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New Legal Measures Restricting Gender-Affirming Care: *Implications for Research Ethics*

Robert Klitzman

ABSTRACT Increasingly, new legal measures are restricting the use of gender-affirming care, raising challenges not only for the medical care of transgender/gender-nonbinary individuals, but also for medical research and research ethics. These restrictions may discourage researchers from conducting various types of research with transgender/gender-nonbinary individuals, such as asking about sexual behavior and gender identity or related issues in studies of adolescents and young adults more broadly. Researchers and institutions may also face professional risks in pursuing such research. Thus, restrictions on the use of gender-affirming care have important implications for researchers, institutional review boards (IRBs), institutional officials, policy-makers, and others. Restrictions could have an impact on the design, implementation, and management of research studies, potentially requiring consent form modifications, reconsent of participants, and asking participants about possible resulting physical/legal/social problems. Researchers and IRBs need to carefully assess these shifting legal restrictions. Input from legal experts may be needed concerning the interpretation, implementation, and enforcement of local and federal legal measures for initial and continuing IRB review of research protocols and the assessment of any changes to relevant legal measures. Researchers, IRBs, and others thus need to recognize, address, and develop "best practices" regarding these new restrictions.

KEYWORDS research ethics, researchers, research institutions, institutional review boards (IRBs), gender-affirming care, LGBTQ+, policy, research, mental health

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Professional organizations have developed evidence-based standards of care to assist transgender individuals.[1] Yet increasingly in recent years, new legal measures restricting gender-affirming care have been proposed and implemented, posing critical challenges for transgender/gender-nonbinary individuals' rights and medical care, but also for research and research ethics. In 2023, state legislators introduced more than 220 bills undermining transgender/nonbinary individuals' rights and well-being, with more than 70 bills enacted, including restrictions on gender-affirming care.[2] These legal measures include categorizing gender-affirming care as "child abuse," prohibiting anyone from aiding or abetting access to gender-affirming care for young people, making provision of such care to patients under 19 years of age a felony, and requiring family and protective services departments to investigate any reported cases of providers or parents offering or seeking gender-affirming care for children. On January 28, 2025, President Trump issued an executive order that ended coverage for certain gender-affirming surgical and chemical interventions for individuals under 19 years old through TRICARE (Department of Defense health insurance) and other health benefits programs for federal employees, and made federal research and education grants and Medi-

care or Medicaid funding conditional on *not* providing such care to such individuals.[3]

Around 1.6.% of the U.S. youth population are transgender/gender-nonbinary, including 300,000 high school students, with 105,200 in states with bans on gender-affirming care.[2] Transgender youth have increased rates of depression, eating disorders, attempted suicide, and self-harm, and research is therefore vital to know how best to meet their mental health and other needs.[3] Legal measures restricting the use of gender-affirming care, generally pursued by conservative politicians, thus raise critical research ethics challenges, as well as medical, mental health, public health, ethical, legal, and policy concerns. While the effects of these restrictions in clinical and public health contexts have received some attention in the mass media,[4] the *research ethics implications* have not been examined and are thus explored here.[5]

RESTRICTIONS ON GENDER-AFFIRMING CARE: CHALLENGES FOR RESEARCH

More research about various types of gender-affirming care is needed, partly because various care interventions for transgender/gender-nonbinary individuals have raised controversies. The 2024 *Cass Review* (the *Independent Review of Gender Identity Services for Children and Young People*), a report that was commissioned by the National Health Service (NHS) of England, concluded that there was a lack of high-quality evidence about care interventions. The report noted that due to limited evidence from randomized clinical trials (RCTs) about various interventions and limited data on long-term outcomes of individuals who obtained care interventions, there is an acute need for research on care interventions.[6] For example, although the authors suggested that the NHS should pay for puberty blockers, this report also said the NHS should do this only when puberty blockers are provided as part of a research protocol to obtain evidence-based data about their safety and effectiveness.

However, conducting RCTs involving a puberty blocker raises ethical concerns since participants would know if they received a placebo that would affect the start of puberty. Moreover, participants might reach irreversible puberty by the time a clinical trial provides evidence that the puberty blocker is safe and effective, which would be too late for them to receive a gender-affirming intervention. An RCT of surgical treatment would similarly pose problems since participants would clearly know whether the surgery has been performed, and conducting sham surgery raises many ethical concerns. Of note, however, the use of gender-affirming surgery involving adolescents is rare.[7]

In other contexts, many medical treatments are considered standard of care, even though evidence for their use was not obtained from RCTs because such experiments would be unethical, impracticable, and/or have other inherent limitations.[8] In the absence of RCTs in the context of gender-affirming care, other types of studies have been filling in knowledge gaps.

Researchers, IRBs, clinicians, institutional officials, and members of the transgender and broader LGBTQ+ communities should work together to develop "best practices" for research and participants' protections.

For instance, a report published in 2023 about a longitudinal study indicated that gender-affirming hormone treatment, such as testosterone or estradiol, increased positive mood and life satisfaction and diminished depression and anxiety among 315 trans and nonbinary individuals who were 12-20 years old (mean age 16), of whom 60.3% were trans male.[9] Moreover, among adolescents, gender-affirming medical interventions are associated with less depression and suicidality.[12]

Opponents of gender-affirming care publicize stories of regretful patients and argue that restrictions protect minors from unsafe experimental treatments and irreversible medical procedures. Yet among adults, regret following gender-affirming mastectomies, the most common gender-affirming intervention, is exceedingly low (0-1%), and satisfaction very high.[10] In a recent study of 220 transgender youth, with a mean age of 16, very few reported dissatisfaction or regret about treatment. Concerning puberty blockers and hormones,

97% reported no dissatisfaction, and 94% and 96%, respectively, had no regrets. Of the nine youths with regrets, four stopped treatment, while the others chose to continue. Some regretted not the initiation of treatment, but the process of care (e.g., adverse effects or developmental delays).[14]

Instead of wholly banning gender-affirming interventions, concerns about protecting adolescents could potentially be addressed by assessing the duration of individuals' gender dysphoria to ensure long-standing consistency over time, and enhancing informed consent processes to ensure thorough, thoughtful, comprehensive and staged approaches for engagement and permission from parents and assent of minors. Indeed, the World Professional Association for Transgender Health contends that health care professionals assessing transgender and gender-diverse adolescents should only recommend gender-affirming or surgical treatments requested by the patients when:

- the experience of gender diversity/incongruence is marked and sustained over time;
- the adolescent demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment;
- the adolescent's mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been addressed; and
- the adolescent has been informed of the reproductive effects, including the potential loss of fertility and the available options to preserve fertility, and these have been discussed in the context of the adolescent's stage of pubertal development.[15]

Some opponents of gender-affirming care seek to delay such treatment for adolescents until adulthood, but by then, puberty blockers would be too late. Legal bans also violate the rights of parents who support and seek gender-affirming care for their trans offspring. Opponents argue that more evidence is needed, yet bans impede the funding and conduct of such research.

IMPLICATIONS FOR RESEARCH ETHICS

Challenges to the ability to conduct research with transgender and other adolescents. The new legal restrictions may cause fewer researchers, clinics, and institutions to have the ability or desire to study transgender/nonbinary adolescents, or to ensure they have staff with relevant training. Moreover, the restrictions pose significant challenges for researchers, IRBs, and institutions if research with adolescents asks participants about sexual behavior, gender identity, or related issues that may reveal participants' interests, needs, or plans for gender-affirming care. Research may therefore end up underrepresenting transgender/nonbinary, and consequently lesbian, gay, bisexual, transgender, questioning, or queer (LGBTQ+) populations and behaviors more generally. For instance, recruiting LGBTQ+ individuals will presumably lead to screening, and making investigators aware of, and obtaining data about transgender/nonbinary individuals. Such topics have important medical and mental health implications, and failure to probe them can significantly lower such studies' scientific and social value. Researchers may also have to report to state officials about anyone seeking gender-affirming care and may face professional and/or legal risks if they ask about these topics, pursue such research, or facilitate such care (e.g., referring participants to out-of-state providers). These risks might limit future job opportunities for research and clinical care providers.

Challenges to research design. Restrictions on gender-affirming care also have implications for study site selection, design, management, and implementation. Researchers and IRBs need to be aware of, and make arrangements for, assessing varying and fluctuating legal restrictions, and the specific nature and extent of the restrictions, and gauging whether studies need to be modified or stopped. For example, researchers and IRBs should consider whether the restrictions include penalties for aiding, abetting, or referring patients for gender-affirming care, and the likelihood of legal enforcement; whether any problems have emerged about existing legal restrictions; whether research staff or research participants have expressed concerns about the restrictions; and whether community engagement involving the research has occurred, and if so, who was included and when. Researchers, IRBs, and institutions also need to be aware of whether gender-affirming care is available locally or elsewhere, and research staff need to be educated and prepared about potential legal and/or professional risks for discussing such care. Given

these evolving legal challenges, researchers and IRBs should seek legal expertise concerning the interpretation, implementation, and enforcement of local and federal legal restrictions; consult with appropriate experts regarding initial and continuing IRB review of research protocols; and ask researchers affected by legal restrictions whether the restrictions have changed, and if so, with what possible research implications. Single IRBs reviewing research in multiple states, some of which may have legal restrictions on gender-affirming care, must be especially vigilant.

Challenges to participant privacy and confidentiality. Researchers, in conjunction with their IRBs, may need to establish special provisions for data privacy and incorporate these protections into study design and implementation, keeping links with study codes offsite and encrypting data appropriately. Despite the Health Insurance Portability and Accountability Act of 1996, legal action may necessitate information disclosure about participants in a study who are receiving or have received gender-affirming care. Certificates of Confidentiality obtained for research supported by the National Institutes of Health may potentially be helpful, but their effectiveness remains uncertain and unclear, since these documents have certain inherent limitations and there are few published court cases about the strength of their protections.[16]

Challenges concerning informed consent. Researchers may need to modify informed consent forms (e.g., regarding legal restrictions and consequent risks), reconsent participants, and consider online, not in-person, study interactions and interventions, which can, however, restrict participants who have less technological literacy or access. Informed consent forms may need to specify possible present or legal threats to privacy and confidentiality resulting from restrictions on gender-affirming care.

Researchers' roles and responsibilities. Researchers, in consultation with their IRBs, should also establish processes and approaches to reduce, monitor, and manage economic, social, and/or other harms research participants may experience. At study visits, research participants should be asked about any physical, legal, social, or economic problems they and/or their partners have experienced resulting from restrictions on gender-affirming care. Researchers have ancillary care obligations to potentially help address such problems and should thus establish or modify the study's design or standard operating procedures accordingly. Researchers and IRBs should recognize how research involving certain groups (e.g., undocumented youth) raise additional concerns. Researchers should also take into consideration the impact that the legal restrictions on gender-affirming care may have on physical/mental health treatment for research participants and stigmatize participants' experience, and gather data on how frequently such challenges arise in various research sites and how these challenges can best be managed.[17] Data and safety monitoring boards should consider safety issues for clinical trials conducted in the context of restrictions on gender-affirming care and what stopping rules may be required if such restrictions significantly shift a clinical trial's risk/benefit ratio.

FUTURE DIRECTIONS

Legal measures restricting gender-affirming care are threatening to impede critical medical, psychosocial, and public health research regarding transgender/nonbinary as well as other LGBTQ+ individuals more broadly in several evolving ways. Researchers, IRBs, clinicians, institutional officials, and members of the transgender and broader LGBTQ+ communities should work together to develop "best practices" for research and participants' protections, drawing on the issues presented above. Guidelines and materials on how best to gauge and manage these issues and inform patients and research participants about these individuals' rights should be developed and disseminated to researchers and their staff, IRBs, relevant institutional officials, clinicians, policy-makers, and others. Researchers should also be prepared to provide participants, parents, and partners with psychological and legal support (e.g., with changing legal name and gender), engage with and help community organizations, and work with public interest law groups to assist with community and organizational resilience. Policy-makers should consider the potential negative impacts that restrictions on gender-affirming care could have on research. ♦

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