Secondary Research Protocol

Colorado Multiple Institutional Review Board (COMIRB)
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Protocol #:
Project Title: What is emergent enough? Quantifying life-threatening pregnancy complications for a post-Dobbs world
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I. Hypotheses and Specific Aims

In this exploratory study, we aim to describe the prevalence of chronic and pregnancy-related disease to quantify the health impact of abortion restrictions.

II. Background and Significance

In June 2022, the Supreme Court of the United States overturned *Roe v. Wade* which established a Constitutional right to abortion access through fetal viability in the United States (US). In the subsequent year and a half, 15 states now ban abortion with limited exceptions and several additional states have further restrictions in various stages of litigation or legislation. Many of the states that have banned abortion also have the highest maternal mortality among US states, which abortion bans are projected to worsen.[1,2]

One reason for the anticipated increase in maternal morbidity and mortality caused by decreased abortion access is that pregnancy puts significant physiologic strain on pregnant people. At baseline, people are 14 times more likely to die during childbirth than during an abortion.[3] However, those with chronic health conditions or pregnancy-related diseases face even greater risk magnitude which abortion can avert or reverse. While most states have exceptions for maternal health, laws are either so narrowly drawn or vague that people will still be unable to access abortions when they need them due to provider fears of prosecution. For example, pulmonary hypertension (high blood pressure in the lungs) causes mortality in pregnancy 9-17% of the time even with optimal management.[4] Some abortion laws only allow for abortion in the setting of a medical emergency. If a person with pulmonary hypertension has an early pregnancy in which they are not yet sick but would be at high risk of morbidity or mortality if the pregnancy continued, some state laws might still not allow an abortion. In this project, we aim to **describe the prevalence of chronic and pregnancy-related disease to quantify the health impact of abortion restrictions.**

III. Research Methods

A. Description of Population to be Studied

The dataset will include all claims related to a pregnancy-related encounter in Colorado and Virginia in the All-Payer Claims Database between 2018-2020.

B. Data/Sample Collection

This project will use data from a novel source, an all payer's claim dataset from Colorado and Virginia. Historically, health care data on adults less than 65 is often fragmented because it occurs in different settings (clinics, hospitals, emergency departments) and has multiple payors (commercial insurers, Medicaid, Medicare). We plan to use three years (2018, 2019, 2020) of Virginia and Colorado data which can be a foundation for future studies including using datasets restricted to one payer or all-payer data from addtional states. Please see the attached appendix "CIVHC Data Request Form v18Jan2024" for a full list of variables in the dataset requested.

C. Study Design

Using codes that identify diagnoses, procedures and surgeries (i.e., International Classification of Diseases (ICD) and Current Procedural Terminology (CPT)) as well as demographic information about the patients, we can use this dataset to identify pregnant people and common conditions that threaten maternal health. Box 1 lists some chronic conditions that may worsen with pregnancy and be an indication for prevention of unwanted pregnancy and, in some cases, abortion. We will use similar coding schemes to identify complications of pregnancy that may also threaten maternal health and may be indications for abortion.

Not all individuals facing potential pregnancy complications will choose to have an induced abortion. We will characterize pregnancy outcomes (live birth, miscarriage, ectopic pregnancy, stillbirth, induced abortion) as well as any sequelae that may be related to underlying conditions. We will use findings on the prevalence of underlying health conditions to model the population impact of legal changes to abortion access.

D. Statistical Considerations

This will be a descriptive study. We will use two-way χ^2 analyses to yield frequencies and confidence intervals. Logsitic regression modeling will be used to generate relative risk estimates for covariates, including age and race.

E. Potential Scientific Problems

This is a claims based database study with inherent limitations in proper identification of cases and associated diagnoses and/or procedures. In addition, because we are comparing multiple states, differences in data collection may affect true incidence rates. In addition, these databases are not able to capture services that do not have insurance claims, including self-pay services, which is common for abortion related services. Nevertheless, previous literature has not been used an all-payors claims database to describe our proposed research questions.

F. Summarize Knowledge to be Gained

We will use findings on the prevalence of underlying health conditions to model the population impact of legal changes to abortion access. Our team is especially interested in health disparities. Already, non-Hispanic Black women have three times greater maternal mortality than other groups. Abortion bans are projected to worsen health disparities because of the racial and ethnic demographics in states banning abortion, economic limitations on ability to travel out-of-state to seek abortion care, and disparate access to health care in general. Virginia is a reasonable state for analysis because of its geographic location in the South, maternal mortality rates indicating a population with significant comorbidities, geographic variation in both distance and access to care, and availability of data. Colorado provides additional diversity to medical co-morbidities, racial and ethnic diversity to the data analysis given its location in the western United States. We hope to eventually use demographic and social risk factors from the

Virginia to also help make projections generalizable to other states in the South. This may help advocacy efforts to maintain abortion access.

G. Risks

There is a risk that people outside of the research team will see the research information collected. All electronic information will be downloaded as de-identified or limited data for purposes of data analysis on secure, HIPAA protected server. Only research team members will have access to this database. We will do all that we can to protect the information, but it cannot be guaranteed.

H. Collaborations

This is a research collaboration between the University of Colorado and Duke University. The University of Colorado will be solely responsible for the database of Colorado claims while Duke University will be solely responsible for the database of Virginia claims. Identifiers will not be shared between institutions. Only de-identified analyses will be shared between the teams to report multi-state results. Identifiers will not be shared between institutions.

I. References

1. Koerth M. Overturning Roe v. Wade Could Make Maternal Mortality Even Worse. FiveThirtyEight. Published May 31, 2022. Accessed October 12, 2022. https://fivethirtyeight.com/features/overturning-roe-v-wade-could-make-maternal-mortality-even-worse/

2. Stevenson AJ. The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant. *Demography*. 2021;58(6):2019-2028. doi:10.1215/00703370-9585908

3. Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. *Obstet Gynecol*. 2012;119(2 Pt 1):215-219. doi:10.1097/AOG.0b013e31823fe923

4. Coursen J, Simpson CE, Mukherjee M, et al. Pregnancy Considerations in the Multidisciplinary Care of Patients with Pulmonary Arterial Hypertension. *J Cardiovasc Dev Dis*. 2022;9(8):260. doi:10.3390/jcdd9080260