The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Bioethics Collaborative

Tuesday, September 10, 2024 | 10:00 AM – 12:30 PM ET
Hybrid Meeting

Impact of *Dobbs* on Reproductive Health: Unintended Consequences for/on Research

Introduction

Roe v. Wade was passed over 50 years ago, on January 22, 1973, establishing constitutional protections for the right to abortion within the United States. Although the U.S. Supreme Court repeatedly reaffirmed this right as an essential liberty, tied to other liberty rights to make personal decisions about family, relationships, and bodily autonomy, in 2022, the Supreme Court overturned *Roe v. Wade* in the case of *Dobbs v. Jackson Women's Health Organization*, striking down the federal right to abortion thereby allowing individual states to restrict or inhibit abortion.

Since *the Dobbs* ruling, states have taken various approaches to abortion. Fourteen states have made abortion illegal, and about half of the remaining states have either partially restricted or have indicated that they are likely to place limitations on abortion (such as rape, incest, and/or risk of harm to the pregnant person. This also includes the potential imposition of criminal penalties. Helpfully, many of the remaining states have taken steps to protect existing rights to abortion and/or expand those rights through legislation, amending state constitutions, as well as other laws and policies, creating additional access to abortion care. In some other states, abortion may continue to be accessible as a matter of fact but is not currently protected by state or territory law.

These new dynamics at the state level have had unintended impacts on clinical research. In many clinical trials, the investigational therapy under evaluation or other trial interventions may expose a developing embryo or fetus to various known and unknown risks (including, for example, the risk of DNA damage and birth defects from genotoxic agents). As a result, clinical trials often exclude people who are pregnant and require periodic pregnancy testing in addition to the use of effective contraceptive measures. While documentation of pregnancy testing and pregnancy status is needed to ensure safety and scientific integrity, these practices can expose

participants and research staff to legal liability in jurisdictions with restrictive abortion laws by providing a record that, in some cases, might permit inferences about whether a pregnancy has been terminated.

Presentations and Discussion

After an introductory presentation, the discussion touched briefly on the impact that *Dobbs* might pose on decisions about site selection and where to conduct trials. Although data are scarce, the group agreed that it is unlikely that sponsors are avoiding establishing trial sites in states with restrictive abortion laws. It was also noted that such a practice may raise concerns about the fair selection of participants (justice) and generalizability based on limited geography. The discussion then turned to informed consent. The group agreed that participants must know about the pregnancy risks of investigational medical products but also understand the privacy risks involved with data collection related to pregnancy generally. While potential risks to pregnancy and the developing fetus are generally described in consent materials, disclosure of *privacy* risks related to pregnancy specifically is variable and does not always occur. There was discussion among the group over who is responsible for ensuring that participants are informed and whether IRBs should require additional consent language concerning pregnancy privacy risks as part of their review. The group identified a need for a model or template consent disclosure language that could be used across studies to inform participants.

The group heard various perspectives on abortion issues related to clinical trials, which particularly highlighted legal and privacy concerns. Potential trial participants' concerns include hesitancy to enroll due to fears of legal consequences, while recruited/enrolled participants may be reluctant to share sensitive health information for similar reasons. Providers have reported that they fear offering either care or information related to pregnancy termination that could expose them to legal risks. These concerns are compounded by variations in state laws and regulations, leading to inconsistent IRB approaches to research that involves pregnancy, whether pregnancy is the condition being studied (e.g., treatments for pre-eclampsia or infertility) or not (e.g., treatments of diseases that occur in people that are or may become pregnant such as migraine, systemic lupus erythematosus, or cancer). Inconsistencies, coupled with fear of both direct exposure and deductive disclosure (i.e., the possibility of inferring sensitive information about pregnancy from seemingly unrelated information), increase the risk of the research, change the IRB review and approval process, and potentially hinder both research and care.

Additionally, concerns were raised about how the use of third-party platforms could risk the security and protection of research data. The protections of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) generally do not apply to, and Certificates of Confidentiality (CoCs) do not bind such platforms. CoCs protect the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except in rare circumstances or when the participant consents. Whenever CoCs are issued, the responsibility rests with the investigator and institution to uphold the protections; unless third-party vendors accept the responsibility by contract or through a business associate agreement (BAA), they would likely be unfamiliar with CoCs. Contracts and BAAs would, therefore, need to specify that vendors must alert the investigator and institution to any legal demand for disclosure that they receive so that the institution can assert the CoC protections. Institutions may not appreciate how far their responsibilities extend and how they must enforce policies that will ensure data protection. It is noteworthy that HIPAA and CoCs protect participants and patients, but they do not protect providers and research staff, leaving them vulnerable when conducting research in states with legal repercussions.

MRCT Center Bioethics Collaborative attendees considered the challenges that investigators, clinicians, and healthcare systems face in a post-*Dobbs* era. In certain states, involvement in any abortion care, whether in a clinic or research setting, can lead to legal action, including revocation of medical licensure or criminal penalties. Should investigators, clinicians, and clinical research staff conduct research in states with restrictive abortion laws? Given that no cases have yet arisen involving clinical research since the *Dobbs'* decision, the actual risks are difficult to evaluate.

Some states have adopted laws that criminalize aiding and abetting abortion, which could encompass verbal advice, educational materials, and any other form of abortion information. Such laws create additional legal risks for investigators and sponsors. Additionally, some anti-abortion advocates are pressing to reinvigorate the 1873 Comstock Act, an anti-vice law that prohibits the shipping and receiving of drugs that can terminate pregnancies safely. Together, these actions create a hostile environment for participants and an understandable fear of safety and security. While these laws are evolving and have not been tested in a court of law, the fear of legal proceedings, financial losses, and the potential time and effort costs currently result in hesitancy to engage in abortion and "abortion-adjacent" research. The group discussed

the need to ensure that participants are safe and feel safe when enrolling in a trial; researchers should consider which safety precautions should be introduced specifically to address privacy concerns and what information should be communicated during the informed consent process. The attendees recognized the importance of developing informed consent templates and guidance on what should and should not be included.

The group then discussed how CoCs can ease some of the concerns for research post-*Dobbs*. As a federal tool to protect the disclosure of identifiable data, CoCs have been upheld in courts of law, although untested in the post-*Dobbs* era. Significant revisions of CoCs in 2016 mandated that all federally funded research issue a certificate; in practice, they are deemed to have been issued. However, investigators conducting non-federally funded research must specifically apply for CoCs on a per-study basis, and not all funders or investigators know that CoCs exist for their research or that they must apply. Further, requests for CoCs can be denied. Reasons for and frequency of denial, if known, were not discussed.

The group agreed that institutions and research staff in abortion-restrictive states need further training on what CoC protections entail and how to handle legal requests for participant data. *All* copies of participants' data are protected, and institutions retain responsibility for their third-party vendors. Bioethics Collaborative attendees urged institutions to review and/or execute contracts with third-party vendors who store, transport, and analyze participant data to ensure privacy protections. A comprehensive review of terms of services, cookies, and other practices is encouraged.

Lastly, the group focused on the possibility of weaponizing data in an era of social media, the internet, and Artificial Intelligence (AI) platforms. Individual internet activity related to pregnancy and abortion can be tracked and could potentially be used against individuals in states with abortion restrictions. Research staff should educate potential participants about these risks and how to protect themselves and their data while participating in research.

[Note, related to the MRCT Center Bioethics Collaborative meeting but not specifically discussed at the meeting, the U.S. District Court for the Northern District of Texas issued an

order declaring unlawful and vacating a portion of the OCR guidance document[1] specifically relating to the use of cookies and other tracking technology. See Am. Hosp. Ass'n v. Becerra, — F. Supp. 3d ----, No. 4:23-cv-1110, 2024 WL 3075865 (N.D. Tex. June 20, 2024). The OCR guidance addressed the responsibilities to data protection—most particularly on hospital and service provider websites—to ensure tracking technology for these services cannot be obtained by Facebook, Google, and other third parties providing abortion-related services. How the OCR guidance will be interpreted and applied remains uncertain since the Texas case more generally addressed the right of OCR to prohibit tracking technologies on unauthenticated websites (for example, when a patient does not sign into a website to confirm identity but is otherwise searching the website for health information more generally).]

Bioethics Collaborative attendees agreed that there was a need to address the ethical issues on the impact of Dobbs on reproductive health and its consequences on research. The meeting concluded with recommendations for potential future work, including addressing sponsors' use of CoCs for protection from privacy risks, the creation of informed consent templates and guidance, and the development of educational tools.

[1] US Department of Health and Human Services. Office for Civil Rights. Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates. June 26, 2024, Available at: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-online-tracking/index.html. Accessed 24 October, 2024.