because there are already alternatives to address that concern that are actually less invasive. Tay Sachs is a recessive condition, but that means three out of four embryos from a couple who are both carriers for Tay Sachs won't have Tay Sachs, so you can already screen and select embryos. And that's already happening. (Stoll 2023)

Chapter 3: The Ethical, Medical, and Disability Rights Perspectives on Prenatal Interventions

The participants in all sessions emphasized that there is a vast difference between heritable human genome editing and fetal surgery—so much so that they were not sure they wanted to talk about them in the same breath. Heritable human genome editing changes a person’s fundamental DNA structure in every cell of the body and can be passed to future generations, and the fetal surgery repairs a particular health issue prenatally for just the individual who would need to be repaired prenatally or postnatally for good health or survival. Fetal surgery for conditions like spina bifida has been validated in multiple studies with known risks and benefits that can be conveyed to families. In contrast, heritable human genome editing in embryos has not been scientifically validated for use in reproduction, and there are so many unknowns that the risks cannot possibly be conveyed for parents to give proper consent.

I would like to comment that there is a vast difference I think between the practice of gene editing and the practice of fetal surgery as a way to imagine treatment technology for people with disabilities. I think there is a great deal of promise for something like fetal surgery and a great deal of risk for all the reasons people have stated before in this gathering today about

gene editing. (Rosemarie Garland-Thomson, “NCD Public Comment Session” 2023k)
[With fetal surgery], you’re just fixing something like a damaged valve whereas [heritable genome editing] could affect people for generations. Because of that, you could have unexpected mutations or things down the road that could not only affect your child but could affect your grandchildren because mutations happen for any number of reasons. That’s a big chance that you’re taking. (Cameron 2023)
[With prenatal surgeries, there is] typically something very significant that’s been identified like open neural tube defect or some condition for which there’s something to treat and that’s being treated by the surgery. (Stoll 2023)

Fetal Surgery

Medical

Participants uniformly expressed that prenatal surgery should be available when research and science demonstrate effectiveness in treating medical conditions that can be life-threatening. However, they said it is essential to establish safeguards for ethical and rigorous scientific processes where surgery is involved since medical procedures on a pregnant patient

and baby are always risky. Moreover, they emphasized the value of gathering data to assess long-term outcomes and outcomes in different populations. For example, a recent survey followed up on the original MOMS survey on the effectiveness of fetal surgery for spina bifida to determine outcomes during childhood, and a subsequent study is already planned for teens and young adults to evaluate mobility and other areas of interest (Paslaru et al. 2021).

Key Quote

For approximately 20 years surgeons have performed complex surgeries on fetuses in utero when babies are first extracted from the mother's uterus and now through less invasive laparoscopic surgery. While there is mounting evidence of better outcomes, long-term evidence must continue to be collected and monitored. ("NCD Public Comment Session" 2023m)

Ethical

Informed Consent About Benefits and Risks

Listening session participants all agreed that parents should be informed of the benefits and limitations of prenatal surgical interventions. For example, fetal surgery for spina bifida offers benefits in reducing the need for shunting and improving mobility but also possesses some risks

for baby and a low risk for the pregnant patient and future pregnancies. The key is to ensure that any interventions are broadly agreed upon as important priorities by the affected community and to give parents the opportunity to accept or reject those interventions after being provided a comprehensive explanation of the risks and benefits.

We also recognize the possibility that some genetic fetal medicine may be of benefit to some people with disabilities.

These technologies should only be used in

ways that are deeply informed by the lived experience of disabled people and their families, that respond to the express needs and goals of affected communities and preserve reproductive autonomy. There's an important difference between fitting an ableist norm

or eliminating pain, not considered by policymakers or healthcare providers.

Within disability communities, there remain complex questions and diverse views about how to define this distinction. Research must be guided by disabled people and informed by rigorous community engaged research. (Liz Bowen, "NCD Public Comment Session" 2023h)

Further, listening session participants discussed that when weighing risks about surgery for pregnant patient and baby,

professionals need to make sure not to exaggerate perceived risks pertaining to the quality of life for people with disabilities to justify real health risks to pregnant patient and baby undergoing medical procedures. Patients need to have a real understanding of the options and consequences and retain the autonomy to choose.

Disparities in Health Coverage and Access: Distributive Justice

Participants further expressed concern that many families are left out of the opportunity to make choices about whether they want to pursue certain treatments available through advances in technology. These disparities are largely because of the quality of their health insurance coverage or where they live, so the participants said it was important to work toward equity in making sure validated treatments are accessible to all families.

Sara Struwe from the Spina Bifida Association explained that the surgery is not available throughout the United States which requires many families to relocate for months of their pregnancies. This can be a heavy financial burden on families, and many cannot afford it. She said, “At this time, there is a health disparity: those with means to access to fetal surgery and those without. The subsequent outcomes are worse for those with the traditional postnatal surgery. In short, while medical advancements have allowed people with Spina Bifida to live longer, we have a population of haves and have nots due to fetal surgery” (“NCD Public Comment Session”

“[W]hile medical advancements have allowed people with Spina Bifida to live longer, we have a population of haves and have nots due to fetal surgery.”

2023m). Katie Stoll added in her interview, “You can imagine for situations like this where it’s not going to be something that’s available in every community hospital because it’s so specialized, and you don’t want these prenatal surgeries to be happening by people who are not skilled at doing them” (Stoll 2023).

Disability Rights

While there can be health benefits to some of these prenatal interventions, contributors to this report expressed that sometimes prenatal conversations about disabilities like spina bifida can be steeped in false assumptions about quality of life and discriminatory attitudes about disability. Therefore, they said it would be helpful

to make progress in eliminating ableism from those conversations and offer disability cultural competency training for medical professionals so that clinicians focus on informing parents

about health care options instead of making value judgments about disabilities.

I think of the prenatal surgeries as a medical technique, a treatment. I do think that disability rights are relevant in that the assessment of risks that is provided to families and to individuals can be skewed if the priority is to eliminate disability and eliminate living with disability. So, you will have people who will say OK for 1% chance of success. But I’ll do anything to make sure I don’t have to live with a disability.

That kind of framing needs disability rights perspectives, principles, and so



forth. But I feel like that's true of virtually all healthcare and medical treatments, and that's why there needs to be education, disability, education for providers and all healthcare to get rid of that bias. (Yee 2023)

Human Heritable Genome Editing

Medical

Listening session participants discussed many medical concerns about the possible use of heritable genome editing for human reproduction. Issues of concern included unintended side effects and additional genetic abnormalities due to off-target edits.

Heritable genome editing raised many more red flags given the potential for off-target editing, the potential for unexpected genetic results for the fetus and future generations, and the potential for embryo loss.

Moreover, new research has shown particular risks for embryos.

Heritable genome editing raised many more red flags given the potential for off-target editing, the potential for unexpected genetic results for

the fetus and future generations, and the potential for embryo loss. Indeed, a study presented in 2023 at the 39th annual meeting of the European Society of Human Reproduction and Embryology (ESHRE) by Nada Kubikova from

the University of Oxford indicated that “the use of CRISPR-Cas9 in early human embryos carries significant risks,” and even though the DNA of

embryo cells can be targeted with high efficiency, this rarely leads to the sort of changes needed to effectively edit a gene. Moreover, the strand of DNA is permanently broken, which can potentially lead to other genetic abnormalities (Mayer 2023). In this study of 24 embryos edited with CRISPR technology (and not used for reproduction), only 9 percent of targeted sites were repaired. The vast majority failed to be repaired or produced additional mutations that impact the viability of the embryo and would carry a risk of serious congenital abnormalities if affected embryos were transferred to the uterus and produced a baby (Mayer 2023). Another substantial risk with heritable genome editing would be the introduction of new genetic abnormalities.

Key Quote

George Estreich explains: To think about germline editing, we have to remember that it is likely to be sold as a product. If it is, then market logic will prevail. The severest conditions will be leveraged for public support but health will be defined to include as many conditions as possible, including blindness, deafness, and achondroplasia. The likely result, commodifying children while entrenching ableist norms. Some future children will likely bear the brunt of error. No engineer would assume a 100% success rate with an experimental technology, let alone one that intervenes in a process as complex as embryonic development, so technology might reinforce ableism while creating new forms of impairment. (“NCD Public Comment Session” 2023n)

Ethical

The ethical concerns surrounding heritable genome editing range broadly between the scientific and disability communities. Public health ethical issues that have dominated scientific discourse concerning heritable genome editing have largely focused on (1) beneficence and utilitarianism in applying heritable genome editing to reduce “human suffering” caused by inherited diseases, (2) individual autonomy in giving parents the opportunity to produce genetically related children who would not be affected by genetic conditions, and (3) equity in the distribution of genetic technology so that it is affordable for the broad population and does not devolve into genetic exceptionalism for the

wealthy (Church et al. 2022). An additional research ethics issue of utmost concern to the scientific community is nonmaleficance in being

cautious with the use of heritable genome editing until the technology is more stable and until the potential impact on future generations is more broadly understood. As noted earlier, misdirected genome editing is currently common and did occur in He Jiankui’s unsanctioned human experiment by his own admission (Rutherford 2023).

Bioethicists and the disability community have echoed similar concerns about the lack of equity in the distribution of heritable genome editing that could create genetic “haves and have-nots” and the risks of harm (nonmaleficance) with the current lack of precision that could be passed down for generations. Additionally, bioethicists within the disability community have raised objections to the scientific claim of beneficence,

arguing that inherited conditions do not uniformly cause suffering and that genetic conditions such as deafness, dwarfism, Down syndrome, autism, and other disabilities with genetic factors are an important part of human diversity. They argue that disabilities are not simply adverse outcomes but rather essential components of identity for individuals and populations. Darnovsky and Yee put forth that ableism is baked into heritable genome editing so fundamentally that it is impossible to extricate it.

Key Quotes

So that's been a central theme that we've tried to push over these many years now. You need to have more civil society organizations, people whose job it is to think about the social consequences of different policies and different technologies. These are the people who are experts about what the scientists in their labs aren't experts about—those social issues—nor would we expect them to be. And yet we are giving them the first say and the dominant power to shape the conversation about heritable genome editing, something that could have profound effects on the future of equality and discrimination and justice. The dominant shapers of

[B]ioethicists within the disability community have raised objections to the scientific claim of beneficence, arguing that inherited conditions do not uniformly cause suffering and that genetic conditions such as deafness, dwarfism, Down syndrome, autism, and other disabilities with genetic factors are an important part of human diversity.

the conversation are the scientists and researchers who are experts in their fields but not experts in thinking about society and about social justice and about human

rights. They may be very sincere in wanting to include those perspectives, but they don't really even know how. Sometimes you have the sense that they're boats passing in the night. (Darnovsky 2023)

Therefore, disability advocates affirm that any policies or

discussions about the eradication of these conditions without input from people with lived experience constitute an ethical violation of (1) procedural justice by not allowing for the participation of affected parties, (2) respect for relational individual and community solidarity by seeking to eradicate segments of the

population based on ableist perceptions of disability (Garland-Thomson and Sufian 2021), and (3) the autonomy of children

and future generations in making decisions about their genetic makeup.

Disability community bioethicists argue these aims to eradicate genetic conditions are particularly egregious and violate the research ethics of respect for persons in a climate where the medical community largely continues to

convey bias against people with disabilities (Iezzoni et al. 2021), harkening back to the eugenics era (Rutherford 2023).

Our main priority should be supporting people with disabilities to live as we are with our disabilities. In other words, eliminating disability and people with disabilities along with that is not a just and equitable solution. It is not a just or equitable or ethical healthcare treatment. (Rosemarie Garland-Thomson, a bioethicist with genetic limb differences, Public Comment Session" 2023!)

Listening session participants emphasized the importance of avoiding eugenics while preserving reproductive autonomy. They indicated that the key to achieving this objective

is to prioritize informed decision making by giving accurate, up-to-date, and balanced information about living with disabilities while also including people with disabilities in the implementation of structural and systemic dynamics that shape the health and life chances of individuals and communities.

Consent

Another research ethics objection raised by disability bioethicists is that the fetus is unable to give consent about whether to participate in genetic enhancement, as are future generations in the community. A theme raised was the importance of consent under the guidelines of the Belmont Report and NIH guidelines regarding consent from pregnant patients for research involving the fetus in 45 CFR 46 Subpart B—Additional Protections for Pregnant



Women, Human Fetuses and Neonates Involved in Research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 2021). For example, can pregnant patients give informed consent for heritable human genomic editing when the risks are so unknown?

Are parents entitled to make decisions about the genetic makeup of their children and future generations without their consent? From a

policy perspective, could parents be held liable if a child is unhappy with their genetic outcomes? These are deep and profound questions about consent that must be debated with policy provisions if these genomic technologies are considered.

To do germline editing is the parents making a determination about a child to be born. That's very different from I think a child who actually does exist who perhaps with parents advising them decides whether or not an operation that could address a condition that they have might be something worth doing because they would have that lived experience that you can't have if you're doing it at the germline editing process. (Robert Dinerstein, "NCD Public Comment Session" 2023a)

Are parents entitled to make decisions about the genetic makeup of their children and future generations without their consent?

They worried about the potential discrimination people with disabilities could experience if their conditions are perceived as avoidable, particularly if a caste system develops between genetic haves and have-nots based on access to genomic editing technology.

Participants also discussed that informed consent should include accurate, up-to-date, balanced information about genetic conditions, including the lived experience of people affected by different conditions.

are not shared fairly in society. She explained that the mass harms that could come from adopting the technology through introducing new and unforeseen genetic abnormalities, loss of embryos, and discriminatory attitudes about disability would not be worth the relatively small benefit of people with recessive genetic conditions being offered the path to have genetically related children. She expressed

potential discrimination people with disabilities could experience if their conditions are perceived as avoidable, particularly if a caste system develops between genetic haves and have-nots

Distributive Justice

In her interview, Katie Stoll discussed the ethical concern of distributive justice where the benefits and costs of heritable genome editing

particular concern that this imbalance could be fueled by for-profit interests.

Security and Privacy

Participants also brought up concerns about the security and privacy of genetic information if heritable human genomic editing is available.

They worried about the

based on access to genomic editing technology. Silvia Yee described that disability would become “accepted as a natural part of life for those who with lower socioeconomic status and not everyone else” (Yee 2023).

Disability Rights

A key concern raised throughout the literature, listening sessions, interviews, and public comment session was the potential impact of heritable genome editing on disability rights and social justice for people with disabilities. The scientific and medical communities are often steeped in the medical model of disability as a problem to be cured. Yet, the way people with disabilities view their own lived experiences is much more complex. The stated objective of the Cystic Fibrosis Foundation is to extend the life expectancy for cystic fibrosis so that people live longer, healthier lives (Cystic Fibrosis Foundation n.d.). Similarly, patient and disability organizations advocate for research and health care dollars to cure diseases, pain, or defects such as pain crises in people with sickle cell disease and heart defects in people with Down syndrome, and these issues can currently be addressed with surgery, somatic gene editing, and other interventions (National Down Syndrome Society n.d.; Sickle Cell Disease Association of America n.d.).

However, leaders in the disability community also say that their disabilities are a core part of their identity, and they appreciate the different perspective on life provided by their experience (Garland-Thomson 2017; Cokley 2023; Hasson 2019). Most vocal in this arena are people with hereditary deafness and dwarfism who do experience their disabilities across generations with shared cultural experiences, including

a complete language in the Deaf population. Moreover, in the case of a condition like Down syndrome with a spectrum of characteristics, research shows that while parents might be willing to get surgery to address their child’s medical issues or even give a pill to help increase cognition, the idea of changing their child’s DNA at a cellular level seems much more invasive in changing their child’s identity (Michie and Allyse 2019). They worry about losing the core of the child they love, and people with disabilities are deeply concerned about losing an identity that is profoundly meaningful to them. **Heritable genome editing is not just fixing a problem for one person; it is eliminating the possibility that people with certain disabilities will ever be born and permanently removing that experience from the human species. And those disabilities are being targeted for elimination because other people have determined that the lives of certain types of people are not worth living.**

Stories about genetic editing typically focus on “progress” and “remediation,” but they often ignore the voice of one key group: the people whose genes would be edited. Proponents of genetic engineering deliberately use vague language, such as “prevention of serious diseases,” leading many people with disabilities to ask what, in fact, is a serious disease. Where is the line between what society perceives to be a horrible genetic mutation and someone’s culture? (Cokley 2023)

I just think the bias needs to be addressed with heritable genome editing. I think the bias is written in in a way that you can’t just inform about the bias. I think the

root of [heritable genome editing] is getting rid of disability. It's the foundation. Changing humanity is sort of an ultimate goal. So that goes beyond medical treatment. (Yee 2023)

Velvet eugenics seems like common sense, yet it hides its violence and inequality behind claims of patient autonomy and under a veil of voluntary consent. Ultimately, market-driven velvet eugenics embodies a similar goal of purging unacceptable human variations that campaigns to eliminate the supposedly unfit and inferior have held in the past. Both enact a mandate to exclude people with disabilities from coming into the world. (Garland-Thomson and Sufian 2021)

Medical and Social Models of Disability

Disability rights advocates also point to the contrast between the social and medical models of disability. Mark Povinelli, President of Little People of America (LPA), points out that society and the medical/scientific community often want to fix people with disabilities or change their bodies. However, the disability rights social model of disability argues that many of the barriers people with disabilities face are imposed by attitudes and a built environment that does not intentionally include people with disabilities. They assert that society needs to be more accommodating to welcome people with disabilities.

Throughout history, society has consistently devalued and dishonored the lived experience of people with dwarfism, but in fact most members of LPA see that it is not our bodies that need fixing; rather, it is society's acceptance of our community

that needs fixing. If society was more accepting, open minded, and accessible, the industry could focus this technology on saving lives, not altering ours, because the removal of dwarfism doesn't just modify a physical condition; it eliminates a culture, an identity, a lived experience that only dwarfs can measure the value of. (Mark Povinelli, President of LPA, "NCD Public Comment Session" 2023o)

Value of Disability Diversity

Disability scholars also shared that disability could provide unique perspectives in society that might not be possible without the impact of disability on a person's life. Rosemarie Garland-Thomson writes that people with disabilities have unique strengths and resiliencies related to their disability as "innovators, early adopters, expert users and technology hackers as we respond to the adversity that the built and natural environments present us" (Garland-Thomson 2017).

Many people with disabilities would not have said, oh, it would have been nice to not have the disability that I have, but rather think of their disability as part of who they are, not completely who they are but an important part of their identity. And I think that gets very much lost. When Stephen Hawking died, people commented on that, "look at what a brilliant man he was, think of how much more he could have achieved if he didn't have the condition that he had." I think many of us heard that and said, maybe he achieved what he did because of his condition or at least as part of it. I think we

lose that when we go this route. (Robert Dinerstein, “NCD Public Comment Session” 2023a)

Editing for Disability

The literature and our participants also brought up how heritable genome editing is often presented as a neutral technology, but the assumptions surrounding it indicate otherwise (Genetics and Society 2022). Some deaf or hard of hearing people or Little People might prefer to purposefully edit their children to have those conditions and be genetically similar if this technology were available. While they were not suggesting that the technology should, in fact, be used at all, they said if researchers and scientists want to use genome editing to create a fetus without disabilities, then it would stand to reason that scientists would also be willing to provide heritable genome editing to preserve certain types of heritable disability cultural identities. If not, then some disability advocates question whether their motivations are likely driven by ableist perspectives on disability.

Technology is not value neutral—what if deaf people want to genetically engineer for deaf children/population? (Teresa Blankmeyer Burke in Genetics and Society 2022)

Commercialization

Participants in these sessions also repeatedly brought up significant concerns about the influence of corporations seeking approval for heritable genome editing for the profit incentive without considerations for the human impacts. They described that these for-profit incentives

could be found among corporations seeking to market genetic testing or heritable genomic editing, entities that perform genetic engineering research, fertility clinics, and other unforeseen market players in this technology. Participants explained that the primary motive for these for-profit entities would be bottom-line cash incentive and not the patients, providers, or disability community. In fact, their fiduciary responsibility is ultimately tied to shareholders and not the broader community.

Another key concern from a disability rights perspective would be the motivation for these companies to catastrophize disabilities to promote these technologies. Sometimes the messages overtly claim that these disabilities can ruin lives or make life harder than is true. Often, the messages can be more subtle in claiming that these tests create healthy, happy babies, and the unspoken message is that disability is silently portrayed as the bogeyman in the room. Healthy, happy babies are portrayed as the outcome of avoiding disability when, in reality, many people with disabilities lead happy, healthy, and fulfilling lives.

Commercialization Concerns

I think I've said this over and over again, but I think that the thing I worry about the most is how the commercialization is driving all of this without thinking about the individuals that it's really affecting. (Stoll 2023)

The main driving forces are too often not the interests and concerns of the public or of patients and healthcare providers nor the concerns that people who have lived experience with disabilities. As with many technologies that have been introduced into this largely unregulated area of reproductive

medicine, the main driving forces are often scientists eager to prove that it can be done and increasingly from those who stand to profit from those technologies should they be commercialized. (Katie Stoll, “NCD Public Comment Session” 2023j)

To think about germline editing, we have to remember that it is likely to be sold as a product. If it is, then market logic will prevail. The severest conditions will be leveraged for public support, but health will be defined to include as many conditions as possible, including blindness, deafness, and achondroplasia. (George Estreich, “NCD Public Comment Session” 2023n))

We develop the story: people with disabilities are living a sad, tragic existence, and only through progress in the genetic sciences can we spare their suffering in future people. This tragedy gets retold and retold, creating urgency for the technology in question: Forget the vibrant disability community. Forget the changes in technology, art, and culture that people with disabilities bring to our world from the insights of living with a disability. We don't have time to worry about ethics or risks! (Beitiks 2016)

I think there's a real potential for heritable genome editing to be used in ways that are less clear in terms of a specific condition that's being treated. For instance, I can imagine especially the way that technologies are often kind of marketed towards people's fears and anxieties around things . . .

For example, the drug companies are manufacturing the treatments that they want to really encourage like Voxzogo [a new treatment to increase height of

people with dwarfism]. The messaging is coming oftentimes from pretty biased sources. I feel like the pursuit of this as a profit making enterprise is largely what threatens the ethical and socially appropriate implementation that's possible here. (Stoll 2023)

There's a really golden possibility that we could do a very good job of implementing these [technologies], and the biggest risk and danger to that is the desire for profit margins and valuing shareholders over stakeholders. (Michie 2023)

Globalization

The literature and participants in our sessions also reflected a range of concerns about the potential impact of globalization with heritable genome editing. Among the concerns were the following:

1. The exclusion of less technologically advanced countries from international conversations about heritable genome editing, even though they will also need to cope with the outcomes.

A specific concern in the listening session was the exclusion of Global South and other countries with less capacity for technological innovation in critical conversations about international human genome editing policies.

2. Disparities in disability rights between countries that may influence decisions about heritable genome editing where social supports for people with disabilities are limited.

A Russian scientist, Denis Rebrikov, was recruiting individuals with hereditary

deafness to utilize CRISPR to prevent deafness in their future babies. Five couples agreed to participate, but Deaf advocates in the United States question the environment in which those couples made that decision. They explain that in countries where deaf people are not provided proper supports and services and face significant discrimination, their decisions may actually be rooted more in the cultural discrimination they experience rather than an actual rejection of hearing loss as a trait. These U.S. advocates fundamentally question the possibility of informed consent in Russia based on lack of support for the Deaf community.

Many members of the signing Deaf community do not consider themselves to be disabled; they consider deafness an embodiment that's not the average one but nevertheless well within the boundaries of normal human variation. Other deaf people think of deafness as an impairment or disability, but not one that prevents a person having a good and fulfilling life—and certainly not so damaging as to justify using a technology that's still experimental and potentially unsafe. (Jackie Leach Scully Interview by Hasson 2019)

Denis Rebrikov says "that he has 'lined up' five couples with hereditary deafness who have agreed to let him try using CRISPR to prevent deafness in their future babies."

Rebrikov's assertions clearly communicate the message that deafness is a condition so serious that it should be prevented even at the cost of using an experimental technology on humans. This perspective runs counter to the

beliefs of many disability rights activists and advocates who believe that variation in ability—and the corresponding cultural differences and contributions—are important to the fabric of our society. (Center for Genetics and Society 2019)

In response to these concerning news reports, in November 2019, the World Health Organization (WHO) Director General issued a statement calling on all nations to support the work of the WHO and to desist from permitting research on heritable human genome editing within their borders (WHO Expert Advisory Committee 2019).

3. Medical tourism.

Participants additionally expressed concern about companies from countries that prohibit human experimentation turning to countries with less regulation to perform unethical research.

Another very important [point] has to do with what might be called global standards, that we want to avoid just coming up with standards that might apply just to the U.S. that would then permit U.S. physicians and others and researchers to go to other countries and engage in a kind of medical tourism and to do experimentation that may not be able to do here. So while we're the National Council on Disability, looking at domestic work initially, we don't want to develop a kind of exceptionalism that then somehow allows us to export practices that we wouldn't engage in here. (Deepti Babu, "NCD Public Listening Session" 2023b)

4. A genetics race between countries to craft more “exceptional” humans.

While this is a dystopian theory, it is conceivable that if heritable genome editing were to be allowed for transhumanist cosmetic and performance enhancements, it could lead to a genetics

race between countries to produce “super humans.” This could produce a version of humanity that would seek to replace vulnerability, resilience, and grit for intelligence, strength, and competition (Church et al. 2022).

Chapter 4: Legal and Policy Considerations

General

Information About Benefits and Limitations of Prenatal Interventions

All literature and contributors to this report affirmed that any technology used for prenatal interventions—whether prenatal testing, fetal surgery, or gene editing—should inform patients of the benefits and limitations of the technology. This is currently a significant area of concern with cfDNA screening given the roller coaster in marketing claims over the past 10 years from commercial labs and broad misunderstandings in the accuracy of the tests leading to increased calls for FDA regulation (Kliff and Bhatia 2022). Therefore, regulatory bodies—whether at the federal, state, or hospital levels—need to be able to provide assurances that patients are being provided the most accurate information about the benefits and limitations of each prenatal intervention to make informed choices. Moreover, they need assurances that the advice given to them is driven by concern for the patient over profits.

Balanced Information About Genetic Conditions

Research shows that expectant parents often struggle to obtain accurate and unbiased information about disabilities following prenatal

screening for known genetic conditions, which can cause trauma for pregnant patients and reinforce disability bias (May, Dein, and Ford 2020). Therefore, participants also emphasized that it is important to make sure funding is available for a patient and provider education infrastructure to develop and disseminate accurate and unbiased information about disabilities for expectant parents. Contributors to the report emphasized the importance of clinicians providing balanced information about genetic conditions when discussing prenatal interventions with input from leaders in the medical and disability community—information that includes medical issues as well as up-to-date life outcomes and supports and services. The fully funded development and dissemination of accurate, balanced, and up-to-date information about genetic conditions for patients and providers needs to be a central priority to achieve equity rather than a casual afterthought after the technology is already in clinical practice. The absence of this educational infrastructure is harming patients and causing trauma to them right now, and the situation can only be expected to worsen if more prenatal interventions are added. In her interview, Sylvia Yee indicated, “I would want a broader understanding of what it means to live with disability and conditions and the range

of choices that families and individuals have. All that needs to be made available and fully funded” (Yee 2023).

Disability Cultural Competence

Another universally supported principle was the need to eliminate ableism from conversations about prenatal interventions and to correspondingly develop and implement disability core competencies for medical professionals and the broader public. Because bias against people with disabilities is ingrained in a society where people with disabilities were subject to institutionalization for over a century and forced sterilization largely driven by the eugenics movement, conversations about whether to pursue prenatal interventions are often steeped in bias against people with disabilities. As cultural competencies are becoming an increasing priority in medical schools, disability also needs to be included in that array of cultural competencies for education and ongoing training and certification.

Training programs must incorporate anti-ableist knowledge and skills into their curricula. Funding should be directed towards developing capacity to counsel patients using accurate, unbiased information about what it is like to live with genetic conditions drawn from the lived experiences of disabled people.

Ableism is rife in medicine, scientific research, and also bioethics. It should be addressed through evidence-based education. There’s a disproportionate emphasis on genetics and health research, often pursuing a vision of health that is not compatible with disability. A recent study found 82% of physicians believe people with disabilities have a lower quality of life despite disabled people typically rating their own quality of life highly. What the medical establishment views as a deficit can be a form of human difference fully compatible with flourishing, especially given adequate

social supports. (Liza Bowen, “NCD Public Comment Session” 2023h)

As cultural competencies are becoming an increasing priority in medical schools, disability also needs to be included in that array of cultural competencies for education and ongoing training and certification.

Many of the recommendations from the participants throughout the sessions included a call to build a better framework

for reinforcing social justice toward people with disabilities among clinicians, researchers, and scientists working on potential prenatal technological interventions, as well as the general public. They recommended the following toward achieving better equity for people with disabilities in this space:

- Establish better education and standards to identify and avoid systemic disability discrimination/ableism in the fields and industries of medicine, bioengineering technology, genetic research, and infertility.

- Provide disability core competency, ethics, and anti-ableism training for medical and genetics professionals who are discussing disabilities at the potential first point on the life course and also provide training for scientific research professionals who conduct research that can impact people with disabilities. The core competencies would need to be a component of licensure and medical school curricula.
- Fund disability rights education for people with disabilities to advocate for themselves in the fields of science, genomics, and medicine. Bioethicist Sandy Sufian writes, “We need to put disability justice and ableism as priorities in a business agenda alongside considerations about diversity” (Sufian 2021).
- Utilize public education awareness campaigns to instruct about the history of disability rights and to challenge stereotypes about disability and reduce stigma.
- Require training on how to discuss disability with expectant parents making complex decisions about reproduction, health, and genetics. The medical model of disability is not sufficient—families also want to know about life with disability and available supports and services. They emphasized that clinicians need training to deliver counseling so that pregnant patients are presented balanced information about disabilities with education modules, units, and possibly certification. This infrastructure needs to be funded and established before proceeding with further genetic interventions and to address the current public health problem.
- Expand health insurance and Medicaid coverage for prenatal genetic counseling so that expectant parents can engage in informative and meaningful conversations with a professional trained to discuss disability and guide them through complex decisions about genetics and genomics. They addressed the genetic counselor access shortages and the need to make genetic counseling services more available through better insurance coverage so that patients have trained professionals who can discuss complicated genetic technology with them.
- Systemically include social justice advocates in medical, research, and science initiatives that target and/or treat them as a population so that they are weighing in on these issues at every stage. They discussed the importance of including people across multiple disabilities and conditions with broad representation of experience and intersectional identities because people with disabilities are not a monolith. These efforts require meaningful engagement between people with disabilities and medical/scientific communities, not tokenism. For example, some social justice advocates have leveled criticism that people with disabilities were not sufficiently included at the International Summit on Human Gene Editing held by the National Academy of Sciences and the National Academy of Medicine. Devandas stressed the absence

of persons with disabilities in crucial debates on medical research and practice as a major concern because “without their experiences directly informing those debates, narratives suggesting that living with disabilities should be prevented become reinforced and socially validated” (United Nations Human Rights 2020).

People with generational disability like hereditary deafness, blindness, autism, and dwarfism can also offer particular insights as people with an understanding of the impact when a disability is passed down to form a cultural identity. They can uniquely experience disability as a “vertical identity,” as described by Andrew Solomon, where families share similar traits that may be chal-

lenging at times for various reasons and also deeply valued (Solomon 2013). Another key demographic to include is pregnant people who are disabled, who are often neglected or forgotten in these conversations but are central to conversations about hereditary disabilities.

Some policy strategies suggested to intentionally invite representation by people with disabilities were to include people with disabilities on Institutional Review Boards for determining what research is ethical; create a disability equity ombudsmen or national-level policymaking group to review policies and practices related to disability and prenatal interventions; fund programs for people with disabilities to



attend summits and meetings where prenatal interventions are being discussed; fund summits and public consultations between the disability, science, and medical communities; create patient education materials with input from the disability and medical communities; and develop a workforce of scientists and researchers that includes people with disabilities as colleagues, including people with intellectual disabilities. They also continued to reinforce that this inclusion needs to include a broad array of voices. Sylvia Yee explained that an ombudsmen can be created to “fund independent advocates and ensure that people with disabilities can be at the table. People with various disabilities should receive the accommodations they need to be at the table to ensure that meetings are actually accessible, to ensure that the comments they have are given full weight. They would have an actual vote” (Yee 2023). Moreover, participants said funding should be available to facilitate social engagement between the medical, scientific, and disability advocacy communities to facilitate public dialogue and meaningful conversations about the ethics and practical application of prenatal technology interventions.

It’s really important to think about the views of anybody who’s affected by this, and the people who don’t end up with their voices represented at the table are people with disabilities and their families, and I think that pregnant women just don’t get listened to in our society at all.

And I think that the bigger the table is, and the more voices are at the table, the less likely you are to have the kinds of eugenic practices that we had at the beginning of the 20th century that had a very, very narrow idea of what a good birth looked like and what a good heritage looked like. One of my mentors always says look around and see who’s not at the table. That’s the voices that you’re missing, and if you’re missing people with disabilities, get them at the table. Listen to their voices and I mean, really listen.

When you think about policy with a small “p,” the people who are making institutional policy, people who are making IRB [Institutional Review Boards] kinds of decisions, those folks need to have input too from the disability community. They also need to have input from particular kinds of scientists. I think this is such a very, very specific area of science, and you need people who have that particular kind of expertise. But you do need to balance that, because sometimes scientists can get overhyped and overexcited about the possibilities of things. And I think that you need a balance between genetic science and people who are really knowledgeable in maternal fetal medicine, for example, to give a bit of a reality check. Like no, this is pregnancy we’re talking about. And then of course you need that patient and family perspective, disability community perspective, and it’s just so unethical to move forward without all of those people’s voices being heard. (Michie 2023)

Key Quotes

Importance of Meaningful Disability Inclusion

Open dialogue and collaboration between scientists, ethicists, policymakers, and the wider community are essential in ensuring the responsible use of these advancements. Only through collective deliberation can we create a future where genetic editing is used ethically and responsibly. In contrast to many European countries, the United States has lagged behind in efforts to hold these difficult but necessary conversations to reach a consensus on guidelines and regulations. We cannot wait any longer. Disabled people, including parents with disabilities, must be active participants in this process. (Kara Ayers, “NCD Public Comment Session” 2023m)

You really need to talk to the disability community, and you need to talk to us extensively. Not just popping in as a little surveyor, a little handful of us. It really needs to be extensive, and then you can understand why many disabled people see this as a genocide of sorts. You really want to be extraordinarily careful about how you go about this before you do anything. Sit down with disabled people—and not just wealthy disabled people. (Cameron 2023)

People with disabilities are uniquely situated to perceive ethical and social dimensions of genetic technology that nondisabled people, including scientists and medical professionals, cannot. . . . It is thus vitally important that the views of those who stand to be most affected by the development of gene editing technology, people with genetic conditions and disabilities, are documented and considered as policies and norms around these technologies are developed. (Hoffman-Andrews et al. 2019)

It is imperative that the leaders in the scientific community listen to those of us living with dwarfism whose future is at risk of being genetically edited out. Before we spiral down this path, we need to put the voices of those with these conditions at the forefront of the conversation and ultimately the decision-making process. (Mark Povinelli, “NCD Public Comment Session” 2023n)

It is critical, therefore, that the literature exploring the views of people with the most vivid and visceral insights into the lived realities of genetic disability is included and valued in the processes of development and evaluation of new technologies such as genome editing. . . . This is not only so that the potential impacts on them can be explored, but also so that informed decisions regarding which conditions are the appropriate targets of genome editing can be made. Indeed, given the inherent potential of germline genome editing, this inclusion is now of paramount importance, when it is considered that such voices and experiences could eventually become a resource of increasing inaccessibility in the future. (Boardman 2020)

Importance of Meaningful Disability Inclusion: *continued*

Bring perspectives of those with lived experience to the table as policies are being developed, and really have those perspectives shaping these policies, but I still think that can be exploited if you've got people with financial interest in doing so. (Stoll 2023)

It cannot be just "find someone with the disability and include them in the conversation" because that puts weight on the person with the disability to try and represent all conditions, all arguments. That's ridiculous, and the immensely unequal playing field when it comes to sort of information—education, background, resources. Being at the table is not enough. (Yee 2023)

- Cultivate a better understanding of the distinctions when considering disease, pain, and disability cultural identity—and the difference and overlap between those different categories among clinicians, researchers, scientists, and the public. Participants explained that scientists and researchers need to consult with the disability community and people with lived experience to determine what they perceive as health issues they want to be corrected as distinguished from components of their disability identity.

[Concerning the attitudes of parents of children with Down syndrome about current and theoretical medical interventions:] The degree to which participants identified with their impairment, more so than how they valued it, was significant in determining attitudes toward selective reproduction. Those who supported genetic screening viewed their impairment as separate to themselves, while participants who considered their impairment as integral to their identity were most likely to report ambivalent or negative attitudes. Policymakers and stakeholders considering the role of genetic carrier screening panels might usefully engage with adults affected by heritable disease as well as disability identity politics when considering the acceptability and social impact of genetic screening programs. (Michie and Allyse 2019)

Sometimes they go along with it, and sometimes they don't. Like one of the things we asked in that study was about a gene silencing technology, which is a possibility in silencing that 3rd 21st chromosome [in Down syndrome]. And people really wrestled with that so much. Like on the one hand, I worry about my kid, and I worry about what's going to happen after I'm gone. And I don't want people to take advantage of them, and I don't want them to have a hard life. But on the other hand, they're so open, and they're so loving. And if doing this changed their personality and made them not open and loving anymore, and the way that they are now, there would be such a loss. (Michie 2023)

Data Collection

Contributors to this report expressed the importance of determining the impact of prenatal interventions on individuals with disabilities and their communities through robust data collection and analysis that can inform evidence-based policies and interventions.

I would like to see us going back to really, really examining the potential benefits and harms of all of these tests and then developing guidance so people can make really informed choices about what, if any, of these tests [or other prenatal interventions] that they want to undergo and how they're going to impact their plans for having a family. . . . I think making sure that people really have an opportunity

to make an informed choice and that they're not being subject to experimental testing—as is happening at this point. And then those types of interventions, like assisted reproductive technology and embryo testing and selection, we really shouldn't be doing that without having more information about what it means to have these genetic variants and really having opportunities for people to make informed choices about what they're testing and selecting for. Hopefully, they have opportunities to have more unbiased information about the conditions that they're testing for—informed by people who have lived experience with these conditions. But that should start before screening at all, in my opinion. (Stoll 2023)



Antidiscrimination Laws

Laws to Guard Privacy and Autonomy

Where prenatal interventions are agreed upon by the medical and disability communities and receive FDA approval, contributors also recommended policies and measures to protect and strengthen privacy and protect autonomy, such as the Genetic Information Nondiscrimination Act. These prenatal interventions should be private decisions based on the values of the expectant parents without being compelled one way or the other. They should not face social or legal pressure to pursue prenatal interventions if they would prefer not to. On the other hand, contributors asserted that expectant parents should not face restrictive reproduction laws that would limit a family's ability to pursue fetal surgery due to the liability a clinician could face if pregnancy loss occurs.

Some of this may start out as voluntary and then turn around and it slowly becomes mandated . . . because after a while it's going to be expected. I think that people have to be made aware: Researchers, doctors, policymakers all of that. (Cameron 2023)

Support for Disability Services

Because perceptions about the preventability of disability can seep into support for people with disabilities across the life span who are

perceived as "avoidable," another key point is to strengthen laws that prohibit discrimination in health care, education, employment, and other areas of life. This is crucial when disability may become experienced less often by the wealthy who can afford costly prenatal interventions and who are in higher positions of privilege when crafting laws. Without legal protections now, the chasm will likely widen significantly between the haves and have-nots, with disability being much more predominant among families whose incomes are below the federal poverty threshold who will be less likely to receive the support they need for a condition seen as "preventable." That being said, we do not suggest that the

[W]e do not suggest that the answer is to eliminate disability among all persons equally but rather to provide support equally so that people with disabilities can live viable and meaningful lives.

answer is to eliminate disability among all persons equally but rather to provide support equally so that people with disabilities can live viable and meaningful lives. An important strategy to address the

root causes of discrimination and inequality is to also invest in disability support services, such as home and community-based waivers, special education services, and equitable health care for people with disabilities to assure that they can thrive.

Financial Incentives

Participants in these conversations discussed the importance of prioritizing health equity for people with disabilities through financial incentives such as contributing funding for greater public engagement or, conversely, punitive damages for health insurance companies not in compliance with providing equitable care.

And in the heritable genome editing conversation everyone will say we need greater public engagement, but that doesn't just happen on its own. It has to be supported. It's work. It takes money, and it takes work, and it takes time. Those things have not been there. Period. (Darnovsky 2023)

Industry Regulation

Because genomic technology can be driven by for-profit industries, participants also expressed the importance of regulating advertising, marketing, and commercialization to govern ethics so that companies do not, for example, use social stigma toward people with disabilities or the vulnerabilities of people with fertility issues to market and sell prenatal intervention technologies ranging from prenatal testing to embryo selection to heritable genome editing if it were available. Therefore, experts have proposed that the marketing of prenatal intervention technologies be regulated to prohibit messages that are discriminatory toward people with disabilities.

Another policy recommendation suggested was tighter regulation of prenatal intervention technologies with the allocation of research funding, the determination of research priorities, the clinical approval and implementation of technology, and requirements for data collection and reporting in order to prevent discrimination against people with disabilities and protect patients from market manipulation.

We should prioritize regulation of lab developed tests, and regulation in the space of the assisted reproductive technologies and these new procedures

and technologies—not just tests but things that they're doing in the lab to manipulate gametes and embryos. I think there's a lot that escapes regulation altogether. (Stoll 2023)

Accessibility

Participants shared the importance of making language about the prenatal interventions accessible in plain language formats, especially for people with intellectual disabilities, to understand them so that they can engage in public debates about their utilization.

Fetal Surgery

Informed Consent

For every prenatal intervention discussed, championing informed consent has been a key message, including fetal surgery. Indeed, any medical procedure, particularly one as complex and high stakes as fetal surgery, must establish a firm foundation of informed consent with policies that ensure all patients—including those from low socioeconomic status, different racial backgrounds, and other potentially marginalized populations—are provided with access to fetal surgeries or other prenatal interventions that have been validated and are available for their child's condition and a comprehensive list of benefits and risks for the fetal surgeries. Furthermore, participants discussed the need for regulations to ensure that surgeons are qualified for highly specialized procedures.

Your unborn child has a valve that needs to be fixed, but if you don't know about it, that's not in your orbit because nobody's going to put that information in the County

Hospital or the City Hospital or the free clinic or whatever. (Cameron 2023)

SBA [Spina Bifida Association] is cautiously optimistic about this research. These advancements are not without their drawbacks, however. Mothers who undergo surgery in utero deliver babies early and must undergo C-section for any future pregnancies. And there are no regulations to ensure that surgeons are qualified for this particular type of fetal surgery. (Sarah Struwe, "NCD Public Comment Session" 2023)

Variable Health Coverage and Access

Lack of universal health care makes equitable distribution of fetal technologies difficult. This means babies in rural areas or who lack proper insurance coverage may not have access to fetal surgeries that could improve their health. Therefore, policies that ensure that proper health care is available during pregnancy are essential to make sure every child has access to the validated medical care needed or preferred. Without these policies to improve access to health care, disadvantaged families will bear the brunt of consequences as public support will begin to dwindle for people with disabilities. The reason would be that those in decision-making positions no longer experience the same level of hardship because they can pursue better, earlier treatment for medical issues. Validated prenatal medical procedures need to be available to everyone regardless of socioeconomic status, rural location, race or ethnicity, and sexual or gender minority status.

Participants in the session also emphasized that policymakers need to make sure less expensive validated medical treatments

are available for everyone, like folic acid supplementation to help prevent spina bifida.

Well, oftentimes these procedures are done in either hospitals or clinics that are way the heck away from other people. Sometimes you have to travel to other cities or other states to take advantage of this. This should be available everywhere and not just in wealthy clinics, but in those neighborhood free clinics. (Cameron 2023)

People in low-income clinics can't even afford folic acid supplementation. I mean at the most basic we know that that baby aspirin can probably help ameliorate some preterm birth. (Michie 2023)

Evaluation of Social Determinants of Health

Participants also discussed the importance of addressing social determinants of health that can impact access to validated prenatal medical interventions such as transportation to doctors' appointments and employment protections and childcare options to make it possible for some patients to attend prenatal visits.

I would imagine in terms of things like surgery for spina bifida, it's going to depend on whether people are accessing basic prenatal care, whether or not they have an ultrasound or an AFP [Alpha Fetoprotein] test to even know if they have a prenatal diagnosis.

I'm not an expert in prenatal surgeries . . . , but it seems to me like what we're talking about is making sure that there is access, and the people have some of the basic determinants of health,

like proper nutrition and basic prenatal care. And then once all those things are in place, there's access in other ways like transportation and childcare and all the other things people need for these kinds of [prenatal] interventions. (Stoll 2023)

Heritable Human Genome Editing

Because heritable human genome editing could significantly increase discrimination against people with disabilities, a complex array of policies, practices, and guidelines needs to be in place to regulate the consideration of that technology. The inclusive policymaking, balanced and accurate information about genetic conditions, industry regulation, access to genetic counseling, antidiscrimination laws, laws protecting autonomy and privacy, disability cultural competency, data collection, support for disability services, and accessibility as described



earlier are all vital when evaluating heritable genome editing. In addition to those crucial concerns regarding all prenatal interventions, heritable genome editing adds more layers to consider including the prohibition/regulation of that technology, the development of parameters for considering the possible use of heritable genome editing, and the prioritization of social determinants of health before costly new technologies. Overall, heritable human genome editing requires the most comprehensive and thorough development of legal protections, ethical guidelines, and inclusive policymaking due to its high potential for errors that can cause additional harms, its strong tendency to promote discrimination against people with disabilities, and its unique capacity to forever change the genetic makeup of humanity.

Prohibition/Regulation

The vast majority of the participants agreed that heritable human genome editing should currently be completely out of bounds for reproduction due to problems with accuracy, unknown health complications, complicated ethical problems related to the preservation of disability identity, the potential of the technology to impact future generations, the potential of the technology to lead to “designer babies” with preferred traits, and problems with achieving equity. Fundamentally, they believed there are not enough safeguards at this time to prevent “Frankensteining” with this technology. Our respondents tended to be more cautious than the UK Nuffield Council on Bioethics report *Genome Editing and Human Reproduction* which called for broad public debate on heritable human genome editing but proceeded to conclude that germline reproductive genome editing should be permissible under certain circumstances without

actually engaging in that substantive public engagement before making that recommendation (Center for Genetics and Society 2018; Nuffield Council on Bioethics 2016).

Notably, sometimes the prohibition of certain treatments can be the preferred course of action as demonstrated by Frances Oldham Kelsey in the mid-twentieth century. When Europe broadly released thalidomide for the treatment of morning sickness during pregnancy, Kelsey refused to provide FDA approval in the United States because the drug had not been tested on pregnant animals. Despite strong commercial and political pressure, Kelsey refused to relent given the lack of safety data for pregnant women, and her decision prevented hundreds if not thousands of children from being subject to human experimentation and the resulting birth defect (“Changing the Face of Medicine: Frances Kathleen Oldham Kelsey” n.d.). Fundamentally, sometimes the answer is not to proceed with human testing for a technology or intervention if its safety has not or cannot be demonstrated using scientific methods that are safe for human subjects.

Develop Parameters for Consideration of Heritable Genome Editing

Some participants in our listening sessions, public comments, and interviews gave an opening for the future use of heritable human genome editing for serious life- or health-threatening conditions if the technology is more developed and accurate. They indicated that many stringent parameters would need to be followed for safety, ethical consensus, and equity in access, but they said broader societal debate would be necessary to determine what those parameters might be. They emphasized that it is important not to close the door on technology

that could be used to prevent death or unwanted comorbidities.

Gene editing of somatic cells offers possibility of a cure for people living with hemophilia of all ages and severities, especially infants and children. Development of a bespoke model of gene editing to orphan diseases for which there are at present few adequate treatments is highly desirable. Ultimately germline editing would be the goal, but I believe that there is much scientific and ethical work that needs to be done before this novel application is considered, including extensive input from those living with diseases, disorders, and disability. (Leonardo Valentino, “NCD Public Comment Session” 2023o)

However, other disability and social justice advocates contended heritable human genome editing should remain prohibited permanently because most concerns about serious life-threatening disorders can be addressed through preimplantation selection and IVF, which are much less risky than heritable human genome editing. They also cautioned against the slippery slope where heritable human genome editing can evolve into editing out conditions that frame disability identity and then evolve further to cosmetic enhancements and human engineering of “designer babies.”

Most contributors left the window open for research on germline gene editing in the lab to develop the science but felt it was too risky and ethically fraught for use in reproduction. They said any research initiatives should be decided by a transparent, distributive process at the federal level.

Fundamentally, all participants agreed that any consideration of the prohibition/regulation of heritable genome editing must consider the disability rights and social justice perspectives to avoid discrimination against people with disabilities. They indicated that policymakers need to seek input from the disability community before adopting controversial fetal technologies that could impact people with disabilities as a historically marginalized population. Anita Cameron emphasized that policymakers need to make sure the times, locations, and accommodations for these social forums are accessible to people with disabilities. She also advised that these social forums be preceded by public education about these technologies in plain language—that intentionally includes people with intellectual disabilities—before deciding whether to adopt heritable genome editing into practice.

Anita Cameron explained, “a lot of people can’t get that scientific jargon, your eyes just glaze over. For the broader public to understand, use plain simple language so you can make informed decisions.” Sylvia Yee suggested that these considerations are essential to avoid discrimination according to Section 504 of the Rehabilitation Act of 1973.

Section 504 of the Rehabilitation Act of 1973 is one of the first federal U.S. laws to recognize and ban discrimination against people with disabilities. The law is just over 70 words. When it was passed, there was no general consensus about what those words meant. It took years to flesh out

[P]olicymakers need to seek input from the disability community before adopting controversial fetal technologies that could impact people with disabilities as a historically marginalized population

what disability discrimination looks like and decades more to achieve a broader understanding of what disability rights and disability justice means.

Within the fields and industries of bioengineering technology, genetic research, and infertility, there has been no translation of what disability discrimination means. As history has shown, scientists and medical providers are not particularly good at distinguishing between therapeutic healthcare and an existential threat like eugenics.

Half a century after 504 was first passed into law, our job is to listen and support

multiple conversations over time between disability communities and larger society. Healthcare providers cannot continue to use prevention of disability as a fundraising point or

standard of care precaution and yet have no clue of how people with disabilities live today. They cannot simply make uneducated assumptions about what makes life with a disability hard, and they cannot fail to make any other efforts in their jobs or lives to address the different things that make it hard. (Sylvia Yee, “NCD Public Comment Session” 2023b)

The statement on heritable genome editing from the American Society of Human Genetics reinforces a similar approach:

The statement includes the following positions. (1) At this time, given the

*nature and number of unanswered scientific, ethical, and policy questions, it is inappropriate to perform germline gene editing that culminates in human pregnancy. (2) Currently, there is no reason to prohibit in vitro germline genome editing on human embryos and gametes, with appropriate oversight and consent from donors, to facilitate research on the possible future clinical applications of gene editing. There should be no prohibition on making public funds available to support this research. (3) Future clinical application of human germline genome editing should not proceed unless, at a minimum, there is (a) a compelling medical rationale, (b) an evidence base that supports its clinical use, (c) an ethical justification, and (d) a transparent public process to solicit and incorporate stakeholder input, . . . including the medical and scientific communities, **persons and families dealing with genetically based disabilities**, and the general public, would be warranted given the potential uses and impacts of germline genome-editing technology. (Ormond et al. 2017)*

Listening session participants said it might also be worthwhile to discuss whether the concerns and issues should be periodically revisited to update policies.

Champion Informed Consent

For any prenatal intervention, session participants emphasized the importance of informed consent. Kara Ayers commented, “We should ensure that patients and families are given comprehensive, unbiased information about consequences and risks associated with these technologies” (“NCD Public Comment Session”

2023h). Because heritable genome editing is particularly fraught with informed consent concerns—and the consequences are irreversible for future generations—any consideration of this technology would need to have strict policy provisions that take into account the consent of both the parents and future generations and address difficult if not impossible questions. How can proper informed consent be obtained if outcomes for a fetus and future generations are unknown? What level of clinical validity would be required before altering the DNA of humans in reproduction? How is it possible to obtain informed consent from future generations for genetic alterations, and what legal accountability would parents and providers have for altering genetics if the future generation objects?

Consider Social Determinants of Health and Community and Social Supports

Another consideration is whether the push for heritable genome editing and any other prenatal interventions are based on a genuine interest in helping people or commercial interests. Participants discussed that shiny new technologies, such as heritable human genomic editing, are often more likely to capture the public imagination and flashy funding to accomplish a goal such as preventing birth defects when, in reality, broader public health actions that address social determinants of health, such as folic acid supplementation and healthy nutrition programs during pregnancy, can actually be strategies that help more people and are more effective at preventing birth defects without the risk of heritable human genomic editing.

CRISPR wants to normalize bodies and minds and tends to garner corresponding

research dollars from federal agencies and industry. But what we need is funding parity for developing and implementing interventions that help disabled people live well as they are. Some suggestions for this might be finding ways to provide access to better assistive technology for disabled people, identifying and eliminating the barriers that prevent disabled people from accessing basic healthcare, which is many times out of reach for the most marginalized of us currently, or figuring out how disability can itself be a social determinant of health and operate in a way that socially diminishes a person's health in various ways.

These sorts of interventions are not valued and not prioritized within federal funding. We need to concern ourselves as disability advocates with that issue even more than we do with identifying parameters for how to use the flashy technologies being developed. (Joseph Stramondo, "NCD Public Comment Session" 2023p)

If Medicare and Medicaid were to reimburse for vitamin D testing as a preventative test, it would help a lot of people without Multiple Sclerosis (MS) and potentially cut way down on the occurrence of MS without any of the ethical issues being the principal concern of this meeting. I think cost effectiveness could be demonstrated. It is certainly much less expensive than gene editing. Medicare and Medicaid could pay for vitamin D testing with each pelvic exam for premenopausal women (to reach women before they become pregnant) and with an annual physical exam for everyone else

(for example, men get MS, but do not become pregnant). Other insurers would likely follow Medicare's lead. If you were to draw attention to this, it would be extremely influential. (Margaret Rose Byrne, "NCD Public Comment Session" 2023q)

International Cooperation

Given the risk for global exploitation of this technology through disparities in health care and disability rights, medical tourism, and a potential genetics race, another key policy provision would involve engaging in international treaties that seek to establish international cooperation and regulation for heritable genome editing while also intentionally including countries from the Global South and other areas where technology might not be as advanced but where perspectives are still crucial for better understanding and more informed global decisions.

Our collective responsibility demands that we take proactive steps to prevent the potential misuse of these powerful technologies. First and foremost, we must ensure that all genetic editing research is subjected to rigorous ethical review, which may mean an international regulatory body such as the World Health Organization that would oversee research proposals involving genetic editing, to mitigate risk of further marginalizing disabled individuals. This will be a challenge because there will be a need to address representation of people with disabilities, power divides, and also the current restrictions on access to reproductive access in our country, including access to abortion services. (Kara Ayers, "NCD Public Comment Session" 2023h))

Conclusion

Even in 2024 with all the technological advancements discussed in this report, people with disabilities still face discrimination in health care, many still languish on waiting lists for support services, and pregnant people still experience profound disparities and limits on prenatal care that could prevent congenital or prenatal anomalies. These pregnant people could benefit from fairly low-cost interventions that we are not providing as a society. While there is promise with some prenatal interventions like fetal surgery to repair known medical issues, even these clinically validated medical interventions are not available to everyone who might need or want them. Given these circumstances, why would we expand to heritable genome editing where the technology poses significant risks to the pregnant person, the baby, the disability community, and future generations with a very high cost that benefits very few?

Genome editing is advertised as promising healthier, better babies in the twenty-first century—like its eugenics forefather in the twentieth century. And like eugenics, heritable genome editing is built upon presumptions about the quality of life for people with disabilities as determined by a privileged elite—who are willing

to take great risks with public health and enjoy great profits for themselves—to avoid lives they deem as unfit. Yet, advances in the twentieth century like the Individuals with Disabilities Education Act and the Americans with Disabilities Act show that when people with disabilities are given social opportunities to thrive, they can fulfill their potential and offer back their own unique talents and skills.

For too long, the disability community, including individuals with disabilities and their families, has been excluded from the most fundamental scientific and medical conversations that impact them and that are based on perceptions of their lives. This disability rights refrain is often repeated, “Nothing about us without us.” In this era of increased concern about representation and social justice, it is no longer acceptable to continue moving forward with any of these initiatives without the input of the disability community in every step of the process, ranging from research priorities to clinical interventions. It is no longer acceptable to allow bias toward people with disabilities in any field, including medicine and science, without requiring cultural competency training for professionals about how to be mindful of disability rights. It is no longer acceptable to

implement broad health policies about disabilities without also providing accurate, balanced information and education about disabilities. This is not the first call to action, as demonstrated by the number of recommendations that echo the 2019 *Genetic Testing and the Rush to Perfection*

NCD Report, but we certainly hope it will be the last by prompting meaningful social and policy change toward promoting equity for people with disabilities in the provision of prenatal interventions.

Recommendations

Congress

- Continue to expressly prohibit the use of human germline gene editing in reproduction, as has been done by the 29 countries that have ratified the Council of Europe’s *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (the Oviedo Convention). Exceptions should not be considered unless and until the medical and scientific communities determine parameters through broad social debate that includes the disability community at every stage of the process.

The Consolidated Appropriations Act, 2023, indicates that none of the funds available in the Act may be used for “the creation of a human embryo or embryos for research purposes” or “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))” (Rep. Connolly 2022).

- Create legislation that would develop a sustainable disability equity funding pool derived from excise taxes on companies that benefit from prenatal genetic testing and interventions. This disability equity funding pool could be modeled on the excise tax funding mechanism for the Patient-Centered Outcomes Research Institute (PCORI) through an excise tax on health insurance plans and TTY (telecommunication technology for those who are hard of hearing) through an excise tax on telephone services. However, this disability equity funding pool would be distinct and separate from PCORI with funds derived from an excise tax on companies that benefit from prenatal genetic testing and interventions and funds extramurally directed toward the development of an ombudsman who would advocate for disability perspectives at medical and scientific meetings; training clinicians/genetics professionals on disability rights; developing and disseminating accurate, up-to-date and balanced information about genetic conditions; developing and maintaining relationships with disability advocacy organizations; and promoting disability education and social initiatives.

(continued)

Congress: *continued*

- Fund education initiatives and social forums for educating about controversial fetal intervention technologies and debating them before adopting them into practice, including all the interested parties, to determine parameters for if or when these technologies might be utilized and under what circumstances.

Funding options for education initiatives include the following:

- making public service announcements (plain language) in newspapers, online, TV, news programs, virtual public spaces, flyers
- creating an app to facilitate discussions
- developing presentations and online learning modules
- communicating via websites, Twitter, email

Funding priorities for forums include the following:

- town halls
 - policy leaders seeking input from people with disabilities in accessible locations: centers for independent living, postsecondary programs for people with disabilities, high-rise buildings for seniors and people with disabilities, nursing homes
 - public comment sessions
 - universities
 - disability organizations
 - other human rights and social change organizations
- Fund the Prenatally and Postnatally Diagnosed Conditions Awareness Act, Pub. L. No. 110-374, 122 Stat. 4051 (2008) (NCD 2019).
 - Incentivize and fund the development of educational units on disability civil rights and eugenics for public education and the education of medical providers and scientific researchers.
 - Provide funding to collect data on the current impact of prenatal interventions accuracy, outcomes, and impact on disability community.
 - Develop enforceable sunshine and conflict-of-interest laws that will bring transparency to any financial relationships among medical providers, researchers, and commercial laboratories (NCD 2019).
 - Protect and establish laws such as the Genetic Information Nondiscrimination Act to prohibit health insurers and other entities from discriminating against families for choices regarding prenatal interventions.

Congress: *continued*

- Expand the appropriation of funding for disability support services such as Medicaid, Individuals with Disabilities Education Act, and Americans with Disabilities Act so that individuals and families do not experience discrimination if they choose to parent people with disabilities.
- Lead and participate in global discussions and treaties to establish accountability for heritable genome editing research and implementation. Include the Global South and other countries historically excluded where research can be performed without oversight—medical tourism.
- Pass the Access to Genetic Counselor Services Act H.R. 3876 to expand access to genetic counseling services by providing for coverage under Medicare for genetic counseling services that are furnished by genetic counselors.
- Pass the HEADs UP Act H.R. 3380 to designate people with disabilities as a Medically Underserved Population so that people with disabilities can be included in NIH funding for research and diversity training initiatives to benefit underserved populations.
- Pass the VALID Act to increase FDA regulatory oversight of laboratory-developed tests (LDTs; commercial prenatal screening tests such as cfDNA screening) due to the widespread misunderstanding of the tests due to variable marketing and reporting claims. Require the collection of data on the accuracy of the tests.
- Provide funding for educational and career development training opportunities for people with disabilities and family members with lived experience to enter the medical/science workforce.
- Protect and expand policies that support comprehensive health coverage during pregnancy.
- Consider prohibiting the commercialization of prenatal interventions.

Office of Management and Budget

- Require that any cost justifications for research funding allocations also include calculations that weigh the cost/benefit analysis per person of technology development **with estimates for equitable dissemination** versus strengthening corresponding social determinants of health for people with disabilities.

Department of Health and Human Services (HHS)

- Establish standing relationships with disability advocacy organizations and include individuals from them on genetic advisory panels (NCD 2019).
- Encourage the attendance of advocates and representatives from disability communities at science and biomedical conferences by offering scholarships that reduce or cover fees and expenses. Invite advocates and representatives from disability communities to serve in leadership positions (NCD 2019).
- Using the principles of patient-centered outcomes research, establish policies so that all research pertaining to prenatal interventions, including heritable genome editing, is informed by patient advocacy group stakeholders. Establish ethical accountability for research and clinical trials.
- Organize a national-level policymaking committee to advise federal regulatory and funding agencies and include people with disabilities, disability scholars, other advocates and scholars grounded in social justice perspectives, and bioethicists to evaluate and provide feedback on prenatal interventions (Michie 2023). This committee would be responsible for reviewing and supporting scientists and researchers at the individual IRB level to determine who should review certain proposals, what kind of expertise is required, and what kinds of issues are important to understand. This committee would provide support and guidance for regulatory bodies including checklists and guidance about who should be at the table, what kind of expertise they need to have in order to review these kinds of studies, and what has been shown to be the best practice for stepwise implementation in prenatal technologies.

Additionally, as noted previously and as described in the Directors Statement linked earlier, “NIH will not fund any use of gene-editing technologies in human embryos.” In addition, “NIH funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) for research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.204(b) and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)).”

HHS, Food and Drug Administration

- Regulate genome editing research labs, fertility clinics, and other prenatal testing commercial entities to establish and enforce standards for the accuracy of any claims and how disability is portrayed, and proactively work with the Federal Trade Commission to oversee marketing being done by labs and commercial entities.
- Regulate ART by requiring clinical trial validation for procedures, a translational pipeline, and implementation guidelines.
- End enforcement discretion and regulate LDTs, specifically, NIPS, to establish and enforce standards for the accuracy of any claims made by prenatal genetic testing entities, and proactively work with the Federal Trade Commission to oversee marketing by genetic testing entities. Provide disability advocacy and medically informed regulatory guidance for LDTs and ART, including the manipulation of gametes and embryos.

HHS, Centers for Medicare and Medicaid Services

- Recognize genetic counselors as health professionals who can receive reimbursement through Medicare and incentivize Medicaid payments for genetic counseling as an independent health care service rather than only reimbursing genetic testing to create an infrastructure of professionals who can discuss complex genetic technology and prenatal interventions (NCD 2019).
- Develop funding mechanisms to ensure that all people who want to pursue fetal interventions, which have been ethically affirmed and clinically validated, have access to those technologies regardless of socioeconomic status, proximity to a specialty center, or race.

Federal Trade Commission

- Actively oversee the marketing claims and practices of for-profit companies developing prenatal tests, embryo screening and selection, genome editing technology, and other prenatal interventions.

Department of Education

- Develop and encourage curricula and units about the history of disability rights and eugenics for broader public understanding in public education, informed by disability advocates with lived experience.

Equal Employment Opportunity Commission

- Leave wellness rules as they are now (May 2019) or, if the Equal Employment Opportunity Commission does revise them, the agency should clarify that no financial incentives or penalties are permitted to induce employees to disclose health and genetic information (NCD 2019).

State Legislatures

- If prenatal interventions are funded as a Medicaid service, the state should also ensure Medicaid funding for neutral genetic counseling by independent professionals *before* and after prenatal interventions are utilized (NCD 2019).
- If prenatal interventions are funded as a Medicaid service, the state should also fully fund Medicaid waiver waiting lists for people with disabilities to ensure that people are not choosing risky prenatal interventions because they lack access to proper supports and services to live with disability.
- Where state Medicaid programs cover prenatal genetic testing, the state should ensure that it collects voluntarily provided information on patient demographics, including disability status, outcomes, and the quality of genetic counseling received before the testing, if any. This information will allow states and researchers to assess the use and results of prenatal genetic testing as a publicly insured service over time (NCD 2019).
- Provide funding for health care and critical social determinants of health that can prevent disabilities such as expanded Medicaid coverage for pregnant persons and babies, folic acid supplementation, nutrition and food vouchers, and transportation to medical appointments. Provide comprehensive and easy-to-access health care coverage for pregnancies to ensure the health of pregnant persons and babies, particularly for those at risk for health complications, so they can access validated prenatal interventions like fetal surgery.

State Legislatures: *continued*

- Assess laws about reproduction to ensure they do not penalize providers and patients if a loss accidentally occurs for parents who want to pursue validated prenatal interventions such as fetal surgery.

Professional Organizations and Training Accreditation Bodies of Health Care Providers Engaged in Obstetrics such as Council on Resident Education in Obstetrics and Gynecology; Maternal-Fetal Medicine; Genetic Counseling such as the Genetics Society of America; American College of Medical Genetics and Genomics; American Board of Medical Genetics and Genomics; American Board of Genetic Counseling; and the Association of Professors of Human and Medical Genetic

- Clarify that disability education and cultural awareness extend beyond examining best practices for effectively communicating with patients with disabilities and include a social and civil rights context for understanding disability (NCD 2019).
- Ensure that the materials used for provider and patient education are passed through a consensus group of reimbursed stakeholders, including representatives from affected disability communities (NCD 2019).
- Professional standards of care for offering prenatal interventions should be established through consensus negotiations that include genetic counselors, obstetrics and gynecology care providers, and representatives from affected disability communities. Commercial entities should not be allowed to market or provide prenatal interventions that have not been vetted through a professional organization using a consensus process (NCD 2019).
- Ensure that online and printed materials used for provider and patient education are fully communication accessible to people with a range of disabilities and diverse linguistic and cultural backgrounds (NCD 2019).
- Accreditation organizations must make disability education and cultural awareness mandatory and more consistent among medical and genetics education programs, within a reasonable range of time and resources. The same holds true of professional ongoing education (NCD 2019).
- Establish certification or licensure requirements to indicate clinicians are qualified to offer complex fetal surgeries.

Prenatal Intervention Researchers and Research Funders

- Require that the development of research priorities and projects for prenatal interventions include individuals with lived experience and families, and advocates or scholars grounded in disability perspectives, as consultants and decision-makers.
- Expand data collection on the current impact of prenatal intervention accuracy, outcomes, and impact on disability community.

State and Federal Public Health Officials

- Engage in the active dissemination of information about prenatally diagnosed conditions to improve patient and provider understanding of the conditions that might be identified.
- Host public forums using Health in All Policies approach to assess the potential societal impact of controversial prenatal interventions by including a range of stakeholders including people with disabilities and their families, medical and genetics professionals, disability scholars, bioethicists, and others (Rudolph et al. 2012).

National Academy of Science

- Require and fund robust inclusion of experts with disabilities as decision-makers and leaders in the development of guidelines, presentations at summits, and any other forums/publications where policies are recommended or standards are set forth for technologies that impact people with disabilities.

Health Care Corporate Governance Organizations and Health Consumer Advocates

- Establish professional guidelines and social norms requiring that the genetics and health corporations have rigorous conflict-of-interest policies, social justice informed marketing, and regular consultation from people with disabilities.

Institutional Review Boards

- Recruit people knowledgeable in maternal-fetal medicine to review pregnancy-related research proposals. Include people with the patient and family perspective and/or disability community perspective to review research proposals that would affect people with disabilities or that could exacerbate disability stigmatization or discrimination.

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