IN THE SUPREME COURT OF WISCONSIN
NO. _____

PLANNED PARENTHOOD OF WISCONSIN,
on behalf of itself, its employees, and its patients,

KATHY KING, M.D.,

and

ALLISON LINTON, M.D.
on behalf of themselves and their patients,

and

MARIA L.,

JENNIFER S.,

LESLIE K.,

and

ANAIS L.,

Petitioners,

v.

JOEL URMANSKI, in his official capacity as District Attorney
for Sheboygan County, Wisconsin,
615 North 6th Street, First Floor
Sheboygan, Wisconsin 42081

ISMAEL R. OZANNE, in his official capacity as District Attorney
for Dane County, Wisconsin,
215 South Hamilton Street, #3000
Madison, Wisconsin 53703

and,

JOHN T. CHISHOLM, in his official capacity as District Attorney
for Milwaukee County, Wisconsin,
821 West State Street, Room 405
Milwaukee, Wisconsin 53233

Respondents, as Class Representatives for
all Wisconsin District Attorneys.

AFFIDAVIT OF COUNSEL FOR PETITIONERS

STATE OF WISCONSIN)
) ss
COUNTY OF DANE)

Diane M. Welsh, being first duly sworn on oath, deposes and says:

1. I am an attorney licensed to practice law in the State of Wisconsin and I am one of the attorneys who represent the Petitioners Planned Parenthood of Wisconsin, Dr. Kathy King, Dr. Allison Linton, Maria L., Jennifer S., Leslie K., and Anais L. in this matter.

2. Attached hereto are copies of various authorities cited in the Petitioners' Petition to the Wisconsin Supreme Court to Take Jurisdiction of an Original Action.

3. Attached hereto as Exhibit A is a true and correct copy of the article titled "Unexpected Complications of Low-Risk Pregnancies in the United States,"

Am. J. Obstetrics & Gynecology, published June 2015, retrieved from https://pubmed.ncbi.nlm.nih.gov/26042957/.

4. Attached hereto as Exhibit B is a true and correct copy of the article titled, "Placenta Accreta: Risk Factors, Perinatal Outcomes, and Consequences for Subsequent Births," Am. J. Obstetrics & Gynecology, published 2013, retrieved from https://www.ajog.org/article/S0002-9378(13)00004-5/abstract.

5. Attached hereto as Exhibit C is a true and correct copy of the article, "Overview of Ectopic Pregnancy Diagnosis, Management, and Innovation," Women's Health, published Mar. 2023, retrieved from https://journals.sagepub.com/doi/10.1177/17455057231160349.

6. Attached hereto as Exhibit D is a true and correct copy of the article titled, "Pregnancy Complications and Long-Term Mortality in a Diverse Cohort," Circulation, published Mar. 2023, retrieved from https://www.ahajournals.org/doi/epub/10.1161/CIRCULATIONAHA.122.062177.

7. Attached hereto as Exhibit E is a true and correct copy of the article titled, "Trends in Maternal Mortality and Severe Maternal Morbidity During Delivery-Related Hospitalizations in the United States, 2008-2021," JAMA Network Open, published June 2023, retrieved from https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2806478.

8. Attached hereto as Exhibit F is a true and correct excerpt from the article titled, "The Safety and Quality of Abortion Care in the United States," Nat'l Acads. Of Scis., Eng'g, and Med. ("NASEM"), published 2018.

9. Attached hereto as Exhibit G is a true and correct copy of the article titled, "The Comparative Safety of Legal Induced Abortion and Childbirth in the United States," Obstetrics & Gynecology, published 2012.

10. Attached hereto as Exhibit H is a true and correct copy of the Affidavit of Dr. Christopher Ford, *Kaul v. Urmanski*, No. 2022CV001594 (Wis. Cir. Ct. Dane Cnty. June. 28, 2022), at Dkt. 165.

11. Attached hereto as Exhibit I is a true and correct copy of the Affidavit of Dr. Jennifer Jury McIntosh, *Kaul v. Urmanski*, No. 2022CV001594 (Wis. Cir. Ct. Dane Cnty. June. 28, 2022), at Dkt. 166.

12. Attached hereto as Exhibit J is a true and correct copy of the Affidavit of Dr. Kristin Lyerly, *Kaul v. Urmanski*, No. 2022CV001594 (Wis. Cir. Ct. Dane Cnty. June. 28, 2022), at Dkt. 164.

13. Attached hereto as Exhibit K is a true and correct copy of the article titled, "Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion," Am. Fam. Physician (2021).

14. Attached hereto as Exhibit L is a true and correct copy of the American Medical Association's Principles of Medical Ethics, retrieved from https://code-medical-ethics.ama-assn.org/principles.

15. Attached hereto as Exhibit M is a true and correct copy of the article titled "Principles of Clinical Ethics and Their Application to Practice," Med. Principles & Prac. (2021).

16. Attached hereto as Exhibit N is a true and correct copy of the article "Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008-2014," Am. J. Pub. Health (2017).

17. Attached hereto as Exhibit O is a true and correct copy of the Plaintiffs' Original Verified Petition for Declaratory Judgment and Application for Temporary Restraining Order and Permanent Injunction in Cox v. Texas, No. D-1-GN-008611 (Dist. Court of Travis Cnty., Texas 2023).

18. Attached hereto as Exhibit P is a true and correct copy of the abstract of the article titled "Education and Labor Market Consequences of Teenage Childbearing," J. Human Resources (2009), retrieved from https://jhr.uwpress.org/content/44/2/303.

19. Attached hereto as Exhibit Q is a true and correct copy of the article titled "Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children," J. Pediatrics (2019).

20. Attached hereto as Exhibit R is a true and correct copy of the advertisement titled, "New and Improved Edition of that Most Extraordinary Work: Married Woman's Private Medical Companion," Wis. Express. (1849).

21. Attached hereto as Exhibit S is a true and correct copy of the advertisement titled "Wholesale and Retail Dealer in Drugs, Medicinds, Paints, Oils, Dye Stufs, Glass, Putty. Sash," Wis. Standard (1849).

22. Attached hereto as Exhibit T is a true and correct copy of the article titled "The Composition of Certain Secret Remedies: VIII. 'Female Medicines,'" Brit. Med. J. (1907).

23. Attached hereto as Exhibit U is a true and correct copy of the article titled "Sheboygan County D.A. says he'll prosecute providers accused of performing abortions in violation of state law," WTMJ-TV News Report (June 28, 2022), retrieved from www.tmj4.com/news/local-news/sheboygan-county-d-a-says-hell-prosecute-providers-accused-of-performing-abortions-in-violation-of-state-law.

24. Attached hereto as Exhibit V is a true and correct copy of the Complaint in *Kaul v. Urmanski*, No. 2022CV001594 (Wis. Cir. Ct. Dane Cnty. June. 28, 2022), Dkt. 4.

25. Attached hereto as Exhibit W is a true and correct copy of the December 5, 2023 Decision and Order in Kaul v. Urmanski, No. 2022CV001594 (Wis. Cir. Ct. Dane Cnty. June. 28, 2022), at Dkt. 183.

26. Attached hereto as Exhibit X is a true and correct copy of the Wisconsin Department of Health Services' Wisconsin Interactive Statistics on Health, Wisconsin Population Module, 2022, retrieved from https://www.dhs.wisconsin.gov/wish/index.htm.

27. Attached hereto as Exhibit Y is a true and correct copy of the Wisconsin Department of Safety and Professional Services report titled "License Counts," (Jan. 31, 2024), retrieved from https://dsps.wi.gov/Credentialing/General/LicenseCounts.pdf.

28. Attached hereto as Exhibit Z is a true and correct copy of the article titled "Interpregnancy Care," Am. Coll. Obstetricians and Gynecologists (Jan. 2019), retrieved from https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2019/01/interpregnancy-care.

29. Attached hereto as Exhibit AA is a true and correct copy of the working paper titled "Estimating Causal Effects of Fertility on Life Course Outcomes: Evidence Using A Dyadic Genetic Instrumental Variable Approach," (Feb. 2023), retrieved from https://www.nber.org/system/files/working_papers/w30955/w30955.pdf.

30. Attached hereto as Exhibit BB is a true and correct copy of the article titled "The Effect of Teenage Childbearing on Adult Soft Skills Development," J. Popular Econ. (2016), retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6049085/#:~:text=We%20find%20that%20teenage%20childbearing%20has%20a%20negative%20effect%20on,a%20child%20as%20a%20teenager.

31. Attached hereto as Exhibit CC is a true and correct copy of the article titled "Republican lawmakers reject special session Evers called to end 1849 abortion law," published June 22, 2022, retrieved from https://www.jsonline.com/story/news/politics/2022/06/22/wisconsin-republicans-gavel-out-tony-evers-special-session-abortion-laws/7691460001/.

Diane M. Welsh

Signed and sworn to before me
this 21 day of February 2024.

LISA PEASE
Notary Public
State of Wisconsin

Notary Public, State of Wisconsin
My Commission expires: 9/23/25

EXHIBIT A

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Unexpected complications of low-risk pregnancies in the United States

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Abstract

OBJECTIVE—Determining appropriate sites of care for any type of medical issue assumes successful matching of patient risks to facility capabilities and resources. In obstetrics, predicting patients who will have a need for additional resources beyond routine obstetric and neonatal care is difficult. Women without prenatal risk factors and their newborns may experience unexpected complications during delivery or postpartum. In this study, we report the risk of unexpected maternal and newborn complications among pregnancies without identified prenatal risk factors.

STUDY DESIGN—We conducted a cross-sectional investigation utilizing US natality data to analyze 10 million birth certificate records from 2011 through 2013. We categorized pregnancies as low risk (no prenatal risk factors) or high risk (at least 1 prenatal risk factor) according to 19 demographic, medical, and pregnancy characteristics. We evaluated 21 individual unexpected or adverse intrapartum and postpartum outcomes in addition to a composite indicator of any adverse outcome.

RESULTS—Among 10,458,616 pregnancies, 38% were identified as low risk and 62% were identified as high risk for unexpected complications. At least 1 unexpected complication was indicated on the birth certificate for 46% of all pregnancies, 29% of low-risk pregnancies, and 57% of high-risk pregnancies. While the risk for unexpected or adverse outcomes was greatly reduced for the low-risk group compared to the high-risk group overall and for several of the individual outcomes, low-risk pregnancies had higher risks of vacuum delivery, forceps delivery, meconium staining, and chorioamnionitis compared to high-risk pregnancies.

CONCLUSION—Of births, 29% identified to be low risk had an unexpected complication that would require nonroutine obstetric or neonatal care. Additionally, for select outcomes, risks were higher in the low-risk group compared to the group with identified risk factors. This information is important for planning location of birth and evaluating birthing centers and hospitals for necessary resources to ensure quality care and patient safety.

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The authors report no conflict of interest.

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Keywords

labor and delivery; labor complications; obstetric delivery; pregnancy; pregnancy outcomes

Women and their providers are presented with a range of choices with respect to the types of facilities providing obstetric care for labor and delivery. Within the hospital setting, facilities range from regional care settings offering advanced care for maternal and neonatal complications, to midwifery-attended birthing centers offering supportive care for uncomplicated pregnancies.[1,2] After decades of decreasing frequency of home births, recent trends have shown increases in out-of-hospital births, both in the home and at freestanding birthing centers.[3] The role of different birth settings in the care of pregnant women considered to be at low risk for unexpected or adverse outcomes continues to be a subject of controversy, particularly among supporters and opponents of home birth.[4–14]

The decision to deliver in any location other than a specialty-care hospital assumes that labor and delivery complications can be predicted with some degree of certainty and truly “low-risk” pregnancies can be identified.[2] In practice, this has yet to be realized and unexpected labor and delivery complications remain a concern.[15–17] Additionally, transfer rates to a hospital during labor or soon after delivery for planned births at home or in a birthing center have ranged from 15–34% in observational studies,[18–22] and 13–77% in a review of randomized or quasi-randomized controlled trials.[23] While these and other studies have compared outcomes among planned or actual nonhospital vs hospital births,[4,11,18–30] such comparisons are potentially biased by women’s self-selection of location of delivery. Only a few studies have examined outcomes among women identified as low risk for adverse outcomes regardless of birth setting.[31,32] We expand on these studies by evaluating risk of unexpected complications in a large, population-based data set of recent births.

In this study, we assessed the risk of medical complications of labor and delivery or use of clinical resources beyond routine obstetric and neonatal care among deliveries expected to be at low risk for such outcomes based on pre-pregnancy and pregnancy risk factors. We quantified the absolute risk of unexpected intrapartum or postpartum complications among all pregnancies and by risk status, and compared the risk of these outcomes between low-risk and high-risk pregnancies.

Materials and Methods

We analyzed data from the 2011 through 2013 US natality files, which consists of select vital statistics information compiled from birth certificates of every birth in the United States. During 2011 through 2013, states utilized either the 1989 or 2003 revision of the US birth certificate. To be consistent and informative of current practice, we restricted the sample to records with the 2003 revision format.

The following characteristics were used to identify pregnancies as low risk: maternal age 20–39 years, gestational age at delivery 37–42 weeks as defined by the obstetric/clinical estimate of gestation, prepregnancy body mass index <30, prenatal care initiated by the sixth month of pregnancy, singleton pregnancy, and cephalic presentation.[25,33,34] Additionally,

we required low-risk mothers to have no evidence of any of the following conditions: prepregnancy diabetes, gestational diabetes, prepregnancy hypertension, history of preterm birth, history of poor pregnancy outcome, history of cesarean delivery, cervical cerclage, premature rupture of membranes, receipt of tocolytics, congenital anomalies (including anencephaly, meningomyelocele/spina bifida, congenital diaphragmatic hernia, omphalocele, gastroschisis, limb reduction defect, cleft lip with or without cleft palate, cleft palate alone, and Down syndrome), syphilis, hepatitis B, and hepatitis C.[35] Pregnancies meeting all of the aforementioned definitions were classified as low risk, and all remaining pregnancies were classified as high risk, having at least 1 prenatal risk factor. For each variable examined, responses of “unknown/not stated” resulted in assignment to the high-risk group, to maintain a strict definition of low risk.

Adverse medical outcomes and additional clinical resource use beyond routine care included the following: eclampsia, chorioamnionitis, meconium staining, uterine rupture, forceps delivery, vacuum delivery, cesarean delivery, maternal transfusion, unplanned hysterectomy, unplanned other maternal operation, admission to adult intensive care unit, mother transfer, birthweight <2500 g, 5-minute Apgar score 0–3, assisted ventilation for the newborn, admission to neonatal intensive care unit, newborn surfactant use, newborn antibiotic use, newborn seizures, birth injury, and infant transfer. A composite indicator of at least 1 unexpected or adverse outcome divided births with any of the individual outcomes and births with none of the individual outcomes. For each outcome variable, responses of “unknown/not stated” were assumed not to have the outcome.

Analyses were performed using software (SAS 9.3; SAS Institute Inc, Cary, NC). We tabulated frequencies of each low-risk characteristic, overall low-risk designation, each unexpected complication, and the composite outcome indicator. We determined the frequency of unexpected complications among low-risk and high-risk pregnancies. We calculated the relative risk and 95% confidence interval (CI) for the relationship between low-risk vs high-risk pregnancy and unexpected or adverse outcomes. We repeated the analysis stratifying by parity: no prior live births (primipara) vs at least 1 prior live birth (multipara). Finally, we conducted a sensitivity analysis to assess the impact of missing data by excluding observations with missing or unknown responses for any of the risk or outcome variables and repeating the analysis. The study was exempt from review by the Women and Infants Hospital of Rhode Island Institutional Review Board (#12-0040).

Results

Among the 11,862,780 births in the United States from 2011 through 2013, 10,458,616 (88%) submitted vital records data using the 2003 revision of the birth certificate and were included in our analysis. For each of the 19 risk characteristics, between 73–100% of women were classified as low risk, and for 12 of the 19 characteristics, at least 95% of women were classified as low risk (Table 1). However, only 38% of pregnancies met the low-risk criteria for each of the 19 characteristics and were classified overall as low risk based on prenatal risk factors (Table 1).

We examined 21 individual unexpected complications in addition to the composite outcome indicator. Among all births, the most common outcomes were cesarean delivery (33%), low birthweight (8%), admission to the neonatal intensive care unit (8%), and meconium staining (5%) (Table 2). The remaining unexpected complications each occurred in <5% of births. Of births, 46% had at least 1 unexpected complication reflected in the composite outcome measure.

Among the 4,011,139 low-risk pregnancies, 29% had at least 1 of the 21 unexpected complications studied (Table 2). The most common outcomes in the low-risk group were cesarean delivery (15%), meconium staining (5%), and vacuum delivery (4%). Among the 6,447,477 births with at least 1 risk factor identified during pregnancy, 57% had at least 1 of the 21 unexpected complications. As expected, low-risk pregnancies had a lower risk of unexpected complications than high-risk pregnancies; however, there were 4 individual outcomes where the risk was actually higher for the low-risk group than the high-risk group: vacuum delivery (risk ratio [RR], 1.60; 95% CI, 1.59–1.61), forceps delivery (RR, 1.50; 95% CI, 1.48–1.53), positive meconium staining (RR, 1.16; 95% CI, 1.15–1.16), and chorioamnionitis (RR, 1.10; 95% CI, 1.09–1.11) (Table 2).

Of mothers, 40% had no prior live births (primipara), and 60% had at least 1 prior live birth (multipara). A higher proportion of primipara pregnancies were low risk (43%) compared to multipara pregnancies (35% low risk). The risks of unexpected complications were similar for high-risk primipara pregnancies (56% with at least 1 complication) and multipara high-risk pregnancies (58% with at least 1 complication). However, unexpected complications were much less common for low-risk multipara pregnancies (19% with at least 1 complication) than low-risk primipara pregnancies (41% with at least 1 complication).

To determine the impact of missing data, a sensitivity analysis was performed. Among the 19 risk variables and 21 outcome variables, the proportion of observations with missing or unknown responses for each variable ranged from 0.0–4.4%. Overall, 1,076,009 observations (10.3%) had at least 1 risk or outcome variable that was missing or unknown and were excluded as part of the sensitivity analysis. In the restricted sample, 43% of observations were low risk and 46% had an unexpected complication (compared to 38% and 46%, respectively, in the unrestricted sample). Among low-risk pregnancies, 29% had an unexpected complication, compared to 29% in the unrestricted sample. Among high-risk pregnancies, 59% had an unexpected complication, compared to 57% in the unrestricted sample.

Comment

In this study, we used a population-based data set to identify low-risk pregnancies and assess unexpected complications among US births. Using strict criteria to identify low-risk pregnancies that included 19 different qualifying characteristics, we classified 38% of pregnancies as low risk. Among low-risk pregnancies, we found that 29% had at least 1 unexpected complication. This nontrivial risk for unexpected or adverse outcomes should be considered when planning where labor and delivery will occur because women planning a

delivery in a low-level facility can unexpectedly require advanced levels of care, even when the pregnancy is seemingly low risk.

The main strength of our study is the use of a large, population-based data set of recent births with universally abstracted data components. The use of these nationwide data reduces the potential for selection bias and improves the generalizability of our findings. There are a few limitations that warrant discussion. First, birth certificate data are subject to issues with data validity and completeness. Authors of studies that examined the 1989 revision of the US certificate of birth raised concerns over the use of birth certificate data for surveillance or research purposes because of low levels of reporting or agreement for certain variables.[36–40] While authors of more recent studies evaluating the 2003 revision of the US certificate of birth continue to identify wide ranges in validity across variables, they also note improvements in the validity of birth certificate data over time.[41–46] In general, it has been found that information on demographics, parity, gestational age, birthweight, Apgar scores, and delivery method are more accurate than information on maternal comorbidities, pregnancy complications, complications of labor and delivery, and congenital anomalies, with conflicting reports of accuracy for prenatal care and obstetric history.[36,38–41,43,44,46] For most items, there is high specificity but concern for underreporting of conditions and procedures.[42–45] If there is low sensitivity for the risk variables in our study, a portion of high-risk persons may have been misclassified as low risk due to lack of evidence of a risk condition. However, high specificity and suboptimal sensitivity would also suggest that persons identified with an unexpected or adverse outcome actually have that outcome, and so the true frequencies of adverse outcomes are at least as high as those observed.

Second, for the low-risk characteristics, responses of “unknown” or “not stated” were assigned to the high-risk group. This likely resulted in misclassification, because the probability of being high risk for any individual characteristic was low. Therefore, we prioritized the low-risk group to be truly low risk at the expense of possibly including some low-risk women in the high-risk group. However, we do not expect that the extent of the misclassification of “unknown” or “not stated” responses into the high-risk group would differ by adverse outcome status. Notably, <0.1% of the high-risk group was without at least 1 known risk factor and thus classified as high risk based on “unknown” or “not stated” responses alone. Also, there was little difference in the proportion of observations with “unknown” or “not stated” responses among the groups with and without adverse outcomes. The same type of misclassification is present when assuming that “unknown” or “not stated” responses for the outcome measures do not have the outcome, but the extent of misclassification is expected to be less extreme because assignment to the group with no unexpected complications has a higher probability of being correct due to the low incidence of nearly all outcomes studied. In addition, the sensitivity analysis restricted to observations without missing data for any risk or outcome variables found similar proportions of low-risk births with unexpected or adverse outcomes and a similar RR compared to the main analysis in the unrestricted sample.

Third, the US natality data are compiled from US live birth certificates, so stillbirths are not included in the data, and we could not include mortality as an adverse outcome. Finally, the US natality data represent a cross-sectional source of information with the potential for

detection bias. In particular, patients experiencing unexpected complications may be more likely to have a corresponding risk factor noted on the birth certificate. Presence of this bias would bias the results toward the null.

Prior studies of obstetrical risk level and medical outcomes often focused on actual or planned birth location. These studies have found births at home and at birthing centers to have lower obstetrical resource use with associated decreases in maternal complications of interventions such as operative vaginal delivery, cesarean delivery, episiotomy, and epidural use.[4,18,20–25,29] Several studies have found that home births increase the risk of adverse neonatal outcomes,[4,11,19,24,28–30] although some have concluded there are no increased risks of adverse perinatal or maternal outcomes.[18,20,26,27] Studies of planned home births compared to planned hospital births involve a mixing of the level of care available at home and the characteristics of women who self-select for home births that make results difficult to interpret.[47] As expected, planned home births tend to be among low-risk mothers, and have been shown to have fewer obstetric risk factors than planned hospital births.[4,19,29] However, a common finding in studies of birth location is the large proportion of women with a planned birthing center or home birth that are ultimately transferred to a hospital during labor or soon after delivery,[18–23] supporting the notion that low-risk births that will not require increased obstetrical or newborn intervention are difficult to identify. Our study can be added to a growing literature suggesting that history of a low-risk pregnancy does not ensure a low-risk delivery, as the absolute risk of unexpected or adverse outcomes among low-risk women was 29%.[11]

Our findings have implications for both individual care and hospital administration decisions. Expectant mothers and their obstetrical providers should be aware of the risk of adverse outcomes even among births expected to be of low risk. Health care systems should ensure that birthing centers and hospitals possess necessary resources to ensure quality care and patient safety. There are differences in outcomes not only between home births and hospital births, but also between hospitals with differing levels of obstetric and neonatal care.[48]

While our study reveals notable risks of complications and outcomes requiring increased clinical resources among low-risk pregnancies, we do not attempt to characterize the appropriate location for a birth of a given risk status. Rather, our results question general recommendations for birth location for a low-risk pregnancy when “low risk” cannot be well defined. Further study is needed to attempt to identify the small proportion of pregnancies that can be considered low risk and to assess costs and health outcomes among comparable women and neonates delivering in different level of care environments.

In summary, among pregnancies deemed to be of low-risk based on maternal and prenatal characteristics, 29% had an unexpected complication in labor, delivery, or the neonatal period. It is difficult to identify a subset of pregnancies for which there is an acceptable level of risk of unexpected complications. This study offers obstetrical providers information to counsel women about the risks for unexpected and adverse obstetric and neonatal outcomes, even among low-risk pregnancies. This information is also important to consider when

evaluating delivery units and birthing centers, and determining the necessary resources to ensure quality care and patient safety.

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TABLE 1

Frequencies of individual and overall low risk characteristics, N = 10,458,616

Low-risk characteristic	%
Maternal age 20–39 y	89.3
Gestational age at delivery 37–42 wk	90.1
Prenatal care began by sixth month of pregnancy	90.5
No prepregnancy diabetes	98.9
No gestational diabetes	94.6
No prepregnancy hypertension	98.2
No previous preterm birth	97.3
No prior poor pregnancy outcome	97.5
No previous cesarean delivery	85.4
No cervical cerclage	99.3
No PROM	96.2
No tocolysis	98.6
Cephalic presentation	91.5
Singleton pregnancies	96.6
No congenital anomalies[a]	99.3
No syphilis	99.5
No hepatitis B	98.3
No hepatitis C	99.3
Prepregnancy BMI <30	72.9
Overall low risk: satisfies all above definitions	4,011,139 (38.4%)

BMI, body mass index; PROM, premature rupture of membranes.

[a]Includes anencephaly, meningomyelocele/spina bifida, congenital diaphragmatic hernia, omphalocele, gastroschisis, limb reduction defect, cleft lip with or without cleft palate, cleft palate alone, Down syndrome.

TABLE 2

Frequencies of individual outcomes and composite indicator of unexpected or adverse outcomes

Outcome	Among all births [10,458,616] n (%)	Among births to low-risk pregnancies [4,011,139] n (%)	Among births to high-risk pregnancies [6,447,477] n (%)	Risk ratio (95% CI) for low- vs high-risk births and unexpected or adverse outcome
Birthweight <2500 g	835,161 (8.0)	84,350 (2.1)	750,811 (11.7)	0.18 (0.18–0.18)
5-min Apgar 0–3	66,084 (0.6)	8914 (0.2)	57,170 (0.9)	0.25 (0.25–0.26)
Eclampsia	22,574 (0.2)	3230 (0.1)	19,344 (0.3)	0.27 (0.26–0.28)
Chorioamnionitis	134,413 (1.3)	54,673 (1.4)	79,740 (1.2)	1.10 (1.09–1.11)
Meconium staining	530,416 (5.1)	222,009 (5.5)	308,407 (4.8)	1.16 (1.15–1.16)
Uterine rupture	2858 (0.03)	350 (0.01)	2508 (0.04)	0.22 (0.20–0.25)
Forceps delivery	65,460 (0.6)	31,641 (0.8)	33,819 (0.5)	1.50 (1.48–1.53)
Vacuum delivery	293,973 (2.8)	146,752 (3.7)	147,221 (2.3)	1.60 (1.59–1.61)
Cesarean delivery	3,411,318 (32.6)	616,238 (15.4)	2,795,080 (43.4)	0.35 (0.35–0.36)
Maternal transfusion	28,709 (0.3)	6877 (0.2)	21,832 (0.3)	0.51 (0.49–0.52)
Unplanned hysterectomy	4166 (0.04)	662 (0.02)	3504 (0.1)	0.30 (0.28–0.33)
Unplanned operation	27,842 (0.3)	8079 (0.2)	19,763 (0.3)	0.66 (0.64–0.67)
Admission to adult intensive care unit	15,751 (0.2)	2498 (0.1)	13,253 (0.2)	0.30 (0.29–0.32)
Mother transferred	53,222 (0.5)	4404 (0.1)	48,818 (0.8)	0.15 (0.14–0.15)
Assisted ventilation for newborn	356,665 (3.4)	69,929 (1.7)	286,736 (4.5)	0.39 (0.39–0.40)
Admission to neonatal intensive care unit	810,350 (7.8)	117,441 (2.9)	692,909 (10.8)	0.27 (0.27–0.27)
Newborn surfactant	42,277 (0.4)	1700 (0.04)	40,577 (0.6)	0.07 (0.06–0.07)
Newborn antibiotics	217,081 (2.1)	42,608 (1.1)	174,473 (2.7)	0.39 (0.39–0.40)
Newborn seizures	3229 (0.03)	889 (0.02)	2340 (0.04)	0.61 (0.56–0.66)
Birth injury	6160 (0.1)	2148 (0.1)	4012 (0.1)	0.86 (0.82–0.91)
Infant transferred	115,496 (1.1)	18,964 (0.5)	96,532 (1.5)	0.32 (0.31–0.32)
Composite indicator of unexpected or adverse outcomes: observation had at least 1 of above outcomes	4,841,011 (46.3)	1,149,872 (28.7)	3,691,139 (57.3)	0.50 (0.50–0.50)

CI, confidence interval.

EXHIBIT B

Am J Obstet Gynecol. 2013 Mar;208(3):219.e1-7. doi: 10.1016/j.ajog.2012.12.037. Epub 2013 Jan 8.

Placenta accreta: risk factors, perinatal outcomes, and consequences for subsequent births

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Affiliations
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Abstract

Objective: We sought to evaluate risk factors and perinatal outcomes of pregnancies complicated with placenta accreta and to study perinatal outcomes in subsequent pregnancies.

Study design: A retrospective study comparing all singleton cesarean deliveries (CD) of women with and without placenta accreta was conducted. In addition, a retrospective comparison of all subsequent singleton CD of women with a previous placenta accreta, with CD of women with no such history, was performed during the years 1988 through 2011. Stratified analysis using multiple logistic regression models was performed to control for confounders.

Results: During the study period, there were 34,869 CD, of which 0.4% (n = 139) were complicated with placenta accreta. Using a multivariable analysis with backward elimination, year of birth (adjusted odds ratio [aOR], 1.06; 95% confidence interval [CI], 1.03-1.09; P < .001), previous CD (aOR, 5.11; 95% CI, 3.42-7.65; P < .001), and placenta previa (aOR, 50.75; 95% CI, 35.57-72.45; P < .001) were found to be independently associated with placenta accreta. There were 30 subsequent pregnancies of women with placenta accreta. Recurrent accreta occurred in 4 patients (13.3%). Previous placenta accreta was significantly associated with uterine rupture (3.3% vs 0.3%, P < .01) peripartum hysterectomy (3.3% vs 0.2%, P < .001), and the need for blood transfusions (16.7% vs 4%, P < .001). Nevertheless, increased risk for adverse perinatal outcomes such as low Apgar scores at 1 and 5 minutes and perinatal mortality was not found in these patients.

Conclusion: Prior CD and placenta previa are independent risk factors for placenta accreta. A pregnancy following a previous placenta accreta is at increased risk for adverse maternal outcomes such as recurrent accreta, uterine rupture, and peripartum hysterectomy. However, adverse perinatal outcomes were not demonstrated.

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EXHIBIT C

Review

WOMEN'S HEALTH

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Overview of ectopic pregnancy diagnosis, management, and innovation

Kellie Mullany[1], Madeline Minneci[1]*, Ryan Monjazeb[1]* and Olivia C. Coiado[2]

Abstract

Ectopic pregnancies are the leading cause of maternal mortality in the first trimester, with an incidence of 5%–10% of all pregnancy-related deaths. Diagnosis of ectopic pregnancies is difficult due to clinical mimics and non-specific symptoms of abdominal pain and vaginal bleeding. The current standard for ectopic pregnancy diagnosis includes ultrasound imaging and β-human chorionic gonadotropin (β-hCG) monitoring. In addition to β-hCG, serum markers are being explored as a potential for diagnosis, with activin-AB and pregnancy-associated plasma protein A specifically showing promise. Other diagnostic methods include endometrial sampling, with dilation and curettage showing the highest specificity; however, frozen section reduces the diagnostic timeline which may improve outcomes. Treatment options for confirmed ectopic pregnancies include medical, surgical, and expectant management. Chosen treatment methodology is based on β-hCG levels, hematologic stability, and risk of ectopic pregnancy rupture. Current innovations in ectopic pregnancy management aim to preserve fertility and include laparoscopic partial tubal resection with end-to-end anastomosis and uterine artery embolization with intrauterine infusion of methotrexate. Psychological interventions to improve patient mental health surrounding ectopic pregnancy diagnosis and treatment are also valuable innovations. This literature review aims to bring light to current ectopic pregnancy diagnostics, treatments, and future directions.

Keywords

ectopic pregnancy, ectopic pregnancy diagnosis, ectopic pregnancy innovation, ectopic pregnancy treatment, global women's health, maternal health, public health, reproductive health, *Roe* v. *Wade*, women's health

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Introduction

Ectopic pregnancy (EP) ruptures are the leading cause of maternal mortality within the first trimester of pregnancy with a rate of 9%–14% and an incidence of 5%–10% of all pregnancy-related deaths.[1] A gestational sac (GS) that implants in a location that is not the uterus is defined as an EP. Women with an EP may have nonspecific symptoms such as lower abdominal pain and vaginal bleeding, often presenting clinically similar to appendicitis, urinary calculi, early pregnancy loss, or trauma.[2] Women with this presentation in the first trimester have an EP prevalence in emergency departments as high as 18%, which can be easily misdiagnosed as the previously described clinical mimics.[3] Descriptions of EPs and their prevalence are found in Table 1.

Tubal EPs are the most common type and have high maternal morbidity and mortality when ruptured.[1] The rate of ruptured EPs is approximately 15% in Western countries, with a retrospective study showing an increased

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Table 1. Types of ectopic pregnancy (EP) and incidence.

EP type	Description	Incidence	Characteristics
Tubal	Gestational sac (GS) implants in the fallopian tube	95%	–
Interstitial	GS implants in interstitial portion of fallopian tube and transverses the myometrium in the uterine fundus	2%–4%	May present later in pregnancy[1]
Cesarean Scar (CSP)	GS implants into the anterior uterine wall of lower uterine segment where Cesarean scar resides	<1%	Treatment has a high success and high complication rate[4]
Heterotopic	Concomitant intrauterine pregnancy (IUP) and EP	1%–3%	Difficult to manage if desired IUP[1]
Cervical	GS implants in the mucosa of the endocervical canal	<1%	Dilation and curettage in a previous pregnancy in 70% of cases[5]
Ovarian	GS implantation in the ovaries	<3%	81% associated with concomitant intrauterine devices[1]
Abdominal	GS implants in the peritoneal cavity of the abdomen	~1%	There are some reported cases of term deliveries of healthy babies[1]

Source: Table modified and summarized from Houser et al.[1,4,5]
EP: ectopic pregnancy; GS: gestational sac; CSP Cesarean scar pregnancy; IUP: intrauterine pregnancy.

rupture rate during the COVID-19 pandemic.[6] Heterotopic EPs are particularly complex, and their incidence is increasing due to a correlation with assisted reproductive technologies (ART), with an incidence of 1/100 pregnancies with in vitro fertilization (IVF) and 1/7000 pregnancies from ART with ovulation induction.[1] Increasing rates of IVF are correlated with rising reports of EPs among those individuals. The EP rate among IVF pregnancies is 2.1%–8.6% after embryo transfer, in comparison to 2% in natural conceptions.[7] Furthermore, the World Health Organization (WHO) notes an increasing rate of cesarean sections, currently reported as 21% of childbirths globally, which may in turn increase the rate of cesarean scar EPs (CSPs) over time.[8] The current standard for diagnostics includes ultrasound (US) imaging—transvaginal (TVUS) or transabdominal (TAUS)—and β-human chorionic gonadotropin (β-hCG) level monitoring. Earlier and more specific EP diagnosis can help reduce maternal mortality rates. Current experimental studies are identifying biomarkers and endometrial sampling techniques that may be useful for more effective diagnostics. Once an EP is diagnosed, treatment can consist of medical, surgical, or expectant management, with innovative emphasis on conservation of fertility.

Research methods

This analysis examines and reviews literature involving the diagnosis and treatment of EPs from 2011 to 2022. Using the online PubMed search engine and Google, this review compiles 64 literature articles. While compiling literature for this review, several methodologies were followed as outlined in Figure 1.

Research was reviewed and screened based on relevance to EP diagnosis, risk factors, treatment, and clinical trials involving EPs. PubMed search results were filtered by article type to examine meta-analysis, reviews, systematic reviews, reviews, clinical trials, and randomized control trials. Literature was included based on direct relevance to EP and was excluded if not relevant. As an example, search results that included the words "ectopic pregnancy" and "diagnosis," but did not have the diagnosis of EP as the primary focus were excluded. Books and documents were also excluded article types, as review of up-to-date literature was the goal of the study. One paper out of the 64 included fell outside of the date range of 2011–2022 due to insufficient research or results within the selected time frame.[9]

In addition to the methodology above, researchers conducted direct Google searches on topics relating to EP with key words as seen in Figure 1. The process of filtering, inclusion, and exclusion followed the outlined methodologies above.

PubMed was the primary search engine for our research and allowed for a comprehensive review of current medical knowledge of EPs. Literature not found in PubMed may not have been included and is one source of bias and limitation to this study. Minimization of search criteria allowed for inclusion of all relevant papers.

At risk populations

Half of patients diagnosed with an EP have no known risk factors.[2] Risk factors include prior EP, damage to fallopian tubes, prior pelvic surgery, complications from ascending pelvic infection, prior fallopian tube surgery or pathology, infertility, smoking, age greater than 35 years old, pelvic inflammatory disease, endometriosis, variant reproductive system anatomy, pregnancy that occurs with an intrauterine device (IUD) in place, or use of ART.[2,3,10,11]

Individuals with IUDs are at lower risk for EP than individuals who do not use contraception; however, 53% of pregnancies that occur in patients with IUDs are ectopic.[3] Patients with a history of one prior EP have a 10% risk of subsequent EP recurrence while those with a history of two or more prior EPS have a risk greater than

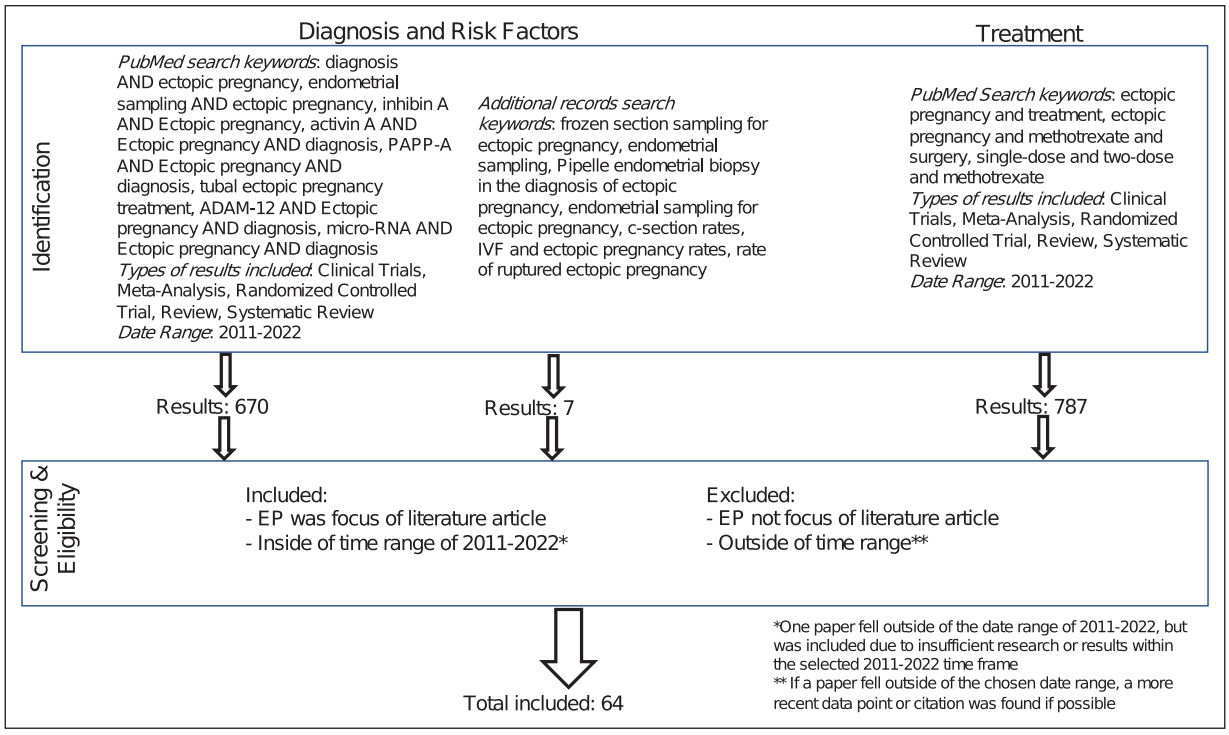

Figure 1. Research methods.

25%.[3] Specific risk factors associated with ART include increased number of embryos transferred, fresh instead of cryo-thawed embryo transfers, and cleavage-stage (Day 3) instead of blastocyst (Day 5) embryo transfers.[11]

Oral contraceptive use, prior termination of pregnancy, emergency contraception failure, cesarean delivery, and loss of pregnancy have not been found to have any significant association with increased risk of EP.[3]

Diagnostic methods

Current diagnostic methods for EP rely on serum β-hCG levels in correlation with TVUS or TAUS findings. TVUS has been shown to be more accurate and sensitive compared to TAUS in the diagnosis of early EP.[12] Specifically, three-dimensional TVUS combined with color Doppler US was shown to be more effective than conventional 3D-US for the diagnosis of early CSP.[13] Imaging mimics make EPs difficult to diagnose; however, awareness of differentiating features on US allows for more effective diagnosis, as summarized in Table 2.

β-hCG trends are used in conjunction with US to determine EP diagnosis. A patient with a β-hCG level >2000 mIU/mL with no sign of intrauterine pregnancy (IUP) is highly suspicious of EP.[1] β-hCG level is monitored to determine a miscarriage or fetal development pattern. Viable IUPs are 99% likely to have a 49% increase in β-hCG levels over 48 h when initial levels were <1500 mIU/mL.[2] Decreasing levels or a slower rate is suggestive of miscarriage or EP, with a decrease of 21% or greater most likely a failed IUP.[2] Overall, the complexity of diagnosis depends on the type of EP.

Experimental markers

In patients with a pregnancy of unknown location (PUL), 50%–70% are found to have either an EP or miscarriage, while the remaining 30% may have a normal IUP.[14] Serial β-hCG levels are monitored to determine pregnancy location and prognosis. A rise less than 35% in 2 days suggests EP with an accuracy of 80.2%.[14]

Outside of β-hCG, experimental markers are being researched for potential use in diagnostics; however, they are not traditionally used in clinical settings. Such markers include inhibin A, activins, pregnancy-associated plasma protein A (PAPP-A), A disintegrin and metalloprotease-12 (ADAM-12), vascular endothelial growth factor (VEGF), and messenger and micro-RNA. Table 3 summarizes the efficacy of markers in various studies. Activin-AB was found to have a strong EP diagnostic correlation.[15] ADAM-12 as a biomarker for PUL was shown to be promising for EP diagnostics in a study performed by Rausch et al.,[16] however Horne et al.[17] was unable to replicate these findings. Micro-RNA as a diagnostic tool for EP has been promising in recent years. Specifically, micro-RNAs are linked to placental pathologies and their relationship with EPs is being studied.[18] Sun et al.[19] found miR-378d in serum exosomes promising in EP diagnosis, with even

Table 2. Ultrasound (US) diagnostics of ectopic pregnancies (EPs) and clinical mimics.

Type	Incidence[a]	US visualization	Clinical mimics	Features
Tubal	~95%	• Extraovarian mass containing yolk sac and/or fetal pole with/without cardiac motion • "blob" or "bagel" sign	• Hemorrhagic cyst • Acute appendicitis	• 70% occur at ampullary segment
Interstitial	2%–4%	• "interstitial line sign" • "bulging sign" • "myometrial mantle sign"	• Angular pregnancy • Fundal fibroid	• 15× higher mortality rate
Cesarean Scar (CSP)	<1%	• Sagittal plane eccentrically embedded within anterior lower uterine segment with thinning/non-existent myometrium anteriorly	• Low-lying intrauterine pregnancy (IUP) • Hematoma/abscess • Pedunculated fibroid	• If growth extends into the uterine cavity normal pregnancy is possible
Heterotopic	1%–3%	• IUP in conjunction with para-ovarian adnexal mass, "tubal ring," or adnexal gestational sac (GS)	• Hyper-stimulated ovaries may obscure presence of adnexal EP	• Incidence rising • 1/100 in vitro fertilization (IVF) pregnancies • 1/7000 assisted reproductive technologies (ART) with ovulation induction pregnancies
Cervical (CEP)	<1%	• Eccentrically located round GS within cervical wall below the cervical os • Cervical ballooning • Negative "sliding sign"	• Abortion in progress • Nabothian cyst	• Massive hemorrhage risk • Recent dilation and curettage reported in 70% of CEPs • 10× more likely in patients with ART
Ovarian	<3%	• GS containing either yolk sac or fetal pole inseparable from the ovary • Thick echogenic trophoblastic rim • Hyper-vascular and "ring of fire" Doppler	• Tubal EP in infundibulum • Corpus luteum cyst • Involuting follicle	• 81% associated with intrauterine devices
Abdominal	0.9%–1.4%	• Intraperitoneal GS with echogenic trophoblastic tissue, located in peritoneum	• Large unruptured tubal EP	• 7.7× risk of organ perforation and catastrophic hemorrhage • Maternal mortality upward of 10%

Source: Table modified and summarized from Houser et al.[1]
US: ultrasound; CSP: cesarean scar; IUP: intrauterine pregnancy; GS: gestational sac; EP: ectopic pregnancy; IVF: in vitro fertilization; ART: assisted reproductive technology; CEP: cervical ectopic pregnancy.
[a]Incidence as a measure of the % of all EPs.

Table 3. Sensitivity and specificity of promising biomarkers for ectopic pregnancy diagnosis.

Biomarker	Reference	Sample size	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Activin-AB	Refaat and Bahathiq[15]	120	92.5	85	75.5	95.8
A disintegrin and metalloprotease-12 (ADAM-12)[a]	Rausch et al.[16]	199	70	84	–	–
β-human chorionic gonadotropin	Refaat and Bahathiq[15]	120	67.5	51.2	40.9	75.9
Micro-RNA *miR-378d*	Sun et al.[19]	36	89.1	64	–	–
Pregnancy-associated plasma protein A	Zhang and Wang[20]	134	92.13	78.33	–	–
Progesterone	Refaat and Bahathiq[15]	120	27.5	50	21.5	58

Source: Table modified from Refaat and Bahathiq.[15,16,19,20]
[a]ADAM-12 levels were obtained using a cut-point of 2.53. ADAM-12 yielded contradictory results in Rausch et al.[16] and Horne et al.[17]

higher significance when miR-100-5p and miR-215-5P are used in conjunction with a panel of β-hCG and progesterone. PAPP-A expression was found to be significantly lower in patients with EP, suggesting diagnostic and therapeutic value.[20] Serum progesterone is higher in IUP compared to failing pregnancies and EPs.[14] EPs have a serum

Table 4. Sensitivity and specificity of endometrial sampling methods.

Method	Reference	Sample size	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Dilation and curettage	Batig et al.[24]	31	88.9	100	100	57.1
Frozen section	Odeh et al.[25]	106	72.7	95.9	88.9	88.6
Karman aspiration	Brady et al.[26]	45	67.7	100	–	–
Pipelle sampling	Batig et al.[24]	31	70.1	100	100	33.3

Source: Table modified from Batig et al.[24–26]

progesterone cutoff of 10 ng/mL in most cases or 30 ng/mL 28–49 days post-menstruation in patients receiving clomiphene citrate fertility treatments.[14] Serum progesterone is non-specific for EP or miscarriages and has been shown to misclassify normal IUPs, making it a less desirable standard for diagnosis.[14]

There is limited literature on the efficacy of the biomarkers described above. For example, ADAM-12 was shown to have conflicting value in diagnostics.[16,17] As such, further studies should be conducted to confirm diagnostic value.

Hematological assessment of complete blood count (CBC) samples has also been investigated as a diagnostic tool for EPs. Retrospective reviews have shown that white blood cell (WBC) levels, specifically monocyte counts, are higher in patients with tubal EPs.[21] When assessing platelet characteristics, platelet distribution width may also indicate the presence of an EP, but the exact trend has been debated.[21,22] Creatinine phosphokinase (CPK) may also be used in the early detection of EP, although further validation of this measurement is required.[23]

Exploratory diagnostics

In addition to experimental markers, endometrial sampling is being explored as a new format for EP diagnosis. Endometrial sampling allows for differentiation of failed IUPs from EPs, thus allowing patients to avoid unnecessary methotrexate (MTX) treatment.[11] EP diagnostic assumption without dilation and curettage (D&C) endometrial sampling resulted in up to 40% of patients being treated for falsely diagnosed EPs.[9] Failed IUPs are confirmed by presence of villi on endometrial sampling and/or a 15%–20% decline of β-hCG the day following the procedure.[14] Endometrial sampling can be completed using endometrial biopsy pipelles, D&C, Karman cannula aspiration, or frozen sections. Table 4 summarizes the sensitivity and specificity of exploratory diagnostic tools as described below.

D&C is found to have higher sensitivity rates for EP diagnosis in comparison to endometrial biopsy pipelles; however, both procedures are limited in accuracy and further studies are needed to confirm diagnostic value.[24] Frozen section technique is performed on endometrial material shortly after curettage and decreases the time needed to disprove EP diagnosis.[25] Of 106 women who underwent frozen section technique, nine patients with IUP were falsely started on MTX therapy and three patients with EPs were incorrectly diagnosed with IUP and discharged.[25] Concurrent methods for diagnosis are necessary to avoid unwanted pregnancy termination and missed EPs. Karman cannula aspiration of endometrium allowed 2/3 of women to avoid EP treatment and showed faster recovery times of 12.6 days for IUP when compared to 26.3 days for patients treated with MTX.[27] Pipelle sampling was found to have higher sensitivity in patients with β-hCG $\leqslant$ 2000 mIU/mL, suggesting selective diagnostic potential.[24]

Review of Table 4 indicates that all methods of endometrial sampling have $>$ 95% specificity for diagnosis; however, D&C demonstrates the highest sensitivity, thus confirming it as the most effective protocol.

EP diagnostics are complex and difficult to determine early in the pregnancy. Current methods of US imaging alongside β-hCG are effective in diagnosis, however serum biomarkers and endometrial sampling show promise as future diagnostic methods. Further studies and investigations can help to confirm their value in early EP diagnostics, in hopes of diminishing the maternal mortality rate.

Treatment

Once diagnosis of EP is confirmed, treatment can take a conservative or aggressive approach depending on EP location, pregnancy timeline, and GS size. There are three different approaches to the treatment of EPs—medical, surgical, and expectant management—which are based on the type of EP, as seen in Table 5.

Medical management

Intramuscular (IM) MTX injection is the current standard for medical management of EPs. MTX, a folate antagonist, inhibits rapid cell division, consequently resulting in EP termination.[2] Contraindications to medical management include hemodynamic instability, anemia, leukopenia, thrombocytopenia, pelvic pain or hemoperitoneum

Table 5. Summary of treatment recommendations for various types of ectopic pregnancies (EP).

Type	Medical management	Surgical management	Expectant management
Tubal	Intramuscular (IM) methotrexate (MTX) may be considered for: • Clinically stable patients with unruptured EP	Recommended for: • Hemodynamically unstable patients May be considered for: • Clinically stable patients with unruptured EP Options include minimally invasive laparoscopy	—
Interstitial	IM MTX may be considered for: • Hemodynamically stable patients	Hysterectomy recommended for: • Patients who experience life-threatening hemorrhage • Patients who do not wish to maintain fertility Laparoscopic guided cornual resection recommended for: • Patients who wish to maintain fertility	—
Cesarean Scar (CSP)[a]	• Intra-gestational MTX is the treatment of choice for medical management • Systemic IM MTX on its own is not recommended	Common approach: • Surgical resection with transvaginal or laparoscopic approach Alternative approaches: • Ultrasound (US)-guided vacuum aspiration • Hysterectomy (if future fertility is not desired) Sharp curettage alone should be avoided, due to risk of uterine rupture	• Recommended against by Society for Maternal Fetal Medicine
Heterotopic[a]	• IM MTX is contraindicated given simultaneous presence of an intrauterine pregnancy (IUP)	Approaches: • Salpingectomy/Salpingostomy • US-guided ablation • Laparoscopic removal of the EP Note: Surgical management has the worst outcomes for IUP	• Greatest maternal mortality
Cervical	MTX can be administered in one of the following ways: • Systemically via IM injection • Directly into the amniotic cavity Optional: • Supplementation with intraamniotic potassium chloride injection to increase efficacy	Fertility preserving techniques that allow for bleeding control: • Uterine artery embolization • Balloon tamponade • Endocervical curettage Cerclage can augment balloon tamponade in patients with severe hemorrhage	–
Ovarian	• Not a common approach	• Gold standard for treatment • All attempts are made to preserve as much ovarian reserve as possible	
Abdominal	–	• Standard treatment	• Recommended against due to risk of catastrophic intra-abdominal hemorrhage

Source: Table modified and summarized from Houser et al.[1]
EP: ectopic pregnancy; IM: intramuscular; MTX: methotrexate; CSP: Cesarean scar pregnancy; US: ultrasound; IUP: intrauterine pregnancy.
[a]There is no standardized treatment or algorithm for management, but common approaches are described.

indicative of EP rupture, renal or hepatic insufficiency, pulmonary disease, active peptic ulcer disease, coinciding IUP, breast feeding, fetal cardiac activity, serum β-hCG levels > 5000 mIU/mL, or EP > 4 cm in diameter.[11] Surgical management is indicated in patients exhibiting MTX contraindications.[11] However, most EPs that are diagnosed early are clinically stable, allowing patients to pursue nonsurgical options.[28] Healthcare accessibility and patient compliance should be considered for medical management, as inability to follow-up may lead to higher risk of complications and treatment failure, thus making surgical management the safer treatment option.[2,11]

MTX is administered in single, double, or multi-dose regimens.[11] The name of each regimen indicates the number of planned doses. The actual number of doses may vary depending on patient β-hCG trends.[3] Patients with higher β-hCG levels may benefit from double-dose MTX therapy.[29] Multi-dose regimens differ in dosing and include coadministration of leucovorin (folinic acid). Leucovorin reduces the adverse effects of MTX, but also reduces treatment efficacy.[30] A breakdown of treatment protocols is described in Table 6.

Common side effects of MTX treatment include vaginal spotting and gastrointestinal issues such as nausea, diarrhea, and vomiting.[3] Some women may exhibit abdominal pain 2–3 days after treatment which can be managed expectantly in the absence of symptoms indicative of EP tubal rupture.[3] Patients undergoing treatment should avoid taking folic acid supplements or non-steroidal anti-inflammatory drugs which can decrease the effectiveness of MTX, refrain from using substances such as opioids, alcohol, or other analgesics that can mask symptoms of EP rupture, and abstain from activities that increase EP rupture risk such as vaginal intercourse.[2] As MTX is a potent teratogen, it is suggested that patients use contraception for 3 months following treatment, although there is limited evidence to support this recommendation.[11]

Current literature estimates the percent resolution of EPs via MTX treatment without need for surgical intervention to be 70%–95%, with lower success rates in patients with higher initial β-hCG levels.[2,3] However, recent meta-analyses display conflicting results regarding success and risks of adverse effects with different treatment regimens.[28–32] As such, there is a need for further investigation into this area of research.

Additional therapeutic agents administered in conjunction with MTX have been studied. Seven days of oral gefitinib in addition to single dose IM MTX effectively treated patients with stable tubal EPs and eliminated the need for surgical intervention.[33] This treatment regimen must be validated by a randomized control trial, but may present as another option with minimal adverse effects.

Independent of the treatment regimen, β-hCG levels that continue to rise correlate with increased risk of treatment failure, which in turn can lead to tubal rupture, abdominal hemorrhage, future infertility, and death.[11,32] If a patient develops significant pain or exhibits hemodynamic instability at any time throughout treatment, surgical management should be pursued.[11]

In addition to declining β-hCG levels, other markers are being studied to determine MTX success.[34] Studies have proposed that women successfully treated for EP will have a significantly higher serum CPK.[35,36] Red cell distribution width, mean platelet volume, and neutrophil-lymphocyte ratio may also inform efficacy of EP MTX treatment.[37,38]

Surgical management

Salpingostomy and salpingectomy are the two common approaches for surgical management of EPs. Salpingostomy consists of removing solely the EP via an incision in the fallopian tube, whereas salpingectomy includes removal of part or all the fallopian tube along with the EP.[2] Salpingectomy is advised for patients with EPs ⩾ 5 cm in diameter, significant tubal damage, tubal rupture, bleeding, or previous tubal ligation.[11] However, patients who undergo salpingectomy and have absent/obstructed contralateral fallopian tubes will be unable to procreate without ART, making salpingostomy preferred by patients who wish to retain fertility.[11] In patients with normal contralateral fallopian tubes, salpingostomy and salpingectomy are shown to have equivalent future pregnancy outcomes, as supported by the ESEP study.[11,39] Following salpingectomy, pathologic confirmation of EP in the removed fallopian tube is sufficient to confirm success of the procedure.[11] Contrarily, salpingostomy requires subsequent β-hCG measurements to ensure absence of residual trophoblastic tissue (~20% of patients), which generally requires additional MTX treatment.[11] A retrospective clinical trial discovered that early post-linear salpingostomy β-hCG values are predictive of persistent EP before Day 5, with a positive predictive value of 88% and negative predictive value of 99%.[40]

Overall, surgical management has been shown to have a higher rate of success in terminating EPs than medical management and is indicated in patients who exhibit signs of EP rupture (e.g. hemodynamic instability), have contraindications to medical management, or express personal preference to pursue surgical treatment.[11] Current literature suggests there is no difference between medical and surgical management regarding their effect on subsequent fertility, with limited exceptions as mentioned above.[2] Disadvantages of surgical management include anesthesia complications, secondary injuries, and blood loss.[28]

Expectant management

Expectant management is the most conservative approach for the treatment of EPs. This method can be considered for patients with decreasing or plateaued β-hCG levels.[3]

Table 6. Methotrexate (MTX) treatment protocols.

Day	Single-dose regimen	Two-dose regimen	Fixed multi-dose regimen
1	Measure β-human chorionic gonadotropin (β-hCG) level and administer single dose of MTX (50 mg/m^2) intramuscularly (IM)	Measure β-hCG level and administer single dose of MTX (50 mg/m^2) IM	Measure β-hCG level and administer MTX (1 mg/kg) IM
2	–	–	Administer leucovorin (0.1 mg/kg) IM
3	–	–	Measure β-hCG level • If β-hCG level decreases > 15% between Days 1–3, measure β-hCG levels weekly until returned to nonpregnant levels (skip remaining steps)[a] • If β-hCG level decreases < 15% between Days 1–3, readminister single dose of MTX (1 mg/kg IM) IM
4	Measure β-hCG level (levels commonly increase between Days 1–4)2	Measure β-hCG level and administer single dose of MTX (50 mg/m^2) IM	Administer leucovorin (0.1 mg/kg) IM
5	–	–	Measure β-hCG level • If β-hCG level decreases > 15% between Days 3–5, measure β-hCG levels weekly until returned to nonpregnant levels (skip remaining steps)[a] • If β-hCG level decreases < 15% between Days 3–5, readminister single dose of MTX (1 mg/kg) IM
6	–	–	Administer leucovorin (0.1 mg/kg) IM
7	Measure β-hCG level • If β-hCG level decreases > 15% between Days 4–7, measure β-hCG levels weekly until returned to nonpregnant levels[a] • If β-hCG level decreases < 15% between Days 4–7 (20% of patients), readminister single dose of MTX (50 mg/m^2) IM and repeat protocol ○ Refer for surgical management if β-hCG does not decline after 2 doses (< 1% of patients) Statistics from Brady[11]	Measure β-hCG level • If β-hCG level decreases > 15% between Days 4–7, measure β-hCG levels weekly until returned to nonpregnant levels (skip remaining steps)[a] • If β-hCG level decreases < 15% between Days 4–7, readminister single dose of MTX (50 mg/m^2) IM	Measure β-hCG level • If β-hCG level decreases > 15% between Days 5–7, measure β-hCG levels weekly until returned to nonpregnant levels (skip remaining steps)[a] • If β-hCG level decreases < 15% between Days 5–7, readminister single dose of MTX (1 mg/kg) IM
8	–	–	Administer leucovorin (0.1 mg/kg) IM
9	–	–	Measure β-hCG level • If β-hCG level decreases > 15% between Days 7–9, measure β-hCG levels weekly until returned to nonpregnant levels[a] • If β-hCG level decreases < 15% between Days 7–9, refer for surgical management
11	–	Measure β-hCG level • If β-hCG level decreases > 15% between Days 7–11, measure β-hCG levels weekly until returned to nonpregnant levels (skip remaining steps)[a] • If β-hCG level decreases < 15% between Days 7–11, readminister single dose of MTX (50 mg/m^2) IM	–
14	-	Measure β-hCG level • If β-hCG level decreases > 15% between Days 11–14, measure β-hCG levels weekly until returned to nonpregnant levels [a] • If β-hCG level decreases < 15% between Days 11–14, refer for surgical management	-
Follow-up	Consider administering MTX treatment for persistent EP if β-hCG levels plateau or increase		

Source: Table modified from "ACOG Practice Bulletin No. 193: Tubal Ectopic Pregnancy," 2018.[2,3,11]
MTX: methotrexate; IM: intramuscular; EP: ectopic pregnancy.
[a]β-hCG levels usually return to nonpregnant level in 2–4 weeks but can take up to 8 weeks.[3]

EPs presenting with β-hCG levels < 200 mIU/mL will spontaneously resolve in 88% of cases; however, the rate of spontaneous resolution declines as β-hCG levels exceed this threshold.[3] Patients who choose to pursue expectant management must have β-hCG tested every 48 h and should consider other options if levels do not decline.[2] Risks of expectant management include tubal rupture, hemorrhage, and emergency surgery.[3] The relative efficacy and safety of expectant management is an area of ongoing research, with medical and surgical management remaining the primary approaches to EP treatment.[11]

Evidence in literature suggests initial β-hCG levels greater or less than 1500 mIU/mL may provide a method to inform expectant management versus MTX treatment for specific types of EP.[41,42] Research has shown that IM MTX injections for patients with confirmed tubal EPs did not result in significantly different outcomes when compared to placebo, especially for clinically stable women with β-hCG < 1500 mIU/mL.[43] Patients with β-hCG > 1500 mIU/mL, however, did have statistically significant changes and negative pregnancy tests after MTX injection compared to placebo.[43] More research is necessary to determine effectiveness of MTX in patients with a confirmed tubal EP and β-hCG > 1500 mIU/mL. Serum markers other than β-hCG may also inform treatment success. Memtsa et al. found progesterone and β-hCG to be significantly different in both successful and failed expectant management of tubal EPs, whereas inhibin A, activin A, and high sensitivity C-reactive protein were unlikely to improve selection for conservative management.[41]

Innovations/other

Innovations in surgical management of EPs may provide better immediate and future fertility outcomes. Studies such as the DEMETER trial have shown that fertility rates between medical treatment and conservative surgery are not significantly different.[42,44] A recent trial exploring the effectiveness of laparoscopic partial tubal resection with end-to-end anastomosis found significantly higher postoperative fallopian tube patency compared to controls.[45] There was no significant difference between ovarian function, operation time, intra blood β-hCG recovery time, and hospital time compared with the control group.[45] This method, however, may be an effective measure to preserve fertility. Uterine artery embolization (UAE) with intrauterine infusion of MTX alone was shown to effectively manage EP and preserve fertility.[46] UAE with local infusion of MTX and 5-fluorouracil (5-FU) has also been studied and shown to be effective, but the addition of 5-FU is linked to more adverse effects.[46] UAE before or after uterine curettage for the treatment of CSP was effective at preventing the need for hysterectomy in 11 of 12 patients.[47] One of the 12 patients in this study required hysterectomy due to continued hemorrhage after uterine curettage followed by emergent UAE and further curettage.[47] High-intensity focused US (HIFU) followed by D&C or UAE are additional methods to treat CSP that have been shown to preserve fertility.[4,48] Nonsurgical approaches being studied, including HIFU, may offer additional benefits for future fertility.

Utility of UAE for successful treatment of EPs and bleeding due to EP resolution has also been studied in recent years. UAE in conjunction with MTX was shown to effectively resolve and control bleeding in the treatment of tubal EPs, CSP, cervical EPs, and abdominal EPs.[47,49–51] Use of UAE in an emergent setting has also been shown to resolve EPs and control bleeding after a misdiagnosis of EP.[47] For patients with persistently high β-hCG levels and vaginal bleeding after systemic MTX treatment, UAE has been shown to be a safe and effective option.[52]

Hysteroscopy also shows promise for the treatment of CSP.[53] Hysteroscopy allows for direct visualization of the uterine cavity and a CSP, and thus may be a promising surgical option.[54,55] A recent systematic review revealed that hysteroscopic treatment after HIFU or UAE resulted in 91% resolution of CSP.[53] Larger studies are required to further assess the safety of hysteroscopic treatment.

Noninvasive treatments are a continued area of study for patients with EPs, especially CSPs. US-guided HIFU has been shown to effectively resolve CSP.[56] HIFU in this study was notably conducted as an outpatient procedure 2–5 times, with patients experiencing minimal side effects.[56] In a 2019 meta-analysis comparing UAE and HIFU, early management of CSP with HIFU resulted in better outcomes, including decreased blood loss, shorter hospital durations, and less adverse events; however, β-hCG levels took longer to normalize.[57]

Psychological interventions are also important to consider in the management of EPs. Counseling and patient education throughout EP intervention has been shown to improve mental health and self-esteem in one randomized controlled clinical trial.[58] Methods in this trial included education on EP medical intervention, the physical and psychological complications of interventions, and the sadness, self-esteem, and mental health changes that can be seen after an EP. Another randomized control study found that patient education, attentive and enhanced perioperative care, including heated blankets, and postoperative and discharge education can lower anxiety and depression after laparoscopic management of EP.[59] Muscle relaxation training after MTX administration has also been shown to reduce anxiety in patients with EPs.[60] Overall, psychological management and patient education play crucial roles in the quality-of-life following an EP.

Implications for practice and/or policy

The reversal of *Roe v. Wade* offers additional challenges in the treatment of EPs. Mifepristone and misoprostol are medications that can be given to treat a PUL. These medications are associated with more rapid exclusion of EP

when administered before a definitive diagnosis is made and traditional treatment of MTX is started.[61] With the overturn of *Roe v. Wade*, some government officials have hinted medications traditionally associated with abortion, including mifepristone and misoprostol, may no longer be readily available. Leading healthcare organizations like the American Medical Association and American College of Obstetricians and Gynecologists consider all forms of healthcare a human right, including abortion and contraception.[62] They also state and believe the government should not be involved in the patient-physician relationship.[63,64] Current legal proceedings and changes to state legislature may affect EP treatment and should be considered in the future management of EPs.

Study limitations

PubMed was the primary search engine for research in this publication and allowed for a comprehensive review of current medical knowledge of EPs. Literature not found in PubMed may not have been included and is one source of bias and limitation to this study. Minimization of search criteria allowed for inclusion of all relevant papers. Overall, there is limited innovation reported in EP diagnosis and treatment, thus opening the opportunity for more research to be conducted.

Conclusion

This review consolidates current diagnostic and treatment strategies for EP. Many tools and markers for EP diagnosis along with treatment strategies have been studied and shown to be effective; however, the amount of large multicenter trials within the last 5 years is sparse.

The current diagnostic standard for EP is a combination of US imaging and serum levels of β-hCG. Imaging mimics make EP difficult to diagnose; however, awareness of differentiating features allows for better diagnosis. Additional serum markers outside of β-hCG are being investigated to confirm diagnosis when US results are inconclusive. While not widely used in clinical practice, these experimental markers, specifically activin-AB and PAPP-A, show promise for EP diagnosis. Utilization of these markers may improve outcomes by allowing for earlier diagnosis. In addition, endometrial sampling is promising for effective EP diagnosis. Review of Table 4 indicates that the majority of methods of endometrial sampling have 100% specificity for diagnosis; however, D&C continues to demonstrate the highest sensitivity for diagnostics, thus confirming it as the most effective protocol to be used.

Medical, surgical, and expectant management are the three main treatment options for the management of EPs. MTX is the most common medication given for the treatment of EP and is administered using single or multi-dose regimens. However, recent meta-analyses have offered conflicting findings regarding success rates and risk of adverse effects between the different treatment regimens.[28,30–32] As such, there is a need for further investigation into this area of research. Dosage of MTX is often governed by serum levels of β-hCG, with additional doses given if β-hCG levels do not decline after MTX administration. Medications given in conjunction with MTX, such as 5-FU, and procedures, such as UAE, HIFU, and D&C, have shown to be effective at resolving extrauterine pregnancy.

When medical management alone is contraindicated or does not resolve EP, surgical interventions including salpingostomy or salpingectomy are often performed. UAE and hysteroscopy are additional surgical procedures being studied, especially for the removal of CSPs. Expectant management via monitoring of β-hCG levels can be used in place of medical management for patients with decreasing or plateaued β-hCG levels; however, more studies are required to assess the safety of this form of treatment.[3,43]

Future fertility is an important factor to consider during the treatment of EP. Studies, such as the DEMETER trial, have shown no significant difference in fertility rates following medical treatment and conservative surgery.[42,44] The ESEP study also showed that salpingotomy and salpingectomy do not significantly affect future pregnancy outcomes.[39] Nonsurgical approaches being studied, including HIFU, may offer additional benefits for future fertility. Increasing the number of multicenter trials is necessary to demonstrate the efficacy of treatments that improve surgical outcomes and future fertility after an EP.

Finally, psychological management is a crucial factor in successful outcomes following EP diagnosis and treatment. Trials have shown that attention to patient mental health, comfort, and education following diagnosis have resulted in lower anxiety and depression.[58–60] Consideration of these factors can improve patient quality-of-life.

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Author contribution(s)

Kellie Mullany: Conceptualization; Investigation; Project administration; Writing—original draft; Writing—review & editing.

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EXHIBIT D

Circulation

ORIGINAL RESEARCH ARTICLE

Pregnancy Complications and Long-Term Mortality in a Diverse Cohort

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BACKGROUND: Pregnancy complications are associated with increased risk of development of cardiometabolic diseases and earlier mortality. However, much of the previous research has been limited to White pregnant participants. We aimed to investigate pregnancy complications in association with total and cause-specific mortality in a racially diverse cohort and evaluate whether associations differ between Black and White pregnant participants.

METHODS: The Collaborative Perinatal Project was a prospective cohort study of 48 197 pregnant participants at 12 US clinical centers (1959–1966). The Collaborative Perinatal Project Mortality Linkage Study ascertained participants' vital status through 2016 with linkage to the National Death Index and Social Security Death Master File. Adjusted hazard ratios (aHRs) for underlying all-cause and cause-specific mortality were estimated for preterm delivery (PTD), hypertensive disorders of pregnancy, and gestational diabetes/impaired glucose tolerance (GDM/IGT) using Cox models adjusted for age, prepregnancy body mass index, smoking, race and ethnicity, previous pregnancies, marital status, income, education, previous medical conditions, site, and year.

RESULTS: Among 46 551 participants, 45% (21 107 of 46 551) were Black, and 46% (21 502 of 46 551) were White. The median time between the index pregnancy and death/censoring was 52 years (interquartile range, 45–54). Mortality was higher among Black (8714 of 21 107 [41%]) compared with White (8019 of 21 502 [37%]) participants. Overall, 15% (6753 of 43 969) of participants had PTD, 5% (2155 of 45 897) had hypertensive disorders of pregnancy, and 1% (540 of 45 890) had GDM/IGT. PTD incidence was higher in Black (4145 of 20 288 [20%]) compared with White (1941 of 19 963 [10%]) participants. The following were associated with all-cause mortality: preterm spontaneous labor (aHR, 1.07 [95% CI, 1.03–1.1]); preterm premature rupture of membranes (aHR, 1.23 [1.05–1.44]); preterm induced labor (aHR, 1.31 [1.03–1.66]); preterm prelabor cesarean delivery (aHR, 2.09 [1.75–2.48]) compared with full-term delivery; gestational hypertension (aHR, 1.09 [0.97–1.22]); preeclampsia or eclampsia (aHR, 1.14 [0.99–1.32]) and superimposed preeclampsia or eclampsia (aHR, 1.32 [1.20–1.46]) compared with normotensive; and GDM/IGT (aHR, 1.14 [1.00–1.30]) compared with normoglycemic. *P* values for effect modification between Black and White participants for PTD, hypertensive disorders of pregnancy, and GDM/IGT were 0.009, 0.05, and 0.92, respectively. Preterm induced labor was associated with greater mortality risk among Black (aHR, 1.64 [1.10–2.46]) compared with White (aHR, 1.29 [0.97–1.73]) participants, while preterm prelabor cesarean delivery was higher in White (aHR, 2.34 [1.90–2.90]) compared with Black (aHR, 1.40 [1.00–1.96]) participants.

CONCLUSIONS: In this large, diverse US cohort, pregnancy complications were associated with higher mortality nearly 50 years later. Higher incidence of some complications in Black individuals and differential associations with mortality risk suggest that disparities in pregnancy health may have life-long implications for earlier mortality.

Key Words: diabetes ■ gestational ■ mortality ■ pre-eclampsia ■ pregnancy ■ pregnancy complications ■ premature birth

Major progress has been made in understanding the implications of pregnancy complications for the long-term health of pregnant women. In 2021, the American Heart Association (AHA) released a statement that adverse pregnancy outcomes, such as hypertensive disorders of pregnancy, gestational

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Clinical Perspective

What Is New?

- This article fills a critical data gap in the field of the long-term implications of adverse pregnancy outcomes, in which much of the previous literature has been limited to primarily White populations, by utilizing a diverse cohort and examining for potential heterogeneity in associations by race.
- Those with common pregnancy complications of preterm delivery, hypertensive disorders of pregnancy, or gestational diabetes/impaired glucose tolerance had a higher mortality risk in the ≈50 years after pregnancy.
- Black pregnant participants had an increased risk for some pregnancy complications, and in some instances, the mortality risk conferred from pregnancy complications was higher in Black compared with White individuals.

What Are the Clinical Implications?

- An important piece of this research is extending the concept of lifelong health implications of pregnancy complications to include Black participants, for whom a greater risk for major pregnancy complications and earlier mortality is present.
- Greater efforts are needed to alleviate racial disparities in cardiovascular and diabetes screenings among individuals with a history of pregnancy complications.

Nonstandard Abbreviations and Acronyms

aHR	adjusted hazard ratio
CPP	Collaborative Perinatal Project
GD/IGT	gestational diabetes/impaired glucose tolerance
NDI	National Death Index
PROM	premature rupture of membranes
SSDMF	Social Security Death Master File

diabetes, preterm delivery, small-for-gestational-age delivery, pregnancy loss, and placental abruption, should be considered when evaluating the cardiovascular disease risk in patients with a pregnancy history.[1] However, much of the focus has been on later cardiovascular health, even though there is some additional evidence suggesting that pregnancy complications are associated with increased risk of other chronic diseases, including diabetes and kidney disease, with mixed findings for dementia.[2–9] Additionally, few studies have had long-term follow-up, limiting outcomes to those that develop in midlife rather than later in life, as well as mortality.

There remains a substantial racial disparity in the research related to adverse pregnancy outcomes and long-term health. As noted in the AHA statement, most of the evidence base related to cardiovascular health is from studies comprising 80% to 95% White individuals.[1,10] Although race is a social construct, and there are no biological hypotheses to suggest that the effects of pregnancy complications differ between White and non-White patients, there may be differences in health care access, treatment, and monitoring, leading to differential effect sizes, which, in turn, may contribute to the racial disparities in chronic diseases and related mortality.[11,12] Additionally, non-White pregnant individuals are at increased risk for developing pregnancy complications and have a higher burden of chronic disease(s) and early mortality than White pregnant individuals.[10,13] Yet, only a few studies have evaluated whether adverse pregnancy complications differentially contribute to the greater incidence of chronic disease and earlier mortality observed in historically marginalized populations. For instance, in studies from the Women's Health Initiative, conducted mostly on White (62–82%) participants, there was no difference by race in the associations between adverse pregnancy outcomes and cardiovascular end points, although inferences of the findings were hindered by the small number of non-White participants.[14,15] In another report from the California Child Health and Development Studies, gestational hypertension was associated with an increase in the risk for cardiovascular disease among Black participants only.[16] Nonetheless, there is clearly an unmet level of representation of non-White participants in research on the long-term health implications of pregnancy complications.

Through analysis of a large, well-characterized cohort that included approximately half Black and half White pregnant participants, our study aimed to investigate common pregnancy complications in association with total and cause-specific mortality >50 years after the index pregnancy.

METHODS

Setting

The Collaborative Perinatal Project (CPP) was a prospective cohort study of 48 197 pregnant participants, with 58 760 pregnancies at 12 US clinical centers from 1959 to 1966. Details of the cohort are described previously.[17–19] For the 8772 (18.2%) participants who had >1 pregnancy recorded in study records, the last pregnancy in the CPP was considered the index pregnancy for this analysis, as it represented the latest point of follow-up for each participant. In 2017, the CPP Mortality Linkage Study was conducted to ascertain vital status of participants as of December 31, 2016.[20] Vital status was ascertained through linkages to the National Death Index (NDI) and the Social Security Death Master File (SSDMF).

There were no institutional review boards or rules for use of human subjects at the CPP inception during the late 1950s, but a general informed consent for participation was obtained. Institutional review board approval was obtained for the

CPP Mortality Linkage Study by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the Emmes Corporation, which performed the abstraction of identifying information from historic CPP records and facilitated the linkages. CPP data are publicly available at https://www.archives.gov/research/electronic-records/nih.html (National Archives Identifier: 606622). Because of privacy concerns, mortality data were not publicly available. Researchers interested in the linked mortality data should contact the Eunice Kennedy Shriver National Institute of Child Health and Human Development for data-sharing agreement details.

Exposure Ascertainment

At the first pregnancy visit, a physical exam was performed, and information on demographics, medical history, socioeconomic status, and behavior were collected via interviews. Participants were followed throughout pregnancy, providing repeat interviews and physical exams. Upon admission to labor and delivery, a trained observer recorded labor and delivery, postpartum, and neonatal events.

Gestational age was defined according to the date of the last menstrual period. Deliveries ≥20 and <37 completed weeks were classified as preterm. Preterm subtypes were further classified according to the following algorithm: preterm deliveries with recorded spontaneous labor onset were included in the "preterm spontaneous labor" category; preterm deliveries with premature rupture of the membranes (PROM) were included in the "preterm PROM" category; preterm deliveries with recorded induction of labor were included in the "preterm induced labor" category; preterm deliveries without record of spontaneous labor, PROM, or induction that were delivered by cesarean were categorized as "preterm prelabor cesarean"; and all other preterm deliveries were categorized as "preterm unknown reason."

Hypertensive disorders were classified according to current clinical definitions.[21] Chronic hypertension was classified if reported on the past medical history or obstetric diagnostic summary, or if blood pressure at <20 weeks gestation was elevated (ie, ≥2 readings of systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg). Gestational hypertension was classified as new-onset blood pressure elevation at ≥20 weeks gestation. Preeclampsia or eclampsia was classified as the presence of gestational hypertension with any of the following: proteinuria (≥20 weeks gestation dipstick readings of 1+ or recorded on obstetric summary), headache or visual disturbance within 1 week of delivery, pulmonary edema, or eclampsia documented on the delivery report or obstetric diagnostic summary. Superimposed preeclampsia or eclampsia was defined as preeclampsia or eclampsia in the presence of chronic hypertension.

Prepregnancy diabetes (type not specified) was identified from either the past medical history, the obstetric summary, or documented insulin use before pregnancy. Gestational diabetes was defined using any of the following criteria in the absence of prepregnancy diabetes: (1) ≥2 abnormal plasma glucose values on the 3-hour glucose tolerance test during pregnancy according to the currently adopted Carpenter and Coustan criteria[22]; (2) documented insulin use during pregnancy; or (3) documented severe diabetic conditions, including diabetic coma or ketoacidosis first recognized in pregnancy. Impaired glucose tolerance was defined as any of the following criteria in the absence of prepregnancy diabetes and gestational diabetes: (1) checked box for "diabetes during pregnancy" or "abnormal glucose tolerance test during pregnancy" (without record of the values) documented on the obstetric diagnosis summary; (2) fasting plasma glucose during pregnancy ≥95 mg/dL; (3) any blood glucose during pregnancy ≥200 mg/dL[22]; or (4) 1, but not 2, abnormal plasma glucose values on the glucose tolerance test during pregnancy. Because few participants met the criteria for gestational diabetes, "any glucose intolerance in pregnancy" was defined by grouping gestational diabetes with impaired glucose tolerance. A glucose tolerance test (63% oral glucose and 37% IV glucose) was performed during pregnancy for 1340 (2.8%) participants.

Outcome Ascertainment

Follow-up time was calculated from the year of the index CPP pregnancy through 2016 or the recorded year of death. Deaths that occurred during pregnancy or immediately postpartum before discharge were recorded on the obstetric forms. All-cause mortality was defined as a death recorded in the NDI, augmented by the SSDMF if there was not a match with the NDI; 89% of the deaths were sourced from the NDI, which is more accurate than the SSDMF.[20,23] Participants without death recorded by December 31, 2016, were censored.

Underlying causes of death were obtained from the NDI, which defines underlying causes of death in accordance with recommendations of the World Health Organization and the International Conference for the Ninth Revision of the *International Classification of Diseases* as "(a) the disease or injury which initiated the train of events leading directly to death, or (b) the circumstances of the accident or violence which produced the fatal injury."[24,25] These coding decisions are automated based on international coding rules. Causes of death were coded according to the *International Classification of Diseases,* 9th revision (*ICD-9*) codes for deaths occurring between 1979 and 1998 and according to the *International Classification of Diseases,* tenth revision (*ICD-10*) codes for deaths occurring between 1999 and 2016 (Table S1). Underlying causes of death were grouped according to *ICD-10* codes and comparable *ICD-9* codes.[26] There were 10 cause-of-death categories[26]: cardiovascular disease, cancer, diabetes, respiratory disease (pneumonia, influenza, chronic obstructive pulmonary disease, and allied conditions), infections (other than pneumonia or influenza), dementia, kidney disease, chronic liver disease, accidents, suicide, and other causes. The dementia category of death was based on the Centers for Disease Control and Prevention definition of dementia mortality, which includes deaths attributable to Alzheimer disease, unspecified dementia, vascular dementia, and other degenerative diseases of the nervous system, not classified elsewhere.[27] Cardiovascular disease was further classified into hypertensive disease, ischemic heart disease, arrhythmia, heart failure, cerebrovascular disease, and atherosclerosis or other diseases of the arteries.[26]

Covariate Ascertainment

Covariates were collected from participants during study enrollment via in-person interviews and defined based on the index pregnancy and included age, smoking status, race and ethnicity (Black, Puerto Rican, other, or White; self-reported), prepregnancy body mass index (in kg/m^2), previous pregnancies (0,

1, 2, 3, or ≥4), marital status (single, married/common law, or other), family income (≤$1999, $2000–3999, $4000–5999, $6000–7999, $8000–9999, or ≥$10 000), education (less than high school, some high school, high school graduate, or some college), previous medical conditions, site, and year. Details on the covariates, their definitions, and functional form are included in Table S2.

Statistical Methods

Participant characteristics at the index pregnancy were compared across categories of diabetes, preterm delivery, and hypertensive disorders in pregnancy using χ^2 tests for categorical variables and ANOVA for continuous variables. Missing data on exposures (1–10%), covariates (<1–12%), and causes of death identified by the SSDMF (4%) were multiply imputed using chained equations under the missing at random assumption.[28] For each of the 50 imputed data sets, the regression models were estimated, and the results were combined using the Rubin rule.[29]

Separate models were estimated for each exposure. We previously compared a standard Cox regression model and modified Cox regression with a double-censoring approach that assumed that nonmatched participants could be either right-censored in 2016 (still alive) or left-censored between index pregnancy and 1979 (deceased before 1979), and the results were nearly identical; therefore, the current study utilized a standard Cox regression model.[20,30] Cox proportional hazards regressions estimated the hazard ratios (HRs) of mortality in association with each exposure, for which the all-cause and cause-specific hazard models were both fitted. The cause-specific hazard, which accounted for the competing risks of deaths attributable to different causes, is interpreted as the instantaneous risk of dying from the cause of interest among the participants who were alive. The cumulative incidence functions were calculated from all-cause Cox models. Then, risk differences were estimated at 50 years after the index pregnancy by taking the differences of cumulative incidence functions among exposure groups. Risk differences were estimated for all-cause mortality only because, in general, we have less power with risk differences than HRs, and this is exacerbated with the cause-specific associations. Additionally, for preterm birth, we restricted the analysis to pregnancies lasting ≥20 weeks. For all-cause mortality, we utilized inverse probability weights to control for potential selection bias introduced by this restriction.[31] Weights included all covariates for the main models.

Effect modification by race was examined and tested by fitting models with the individual exposure category, race, and an interaction term between the exposure of interest and race.[12] Only participants who were White or Black were included for these analyses because of small sample sizes in the other groups. A sensitivity analysis examined whether pregnancies affected by hypertensive disorders were delivered preterm (<37 weeks) or at term (≥37 weeks). Statistical significance was defined as $P<0.05$, and all tests were 2-sided. Analyses were conducted using SAS version 9.4 (SAS Institute) and R.

RESULTS

The CPP cohort included 48 197 pregnant participants. Those who died during the index CPP pregnancy were excluded (n=9) to focus on postpregnancy mortality. Participants without identifiable information who were unable to be submitted for vital status linkage were excluded from the analysis (n=1637 [3.4%]). The final analysis included 46 551 participants (Figure S1).

The majority of study participants were either Black (45%) or White (46%; Table 1). Black participants were younger than White participants at the index pregnancy, less likely to have had a previous pregnancy, more likely to have obesity, more likely to be single, had lower incomes, less attained education, and were more likely to have cardiovascular conditions before pregnancy than White participants. Detailed distributions of the participant characteristics across pregnancy complications are shown in Tables S3 to S5.

The median time between the index pregnancy and death or censoring as of 2016 was 52 years (interquartile range, 45–54), for a total of 2 229 721 person-years. As of 2016, 18 170 (39%) deaths were observed (Table 2). Mortality was higher among Black compared with White participants (41% versus 37%). Across all the race and ethnic groups, the top 2 leading causes of death were cardiovascular disease (27% to 34% of total deaths) and cancer (24% to 34% of total deaths).

Overall, 15% of pregnancies were delivered preterm (13% preterm spontaneous labor; <1% preterm PROM; <1% induced labor; <1% preterm prelabor cesarean delivery; and <1% preterm reason unknown). The proportion of spontaneous preterm deliveries differed substantially between Black (18%) and White participants (7%); no differences were observed for other preterm deliveries (<1% in both Black and White participants). All preterm deliveries, except for those with an unknown cause, were associated with an increased adjusted all-cause mortality. Compared with term births (≥37 weeks), the adjusted HRs for preterm spontaneous labor, preterm PROM, preterm induced labor, preterm prelabor cesarean delivery, and preterm reason unknown were 1.07 (95% CI, 1.03–1.12), 1.23 (1.05–1.44), 1.31 (1.03–1.66), 2.09 (1.75–2.48), and 0.92 (0.79–1.07), respectively, with corresponding risk differences of 1.5 (−0.6 to 3.6), 4.5 (0.3–8.7), 6.0 (−0.1 to 12.1), 19.1 (13.2–25.1), and −1.7 (−5.1 to 1.7) deaths per 100, respectively (Table 3). The *P* value for interaction the between Black and White race and preterm delivery was $P=0.009$ (Table S6). There was no major difference in the HRs for preterm spontaneous labor and preterm PROM, whereas for preterm induced labor, the mortality association was slightly stronger among Black participants, and for preterm prelabor cesarean delivery, the mortality association was stronger for White participants. For participants with a spontaneous preterm delivery, the increased mortality risk was generally because of an increase in cardiovascular disease mortality (HR, 1.18 [1.09–1.28]). For participants with preterm PROM, the increased mortality risk was generally attributable to the increased mortality from

Table 1. Participant Characteristics of the Collaborative Perinatal Project Mortality Linkage Study

Characteristic at index pregnancy	Overall (n=46 551)	Black (n=21 107 [45%])	White (n=21 502 [46%])	Puerto Rican (n=3462 [7%])	Other* (n=480 [1%])
Age, y	24.5±6.2	24.0±6.4	25.1±6.0	23.7±5.4	25.8±5.5
Previous pregnancies					
0	12 372 (27)	5346 (26)	5921 (29)	935 (27)	170 (36)
1	9590 (21)	4057 (20)	4612 (23)	807 (23)	114 (24)
2	7115 (16)	3103 (15)	3338 (16)	606 (18)	68 (15)
3	5102 (11)	2359 (11)	2311 (11)	399 (12)	33 (7)
≥4	10 986 (24)	5916 (28)	4294 (21)	694 (20)	82 (18)
Prepregnancy body mass index					
<18.5 kg/m^2	3838 (9)	1713 (9)	1754 (10)	298 (10)	73 (18)
18.5–24.9 kg/m^2	28 212 (69)	12 848 (65)	12 992 (72)	2099 (69)	273 (69)
25.0–29.9 kg/m^2	6336 (15)	3505 (18)	2285 (13)	514 (17)	32 (8)
≥30.0 kg/m^2	2761 (7)	1680 (9)	911 (5)	152 (5)	18 (5)
Marital status					
Single	6953 (15)	5487 (26)	1167 (5)	257 (7)	42 (9)
Married/common law	35 539 (76)	13 305 (63)	18 733 (87)	3099 (90)	402 (84)
Other	4054 (9)	2313 (11)	1599 (7)	106 (3)	36 (8)
Smoking					
Nonsmoker	24 030 (53)	11 958 (58)	9395 (46)	2371 (69)	306 (66)
<1 pack/day	14 174 (32)	7212 (35)	6006 (30)	843 (25)	113 (24)
≥1 pack/day	6728 (15)	1599 (8)	4871 (24)	213 (6)	45 (10)
Annual income					
≤$1999	5935 (14)	4013 (21)	1681 (9)	185 (6)	56 (13)
$2000–3999	18 465 (44)	9703 (51)	6345 (34)	2254 (68)	163 (39)
$4000–5999	10 187 (24)	3622 (19)	5737 (30)	700 (21)	128 (31)
$6000–7999	4443 (11)	1268 (7)	2949 (16)	172 (5)	54 (13)
$8000–9999	1584 (4)	362 (2)	1189 (6)	21 (<1)	12 (3)
≥$10 000	1127 (3)	157 (<1)	959 (5)	7 (<1)	4 (1)
Education					
Less than high school	8093 (18)	3900 (19)	2638 (13)	1487 (44)	68 (15)
Some high school	17 319 (39)	9590 (47)	6254 (32)	1353 (40)	122 (27)
High school graduate	13 259 (30)	6027 (29)	6641 (34)	518 (15)	73 (16)
Some college	5453 (12)	1056 (5)	4169 (21)	47 (1)	181 (41)
Previous medical conditions					
Cardiovascular diseases†	5414 (12)	2894 (14)	2283 (11)	186 (5)	51 (11)
Respiratory diseases‡	3463 (8)	1489 (7)	1545 (7)	369 (11)	60 (13)
Renal diseases‖	3961 (9)	1813 (9)	2041 (10)	77 (2)	30 (6)
Neurologic diseases§	4572 (10)	1657 (8)	2676 (13)	192 (6)	47 (10)
Cancer and tumors#	1767 (4)	655 (3)	1064 (5)	38 (1)	10 (2)
Diabetes	742 (2)	191 (<1)	524 (3)	23 (<1)	4 (<1)
Delivery**					
Elective or spontaneous abortion	700 (2)	268 (1)	385 (2)	41 (1)	6 (1)
Preterm spontaneous labor	5688 (13)	3704 (18)	1405 (7)	540 (17)	39 (9)
Preterm PROM	298 (<1)	153 (<1)	125 (<1)	18 (<1)	2 (<1)
Preterm induced labor	149 (<1)	50 (<1)	90 (<1)	8 (<1)	1 (<1)

(*Continued*)

Table 1. Continued

Characteristic at index pregnancy	Overall (n=46 551)	Black (n=21 107 [45%])	White (n=21 502 [46%])	Puerto Rican (n=3462 [7%])	Other* (n=480 [1%])
Preterm prelabor cesarean delivery	252 (<1)	55 (<1)	179 (<1)	8 (<1)	1 (<1)
Preterm reason unknown	366 (<1)	183 (<1)	142 (<1)	37 (<1)	4 (<1)
Term	36 516 (83)	15 875 (78)	17 637 (88)	2617 (80)	387 (88)
Hypertensive disorders of pregnancy					
Normotensive	41 966 (91)	18 749 (89)	19 396 (93)	3365 (97)	456 (96)
Chronic hypertension	1776 (4)	1164 (6)	579 (3)	28 (<1)	5 (1)
Gestational hypertension	775 (2)	291 (1)	462 (2)	18 (<1)	4 (<1)
Preeclampsia/eclampsia	453 (1)	201 (1)	232 (1)	18 (<1)	2 (<1)
Superimposed	927 (2)	642 (3)	253 (1)	25 (<1)	7 (1)
Diabetes					
Normoglycemic	44 608 (97)	20 589 (98)	20 152 (96)	3403 (98)	464 (98)
Prepregnancy diabetes	742 (2)	191 (1)	524 (3)	23 (<1)	4 (<1)
Gestational diabetes, impaired glucose tolerance	540 (1)	263 (1)	242 (1)	29 (<1)	6 (1)

Data presented as mean±SD for continuous variables or n (%) for categorical variables. Missing data: age (n=2), previous pregnancy (n=1386); prepregnancy body mass index (n=5404), marital status (n=5), smoking (n=1619), income (n=4810), education (n=2427), previous medical conditions (cardiovascular diseases [n=717], respiratory diseases [n=717], renal diseases [n=717], neurological diseases [n=717], cancer and tumors [n=717], and diabetes [n=661]), preterm delivery (n=2592), and hypertensive disorders of pregnancy (n=654). PROM indicates premature rupture of membranes.

*The "other" category includes participants self-reporting race and ethnicity as Asian or "other."

†Including hypertension, rheumatic fever, and any other cardiovascular diseases.

‡Including tuberculosis, asthma, other chronic pulmonary diseases, and other conditions requiring thoracic surgery.

‖Including pyelitis, glomerulonephritis, and other conditions requiring kidney, urinary, or bladder surgery.

§Including neuromuscular diseases, convulsive disorders, psychosis, alcohol or drug addiction, or other neurological diseases.

#Including any history of cancer, or gastrointestinal, kidney, urinary, bladder, or gynecological tumors.

**Elective and spontaneous abortions, <20 weeks' gestation; preterm deliveries, 20 to <37 weeks gestation; term deliveries, ≥37 weeks gestation.

cardiovascular disease (HR, 1.37 [1.04, 1.80]) and diabetes (HR, 1.83 [0.98, 3.41]). Comparatively, for participants with preterm induced labor, a heightened mortality risk was observed with kidney disease (HR, 5.22 [2.14, 12.75)], diabetes (HR, 4.20 [2.25, 7.83]), and cardiovascular disease (HR, 1.74 [1.19, 2.54]). For participants with preterm prelabor cesarean delivery, a heightened mortality risk was observed with diabetes (HR, 5.39 [3.41, 8.52]), kidney disease (HR, 3.53 [1.43, 8.68]), cardiovascular disease (HR, 2.80 [2.19, 3.58]), and respiratory disease (HR, 1.80 [1.02, 3.18]).

Overall, 4% of pregnancies were affected by chronic hypertension, 2% by gestational hypertension, 1% by preeclampsia or eclampsia, and 2% by superimposed preeclampsia or eclampsia. Black participants were more likely to have chronic hypertension (6% versus 3%) or superimposed preeclampsia or eclampsia (3% versus 1%) than White participants. Gestational hypertension, preeclampsia or eclampsia, and superimposed preeclampsia or eclampsia were associated with higher all-cause mortality adjusted HRs of 1.09 (0.97–1.22), 1.14 (0.99–1.32), and 1.32 (1.20–1.46), respectively, and corresponding excess risks of 1.7 (−1.2 to 4.7), 2.8 (−0.8 to 6.5), and 6.2 (3.1–9.3) deaths per 100 participants, respectively, compared with normotensive participants (Table 4). Gestational hypertension was associated with higher risks for cardiovascular and diabetes mortality. Preeclampsia was associated with higher risks for cardiovascular, diabetes, infection, and kidney disease mortality, albeit some of the estimates were imprecise because of the small sample for some of the specific causes of mortality. Finally, superimposed preeclampsia was associated with higher risks for cardiovascular and kidney disease mortality. The *P* value for an interaction between Black and White participants was *P*=0.05 (Table S7); the mortality risk associated with preeclampsia appeared stronger for Black (HR, 1.33 [1.08, 1.63]) compared with White (HR, 1.00 [0.81, 1.23]) participants, whereas the risk associated with superimposed preeclampsia or eclampsia appeared stronger for White (HR, 1.50 [1.26, 1.79]) compared with Black (HR, 1.27 [1.13, 1.43]) participants. Sensitivity analyses were performed to classify hypertensive disorders of pregnancy according to preterm delivery status. The estimates were imprecise because of small numbers, but there was not a consistent pattern of increasing risk with preterm delivery and hypertensive disorders in pregnancy (Table S8). Notably, even among normotensive deliveries, preterm delivery was associated with an increase in all-cause mortality risk (HR, 1.12 [1.07–1.17]).

Overall, 1% of pregnancies were affected by gestational diabetes/impaired glucose tolerance (GD/IGT) with

Table 2. All-Cause and Underlying Cause–Specific Mortality by Race and Ethnicity in the Collaborative Perinatal Project Mortality Linkage Study

	Overall (n=46 551)	Black participants (n=21 107 [45%])	White participants (n=21 502 [46%])	Puerto Rican participants (n=3462 [7%])	Other* participants (n=480 [1%])
All deaths	18 124 (39)	8714 (41)	8019 (37)	1241 (36)	150 (31)
Major causes of cause-specific deaths					
Cardiovascular	4914 (31)	2604 (34)	1912 (27)	356 (33)	42 (31)
Cancer	5094 (32)	2325 (30)	2455 (34)	268 (24)	46 (34)
Diabetes	790 (5)	435 (6)	279 (4)	67 (6)	9 (7)
Respiratory	1245 (8)	401 (5)	760 (11)	76 (7)	8 (6)
Dementia	574 (4)	333 (4)	171 (2)	65 (6)	5 (4)
Infection	581 (4)	238 (3)	304 (4)	35 (3)	4 (3)
Kidney	348 (2)	229 (3)	105 (1)	11 (1)	3 (2)
Other	219 (1)	105 (1)	73 (1)	36 (3)	5 (4)
Cardiovascular-specific causes					
Hypertensive diseases	485 (3)	349 (5)	4 (3)	41 (4)	91 (1)
Ischemic heart disease	2191 (14)	1029 (13)	18 (13)	189 (17)	955 (13)
Arrhythmia	287 (2)	155 (2)	1 (1)	14 (1)	117 (2)
Heart failure	281 (2)	139 (2)	3 (2)	9 (1)	130 (2)
Cerebrovascular	902 (6)	522 (7)	9 (7)	63 (6)	308 (4)

Data expressed as n (%). Data reflect pregnancies from 1959 to 1965; vital status ascertainment through 2016.
*"Other" category included pregnant participants who checked the "other" category as well as those who identified as Asian.

no difference between Black (1%) and White (1%) participants. GD/IGT was associated with an adjusted higher hazard of 1.14 (1.00–1.30) for all-cause mortality and a corresponding excess risk of 2.8 (−0.6 to 6.1) deaths per 100 compared with normoglycemic participants (Table 5). GD/IGT was associated with higher risks for diabetes, infection, and kidney disease mortality. There were no differences in the estimates for all-cause mortality between Black and White participants (P=0.92; Table S9).

DISCUSSION

In this large cohort, consisting of almost half Black and half White pregnant participants from the 1950s through 1960s, those experiencing common pregnancy complications of preterm delivery, hypertensive disorders of pregnancy, or GD/IGT had an increased risk for mortality in the ≈50 years after pregnancy. Because much of the previous literature has been limited to primarily White populations, this article fills a critical data gap in the field of long-term implications of adverse pregnancy outcomes by using a diverse cohort and examining for potential heterogeneity in associations by race. Black individuals have a higher risk for pregnancy complications and earlier mortality, and in some instances, the mortality risks conferred from pregnancy complications were higher in Black compared with White individuals.

Preterm delivery was related to increased mortality. Interestingly, the risk differed according to the reason for the preterm delivery, the risk was highest in individuals with preterm prelabor cesarean delivery. Whereas preterm deliveries attributable to spontaneous labor were associated with an increased risk for cardiovascular mortality, preterm deliveries attributable to other reasons were also associated with mortality resulting from additional causes, including diabetes and kidney and respiratory diseases. Preterm delivery may contribute to disparities in earlier mortality. Preterm deliveries attributable to induced labor were associated with greater mortality risk among Black compared with White participants. Additionally, even as the mortality risk associated with spontaneous labor was similar for Black and White participants, the incidence was substantially higher for Black compared with White pregnant participants (19% versus 8%), also contributing to disparities in premature mortality.[12] Our findings advance previous work by extending the follow-up period to >50 years and by including a diverse population. Previous cohort studies on preterm and all-cause or cardiovascular mortality were based on primarily White populations and had follow-up times ranging from only 14 to 25 years.[16,32–34] We have demonstrated that the etiology of the differing types of preterm delivery contributes to substantially different mortality risks, especially when considering causes of mortality outside of cardiovascular disease, which is consistent with the few previous studies that have also separated by indication.[32,34] The observed association of an increased risk for diabetes and kidney disease mortality with preterm induced labor and prelabor cesarean

Table 3. Associations of Preterm Delivery and Long-Term All-Cause and Cause-Specific Underlying Mortality of the Collaborative Perinatal Project Mortality Linkage Study

	Term	Reason for preterm delivery				
		Spontaneous	PROM	Induced	Prelabor cesarean delivery	Unknown
All-cause mortality						
Total, n (%)*	14 814 (38.2)	2353 (41.4)	162 (54.4)	75 (50.3)	174 (71.9)	261 (38.0)
Risk difference per 100 (95% CI), unadjusted†	0 Reference	2.9 (1.7–4.2)	15.4 (10.2–20.7)	12.3 (4.7–19.8)	34.1 (28.3–39.9)	−0.4 (−4.2 to 3.4)
Risk difference per 100 (95% CI), adjusted†‡	0 Reference	1.5 (−0.6 to 3.6)	4.5 (0.3–8.7)	6.0 (−0.1 to 12.1)	19.1 (13.2–25.1)	−1.7 (−5.1 to 1.7)
HR (95% CI), unadjusted†	1 Reference	1.11 (1.07–1.16)	1.67 (1.43–1.94)	1.51 (1.20–1.90)	2.80 (2.39–3.27)	0.98 (0.85–1.14)
HR (95% CI), adjusted†‡	1 Reference	1.07 (1.03–1.12)	1.23 (1.05–1.44)	1.31 (1.03–1.66)	2.09 (1.75–2.48)	0.92 (0.79–1.07)
Cause-specific mortality, adjusted‡ HR (95% CI)						
Major causes						
Cancer	1 Reference	1.05 (0.97–1.14)	1.07 (0.79–1.45)	0.94 (0.57–1.54)	1.34 (0.95–1.90)	0.89 (0.68–1.16)
Cardiovascular	1 Reference	1.18 (1.09–1.28)	1.37 (1.04–1.80)	1.74 (1.19–2.54)	2.80 (2.19–3.58)	1.01 (0.79–1.30)
Diabetes	1 Reference	1.06 (0.86–1.31)	1.83 (0.98–3.41)	4.20 (2.25–7.83)	5.39 (3.41–8.52)	1.07 (0.58–2.00)
Respiratory	1 Reference	1.05 (0.88–1.25)	1.41 (0.83–2.39)	0.24 (0.03–1.74)	1.80 (1.02–3.18)	0.98 (0.56–1.72)
Dementia	1 Reference	0.89 (0.67–1.19)	0.52 (0.17–1.63)	1.02 (0.25–4.08)	1.05 (0.39–2.83)	0.61 (0.24–1.55)
Infection	1 Reference	1.05 (0.83–1.33)	1.27 (0.53–3.01)	1.11 (0.28–4.45)	1.90 (0.70–5.13)	0.44 (0.13–1.52)
Kidney	1 Reference	0.98 (0.71–1.35)	1.32 (0.42–4.11)	5.22 (2.14–12.75)	3.53 (1.43–8.68)	0.96 (0.38–2.43)
Cardiovascular-specific causes						
Hypertensive diseases	1 Reference	1.34 (1.06–1.69)	0.60 (0.15–2.38)	1.63 (0.40–6.62)	1.30 (0.32–5.23)	0.87 (0.37–2.06)
Ischemic heart disease	1 Reference	1.15 (1.02–1.31)	1.30 (0.85–1.98)	1.90 (1.12–3.24)	3.86 (2.74–5.45)	1.09 (0.77–1.54)
Arrhythmia	1 Reference	0.99 (0.69–1.43)	3.18 (1.49–6.76)	4.44 (1.61–12.25)	3.48 (1.39–8.72)	0.87 (0.29–2.60)
Heart failure	1 Reference	1.34 (0.94–1.89)	1.29 (0.41–4.06)	–‖	2.47 (0.91–6.76)	1.13 (0.42–3.03)
Cerebrovascular	1 Reference	1.06 (0.88–1.28)	0.57 (0.21–1.52)	1.41 (0.52–3.79)	1.93 (0.95–3.91)	0.59 (0.25–1.37)

Data reflect pregnancies from 1959 to 1965; vital status ascertainment through 2016. Elective and spontaneous abortions, <20 weeks gestation; preterm deliveries, 20 to <37 weeks gestation; term deliveries, ≥37 weeks gestation. HR indicates hazard ratio; and PROM, premature rupture of membranes.

*Cases and percentage based on imputed data.

†Models were weighted to control for potential selection bias introduced by restricting to pregnancies lasting ≥20 weeks.

‡Analyses adjusted for the following index pregnancy variables: age, smoking, race and ethnicity, previous pregnancies, marital status, income, education, previous medical conditions (diabetes, cardiovascular, respiratory, renal, and neurological diseases, and cancer and tumors), site, year, and prepregnancy body mass index.

‖HR could not be estimated because there were too few cases.

deliveries is consistent with previous studies, although these studies examined morbidity and not mortality.[5,6,35] More research is needed to expand the understanding of preterm delivery on outcomes beyond cardiovascular disease, particularly in cohorts that are not primarily comprised of White participants only. Finally, while indications for preterm delivery have changed since the participants in this study were pregnant, we observed adverse associations with spontaneous preterm delivery as well. Our findings highlight the importance of understanding the etiology of the preterm delivery when considering future risk of complications.

In general, hypertensive disorders of pregnancy were associated with an increased risk of all-cause mortality, with the associations strongest for superimposed preeclampsia or eclampsia. Our findings are consistent with reports of hypertensive disorders of pregnancy and increased mortality risks—specifically cardiovascular disease mortality—among cohorts of predominantly White participants.[4] Importantly, we extend these studies with the inclusion of a cohort that was composed of >50% non-White participants. Another previous study also evaluated for an interaction between hypertensive disorders of pregnancy and prepregnancy hypertension status and race and ethnicity for all-cause mortality, but they were limited to a follow-up of only ≤5 years after pregnancy.[36] They found a stronger association for hypertensive disorders of pregnancy (combined) among non-Hispanic Black compared with non-Hispanic White and similar associations for prepregnancy hypertension in the presence of hypertensive disorders of pregnancy. We observed that preeclampsia or eclampsia may be associated with a greater mortality risk in Black compared with White pregnant participants. Moreover, the 3-fold higher incidence of superimposed preeclampsia or eclampsia during pregnancy in Black compared with

Table 4. Associations for Hypertensive Disorders of Pregnancy and Long-Term All-Cause and Cause-Specific Underlying Mortality of the Collaborative Perinatal Project Mortality Linkage Study

	Normotensive	Gestational hypertension	Preeclampsia/ eclampsia	Superimposed preeclampsia/eclampsia*
All-cause mortality				
Total, n (%)†	15 978 (37.5)	338 (42.6)	218 (47.2)	596 (63.8)
Risk difference per 100 (95% CI)				
Unadjusted	0 Reference	5.4 (2.2–8.6)	10.0 (5.8–14.2)	27.0 (23.8–30.1)
Adjusted‡	0 Reference	1.7 (−1.2 to 4.7)	2.8 (−0.8 to 6.5)	6.2 (3.1–9.3)
Hazard ratio (95% CI)				
Unadjusted	1 Reference	1.22 (1.09–1.36)	1.42 (1.24–1.62)	2.33 (2.13–2.54)
Adjusted‡	1 Reference	1.09 (0.97–1.22)	1.14 (0.99–1.32)	1.32 (1.20–1.46)
Cause-specific mortality, adjusted‡ HR (95% CI)				
Major causes				
Cancer	1 Reference	0.87 (0.69–1.09)	0.79 (0.57–1.08)	0.99 (0.81–1.20)
Cardiovascular	1 Reference	1.34 (1.11–1.61)	1.37 (1.09–1.72)	1.61 (1.40–1.86)
Diabetes	1 Reference	1.72 (1.16–2.56)	2.44 (1.58–3.75)	1.28 (0.90–1.82)
Respiratory	1 Reference	0.69 (0.41–1.18)	0.99 (0.56–1.74)	0.90 (0.59–1.35)
Dementia	1 Reference	1.14 (0.67–1.96)	0.62 (0.23–1.66)	0.83 (0.49–1.42)
Infection	1 Reference	1.26 (0.71–2.22)	1.81 (0.97–3.37)	1.33 (0.81–2.19)
Kidney	1 Reference	1.05 (0.49–2.26)	1.99 (0.98–4.04)	2.40 (1.53–3.77)
Cardiovascular-specific causes				
Hypertensive diseases	1 Reference	1.34 (1.11–1.61)	1.37 (1.09–1.72)	1.61 (1.40–1.86)
Ischemic heart disease	1 Reference	1.14 (0.54–2.42)	1.68 (0.79–3.57)	1.91 (1.26–2.91)
Arrhythmia	1 Reference	1.48 (1.11–1.97)	1.36 (0.94–1.96)	1.76 (0.94–3.31)
Heart failure	1 Reference	0.58 (0.19–1.81)	1.01 (0.33–3.12)	1.25 (0.61–2.56)
Cerebrovascular	1 Reference	1.55 (0.78–3.07)	0.71 (0.18–2.86)	2.32 (1.39–3.88)

Data reflect pregnancies from 1959 to 1965; follow-up through 2016.

*Estimates for chronic hypertension not shown. Superimposed preeclampsia or eclampsia is preeclampsia or eclampsia with pre-existing chronic hypertension.

†Patients, expressed as n (%), based on imputed data.

‡Analyses adjusted for the following index pregnancy variables: age, smoking, race and ethnicity, previous pregnancies, marital status, income, education, previous medical conditions (diabetes, cardiovascular, respiratory, renal, and neurological diseases, and cancer and tumors), site, year, and prepregnancy body mass index.

White pregnant participants also signals that disparities in pregnancy health may have lifelong implications for earlier mortality.

GD/IGT in pregnancy was associated with an increased all-cause and cause-specific mortality attributable to diabetes, infection, and kidney disease. There was no difference in the incidence or size of the associations between Black and White individuals. Although the relationship between gestational diabetes and future development of cardiovascular disease, type 2 diabetes, and kidney disease is well reported, few studies have examined long-term mortality risks.[4,37,38] Interestingly, while gestational diabetes has been associated with future cardiovascular morbidity, we did not observe an association with cardiovascular end points as the underlying cause of mortality. The lack of research on mortality associated with gestational diabetes corresponds with the shorter follow-up time observed in many of the previous studies. During the CPP study period (1959–1966), gestational diabetes was lower than currently observed, which may be largely attributable to a lack of major risk factors (eg, obesity) and inconsistent screening practices.[39] In addition, the criteria for diagnosis differed from current guidelines. Nevertheless, these findings further demonstrate the long-term implications of glucose intolerance in pregnancy, reinforcing the importance of current measures screening for type 2 diabetes in the postpartum period after gestational diabetes, enabling earlier diagnosis and disease management.[40]

The major strength of this study was its racial and socioeconomic diversity: the cohort was nearly equally split among Black and White participants. There is a dearth of diversity in the existing studies on pregnancy complications and long-term morbidity and mortality. The size of the cohort was also a strength, as it allowed us to not only report the associations overall, but also to examine for interactions between race and pregnancy complications. An additional strength of this study was the long-term follow-up (median,

Table 5. Associations for Gestational Diabetes/Impaired Glucose Tolerance in Pregnancy and Long-Term All-Cause and Cause Specific Underlying Mortality, Collaborative Perinatal Project Mortality Linkage Study

	Normoglycemic*	Gestational diabetes/impaired glucose tolerance
All-cause mortality		
Cases, n (%)†	17359 (38.4)	267 (49.0)
Risk difference per 100 (95% CI)		
Unadjusted	0 Reference	11.3 (7.3–15.2)
Adjusted‡	0 Reference	2.8 (−0.6 to 6.1)
HR (95% CI)		
Unadjusted	1 Reference	1.47 (1.30–1.66)
Adjusted‡	1 Reference	1.14 (1.00–1.30)
Cause-specific mortality, adjusted HR (95% CI)†‡		
Major causes		
Cancer	1 Reference	0.93 (0.72–1.21)
Cardiovascular	1 Reference	0.94 (0.74–1.20)
Diabetes	1 Reference	3.12 (2.22–4.37)
Respiratory	1 Reference	0.83 (0.47–1.47)
Dementia	1 Reference	1.27 (0.70–2.32)
Infection	1 Reference	1.79 (1.02–3.12)
Kidney	1 Reference	2.13 (1.16–3.92)
Cardiovascular-specific causes		
Hypertensive diseases	1 Reference	0.94 (0.74–1.20)
Ischemic heart disease	1 Reference	0.27 (0.07–1.09)
Arrhythmia	1 Reference	1.17 (0.83–1.66)
Heart failure	1 Reference	0.91 (0.30–2.75)
Cerebrovascular	1 Reference	1.13 (0.46–2.76)

Data reflect pregnancies from 1959 to 1965; follow-up through 2016.
*Estimates for preexisting diabetes not shown.
†Cases and percentage based on imputed data.
‡Analyses adjusted for the following index pregnancy variables: age, smoking, race and ethnicity, previous pregnancies, marital status, income, education, previous medical conditions (diabetes, cardiovascular, respiratory, renal, and neurological diseases, and cancer and tumors), site, year, prepregnancy body mass index.

52 years). When interpreting the findings, it is important to remember that they represent the underlying cause of death and not a contributing cause of death, an important distinction, as these are mutually exclusive mortality categories that do not represent the overall prevalence of disease in participants. More research into the contributing causes of death and coexisting morbidities is warranted. Additionally, because this study stemmed from a well-characterized prospective pregnancy cohort, we were able to adjust for important confounders, such as prepregnancy body mass index and previous medical conditions, that have been missing from many previous studies. We cannot distinguish whether the pregnancy complications cause harm that put individuals at a greater risk for disease later in life or whether these individuals were more prone to pregnancy complications attributable to unmeasured causes. Thus, these pregnancy complications should be regarded as predictive factors and not necessarily causal factors for morbidity and mortality.

There are also limitations to this work. First, the participants were pregnant in the 1950s to 1960s. As expected, the prevalence of pregnancy complications, as well as risk factors such as obesity and smoking, differ from the current obstetric setting.[41] Nonetheless, long-term mortality is a critical outcome that is, by definition, impossible to study in a current obstetric cohort. To address this limitation, and importantly, to make our findings more relevant to current clinical practice, we utilized the well-documented data on blood pressure in pregnancy and proteinuria to apply the current definitions of preeclampsia/gestational hypertension. Additionally, there was less obstetrical intervention in the 1950s and 1960s, with fewer inductions and planned cesareans deliveries, highlighting an advantage of using the CPP. In modern obstetrics, the iatrogenic earlier deliveries lead to less time in which pregnancy complications such as preeclampsia can develop; the CPP enabled us to more fully explore those relationships.

Because of the different clinical definitions for gestational diabetes, we conservatively labeled this variable as "gestational diabetes or impaired glucose tolerance" to avoid overgeneralizing that these were directly comparable to the current obstetric setting. Also, because of the likely low-true incidence of gestational diabetes (attributable to lower prevalence of obesity) and low, potentially underreported rates of gestational diabetes (attributable to limited surveillance), we did not have a large enough sample size to evaluate risk for GD/IGT separately. This analysis was based on only a single pregnancy. Future studies including complete pregnancy histories may examine the "dose–response" of experiencing pregnancy complications in more than one pregnancy. Finally, there may be misclassification of deaths because of linkages with the NDI and SSDMF. Of those classified as deceased, 89% were sourced from the NDI. We previously found that there was good agreement between the NDI and vital status determined by review from an expert genealogist (κ=0.66 [95% CI, 0.61–0.70]).[20,42] With bias estimates informed by expert genealogist review,[20] we used the quantitative bias analysis tools for outcome misclassification from Fox et al,[43] and estimate that this misclassification may have biased our findings slightly toward null.

Pregnancy has been regarded as a stress test that can unveil those who are at increased risk for chronic diseases in the future.[44] Alternatively, pregnancy complications themselves may cause vascular dysfunction that may lead to lifelong health impacts.[45] Irrespective of the mechanisms, current efforts are focused on educating pregnant and postpartum individuals and their health care professionals, particularly in primary care, to recognize the risks associated with pregnancy complications.[1] An important piece of this research is extending this concept of lifelong health implications from pregnancy complications to a cohort that was nearly half comprised of Black individuals—those often at greater risk for major pregnancy complications. Significant efforts are needed, particularly toward alleviating racial disparities in cardiovascular and diabetes screenings, among patients with a history of pregnancy complications.[46]

ARTICLE INFORMATION

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Disclosures

None.

Supplemental Material

Tables S1–S9

Figure S1

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EXHIBIT E

JAMA Network Open

Original Investigation | Obstetrics and Gynecology

Trends in Maternal Mortality and Severe Maternal Morbidity During Delivery-Related Hospitalizations in the United States, 2008 to 2021

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Abstract

IMPORTANCE Maternal mortality and severe maternal morbidity (SMM) are important focus areas in public health. Further understanding trends, health disparities, and risk factors for these adverse outcomes is vital to public health decision-making.

OBJECTIVE To describe trends and risk factors for delivery-related maternal deaths and SMM in the United States.

DESIGN, SETTING, AND PARTICIPANTS This is a retrospective cross-sectional study using data from a large, geographically diverse, all-payer hospital administrative database. Hospital discharges from January 2008 to December 2021 with any Medicare Severity Diagnosis Related Group, *International Classification of Diseases, Ninth Revision, Clinical Modification*, or *International Classification of Diseases, Tenth Revision, Clinical Modification* delivery diagnosis or procedure code were included. Data analysis took place from February 2021 to March 2023.

EXPOSURES Year, quarter (Q), age, race and ethnicity, delivery method.

MAIN OUTCOMES AND MEASURES Maternal mortality, SMM during delivery-related hospitalization.

RESULTS Overall, 11 628 438 unique hospital discharges were analyzed, with a mean (SD) age of 28 (6) years. There were 437 579 (3.8%) Asian, 92 547 (0.8%) American Indian, 1 640 355 (14.1%) Black, 1 762 392 (15.2%) Hispanic, 83 189 (0.7%) Pacific Islander, and 6 194 139 (53.3%) White patients. Regression-adjusted maternal mortality per 100 000 discharges declined from 10.6 deaths in Q1 2008 to 4.6 deaths in Q4 2021. Mortality was significantly higher among patients with advanced maternal age (eg, age 35-44 years vs 25-34 years: adjusted odds ratio [aOR], 1.49; 95% CI, 1.22-1.84). Other significant risk factors for mortality included cesarean delivery, comorbid conditions, complications, and COVID-19 diagnosis (eg, cesarean delivery: aOR, 2.28; 95% CI, 1.87-2.79). The prevalence of any SMM increased from 146.8 per 10 000 discharges in Q1 of 2008 to 179.8 per 10 000 discharges in Q4 of 2021. SMM risk factors included age 24 years or younger or age 35 years or older, belonging to a racial or ethnic minority group, cesarean delivery, Medicaid insurance, and having 1 or more comorbidities (eg, age 10-19 years: aOR, 1.39; 95% CI, 1.36-1.42).

CONCLUSIONS AND RELEVANCE This cross-sectional study found that delivery-related mortality in US hospitals decreased for all racial and ethnic groups, age groups, and modes of delivery during 2008 to 2021, likely demonstrating the impact of national strategies focused on improving maternal quality of care provided during delivery-related hospitalizations. SMM prevalence increased for all patients, with higher rates for racial and ethnic minority patients of any age. Advanced maternal age,

(continued)

Key Points

Question What were trends of and risk factors associated with maternal mortality and severe maternal morbidity (SMM) among women giving birth in US hospitals during 2008 to 2021?

Findings In this cross-sectional study of more than 11.6 million delivery-related hospitalizations, regression-adjusted in-hospital maternal delivery-related mortality per 100 000 discharges declined from 10.6 to 4.6, while the prevalence of SMM per 10 000 discharges increased from 146.8 to 179.8 during 2008 to 2021. Differences were found across racial and ethnic groups, age, mode of delivery, and comorbidities for mortality and SMM.

Meaning In this study, in-hospital maternal mortality improved between 2008 and 2021 despite increases in SMM prevalence and presence of comorbidities for the overall population.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

Abstract (continued)

racial or ethnic minority group status, cesarean delivery, and comorbidities were associated with higher odds of mortality and SMM.

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Introduction

Complications from pregnancy and childbirth are leading contributors to mortality and severe morbidities, resulting in significant burden on pregnant patients and their babies. Among developed countries, the United States has the highest maternal mortality ratio.[1] In 2019, there were 3 747 540 births in the United States, with an estimated birth rate of 11.4 per 1000 population.[2] According to US Pregnancy Mortality Surveillance System (PMSS) data, the pregnancy-related mortality ratio in the United States had increased since 1987 from 7.2 deaths per 100 000 live births to 17.3 deaths per 100 000 live births in 2017, although the trend slowed substantially after 2008.[3]

Maternal mortality has been described as the "tip of the iceberg" and maternal morbidity as a larger problem, "the base."[4] For every individual who dies as a result of their pregnancy, it is estimated that 20 or 30 more experience significant lifelong complications that affect their health and well-being.[5,6] Severe maternal morbidity (SMM), which the US Centers for Disease Control and Prevention (CDC) defines as "unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health,"[1] has steadily increased in the United States in recent years and is estimated to affect more than 50 000 patients annually.

Causes of maternal deaths and SMM at the time of delivery are multifactorial and are not well documented.[7] Measuring specific outcomes occurring during delivery and hospitalization could improve understanding of how to predict, manage, and mitigate maternal outcomes. In addition, enhanced understanding of the causes of delivery-related death and SMM can inform potential strategies to improve overall maternal health outcomes in the United States. This study aimed to provide evidence to enhance understanding of patterns, trends, and risk factors associated with delivery-related deaths and SMM in US hospitals using a large maternal sample in the hospital setting.

Methods

Study Design

This retrospective cross-sectional study was conducted to examine trends associated with delivery-related maternal in-hospital mortality and SMM between January 2008 and December 2021, using data from the Premier PINC AI Healthcare Database (PHD). All data were statistically deidentified and adherent to the Health Insurance Portability and Accountability Act. Based on US Title 45 Code of Federal Regulations, Part 46, this study was exempted from institutional review board approval and informed consent. The study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Data Source

The PHD is a large, all-payer (including Medicaid), geographically diverse administrative database comprising more than 1200 US hospitals and health systems.[8] This database represents approximately 25% of all US inpatient admissions. All data were validated at both facility and patient levels. The CDC, the National Institute of Health, and academic and industry researchers have used PHD data for studies in a variety of disease areas.[9-15]

Study Population

This study reviewed inpatient hospitalizations between January 1, 2008, and December 31, 2021, with any Medicare Severity Diagnosis Related Group (MS-DRG) or *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) diagnosis or procedure codes (on or before September 30, 2015) or *International Classification of Diseases and Related Health Problems, Tenth Revision, Clinical Modification* (*ICD-10-CM*) codes (on or after October 1, 2015) indicating delivery (eTable 1 in Supplement 1). Hospitalizations for patients younger than 10 years at time of admission and those with evidence of abortive outcomes were excluded from the study. The index date was defined as the discharge date for the qualifying hospitalization. Missing data for categorical variables were included in the other or unknown group. Only a small percentage of patients had missing data, which should not have affected the trend analysis.

Study Variables

SMM

Complications or procedures indicative of SMMs were examined during the delivery-related hospitalization; these included acute myocardial infarction, acute kidney failure, amniotic fluid embolism, aneurysm, cardiac arrest or ventricular fibrillation, cardioversion, disseminated intravascular coagulation, eclampsia, heart failure or arrest during procedure, puerperal cerebrovascular disorders, acute heart failure or pulmonary edema, severe anesthesia complications, sepsis, shock, sickle cell anemia with crisis, air and thrombotic embolism, blood transfusion, hysterectomy, temporary tracheostomy, and ventilation. The diagnosis and procedure codes to identify the complications are listed in eTable 2 in Supplement 1. The presence of any SMM was used as a measure for the adverse event occurring during delivery. Morbidities were reported as number of patients with each SMM or any SMM of interest per 10 000 eligible discharges.

In-Hospital Delivery-Related Mortality

Death was defined as having delivery-related hospitalization discharge status as deceased. In-hospital mortality was reported as the number of patients who died during index hospitalization per 100 000 eligible discharges.

Patient, Hospital, and Visit Characteristics

Patient characteristics included age (10-19, 20-24, 25-34, 35-44, ≥45 years), race and ethnicity (categorized as American Indian, Asian, Black, Hispanic, Pacific Islander, White, and other or unknown), and primary insurance payer. The other or unknown category captures all patients who selected other category for race, had missing data for race or ethnicity, or had a hospital-reported race that could not be matched to the standard race categories used in this article. Race and ethnicity were reported by the hospital. For the purposes of this study, we defined racial or ethnic minority patients as those with race or ethnicity classifications other than White. Hospital characteristics included population served (urban, rural), teaching status, US census divisions (ie, Middle Atlantic, Mountain, East North Central, East South Central, New England, Pacific, South Atlantic, West North Central, and West South Central), and hospital size (1-299, 300-499, and ≥500 beds). Visit information, such as index year, quarter (Q), admission type (elective, emergency, urgent, or trauma center), and an indicator for pre–*ICD-10-CM* or post–*ICD-10-CM* coding system change on October 1, 2015, were also examined.

Clinical Characteristics

The individual conditions in the Maternal Comorbidity Index (MCI)[16] were assessed as potential risk factors of maternal mortality or morbidity, including pulmonary hypertension, placenta previa, sickle cell disease, gestational hypertension, mild or unspecified preeclampsia, severe preeclampsia, chronic kidney disease, preexisting hypertension, chronic ischemic heart disease, congenital heart disease, systemic lupus erythematosus, HIV, multiple gestation, substance use disorder, alcohol

abuse, tobacco use, cardiac valvular disease, chronic congestive heart failure, asthma, preexisting diabetes, gestational diabetes, obesity, cystic fibrosis, and previous cesarean delivery (eTable 3 in Supplement 1). The type of delivery (vaginal, cesarean) and COVID-19 status were also examined.

All SMMs were included as covariates for the mortality analysis. Because of overlap across comorbid conditions, certain SMMs were grouped together. Per CDC recommendations, cardiac conditions (including acute myocardial infarction, cardiac arrest or ventricular fibrillation, conversion of cardiac rhythm, heart failure or arrest during surgery or procedure, and pulmonary edema or acute heart failure) were grouped into 1 binary variable called cardiovascular complications for multivariable modeling. Acute respiratory conditions (including acute respiratory distress syndrome, temporary tracheostomy, and ventilation) were grouped into a binary variable called respiratory complications.[17] Hemorrhage and blood transfusion were combined into bleeding complications with 3 categories: no bleeding, hemorrhage with no blood transfusion, and blood transfusion. Eclampsia, severe preeclampsia without eclampsia, mild or unspecified preeclampsia without eclampsia, or severe preeclampsia, and no preeclampsia or eclampsia were grouped into one 4-level covariate.

Statistical Analysis

Descriptive analysis was performed to assess the distribution of demographics and hospital and clinical characteristics for each year. Categorical variables were expressed as counts and percentages. Owing to space limitations, we only included specific descriptive results for 2008, 2014 (ie, the year before the *ICD-9-CM* to *ICD-10-CM* coding change), 2016 (ie, the year after the *ICD-9-CM* to *ICD-10-CM* coding change), 2019 (ie, the year before the COVID-19 pandemic), 2020, and 2021 (ie, years during the COVID-19 pandemic), rather than for all years in this study.

Two separate multivariable logistic regression models were created to assess the independent associations of potential risk factors with delivery-related maternal mortality and SMM, adjusting for confounders. For both models, patient demographics, hospital and visit characteristics, and MCI conditions were included as covariates. In the mortality regression, the SMM complications were added to the model to account for disease conditions that happened during the delivery-related hospitalization before the occurrence of mortality. In addition, a logistic regression of mortality without SMMs as covariates was performed as a sensitivity analysis. Backward selection with $P < .05$ was used to select final models, with the exception that patient age, race and ethnicity, delivery type, and study year and Q were kept in the model regardless of *P* values. For the mortality model, SMM conditions that were closely related to each other were combined. Combined variables included bleeding complications, cardiovascular complications, respiratory complications, and an eclampsia or preeclampsia category. In the regression of SMM, eclampsia was 1 component of the SMM outcome, while the preeclampsia conditions were used as separate covariates in the model.

Adjusted mortality and SMM rates for the overall study population were calculated using recycled prediction methods[16,18] based on estimates from the regressions. Adjusted mortality and SMM rates were also reported by age group, race and ethnicity, and type of delivery, based on additional regression models that included interaction terms between year and the variable of interest.

All analyses were conducted using Python Scikit-Learn package version 0.22.1 (Python Software Foundation). Analysis of the data took place from February 2021 through March 2023. *P* values were 2-sided, and statistical significance was set at $P < .05$.

Results

Patient Characteristics

Among the 11 628 438 eligible discharges related to delivery, more than half (6 498 217 [55.9%]) were among patients aged 25 to 34 years, 1 885 571 (16.2%) were among patients aged 35 years or older, and 759 301 (6.5%) were among patients aged 10 to 19 years. There were 437 579 (3.8%) Asian patients, 92 547 (0.8%) American Indian patients, 1 640 355 (14.1%) Black patients, 1 762 392

(15.2%) Hispanic patients, 83 189 (0.7%) Pacific Islander patients, and 6 194 139 (53.3%) White patients. Medicaid was identified as the primary payer for 4 958 174 discharges (42.6%). The census region distribution reflected the geographic distribution of the PHD patient population. Approximately one-third of the sample underwent cesarean delivery. The proportion of discharges in younger age groups decreased while the proportion in older age groups increased over the study period. The distribution of race and ethnicity, primary payer type, census region, and delivery type did not differ significantly across years (**Table 1**).

Maternal Comorbid Conditions

As shown in Table 1, obesity (91.0 per 1000 discharges), gestational diabetes (74.3 per 1000 discharges), and tobacco use (58.2 per 1000 discharges) were the most common comorbidities, followed by gestational hypertension, asthma, preeclampsia, preexisting hypertension, and substance use disorder. Compared with the prevalence in 2008, higher prevalence of sickle cell disease, gestational hypertension, severe preeclampsia, preexisting hypertension, substance use disorder, asthma, gestational diabetes, obesity, and hemorrhage were observed in 2021 (Table 1).

Prevalence and Trend of SMMs

The unadjusted prevalence of any SMM was estimated to be 163.3 per 10 000 discharges for the overall sample from 2008 to 2021, with higher prevalence observed in 2021 (206.1 per 10 000 discharges) compared with 2008 (135.2 per 10 000 discharges). Blood transfusion was the most common SMM observed, with a prevalence of 108.4 per 10 000 discharges. Other relatively common SMMs included disseminated intravascular coagulation (24.7 per 10 000 discharges), hysterectomy (11.0 per 10 000 discharges), acute respiratory distress syndrome (9.8 per 10 000 discharges), acute kidney failure (9.7 per 10 000 discharges), sepsis (7.4 per 10 000 discharges), eclampsia (7.2 per 10 000 discharges), shock (6.1 per 10 000 discharges), and acute heart failure or pulmonary edema (5.6 per 10 000 discharges). Prevalence of acute kidney failure, acute respiratory distress syndrome, sepsis, shock, mechanical ventilation, blood transfusion, and hysterectomy were higher in 2021 than in 2008 (Table 1).

As seen in **Figure 1**A, the adjusted prevalence of any SMM increased from Q1 2008 (146.8 per 10 000 discharges) to Q4 2021 (179.8 per 10 000 discharges). The increasing trend was observed in all age groups with the greatest change observed in patients aged 45 years or older and those aged 10 to 19 years (Figure 1B). Consistent increasing trend was also observed in all racial and ethnic groups, with the biggest increase observed among Pacific Islander patients (from 132.0 per 10 000 discharges in Q1 2008 to 298.8 per 10 000 discharges in Q4 2021), American Indian patients (from 156.5 per 10 000 discharges in Q1 2008 to 245.0 per 10 000 discharges in Q4 2021), and Asian patients (from 133.4 per 10 000 discharges in Q1 2008 to 238.2 per 10 000 discharges in Q4 2021) (Figure 1C). A significant increase in adjusted SMM prevalence was observed in patients undergoing cesarean delivery (from 252.4 per 10 000 discharges in Q1 of 2008 to 312.1 per 10 000 discharges in Q4 of 2021), and a similarly increasing trend was seen in patients with vaginal delivery (from 84.4 per 10 000 discharges in Q1 of 2008 to 108.4 per 10 000 discharges in Q4 of 2021) (Figure 1D).

Unadjusted and Adjusted Trend of In-Hospital Delivery-Related Mortality

As shown in **Figure 2**A, a downward trend was observed for in-hospital mortality among deliveries after adjusting for changes in patient demographic, visit, hospital, and clinical characteristics. From Q1 of 2008 to Q4 of 2021, the adjusted in-hospital mortality decreased from 10.6 per 100 000 discharges to 4.6 per 100 000 discharges. Each subsequent year after 2008 had an 11% decrease in odds of death compared with the previous year (adjusted odds ratio [aOR], 0.89; 95% CI, 0.87-0.92) (**Table 2**). There was an increase in mortality from Q2 of 2020 through Q4 of 2021 that may be associated with the COVID-19 pandemic. However, after controlling for COVID-19 diagnosis, the adjusted trend decreased consistently across the full study period. The downward trend for in-hospital mortality was observed in all age groups, with the biggest decrease occurring in patients

Table 1. Demographic and Clinical Characteristics of Hospital Inpatient Discharges for Newborn Delivery From 2008 to 2021

Characteristic	Overall (2008-2021) (N = 11 628 438)	2008 (n = 545 297)	2014 (n = 959 874)	2016 (n = 947 865)	2019 (n = 895 086)	2020 (n = 816 259)	2021 (n = 737 241)
Demographic characteristics, No. (%)							
Age group, y							
10-19	759 301 (6.5)	54 859 (10.1)	61 862 (6.4)	50 844 (5.4)	43 283 (4.8)	37 984 (4.7)	31 551 (4.3)
20-24	2 485 349 (21.4)	131 265 (24.1)	214 382 (22.3)	193 547 (20.4)	172 562 (19.3)	155 545 (19.1)	135 711 (18.4)
25-34	6 498 217 (55.9)	280 481 (51.4)	537 605 (56.0)	546 059 (57.6)	517 947 (57.9)	472 928 (57.9)	430 853 (58.4)
35-44	1 863 674 (16.0)	77 861 (14.3)	144 381 (15.0)	155 624 (16.4)	159 443 (17.8)	147 978 (18.1)	137 560 (18.7)
≥45	21 897 (0.2)	831 (0.2)	1644 (0.2)	1791 (0.2)	1851 (0.2)	1824 (0.2)	1566 (0.2)
Race and ethnicity							
American Indian	92 547 (0.8)	3614 (0.7)	7400 (0.8)	7031 (0.7)	7078 (0.8)	6452 (0.8)	5998 (0.8)
Asian	437 579 (3.8)	97 (<0.1)	40 970 (4.3)	45 423 (4.8)	38 467 (4.3)	37 268 (4.6)	33 805 (4.6)
Black	1 640 355 (14.1)	76 464 (14.0)	127 521 (13.3)	130 219 (13.7)	130 805 (14.6)	121 362 (14.9)	107 857 (14.6)
Hispanic	1 762 392 (15.2)	71 490 (13.1)	133 203 (13.9)	127 114 (13.4)	149 926 (16.7)	146 098 (17.9)	142 558 (19.3)
Pacific Islander	83 189 (0.7)	2 (<0.1)	7432 (0.8)	7584 (0.8)	7236 (0.8)	6745 (0.8)	5991 (0.8)
White	6 194 139 (53.3)	267 502 (49.1)	516 803 (53.8)	539 920 (57.0)	483 398 (54.0)	437 934 (53.7)	396 643 (53.8)
Other or unknown	1 418 237 (12.2)	126 128 (23.1)	126 545 (13.2)	90 574 (9.6)	78 176 (8.7)	60 400 (7.4)	44 389 (6.0)
Payer							
Medicaid	4 958 174 (42.6)	225 608 (41.4)	408 037 (42.5)	395 360 (41.7)	382 978 (42.8)	352 971 (43.2)	314 442 (42.7)
Commercial	5 828 008 (50.1)	276 056 (50.6)	481 244 (50.1)	485 290 (51.2)	451 857 (50.5)	409 232 (50.1)	376 045 (51.0)
Charity or indigent	18 816 (0.2)	1076 (0.2)	1792 (0.2)	1711 (0.2)	1240 (0.1)	964 (0.1)	706 (0.1)
Other	823 440 (7.1)	42 557 (7.8)	68 801 (7.2)	65 504 (6.9)	59 011 (6.6)	53 092 (6.5)	46 048 (6.2)
Census region							
West North Central	706 715 (6.1)	31 165 (5.7)	62 499 (6.5)	64 931 (6.9)	58 928 (6.6)	48 407 (5.9)	45 065 (6.1)
South Atlantic	3 134 865 (27.0)	154 102 (28.3)	241 336 (25.1)	244 261 (25.8)	234 747 (26.2)	217 066 (26.6)	184 555 (25.0)
East South Central	782 615 (6.7)	24 419 (4.5)	74 856 (7.8)	69 372 (7.3)	65 104 (7.3)	62 533 (7.7)	60 427 (8.2)
East North Central	1 639 978 (14.1)	62 432 (11.4)	135 177 (14.1)	134 357 (14.2)	145 291 (16.2)	135 827 (16.6)	127 165 (17.2)
Middle Atlantic	1 385 382 (11.9)	75 875 (13.9)	94 350 (9.8)	107 311 (11.3)	118 432 (13.2)	101 991 (12.5)	85 193 (11.6)
Pacific	1 585 909 (13.6)	100 431 (18.4)	136 760 (14.2)	153 325 (16.2)	79 905 (8.9)	74 353 (9.1)	68 644 (9.3)
West South Central	1 411 885 (12.1)	59 814 (11.0)	122 417 (12.8)	108 469 (11.4)	112 469 (12.6)	97 420 (11.9)	85 263 (11.6)
Mountain	705 575 (6.1)	25 806 (4.7)	68 574 (7.1)	44 687 (4.7)	63 908 (7.1)	62 070 (7.6)	63 692 (8.6)
New England	275 514 (2.4)	11 253 (2.1)	23 905 (2.5)	21 152 (2.2)	16 302 (1.8)	16 592 (2.0)	17 237 (2.3)
Delivery type							
Vaginal	7 748 427 (66.6)	359 909 (66.0)	641 973 (66.9)	629 087 (66.4)	604 494 (67.5)	547 666 (67.1)	493 125 (66.9)
Cesarean	3 830 448 (32.9)	184 583 (33.8)	316 392 (33.0)	306 935 (32.4)	285 510 (31.9)	263 072 (32.2)	239 587 (32.5)
Unknown	49 563 (0.4)	805 (0.1)	1509 (0.2)	11 843 (1.2)	5082 (0.6)	5521 (0.7)	4529 (0.6)
Maternal comorbid conditions, No. (rate per 1000 discharges)							
Pulmonary hypertension	2692 (0.2)	115 (0.2)	205 (0.2)	177 (0.2)	232 (0.3)	220 (0.3)	233 (0.3)
Placenta previa	70 431 (6.1)	2976 (5.5)	5537 (5.8)	5894 (6.2)	5934 (6.6)	5639 (6.9)	5177 (7.0)
Sickle cell disease	48 352 (4.2)	720 (1.3)	1922 (2.0)	5461 (5.8)	6375 (7.1)	6256 (7.7)	5536 (7.5)
Gestational hypertension	584 415 (50.3)	17 728 (32.5)	39 796 (41.5)	47 693 (50.3)	60 811 (67.9)	60 194 (73.7)	60 685 (82.3)

(continued)

Table 1. Demographic and Clinical Characteristics of Hospital Inpatient Discharges for Newborn Delivery From 2008 to 2021 (continued)

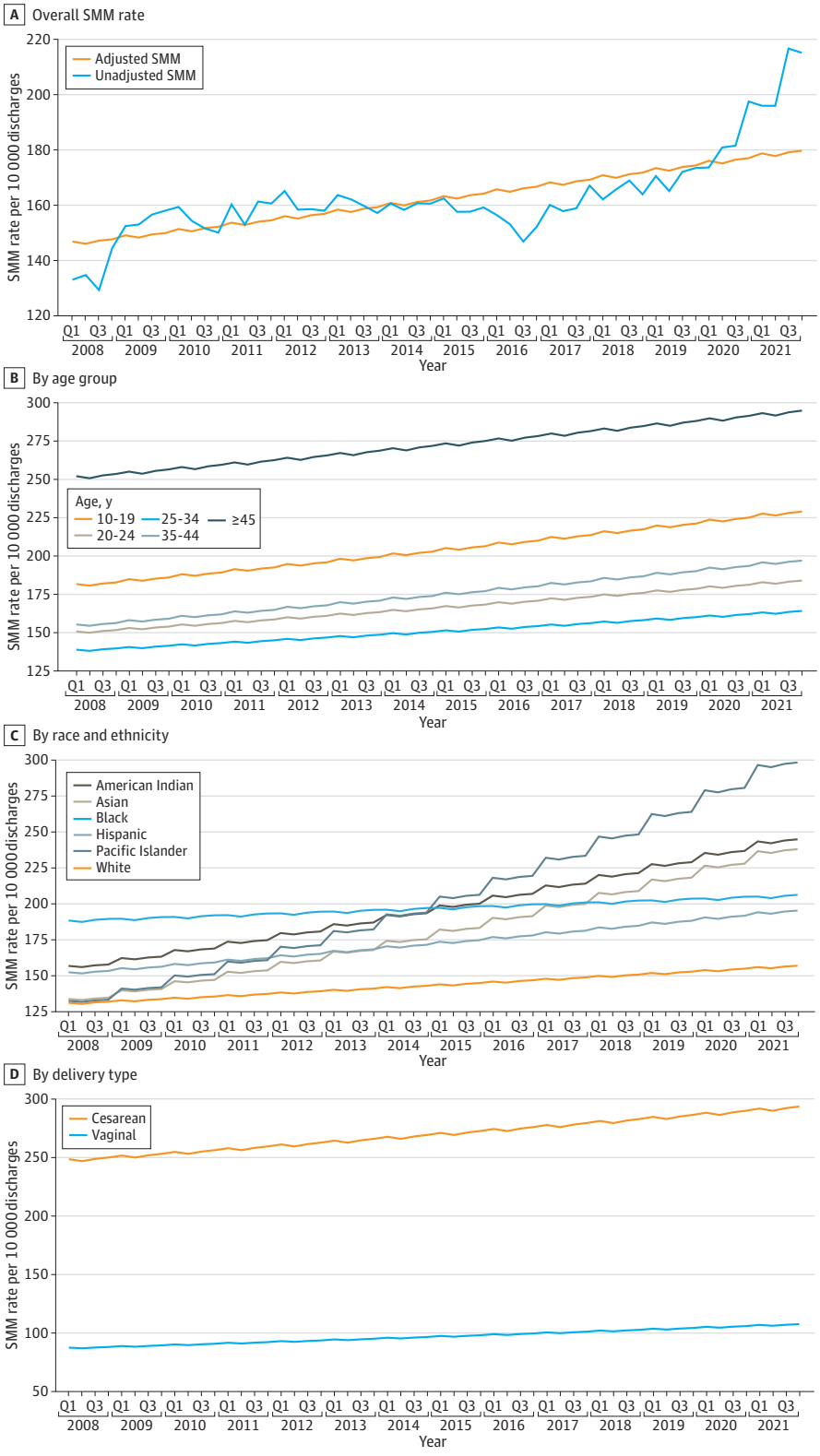
Characteristic	Overall (2008-2021) (N = 11 628 438)	2008 (n = 545 297)	2014 (n = 959 874)	2016 (n = 947 865)	2019 (n = 895 086)	2020 (n = 816 259)	2021 (n = 737 241)
Mild preeclampsia or unspecified preeclampsia	329 904 (28.4)	14 760 (27.1)	28 488 (29.7)	22 786 (24.0)	26 110 (29.2)	24 839 (30.4)	23 182 (31.4)
Severe preeclampsia	342 672 (29.5)	9888 (18.1)	23 600 (24.6)	27 187 (28.7)	36 222 (40.5)	35 129 (43)	35 278 (47.9)
Chronic kidney disease	23 557 (2.0)	1293 (2.4)	2815 (2.9)	1101 (1.2)	1113 (1.2)	1101 (1.3)	1031 (1.4)
Preexisting hypertension	310 054 (26.7)	10 242 (18.8)	23 948 (24.9)	27 794 (29.3)	26 953 (30.1)	27 114 (33.2)	27 119 (36.8)
Congenital heart disease	10 250 (0.9)	395 (0.7)	875 (0.9)	728 (0.8)	837 (0.9)	846 (1.0)	852 (1.2)
Systemic lupus erythematosus	15 092 (1.3)	498 (0.9)	1283 (1.3)	1172 (1.2)	1228 (1.4)	1292 (1.6)	1213 (1.6)
HIV	9612 (0.8)	487 (0.9)	695 (0.7)	762 (0.8)	667 (0.7)	687 (0.8)	584 (0.8)
Multiple gestation	214 087 (18.4)	10 360 (19.0)	18 208 (19.0)	17 476 (18.4)	15 604 (17.4)	13 606 (16.7)	12 751 (17.3)
Drug abuse	250 039 (21.5)	6353 (11.7)	18 887 (19.7)	21 921 (23.1)	25 035 (28.0)	25 489 (31.2)	24 114 (32.7)
Alcohol abuse	10 591 (0.9)	501 (0.9)	1066 (1.1)	731 (0.8)	649 (0.7)	622 (0.8)	634 (0.9)
Tobacco use	676 360 (58.2)	31 371 (57.5)	61 885 (64.5)	52 893 (55.8)	49 195 (55.0)	43 355 (53.1)	36 879 (50.0)
Cardiac valvular disease	24 109 (2.1)	2697 (4.9)	1974 (2.1)	1336 (1.4)	1167 (1.3)	1129 (1.4)	1060 (1.4)
Chronic congestive heart failure	10 250 (0.9)	395 (0.7)	875 (0.9)	728 (0.8)	837 (0.9)	846 (1)	852 (1.2)
Asthma	532 746 (45.8)	17 054 (31.3)	41 758 (43.5)	44 603 (47.1)	49 168 (54.9)	49 847 (61.1)	48 420 (65.7)
Preexisting diabetes	116 122 (10.0)	4688 (8.6)	10 306 (10.7)	9512 (10.0)	8702 (9.7)	8650 (10.6)	7241 (9.8)
Gestational diabetes	864 546 (74.3)	29 409 (53.9)	66 520 (69.3)	71 338 (75.3)	77 422 (86.5)	80 041 (98.1)	76 955 (104.4)
Obesity	1 057 844 (91.0)	18 550 (34.0)	76 178 (79.4)	91 702 (96.7)	116 107 (129.7)	122 908 (150.6)	121 771 (165.2)
Cystic fibrosis	959 (0.1)	36 (0.1)	55 (0.1)	92 (0.1)	54 (0.1)	130 (0.2)	126 (0.2)
Previous cesarean delivery	2 027 278 (174.3)	86 087 (157.9)	170 848 (178.0)	168 750 (178.0)	160 945 (179.8)	145 359 (178.1)	131 693 (178.6)
Other clinical conditions							
Hemorrhage	551 647 (47.4)	18 108 (33.2)	38 522 (40.1)	50 010 (52.8)	52 302 (58.4)	50 408 (61.8)	49 398 (67.0)
Severe maternal morbidities, No. (rate per 10 000 discharges)							
Acute myocardial infarction	370 (0.3)	7 (0.1)	18 (0.2)	24 (0.3)	40 (0.4)	54 (0.7)	40 (0.5)
Acute kidney failure	11 304 (9.7)	262 (4.8)	702 (7.3)	905 (9.5)	1275 (14.2)	1350 (16.5)	1426 (19.3)
Acute respiratory distress syndrome	11 430 (9.8)	245 (4.5)	820 (8.5)	899 (9.5)	994 (11.1)	1272 (15.6)	1695 (23.0)
Amniotic fluid embolism	571 (0.5)	25 (0.5)	36 (0.4)	51 (0.5)	55 (0.6)	44 (0.5)	37 (0.5)
Aneurysm	289 (0.2)	5 (0.1)	20 (0.2)	30 (0.3)	30 (0.3)	31 (0.4)	21 (0.3)
Cardiac arrest or ventricular fibrillation	1065 (0.9)	38 (0.7)	87 (0.9)	102 (1.1)	70 (0.8)	86 (1.1)	137 (1.9)
Cardioversion	1040 (0.9)	35 (0.6)	73 (0.8)	78 (0.8)	85 (0.9)	94 (1.2)	103 (1.4)
Disseminated intravascular coagulation	28 722 (24.7)	1418 (26.0)	2709 (28.2)	1848 (19.5)	1789 (20)	1594 (19.5)	1614 (21.9)
Eclampsia	8367 (7.2)	448 (8.2)	571 (5.9)	969 (10.2)	602 (6.7)	562 (6.9)	530 (7.2)
Heart failure or arrest during procedure	677 (0.6)	84 (1.5)	72 (0.8)	7 (0.1)	13 (0.1)	7 (0.1)	12 (0.2)
Puerperal cerebrovascular disorders	3492 (3.0)	186 (3.4)	260 (2.7)	287 (3.0)	274 (3.1)	268 (3.3)	291 (3.9)
Acute heart failure or pulmonary edema	6567 (5.6)	264 (4.8)	426 (4.4)	575 (6.1)	601 (6.7)	580 (7.1)	576 (7.8)
Severe anesthesia complications	1111 (1.0)	103 (1.9)	107 (1.1)	71 (0.7)	59 (0.7)	40 (0.5)	42 (0.6)
Sepsis	8594 (7.4)	249 (4.6)	606 (6.3)	760 (8.0)	858 (9.6)	871 (10.7)	973 (13.2)
Shock	7112 (6.1)	161 (3.0)	488 (5.1)	633 (6.7)	745 (8.3)	726 (8.9)	784 (10.6)
Sickle cell anemia with crisis	1131 (1.0)	56 (1.0)	82 (0.9)	86 (0.9)	99 (1.1)	88 (1.1)	68 (0.9)

(continued)

Table 1. Demographic and Clinical Characteristics of Hospital Inpatient Discharges for Newborn Delivery From 2008 to 2021 (continued)

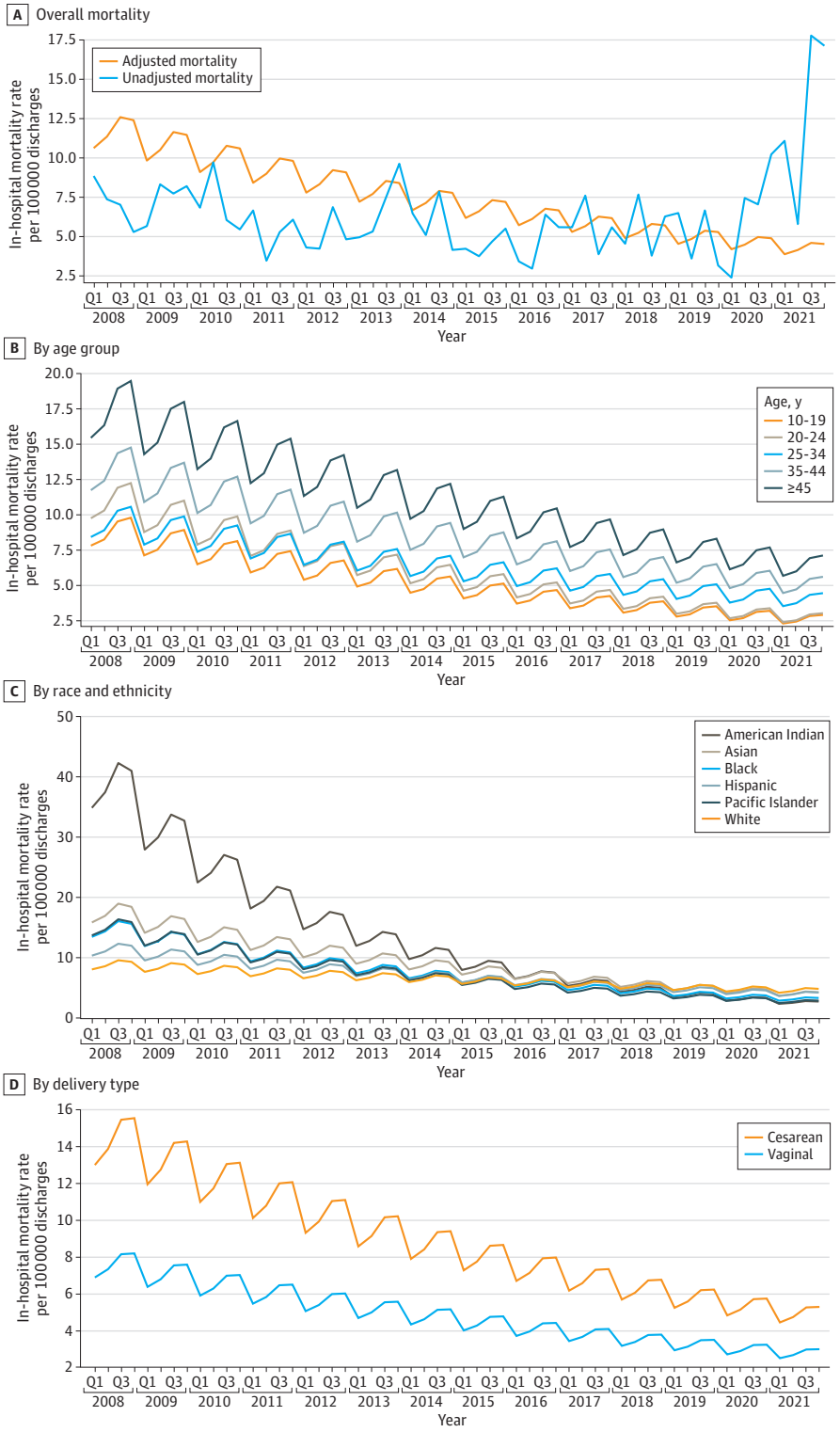
Characteristic	Overall (2008-2021) (N = 11 628 438)	2008 (n = 545 297)	2014 (n = 959 874)	2016 (n = 947 865)	2019 (n = 895 086)	2020 (n = 816 259)	2021 (n = 737 241)
Air and thrombotic embolism	2877 (2.5)	90 (1.7)	179 (1.9)	271 (2.9)	291 (3.3)	258 (3.2)	300 (4.1)
Blood transfusion	125 999 (108.4)	4746 (87.0)	10 498 (109.4)	9347 (98.6)	9971 (111.4)	9704 (118.9)	9727 (131.9)
Hysterectomy	12 738 (11.0)	476 (8.7)	977 (10.2)	1033 (10.9)	1121 (12.5)	1134 (13.9)	944 (12.8)
Temporary tracheostomy	324 (0.3)	14 (0.3)	26 (0.3)	15 (0.2)	17 (0.2)	27 (0.3)	57 (0.8)
Ventilation	4154 (3.6)	39 (0.7)	128 (1.3)	524 (5.5)	506 (5.7)	519 (6.4)	675 (9.2)
Any severe maternal morbidity	189 908 (163.3)	7374 (135.2)	15 366 (160.1)	14 410 (152)	15 250 (170.4)	14 961 (183.3)	15 192 (206.1)

Figure 1. Trend of Unadjusted and Regression-Adjusted Severe Maternal Morbidity (SMM) Rates Among Hospital Inpatient Discharges for Newborn Delivery, 2008 to 2021, Overall and by Age Group, Race and Ethnicity, and Delivery Type



Q indicates quarter.

Figure 2. Trend of Unadjusted and Regression-Adjusted In-Hospital Mortality Among Hospital Inpatient Discharges for Newborn Delivery, 2008 to 2021, Overall and by Age Group, Race and Ethnicity, and Delivery Type



Q indicates quarter.

Table 2. Estimates From the Multivariable Logistic Regression of In-Hospital Mortality and Any SMM Among Hospital Inpatient Discharges for Newborn Delivery, 2008 to 2021

Variable	Adjusted OR (95% CI)		
	In-hospital mortality[a]	In-hospital mortality sensitivity analysis[b]	Any SMM[c]
Age group, y			
10-19	0.74 (0.48-1.14)	0.61 (0.42-0.89)	1.39 (1.36-1.42)
20-24	0.90 (0.70-1.15)	0.70 (0.56-0.86)	1.10 (1.08-1.11)
25-34	1 [Reference]	1 [Reference]	1 [Reference]
35-44	1.49 (1.22-1.84)	2.16 (1.83-2.54)	1.17 (1.16-1.19)
≥45	1.95 (0.83-4.55)	6.01 (3.16-11.41)	1.76 (1.65-1.88)
Year	0.89 (0.87-0.92)	0.95 (0.93-0.97)	1.02 (1.01-1.02)
Diagnosis code version (*ICD-10-CM* vs *ICD-9-CM*)	NE	NE	0.92 (0.90-0.94)
Race			
White	1 [Reference]	1 [Reference]	1 [Reference]
American Indian	1.86 (0.95-3.64)	1.93 (1.10-3.39)	1.41 (1.35-1.48)
Asian	1.37 (0.88-2.14)	1.61 (1.11-2.34)	1.33 (1.30-1.36)
Black	1.09 (0.86-1.37)	1.78 (1.47-2.15)	1.39 (1.38-1.41)
Hispanic	1.06 (0.81-1.39)	1.04 (0.83-1.31)	1.22 (1.20-1.24)
Other or unknown	1.02 (0.77-1.35)	1.19 (0.94-1.51)	1.21 (1.19-1.22)
Pacific Islander	0.89 (0.29-2.76)	1.25 (0.48-3.26)	1.53 (1.45-1.61)
Quarter			
First	0.80 (0.62-1.04)	0.91 (0.74-1.13)	0.99 (0.98-1.01)
Second	0.88 (0.68-1.14)	0.91 (0.74-1.13)	0.99 (0.98-1.00)
Third	1.02 (0.80-1.31)	1.03 (0.85-1.26)	1.00 (0.98-1.01)
Fourth	1 [Reference]	1 [Reference]	1 [Reference]
Urbanicity of hospital population served (rural vs urban)	NE	NE	0.88 (0.87-0.90)
Primary payer			
Commercial	1 [Reference]	1 [Reference]	1 [Reference]
Charity or indigent	1.51 (0.27-8.53)	2.36 (0.78-7.09)	1.57 (1.42-1.73)
Medicaid	1.73 (1.41-2.13)	1.66 (1.4-1.97)	1.22 (1.20-1.23)
Other	1.72 (1.25-2.36)	1.69 (1.31-2.20)	1.23 (1.21-1.25)
Teaching hospital (vs nonteaching)	NE	NE	1.18 (1.17-1.20)
Hospital region			
South Atlantic	1 [Reference]	1 [Reference]	1 [Reference]
East North Central	0.91 (0.67-1.24)	0.87 (0.68-1.11)	0.94 (0.93-0.95)
East South Central	1.42 (1.00-2.02)	1.29 (0.96-1.72)	0.90 (0.88-0.92)
Middle Atlantic	0.93 (0.68-1.27)	0.91 (0.70-1.18)	1.15 (1.13-1.16)
Mountain	1.04 (0.70-1.54)	1.31 (0.95-1.79)	0.87 (0.85-0.89)
New England	0.73 (0.35-1.53)	0.62 (0.32-1.18)	1.09 (1.06-1.12)
Pacific	0.66 (0.48-0.92)	0.66 (0.50-0.88)	0.84 (0.83-0.86)
West North Central	1.36 (0.90-2.07)	1.28 (0.91-1.80)	0.88 (0.86-0.90)
West South Central	1.07 (0.80-1.45)	1.11 (0.88-1.42)	1.09 (1.08-1.11)
Admission type			
Elective	1 [Reference]	1 [Reference]	1 [Reference]
Emergent	3.17 (2.48-4.04)	5.17 (4.26-6.26)	1.50 (1.48-1.52)
Urgent	1.20 (0.96-1.49)	1.55 (1.29-1.87)	1.08 (1.06-1.09)
Trauma center	16.65 (9.89-28.04)	16.21 (10.36-25.35)	1.40 (1.31-1.50)
Other or unknown	1.46 (0.90-2.36)	1.43 (0.96-2.15)	1.28 (1.25-1.31)
Delivery type			
Vaginal	1 [Reference]	1 [Reference]	1 [Reference]
Cesarean	2.28 (1.87-2.79)	3.94 (3.34-4.64)	3.00 (2.97-3.03)
Comorbidities (yes vs no)			
COVID-19 diagnosis	13.31 (8.95-19.79)	41.63 (31.7-54.67)	4.44 (4.23-4.66)

(continued)

Table 2. Estimates From the Multivariable Logistic Regression of In-Hospital Mortality and Any SMM Among Hospital Inpatient Discharges for Newborn Delivery, 2008 to 2021 (continued)

Variable	Adjusted OR (95% CI)		
	In-hospital mortality[a]	In-hospital mortality sensitivity analysis[b]	Any SMM[c]
Placenta previa	NE	NE	6.32 (6.17-6.47)
Sickle cell disease	NE	NE	2.93 (2.82-3.05)
Gestational hypertension	NE	NE	1.29 (1.26-1.31)
Mild or unspecified preeclampsia	NE	NE	1.93 (1.89-1.97)
Severe preeclampsia	NE	NE	4.55 (4.48-4.62)
Chronic kidney disease	NE	NE	5.21 (4.99-5.44)
Preexisting hypertension	NE	NE	1.54 (1.50-1.57)
Chronic ischemic heart disease	NE	NE	3.92 (3.50-4.39)
Congenital heart disease	0.07 (0.01-0.34)	1.8 (0.46-7.08)	2.43 (2.23-2.66)
Systemic lupus erythematosus	3.68 (1.70-7.97)	7.63 (4.28-13.62)	1.95 (1.81-2.10)
HIV	3.94 (1.30-11.92)	3.03 (1.29-7.13)	1.47 (1.33-1.63)
Multiple gestation	NE	NE	2.20 (2.16-2.24)
Substance use disorder	1.38 (1.00-1.91)	3.44 (2.67-4.43)	1.71 (1.67-1.75)
Alcohol abuse	NE	NE	1.68 (1.52-1.85)
Cardiac valvular disease	0.19 (0.10-0.33)	6.73 (4.07-11.14)	3.50 (3.32-3.69)
Asthma	NE	NE	1.26 (1.24-1.28)
Preexisting diabetes	1.70 (1.20-2.42)	3.69 (2.81-4.86)	1.22 (1.18-1.25)
Gestational diabetes	NE	NE	0.96 (0.95-0.98)
Cystic fibrosis	40.17 (7.22-223.56)	35.97 (9.32-138.81)	1.76 (1.22-2.52)
Previous cesarean delivery	NE	NE	0.88 (0.87-0.89)
SMM (yes vs no)			
Acute kidney failure	1.30 (1.01-1.67)	Not included	Not included
Amniotic fluid embolism	7.67 (5.28-11.14)	Not included	Not included
Aneurysm	25.07 (7.40-84.91)	Not included	Not included
Disseminated intravascular coagulation	2.21 (1.69-2.88)	Not included	Not included
Puerperal cerebrovascular disorder	9.09 (6.11-13.51)	Not included	Not included
Sepsis	1.90 (1.45-2.51)	Not included	Not included
Shock	3.81 (2.96-4.91)	Not included	Not included
Air and thrombotic embolism	2.63 (1.79-3.86)	Not included	Not included
Sickle cell anemia with crisis	4.96 (2.17-11.33)	Not included	Not included
Bleeding complications (hemorrhage with no blood transfusion vs no bleeding)	2.73 (2.06-3.61)	Not included	Not included
Bleeding complications (blood transfusion vs no bleeding)	3.87 (3.05-4.91)	Not included	Not included
Hysterectomy	1.69 (1.24-2.318)	Not included	Not included
Respiratory complications[d]	5.92 (4.56-7.69)	Not included	Not included
Cardiovascular complications[e]	111.11 (86.69-142.42)	Not included	Not included

Abbreviations: *ICD-9-CM*, *International Classification of Diseases, Ninth Revision, Clinical Modification*; *ICD-10-CM*, *International Statistical Classification of Diseases, Tenth Revision, Clinical Modification*; NE, not entered in final model; OR, odds ratio; SMM, severe maternal morbidity.

[a] Overall, 728 deaths among 11 628 380 inpatient hospitalizations were included in the analysis; 58 patients reported by hospitals with in-hospital mortality followed by readmission were excluded from the regression of mortality. Additional covariates included in the regression of mortality are described in the Statistical Analysis section.

[b] A logistic regression of mortality without SMMs as covariates was performed as a sensitivity analysis.

[c] A total of 189 908 discharges with SMM (of 11 628 438 inpatient hospitalizations) were included in the analysis. Additional covariates included in the regression of severe maternal morbidity are described in the Statistical Analysis section.

[d] Respiratory complications included acute respiratory distress syndrome, temporary tracheostomy and ventilation as defined by the US Centers for Disease Control and Prevention.

[e] Cardiovascular complications included any of the following severe maternal morbidities: acute myocardial infarction, cardiac arrest or ventricular fibrillation, conversion of cardiac rhythm, heart failure or arrest during surgery or procedure, and pulmonary edema or acute heart failure as defined by the US Centers for Disease Control and Prevention.

aged 45 years or older (Figure 2B). A decreasing trend for in-hospital mortality was observed in all racial and ethnic groups. In particular, the greatest decrease in adjusted mortality was observed for American Indian patients: from 34.8 per 100 000 discharges in Q1 of 2008 to 2.7 per 100 000 discharges in Q4 of 2021 (Figure 2C; the 95% CI for mortality among American Indian patients is

provided in eTable 4 in Supplement 1). In-hospital mortality consistently decreased during the study period for patients with cesarean delivery (from 12.6 per 100 000 discharges in Q1 of 2008 to 5.2 per 100 000 discharges in Q4 of 2021) and also for patients with vaginal delivery (from 6.6 per 100 000 discharges in Q1 of 2008 to 3.0 per 100 000 discharges in Q4 of 2021) (Figure 2D).

Risk Factors for In-Hospital Mortality and SMM

Compared with patients aged 25 to 34 years, those between 35 and 44 years had higher odds of dying during the index hospitalization (aOR, 1.49; 95% CI, 1.22-1.84). Although the association between race and mortality was not statistically significant in the regression in which SMMs were included as covariates, a sensitivity analysis showed that American Indian (aOR, 1.93, 95% CI, 1.10-3.39), Black (aOR, 1.78; 95% CI, 1.47-2.15), and Asian patients (aOR, 1.61, 95% CI, 1.11-2.34) had increased risk of death compared with White patients, suggesting that the racial disparity was partly attributable to the difference in the SMM rates across racial and ethnic groups. The mortality of Pacific Islander patients and Hispanic patients was not statistically significantly different from White patients in the sensitivity analysis. Patients with cesarean delivery had 2-fold higher odds of death than those with vaginal delivery (aOR, 2.28; 95% CI, 1.87-2.79). Patients with a COVID-19 diagnosis had a 13-fold increased odds of mortality compared with those without COVID-19 (aOR, 13.31; 95% CI, 8.95-19.79). Among comorbidity and acute complications assessed, cardiac complications, cystic fibrosis, aneurysm, trauma, and puerperal cerebrovascular disorder were among the risk factors associated with death during delivery-related hospitalization (Table 2).

As seen in Table 2, after adjusting for other risk factors and compared with patients aged 25 to 34 years, both patients younger than 24 years (eg, age 10-19 years: aOR, 1.39; 95% CI, 1.36-1.42) and older than 35 years (eg, age ≥45 years: aOR, 1.76; 95% CI, 1.65-1.88) had increased odds of SMM. All minority racial and ethnic groups were associated with increased odds of experiencing any SMM (Pacific Islander: aOR, 1.53; 95% CI, 1.45-1.61; American Indian: aOR, 1.41; 95% CI, 1.35-1.48; Black: aOR, 1.39; 95% CI, 1.38-1.41; Asian: aOR, 1.33; 95% CI, 1.30-1.36; Hispanic: aOR, 1.22; 95% CI, 1.20-1.24). Cesarean delivery (aOR, 3.00; 95% CI, 2.97- 3.03) and COVID-19 diagnosis (aOR, 4.44; 95% CI, 4.23-4.66) were also associated with substantially higher adjusted odds of SMM. Among all the chronic comorbidities assessed, placenta previa (aOR, 6.32; 95% CI, 6.17-6.47), chronic kidney disease (aOR, 5.21; 95% CI, 4.99-5.44), severe preeclampsia (aOR, 4.55; 95% CI, 4.48-4.62), cardiac valvular disease (aOR, 3.50; 95% CI, 3.32-3.69), chronic ischemic heart disease (aOR, 3.92; 95% CI, 3.50-4.39), and sickle cell disease (aOR, 2.93; 95% CI, 2.82-3.05) were associated with the highest odds of experiencing SMM (Table 2).

Discussion

This cross-sectional study examined rates of delivery-related in-hospital maternal mortality and SMM in a large national inpatient database. In this sample encompassing more than 11 million inpatient discharges, delivery-related in-hospital mortality was found to decrease significantly over a period of 14 years. The adjusted mortality per 100 000 discharges decreased by more than 50% from Q1 of 2008 to Q4 of 2021, likely demonstrating the impact of national strategies focused on improving the maternal quality of care provided by the hospitals during delivery-related hospitalizations. In contrast, the rates of overall SMM increased over time for the overall population, which may be attributable to preexisting conditions and the increasing trend in the age of delivering patients in the past decade. The increasing trend of adjusted SMM rates was seen in all racial and ethnic minority groups and was most prominent in Asian, American Indian, and Pacific Islander patients. The fact that many of the comorbid conditions are risk factors for mortality and SMM indicates that it is essential to consider comorbid conditions when assessing SMM and mortality and that better management of patients' comorbid conditions during pregnancy may help reduce SMM occurrence and ultimately decrease mortality risk. Further improvement in patient outcomes could be achieved if patients with known risk factors could access improved care during pregnancy and during hospital delivery.

Delivery-related in-hospital maternal mortality in this study was lower than that reported in PMSS data, which defined pregnancy-related death as death during pregnancy or within 1 year of the end of pregnancy, from a cause related to pregnancy or its management.[3] PMSS data showed an increasing trend in pregnancy-related mortality during 1987 to 2017, which differs from our findings. A plausible explanation for these differences is that the timeframe for assessing mortality was substantially different between our study and the PMSS. Our study focused on mortality during delivery-related hospitalizations, which was associated with the change in quality of care for all patients in a hospital setting. In contrast, the PMSS estimates cover the entire pregnancy and postpartum period, which are associated with the overall burden of deaths among pregnant patients. Because a proportion of pregnancy-related deaths occur during delivery hospitalization, the differences between our findings and the PMSS estimates reinforced the importance of examining mortality separately for different stages of pregnancy and postpartum.

The study found that mortality risk was associated with several factors, including advanced maternal age, Medicaid as primary insurance, cesarean delivery, comorbid conditions, and severe complications during delivery. Similarly, a maternal age younger than 19 years or older than 35 years; being Asian, American Indian, Black, Hispanic, Pacific Islander; cesarean delivery; Medicaid enrollment; and maternal comorbid conditions were associated with higher risk of developing SMM during delivery. The racial and ethnic differences observed in delivery-related maternal mortality seem to be at least partly attributable to the racial and ethnic variation observed in SMM based on the main and sensitivity analyses of this study. Therefore, further research and understanding on the causes of both mortality and SMM, including the impact of comorbidities on maternal outcomes, is needed. Additionally, developing a national hospital measure to more clearly identify and reduce SMMs will likely have a beneficial impact on improving national quality strategies aimed at improving maternal health outcomes in the United States.

Limitations

The study has limitations. The PHD is a hospital administrative database and does not include as much clinical details as electronic health records. Identifying clinical conditions and procedures relied on the accuracy of hospital-reported diagnosis and procedure codes. Coding errors may lead to misclassification of variables. The definition of mortality was based on in-hospital death during the visit for delivery, without accounting for death before delivery admission or after discharge.

Maternal comorbid conditions were defined based on diagnosis during the visit for delivery. Conditions occurring before admission may not have been captured. Since the study spanned 14 years, there were changes in how hospitals collected and reported race and ethnicity. Hispanic was reported as a race category before 2011, while ethnicity was listed as a separate field in the patient admission form in later years. Hispanic race or ethnicity as defined in this study included patients who reported Hispanic as their race before 2011 and those who reported Hispanic as their ethnicity in 2012 and later, regardless of their reported race.

Conclusions

This large national study found a decreasing trend of in-hospital delivery-related maternal mortality during 2008 to 2021, regardless of racial or ethnic group, age, or mode of delivery, likely demonstrating the impact of national and local strategies focused on improving the maternal quality of care provided by hospitals during delivery-related hospitalizations. Risk factors for in-hospital delivery-related mortality included cesarean delivery, COVID-19 diagnosis, and comorbidities and acute complications. Analysis indicated that American Indian, Black, and Asian patients had a statistically significant increased risk of death compared with White patients only when not controlling for SMMs, suggesting that the racial difference in mortality could be at least partly attributable to the differences in SMM rates across racial groups (analysis of Pacific Islander and Hispanic patients were not statistically significant).

From 2008 to 2021, there was an increasing trend of SMM rates, and chronic comorbid conditions were associated with higher rates. SMMs are known risk factors of maternal deaths and impose substantial social and economic burdens. Notably, disparities in both mortality and SMM remained across age, delivery mode, and racial and ethnic groups. These characteristics should be considered when designing maternal care quality improvement programs. As current national strategies increasingly focus on improving delivery-related maternal outcomes among high-risk groups, including racial and ethnic minority groups, it will become important to evaluate the effectiveness of these strategies in reducing occurrences of maternal mortality and SMM.

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SUPPLEMENT 1.

eTable 1. *ICD-9-CM* and *ICD-10-CM* Diagnosis and Procedure Codes Used for Patient Inclusion and Exclusion
eTable 2. *ICD-9-CM* and *ICD-10-CM* Diagnosis and Procedure Codes Used to Identify Severe Maternal Morbidities
eTable 3. *ICD-9-CM* and *ICD-10-CM* Diagnosis Codes Used to Identify Maternal Comorbidities
eTable 4. Rates of Adjusted Mortality for American Indian Patients with 95% Poisson CIs

SUPPLEMENT 2.

Data Sharing Statement

EXHIBIT F

The Safety and Quality of Abortion Care in the United States (2018)

DETAILS

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Aspiration Abortion

Aspiration is a minimally invasive and commonly used gynecological procedure (Meckstroth and Paul, 2009; Roblin, 2014).[6] The procedure time is typically less than 10 minutes (Edelman et al., 2001; Goldberg et al., 2004). As noted in the previous chapter, aspiration is currently the most common abortion method used in the United States regardless of gestation, accounting for almost 68 percent of abortions in 2013.[7] The method may be used up to 14 to 16 weeks' gestation. Aspiration is also used in cases of early pregnancy loss (miscarriage) and management of incomplete abortion for medication abortion.

The first steps in the procedure are cervical dilation and priming (when appropriate) so that the contents of the uterus can be evacuated. Cervical dilation is usually done using tapered mechanical dilators and is recommended over routine priming except for adolescents and others for whom cervical dilation may be challenging (Allen and Goldberg, 2016). Cervical priming is accomplished with either osmotic dilators[8] or pharmacological agents (e.g., misoprostol), or both. When placed in the cervix, the osmotic dilator absorbs moisture from the tissues surrounding the cervix and gradually swells to slowly open the cervical orifice (os). The pharmaceutical agents are prostaglandin analogues or progesterone antagonists, such as the drug misoprostol, which is also used in medication abortion.

After cervical dilation and, when indicated, priming, a suction cannula (plastic or metal tube) is inserted through the cervix into the uterus. The cannula is attached to a vacuum source—an electric vacuum pump for electric vacuum aspiration or a handheld, hand-activated aspirator (syringe) for manual vacuum aspiration—to empty the uterine contents. Ultrasound guidance is sometimes used (RCOG, 2011).

See later in this chapter for a discussion of the use of sedation and anesthesia during abortion procedures, including the implications for personnel needs and facility requirements.

[6]There is no standard terminology for this type of abortion. As noted in Chapter 1, this report uses the term "aspiration abortion," although others commonly refer to the same procedure as "surgical abortion," "vacuum aspiration," "suction curettage," or "suction evacuation."

[7]Centers for Disease Control and Prevention (CDC) surveillance reports use the catchall category of "curettage" to refer to nonmedical abortion methods. The committee assumed that CDC curettage estimates before 13 weeks' gestation refer to aspiration procedures and that curettage estimates after 13 weeks' gestation are D&E procedures.

[8]Laminaria, small tubes made of dried seaweed, and manmade sterile sponges are common types of osmotic dilators.

Effectiveness of Aspiration Abortion

Recent comparisons of aspiration and medication abortion methods indicate that aspiration may be only slightly more effective than medication abortion in early pregnancy. In Ireland and colleagues' (2015) study of private Los Angeles clinics described in the prior section, the efficacy rate for almost 17,000 aspiration abortions performed up to 9 weeks' gestation was 99.8 percent, compared with 99.6 percent for medication abortions[9] for the same gestational period (Ireland et al., 2015).

Expected Side Effects

As in medication abortion, bleeding, uterine pain, and cramping are expected and normal consequences of aspiration abortion.

Complications

Aspiration abortions rarely result in complications. In a recent retrospective analysis of California fee-for-service Medicaid claims data, 57 of almost 35,000 women (0.16 percent) were found to have experienced a serious complication (hospital admission, surgery, or blood transfusion) after an aspiration abortion (Upadhyay et al., 2015). A systematic review on aspiration-related complications documents a somewhat higher complication rate (ranging from 0 to 5 percent), but a large proportion of the studies in that review included now outdated procedures, including dilation and sharp curettage (White et al., 2015).

In a historical cohort study, Guiahi and colleagues (2015) analyzed the outpatient medical records of women who had undergone an aspiration abortion between January 2009 and March 2014 in a Colorado clinic. The researchers compared the outcomes of women with (n = 587) and without (n = 1,373) medical comorbidities, including diabetes, hypertension, obesity (weight ≥200 lb or BMI ≥30), HIV, epilepsy, asthma, thyroid disease, and/or bleeding and clotting disorders having aspiration abortions. The researchers found no difference in the rate of complications between the women with at least one comorbidity and those with no comorbidity (odds ratio [OR] = 0.9; 95% CI = 0.5, 1.6).

Need for repeat aspiration Repeat aspiration is most often required for retained products of conception after an abortion. Rates of <0.1 to 8.0 percent have been reported for this complication, related to gestation, experience of the provider, and use of ultrasound guidance (White et al., 2015).

[9] $p < .001$.

Studies showing the highest rates of repeat aspiration included women at ≤6 weeks' gestation and were conducted more than 20 years ago (Bassi et al., 1994). Tissue inspection is recommended after aspiration abortion, regardless of gestation, but products of conception may be difficult to identify prior to 7 weeks' gestation (NAF, 2017a; SFP, 2013). Additional protocols, including magnification of aspirate, follow-up by serum beta-hCG estimation, and flotation of tissue with backlighting may be used to confirm abortion completion (NAF, 2017a; RCOG, 2011; SFP, 2013).

Hemorrhage Hemorrhage requiring transfusion or other treatment (medication administration or repeat aspiration) complicates 0.0 to 4.7 percent of aspiration abortions, with more recent studies reporting a rate of 1.3 percent (Upadhyay et al., 2015; White et al., 2015). In the California Medicaid study, 0.13 percent of aspiration procedures were complicated by hemorrhage (Upadhyay et al., 2015).

Infection Current clinical guidelines recommend routine antibiotic prophylaxis before all aspiration abortions (NAF, 2017a; RCOG, 2015; SFP, 2011b; WHO, 2014). Like any invasive procedure, aspiration abortion carries some risk of infection. If untreated, an upper genital tract infection subsequent to abortion can lead to chronic pelvic pain, dyspareunia, ectopic pregnancy, and infertility (Low et al., 2012). Serious infection after aspiration, however, is rare. In a 2012 systematic review, the Cochrane Collaboration evaluated the effectiveness of perioperative antibiotics in preventing upper genital tract infection (including infection of the uterus and fallopian tubes) (Low et al., 2012). The researchers concluded that universal antibiotic prophylaxis is effective in preventing infection after an aspiration procedure: the incidence of upper genital tract infection among women who received prophylactic antibiotics was 59 percent of that among women who received a placebo. The rate of infection was 5.8 percent among women who received antibiotics (n = 3,525) and 9.4 percent among women in the placebo group (n = 3,500).

In a more recent systematic review of complications following aspiration abortion (up to 14 weeks' gestation), White and colleagues (2015) report that 0.0 to 0.4 percent of 188,395 women undergoing aspiration abortions required intravenous (IV) antibiotics after the procedure in 11 of 12 office-based settings. In Upadhyay and colleagues' (2015) analysis of almost 35,000 aspiration abortions in California, 94 women (0.27 percent) developed an infection after the procedure. Most infections after outpatient aspiration procedures are treated with oral antibiotics, with up to 0.4 percent of patients with infection requiring IV antibiotic administration (White et al., 2015).

Uterine perforation Uterine perforation involves injury to the uterine wall, as well as potential injury to other abdominal organs. While the risk of uterine perforation in older studies has been reported as ≤0.1 to 2.3 percent, the majority of more recent studies of aspiration abortion report no cases of uterine perforation or note that perforations that occurred were successfully managed conservatively without the need for additional surgery or hospitalization (White et al., 2015). In the study of almost 35,000 California Medicaid-covered aspiration abortions referenced above, 0.01 percent resulted in a perforation (Upadhyay et al., 2015).

Cervical laceration Cervical laceration (injury to the cervix from instrumentation) is also very rare, with most studies reporting none or 1 case (<0.1 to 0.6 percent) (Ohannessian et al., 2016; White et al., 2015). In a study evaluating the risks of aspiration abortion in teens versus adults, an increased risk of cervical laceration was noted for adolescent patients (0.5 versus 0.2 percent), but this study was conducted prior to current approaches to cervical preparation (Cates et al., 1983; White et al., 2015). Use of osmotic dilators was common in older studies, but the more common approach today is medical, using misoprostol 2 to 3 hours prior to the procedure (Allen and Goldberg, 2016; O'Connell et al., 2009). While current recommendations do not include routine use of medical or mechanical cervical preparation because of the delay that would result, misoprostol is commonly used in nulliparous women and young adolescents between 12 and 14 weeks' gestation (Allen and Goldberg, 2016).

Dilation and Evacuation

Fewer than 9 percent of abortions in the United States occur after 13 weeks' gestation (Jatlaoui et al., 2016). The D&E method, sometimes referred to as a second-trimester surgical abortion, appears to account for the majority of procedures performed between 14 and 20 weeks' gestation. Precise estimates of the rate of abortions by type during these weeks are not available. Reports often cite CDC surveillance statistics as suggesting that D&Es account for up to 96 percent of abortions between 14 and 20 weeks' gestation (ACOG, 2013; Hammond and Chasen, 2009). However, the oft-cited CDC data are actually aggregate estimates that include not only D&E but also other methods (Jatlaoui et al., 2016; Pazol et al., 2009).

D&E techniques have evolved in the decades since the method was first developed (ACOG, 2013; Hammond and Chasen, 2009; Lohr et al., 2008). The procedure is typically performed in two stages, although the specific approaches to cervical preparation, instrumentation, and other aspects may vary (Grossman et al., 2008; Ibis Reproductive Health, 2015; Lohr et al., 2008). The procedure itself generally takes less than 30 minutes

(Ben-Ami et al., 2009; Grossman et al., 2008, 2011b). The first step is cervical preparation, dilating the cervix with laminaria (or other type of osmotic dilator) and/or a prostaglandin (e.g., misoprostol). Slow dilation is recommended (e.g., over a few hours, overnight, or sometime repeated over 24 to 48 hours) to minimize the need for supplemental manual or mechanical dilation (Grossman et al., 2008; Lohr et al., 2008). With a greater degree of dilation, the uterus is more easily emptied, instruments are easier to use, and procedure time is shortened (Hern, 2016). Once dilation is adequate and analgesia, sedation, and/or anesthesia have been administered, the amniotic fluid is aspirated (Lohr et al., 2008; WHO, 2014). Before 16 weeks' gestation, suction aspiration may suffice to empty the uterus. At 16 weeks, forceps extraction may also be required. Beyond 16 weeks, suction is not effective, and forceps should be used to remove fetal parts and the placenta. A curette and/or additional suction are also used to remove any remaining tissue or blood clots. Following the procedure, the provider examines the tissue to confirm that the evacuation was complete. Patients should be observed following the procedure to monitor for any postoperative complications (Hammond and Chasen, 2009; Lohr et al., 2008).

Ultrasonography is recommended so the physician can visualize the surgical instruments, locate fetal parts, and confirm an empty uterus (NAF, 2017a). Routine intraoperative ultrasonography has been demonstrated to significantly reduce the risk of uterine perforation and shorten the time required to complete the procedure (Darney and Sweet, 1989).

Performing D&E procedures requires advanced training and/or experience (Cates et al., 1982; Hern, 2016; Lohr et al., 2008; RCOG, 2015; WHO, 2012). Chapter 3 reviews the required clinical skills for performing abortions.

Complications

Although the risk of complications increases with weeks' gestation (Bartlett et al., 2004; Grossman et al., 2008; Zane et al., 2015), a range of retrospective cohort studies, case series, chart reviews, and a prospective case series have shown D&E to be effective with minimal rates of complications, ranging from 0.05 to 4 percent (ACOG, 2013; Autry et al., 2002; Bryant et al., 2011; Cates et al., 1982; Frick et al., 2010; Grimes et al., 1977; Grossman et al., 2008; Jacot et al., 1993; Mauelshagen et al., 2009; Peterson et al., 1983).

One study, however, suggests that a history of multiple prior cesarean deliveries may significantly increase the risk of a major complication. In a multivariable logistic analysis of 2,973 D&Es performed between 2004 and 2007 at an urban public hospital, Frick and colleagues (2010) found

an overall rate of major complications (i.e., transfusion required; disseminated intravascular coagulation; or a reoperation involving uterine artery embolization, laparoscopy, or laparotomy) of about 1.0 percent. However, women with two or more prior cesarean sections had a sevenfold increased risk of a major complication (OR = 7.37; 95% CI = 3.35, 15.80) (Frick et al., 2010). A history of one prior cesarean section was not associated with an increased risk of complications, although the authors note that a larger sample might lead to different results.

Obesity has also been studied as a possible risk factor for women undergoing D&E abortions (Benson et al., 2016; Lederle et al., 2015; Murphy et al., 2012). In a retrospective cohort study of 4,968 women undergoing aspiration and D&E abortions at a large outpatient clinic in 2012–2014, obesity was not associated with increased risk of complications[10] (Benson et al., 2016). The same conclusion resulted from a retrospective cohort study of 4,520 D&Es performed in a hospital-based abortion practice in 2009–2013 and a retrospective review of 1,044 women undergoing D&E or dilation and suction (D&S)[11] between 13 and 24 weeks' gestation in 2007–2010 (Lederle et al., 2015; Murphy et al., 2012). Lederle and colleagues (2015) found no association between BMI and D&E complications[12] after adjustment for age, ethnicity, prior vaginal delivery, prior cesarean delivery, and gestational duration. Murphy and colleagues (2012) compared complication rates, operative times, and anesthesia times between obese and nonobese (BMI <30) women and found no significant difference in complication rates. Finally, a retrospective analysis of D&E procedures performed between 2009 and 2014 found an association between obesity and increased risk for complications[13] in abortions performed after 14 weeks' gestation (Mark et al., 2017). Complications increased by BMI category,[14] and the increase in

[10]Complications assessed included need for uterine reaspiration (including same-day reaspiration), uterine perforation, cervical laceration, infection, emergency department visit or hospitalization, and excessive blood loss (defined as estimated blood loss greater than or equal to 100 mL).

[11]Dilation and curettage/suction denoted procedures performed when no other instruments besides suction were used; 5.3 percent of procedures in the study were D&S.

[12]Complications assessed included cervical laceration, hemorrhage, uterine atony, anesthesia complications, uterine perforation, disseminated intravascular coagulation, retained products of conception, and major complications (defined as those requiring hospitalization, transfusion, or further surgical intervention).

[13]Complications assessed included hemorrhage, need for repeat evacuation, uterine perforation, cervical laceration, medication reaction, unexpected surgery, or unplanned admission to the hospital.

[14]The cohort was classified into categories based on the WHO classification of underweight (BMI <18.5), normal weight (BMI 18.5–24.9), overweight (BMI 25.0–29.9), obese Class I (BMI 30–34.9), obese Class II (BMI 35–39.9), and obese Class III (BMI 40 or greater).

complications in women with Class III obesity was significant (OR = 5.04; 95% CI = 1.65–15.39).

Hemorrhage In studies of abortions performed in the year 2000 or later, D&E-related hemorrhage requiring transfusion or other treatment occurred in 0.0 to 1.0 percent of cases (Frick et al., 2010; Grossman et al., 2011a; Mauelshagen et al., 2009).

Infection Routine antibiotic prophylaxis is recommended for all surgical abortions (ACOG, 2013; NAF, 2017a; RCOG, 2015; WHO, 2014). Infection after a D&E is uncommon, with rates ranging from 0.0 to 2.0 percent (Autry et al., 2002; Grossman et al., 2011a; Mauelshagen et al., 2009). In the California Medicaid study described above, Upadhyay and colleagues (2015) found that 0.3 percent or 18 of 8,837 abortions performed after 13 weeks' gestation resulted in an infection, although these procedures included both D&Es and inductions.

Cervical lacerations Injuries to the cervix and uterus have decreased significantly with routine cervical preparation prior to D&E (ACOG, 2013). Recent studies have reported rates of 0.02 to 3.3 percent (Autry et al., 2002; Frick et al., 2010). The risk of cervical laceration is associated with mechanical dilation, nulliparity, advanced gestation, and provider inexperience (ACOG, 2013). Thus, as noted above, performing D&E procedures requires advanced training and/or experience.

Uterine perforation While uterine perforation is more common in D&E than in aspiration procedures, the incidence remains quite low and is likely related to the availability of cervical preparation and ultrasound guidance (Grossman et al., 2008). Limited clinician experience and underestimation of the duration of pregnancy are also factors that have been associated with uterine perforation (Grossman et al., 2008). A 1989 study compared the incidence of perforation during 810 D&E procedures with and without sonography (Darney and Sweet, 1989). Using ultrasound to guide the use of intrauterine forceps clearly improved the safety of the procedure: the rate of perforation declined significantly from 1.4 to 0.2 percent. Studies dating from 2010 to 2015 report perforation rates ranging from 0.2 to 0.8 percent (Frick et al., 2010; Upadhyay et al., 2015).

The facility requirements that are appropriate for D&Es depend on the level of sedation and anesthesia that is used. (See later in this chapter for a review of the use of analgesia, sedation, and anesthesia during abortions.)

(e.g., qualified advanced practice clinicians [APCs] or physicians without hospital privileges may be barred from performing abortions); how the informed consent process is conducted (e.g., providers may be required to misrepresent the risks of the procedure); the abortion method that is used (e.g., D&Es may be banned); the timing and scheduling of procedures (e.g., women may have to wait 18 to 72 hours after a counseling appointment); the physical attributes of the clinical setting (e.g., procedure room size, corridor width); and other basic elements of care. In most states, the regulations apply to all abortion methods regardless of weeks' gestation, use of sedation, or the invasiveness of the procedure.

See Table 1-1 in Chapter 1 for a listing of abortion-specific regulations by states as of September 1, 2017.

SUMMARY

The clinical evidence presented in this chapter on the provision of safe and high-quality abortion care stands in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services. These requirements may influence the efficiency of abortion care by requiring medically unnecessary services and multiple visits to the abortion facility, in addition to requiring that care take place in costlier and more sophisticated settings than are clinically necessary. These requirements go beyond the accepted standards of care in the absence of evidence that they improve safety. Some requirements, such as multiple visits and waiting periods, delay abortion services, and by doing so may increase the clinical risks and cost of care. They may also limit women's options for care and impact providers' ability to provide patient-centered care. Furthermore, many of these laws have been documented to reduce the availability of care by imposing unneeded regulations on abortion providers and the settings in which abortion services are delivered. The implications of abortion-specific regulations for the safety and quality of abortion care are described below.

Delaying the Procedure

The clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective. Serious complications are rare; in the vast majority of studies, they occur in fewer than 1 percent of abortions, and they do not exceed 5 percent in any of the studies the committee identified. However, the risk of a serious complication increases with weeks' gestation. As the number of weeks increases, the invasiveness of the required procedure and the need for

deeper levels of sedation also increase. Thus, delaying the abortion increases the risk of harm to the woman.

State regulations that require women to make multiple in-person visits and wait multiple days delay the abortion. If the waiting period is required *after* an in-person counseling appointment, the delay is exacerbated (Roberts et al., 2016; Sanders et al., 2016; White et al., 2017). Restrictions on the types of providers and on the settings in which abortion services can be provided also delay care by reducing the availability of care (Baum et al., 2016; Fuentes et al., 2016; Gerdts et al., 2016; Grossman et al., 2014, 2017).

Financial burdens and difficulty obtaining insurance are frequently cited by women as reasons for delay in obtaining an abortion (Bessett et al., 2011; Drey et al., 2006; Finer et al. 2006; Foster and Kimport, 2013; Foster et al., 2008; French et al., 2016; Janiak et al., 2014; Kiley et al., 2010; Roberts et al., 2014; Upadhyay et al., 2014). As noted in Chapter 1, 33 states prohibit public payers from paying for abortions, and other states have laws that either prohibit health insurance exchange plans (25 states) or private insurance plans (11 states) sold in the state from covering or paying for abortions, with few exceptions.[26]

Counseling and Informed Consent

Long-established ethical and legal standards for informed consent in health care appear to have been compromised in the delivery of abortion care in many areas of the country. Thirty-five states have abortion-specific regulations requiring women to receive counseling before an abortion is performed, and abortion patients in many of these states are offered or given inaccurate or misleading information (verbally or in writing) on reversing medication abortions, risks to future fertility, possible breast cancer risk, and/or long-term mental health consequences of abortion (Guttmacher Institute, 2017a) (see Table 1-1 in Chapter 1). As noted earlier in this chapter, the principal objective of the informed consent process is that patients understand the nature and risks of the procedure they are considering (AAAHC, 2016; AMA, 2016; HHS, 2017a; Joint Commission, 2016). However, legally requiring providers to inform women about risks that are not supported and are even invalidated by scientific research violates the accepted standards of informed consent. For example, some states require that providers inform women that abortion puts them at greater risk for breast cancer; mental health disorders; and difficulties in having a healthy, successful pregnancy

[26]Exceptions are limited and vary by state. They are often made for pregnancies resulting from rape or incest, pregnancies that endanger the woman's life or severely threaten the health of the woman, and cases of fetal impairment.

(Guttmacher Institute, 2017a) (see Table 1-1 in Chapter 1 for a detailed list of states' informed consent requirements). Three states require providers to inform women that a medication abortion can be reversed after the woman takes mifepristone (Guttmacher Institute, 2017a). This information is not supported by research that meets scientific standards. See Chapter 4 for an in-depth review of the long-term health effects of abortion.

Medication Abortion

There is no evidence that the dispensing or taking of mifepristone tablets requires the physical presence of a clinician[27] or a facility with the attributes of an ASC or hospital to ensure safety or quality. The effects of mifepristone occur after women leave the clinic, and extensive research shows that serious complications are rare. The risks of medication abortion are similar in magnitude to the risks of taking commonly prescribed and over-the-counter medications such as antibiotics and NSAIDs. In 35 states, however, only physicians are permitted to give women the mifepristone tablet(s) required to begin the process of medication abortion (RHN, 2017). In 19 states, the clinician (a physician or other provider if allowed) must be physically present to provide the medication, thus prohibiting the use of telemedicine to prescribe the medication remotely for abortion (Guttmacher Institute, 2017b). In 17 states, medication abortions must be performed in a facility that meets the structural standards of ASCs even though the abortion will occur outside the clinical setting, and there is no evidence to suggest that these regulations improve safety or quality.

Aspiration Abortions

Aspirations are minimally invasive and commonly used for a variety of purposes in gynecology practices, including for early pregnancy loss (miscarriage). Aspiration abortions are performed safely in office-based settings and can be provided by appropriately trained APCs, as well as family practice physicians and OB/GYNs. If moderate sedation is used, the procedure should be performed in a facility that meets the relevant ASA facility standards. There is no evidence that performing aspiration abortions in ASCs increases the safety or efficacy of the procedure. The state regulations described above also affect aspiration abortion procedures: 44 states do not allow APCs to perform aspirations, and 16 states mandate that the procedure be performed in an ASC-like facility.

[27]Chapter 3 reviews the clinical competencies needed to provide safe and high-quality abortions, as well as state regulations regarding the role of APCs.

D&E and Induction Abortions

D&E is usually the medically preferred method for abortions at 14 weeks' gestation or later. The alternative—induction—is more painful, slower, and more expensive. D&Es are banned in Mississippi[28] and West Virginia[29] except if the woman's physical health or life is severely threatened.

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[29]Unborn Child Protection from Dismemberment Abortion Act, West Virginia SB 10, Reg. Sess. 2015–2016 (2016).

abortion, patients should receive the contraceptive method of their choice or be referred elsewhere if the preferred method is unavailable (NAF, 2017; RCOG, 2015; WHO, 2012). The Centers for Disease Control and Prevention and the U.S. Office of Population Affairs recommend the following for providers offering contraceptive services, including contraceptive counseling and education (Gavin et al., 2014):

- Establish and maintain rapport with the client.
- Obtain clinical and social information from the client (medical history, pregnancy intention, and contraceptive experiences and preferences).
- Work with the client interactively to select the most effective and appropriate contraceptive method (providers should ensure that patients understand the various methods' effectiveness, correct use, noncontraceptive benefits, side effects, and potential barriers to their use).
- Conduct a physical assessment related to contraceptive use, when warranted.
- Provide the selected contraceptive method along with instructions for its correct and consistent use, help the client develop a plan for using the selected method and for follow-up, and confirm the client's understanding of this information.

Competencies Required for Abortion Methods

Medication Abortion

Medication abortion is a method commonly used to terminate a pregnancy up to 70 days' (or 10 weeks') gestation with a combination of medications—mifepristone followed by misoprostol. The skill set required for early medication abortion has been outlined by several organizations and is similar to the management of spontaneous loss of a pregnancy with medications (Goodman et al., 2016). The skills include the essential competencies outlined in the section above, plus the knowledge of medication abortion protocols, associated health effects, and contraindications. Prescribing medication abortion is no different from prescribing other medications—providers must be able to recognize who is clinically eligible; counsel the patient regarding medication risks, benefits, and side effects; and instruct the patient on how to take the medication correctly and when to seek follow-up or emergency care.

Chapter 2 describes the U.S. Food and Drug Administration's (FDA's) Risk Evaluation and Mitigation Strategy (REMS) for Mifeprex, the brand name for mifepristone, the first drug administered during a medication

abortion. Distribution of Mifeprex is restricted to REMS-certified health care providers, but any physician specialty or APC can become certified. In March 2016, the FDA issued revisions to the label and REMS for Mifeprex, changing the language from "physician" to "health care provider" and thereby expanding opportunities for APCs with relevant clinical competencies to obtain and distribute the drug (Simmonds et al., 2017; Woodcock, 2016). A component of the REMS process requires prescribers of Mifeprex to meet the following qualifications (FDA, 2016; Woodcock, 2016):

- ability to assess the duration of pregnancy accurately;
- ability to diagnose ectopic pregnancies; and
- ability to provide surgical intervention in cases of incomplete abortion or severe bleeding or have made plans to provide such care through others, and ability to ensure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

Aspiration Abortion

Aspiration abortion is a minimally invasive procedure that uses suction to empty the uterus. Aspiration abortion is an alternative to medication abortion up to 70 days' (or 10 weeks') gestation and the primary method of abortion through 13 weeks' gestation (Jatlaoui et al., 2016). The procedure and required skills are the same as those for the management of spontaneous loss of a pregnancy with uterine aspiration (Goodman et al., 2016; Nanda et al., 2012). The essential competencies for all abortion procedures form the basis of the skill set required for aspiration abortion. Additional competencies have been defined by the UCSF Bixby Center and NAF (Goodman et al., 2016; NAF, 2017). They include cervical preparation, experience with manual or electric vacuum aspiration, and evaluation of the products of conception for appropriate gestational tissue.

Dilation and Evacuation (D&E)

D&E is usually performed starting at 14 weeks' gestation, and most abortions after 14 weeks' gestation are performed by D&E (ACOG, 2015; Hammond and Chasen, 2009; Jatlaoui et al., 2016; O'Connell et al., 2008; Stubblefield et al., 2004). The procedure and required skills are similar to those for the surgical management of miscarriage after 14 weeks' gestation (Nanda et al., 2012). D&E requires clinicians with advanced training and/or experience, a more complex set of surgical skills relative to those required for aspiration abortion, and an adequate caseload to maintain these surgical skills (Gemzell-Danielsson and Lalitkumar, 2008;

Grossman et al., 2008; Hammond and Chasen, 2009; Hern, 2016; Kapp and von Hertzen, 2009; Lohr et al., 2008; RCOG, 2015). The additional skills required for D&E include surgical expertise in D&E provision and training in the use of specialized forceps. Cervical preparation, achieved by osmotic dilators or prostaglandin analogues (misoprostol), is standard practice for D&E after 14 weeks' gestation (Newmann et al., 2008, 2010; SFP, 2014).

Induction Abortion

Induction abortion is the termination of pregnancy using medications to induce delivery of the fetus. Induction abortion requires a clinician skilled in cervical preparation and delivery (ACOG, 2015; Baird et al., 2007; Hammond and Chasen, 2009; Kapp and von Hertzen, 2009). As with any woman in labor, providing supportive care for women undergoing induction abortion is of utmost importance. Physical as well as emotional support should be offered (Baird et al., 2007). Women should be encouraged to have a support person with them if possible.

WHICH PROVIDERS HAVE THE CLINICAL SKILLS TO PERFORM ABORTIONS?

While OB/GYNs provide the greatest percentage of abortions (O'Connell et al., 2008, 2009), other types of clinicians (both generalist physicians and APCs) also perform abortions. The committee identified systematic reviews, randomized controlled trials, and a variety of cohort studies assessing the outcomes of abortions provided by family medicine physicians or comparing the outcomes of abortions performed by physicians and nurse practitioners (NPs), certified nurse-midwives (CNMs), and/or physician assistants (PAs) (Bennett et al., 2009; Goldman et al., 2004; Kopp Kallner et al., 2015; Ngo et al., 2013; Paul et al., 2007; Prine et al., 2010; Renner et al., 2013; Weitz et al., 2013). Many of the comparative studies were based in parts of the world where provider shortages are particularly acute, often in developing countries. All the available systematic reviews include this international research and also judge much of the research to be of poor quality (Barnard et al., 2015; Ngo et al., 2013; Renner et al., 2013; Sjöström et al., 2017). The literature is less robust regarding other generalist physicians, yet the same judgment and clinical dexterity necessary to perform first-trimester abortion are possessed by many specialties.

This section reviews the primary research on which providers have the clinical skills to provide abortions that is most relevant to the delivery of abortion care in the United States. It is noteworthy that numerous professional and health care organizations, including ACOG, NAF, the American

EXHIBIT G

Original Research

The Comparative Safety of Legal Induced Abortion and Childbirth in the United States

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OBJECTIVE: To assess the safety of abortion compared with childbirth.

METHODS: We estimated mortality rates associated with live births and legal induced abortions in the United States in 1998–2005. We used data from the Centers for Disease Control and Prevention's Pregnancy Mortality Surveillance System, birth certificates, and Guttmacher Institute surveys. In addition, we searched for population-based data comparing the morbidity of abortion and childbirth.

RESULTS: The pregnancy-associated mortality rate among women who delivered live neonates was 8.8 deaths per 100,000 live births. The mortality rate related to induced abortion was 0.6 deaths per 100,000 abortions. In the one recent comparative study of pregnancy morbidity in the United States, pregnancy-related complications were more common with childbirth than with abortion.

CONCLUSION: Legal induced abortion is markedly safer than childbirth. The risk of death associated with childbirth is approximately 14 times higher than that with abortion. Similarly, the overall morbidity associated with childbirth exceeds that with abortion.

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LEVEL OF EVIDENCE: II

See related editorial on page 212.

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Decades of research have demonstrated that legal induced abortion is safe. Mortality and serious acute complications are extremely rare.[1–4] Recently, allegations of later sequelae—breast cancer and mental illness—were refuted.[5,6] However, laws in 22 states in the United States now require that before an abortion is performed, the patient must be given detailed, specific verbal or written information about potential risks. In some cases, this material is misleading or patently wrong.[7]

Health policy and medical practice should be based on the best available evidence. In the past 10 years, the introduction of new abortion methods may have affected the overall safety of the procedure. Notably, mifepristone was approved by the U.S. Food and Drug Administration for medical abortion in 2000; by 2008, approximately 17% of all nonhospital abortions were performed medically rather than surgically.[8] In addition, changes in the risk profile of pregnant women—for example, as a result of growing obesity[9] and an upward shift in the maternal age distribution[10]—as well as the rising cesarean delivery rate[10] may have enhanced the risks of the alternative to abortion, childbirth. The objective of this review is to provide an updated assessment[2] of the safety of abortion relative to delivery.

MATERIALS AND METHODS

We estimated mortality rates associated with live births and legal induced abortions in the United States in 1998–2005 by combining published data from several national data sets. For mortality related to live birth, we divided the number of pregnancy-related deaths among women delivering live neonates as reported by the Centers for Disease Control and Prevention's (CDC) Pregnancy Mortality Surveillance System[11] by the number of live births as reported on birth certificates.[10] The Pregnancy Mortality Surveillance System collects and reviews death certificates and other information from deceased women who were recorded as pregnant within a

specified time period before death in all 50 states and Washington, DC. To estimate abortion-related mortality, we divided the number of legal abortion-related deaths from the 50 states and Washington, DC, reported by the CDC[12] by the number of legal abortions estimated by the Guttmacher Institute from its annual surveys of all U.S. hospitals, clinics, and physician offices known or suspected to have provided abortion services.[8] We did not calculate confidence intervals around mortality rates because these estimates are derived from the full population.

In addition, we searched PubMed for relevant studies for other population-based comparative data on mortality and morbidity of abortion and childbirth in the United States since 2000. We used the following search strategies: (maternal morbidity [MESH] OR maternal mortality [MESH]) AND pregnancy outcome AND United States [MESH] (73 results); pregnancy outcome AND (maternal morbidity [MESH] OR maternal mortality [MESH]) AND United States [tiab] (49 results); pregnancy outcome AND abortion, induced AND morbidity AND United States [MESH] (94 results). We limited our review to reports that included data on both pregnancy outcomes in a single population with contemporaneous, uniform ascertainment of outcomes.

Because women who choose abortion differ in underlying risk for adverse outcomes from women who opt to continue a pregnancy, we also compared the characteristics of each group. We obtained data about characteristics of U.S. women having abortions and live births in 2008 from the Guttmacher Institute 2008 Abortion Patient survey[13] and from birth certificate data[11] (www.cdc.gov/nchs/data_access/vitalstats/VitalStats_Births.htm. Retrieved 28 May 2011).

RESULTS

Between 1998 and 2005, the pregnancy-associated mortality rate among women known to have delivered live neonates in the United States was 8.8 deaths per 100,000 live births (Table 1). Of all pregnancy-associated deaths of women with known pregnancy outcome, 71% occurred after live births[11]; if 71% of women with unknown pregnancy outcome who died of pregnancy-associated causes are also assumed to have had live births, the mortality estimate increases to 10.4 deaths per 100,000 live births. The mortality rate related to legal induced abortion during that same interval was 0.6 deaths per 100,000 abortions. Thus, according to federal statistics, the risk of death associated with childbirth was approximately 14 times higher than that with abortion.

Table 1. Pregnancy-Related Mortality in Women With Live Births or Legal Induced Abortions in the United States, 1998–2005

	Deaths*	Pregnancies†	Deaths per 100,000 Pregnancies
Live birth		32,347,794	
Known live birth	2,856		8.8
Known live births+71% of pregnancies with unknown outcome	3,352		10.4
Legal abortion	64	10,185,100	0.6

* Number of deaths related to live births from Berg et al[11]; number of deaths related to abortion from Pazol et al.[12]

† Number of live births from Martin et al[10]; number of abortions from Jones et al.[8]

Only one recent study provided comparative data on morbidity associated with various pregnancy outcomes in the United States.[14] Epidemiologists at the CDC examined all International Classification of Diseases, 9th Revision, Clinical Modification diagnoses reported during or within 8 weeks after all 24,481 pregnancies among members of the Kaiser Permanente Northwest Health Maintenance Organization between 1998 and 2001. Of these pregnancies, 16,824 ended in live birth, 4,192 in induced abortion, and the rest in spontaneous abortions, stillbirths, or other outcomes. Common maternal morbidities were defined as conditions either unique to pregnancy or potentially exacerbated by pregnancy that occurred in at least 5% of all pregnancies.

Every complication was more common among women having live births than among those having abortions (Fig. 1). The relative risks of morbidity with live birth compared with abortion were 1.3 for mental health conditions, 1.8 for urinary tract infection, 4.4 for postpartum hemorrhage, 5.2 for obstetric infections, 24 for hypertensive disorders of pregnancy, 25 for antepartum hemorrhage, and 26 for anemia.

In 2008, the median age of women having abortions was younger than that of women having live births, but the proportion of women age 40 years or older was comparable (Table 2). Nearly half of women in each group had no education beyond high school. Patients undergoing abortion were twice as likely to be unmarried or non-Hispanic African American women. Nulliparity was equally common in the two groups.

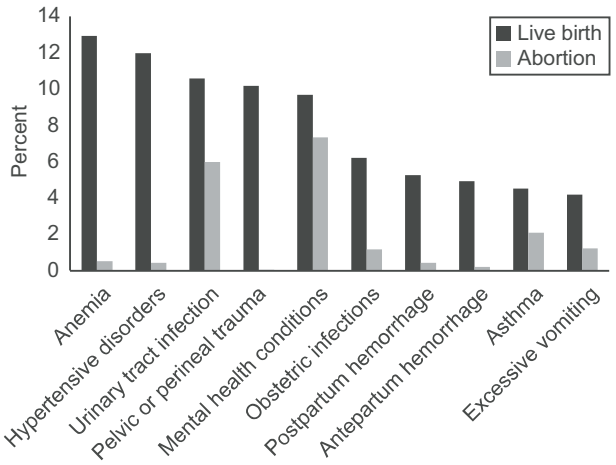

Fig. 1. Common maternal morbidities associated with live birth and abortion, 1998–2001. Common maternal morbidities defined as conditions either unique to pregnancy or potentially exacerbated by pregnancy that occurred in at least 5% of all pregnancies. Data from Bruce FC, Berg CJ, Hornbrook MC, Whitlock EP, Callaghan WM, Bachman DJ, et al. Maternal morbidity rates in a managed care population. Obstet Gynecol 2008;111:1089–95.

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DISCUSSION

Legal abortion in the United States remains much safer than childbirth. The difference in risk of death is approximately 14-fold. Abortion also is associated with substantially less pregnancy-related morbidity. These results are consistent with prior analyses of national data.[2] Indeed, the relative safety of abortion has increased substantially since the first decade after nationwide legalization, when child birth-related mortality was approximately seven times the mortality related to abortion.[15] Although we could not find data that allowed comparable calculations of mortality or morbidity associated with surgical and medical abortion, Danco Laboratories, the distributor of mifepristone in the United States, has identified only 11 pregnancy-related deaths among the estimated 1.6 million women who have used the drug in the United States since 2000, which is a mortality rate of 0.7 per 100,000 users (Abigail Long, Danco Laboratories, LLC, personal communication). Clearly, the growing use of medical regimens has not increased relative abortion risk overall.

The disparity between abortion and childbirth safety is not surprising. Pregnancies ending in abortion are substantially shorter than those ending in childbirth and thus entail less time for pregnancy-related problems to occur. Many dangerous pregnancy-related complications such as pregnancy-induced hypertension and placental abnormalities manifest themselves in late pregnancy; early abortion avoids these hazards. Moreover, in the United States in 2008, one third of births occurred by cesarean delivery, an abdominal operation with substantial morbidity.[10,16]

These results may underestimate the relative safety of choosing abortion over continuing a pregnancy for two reasons. First, our comparison was limited to live

Table 2. Characteristics of Women Having Live Births and Abortions in the United States, 2008

	Live Births*	Abortions†
Age (y)		
Younger than 15	5,764 (0.1)	4,850 (0.4)
15–19	434,758 (10.2)	208,520 (17.2)
20–24	1,052,184 (24.8)	404,920 (33.4)
25–29	1,195,774 (28.2)	295,810 (24.4)
30–34	956,716 (22.5)	163,670 (13.5)
35–39	488,875 (11.5)	99,410 (8.2)
40 or older	113,623 (2.7)	35,160 (2.9)
Total	4,247,694 (100)	1,212,340 (100)
Ethnicity or race		
Hispanic	1,041,239 (24.7)	301,880 (24.9)
Non-Hispanic white	2,267,817 (53.8)	437,660 (36.1)
Non-Hispanic African American	623,029 (14.8)	358,860 (29.6)
Non-Hispanic other	282,783 (6.7)	113,960 (9.4)
Total	4,214,868 (100)	1,212,360 (100)
Marital status		
Married	2,521,128 (59.4)	179,430 (14.8)
Unmarried	1,726,566 (40.6)	1,032,930 (85.2)
Total	4,247,694 (100)	1,212,360 (100)
Education among women aged 20 y and older		
Less than high school	435,462 (18.1)	122,870 (12.3)
High school or GED	630,970 (26.2)	282,710 (28.3)
Some college	685,206 (28.4)	394,590 (39.5)
College graduate	659,044 (27.3)	198,800 (19.9)
Total	2,410,682 (100)	998,970 (100)
Number of prior births		
0	1,703,921 (40.4)	474,030 (39.1)
1	1,330,540 (31.5)	321,270 (26.5)
2 or more	1,186,657 (28.1)	418,260 (34.5)
Total	4,221,118 (100)	1,213,560 (100)

GED, high school equivalency certification.
Data are n (%).
* Data on live births from Martin[10] and the National Center for Health Statistics. Numbers with unknown status are excluded from the table.
† Data on abortion from Jones et al.[13]

births; we omitted other pregnancy outcomes: spontaneous abortion, stillbirths, ectopic pregnancies, and gestational trophoblastic disease. The number of pregnancies ending in these outcomes was not available. Stillbirths and ectopic pregnancies are associated with higher risks of death than is live birth.[2] We likely therefore underestimated the mortality associated with opting for pregnancy continuation.

Second, patients undergoing abortion appear to be at higher underlying risk than women who opt for delivery. Women who had abortions were more likely to be African American or unmarried, demographic characteristics strongly associated with increased mortality.[11,17] In addition, because comorbidities are sometimes the motivation for abortion, the underlying medical risk of patients undergoing abortion may be higher than that of other pregnant women. Women in good health may be more likely to choose to continue their pregnancies than those who are ill (selection bias termed the "healthy mother" effect[18]). Thus, mortality among patients undergoing abortion may overestimate the mortality risk of the procedure itself.

This study has both strengths and weaknesses. Strengths include the use of the most recent CDC statistics on pregnancy-related mortality for the entire country. Similarly, the cohort study of morbidity had uniform, contemporaneous ascertainment of outcomes in a large health maintenance organization. We systematically reviewed the past decade of PubMed publications for relevant data. Weaknesses include the likely underreporting of deaths, possibly differential by pregnancy outcome (abortion or childbirth).[19] The analytic rules used by the original researchers to handle incomplete or inconsistent data on women's characteristics may have led to errors. Our assessment of women's underlying risk was necessarily incomplete. Moreover, both abortion and childbirth can cause mortality and morbidity long after the end of the pregnancy; these cases are not included in our analysis. However, these weaknesses are unlikely to account for the large differences in mortality and morbidity found in this analysis.

Pregnant women considering their options deserve accurate information about comparative risks. Currently, some state laws and policies violate this standard. In Texas, for example, the mandatory 23-page pamphlet, "A Woman's Right-to-Know," lists 12 potential complications of medical abortion with mifepristone and misoprostol, 12 of suction curettage, and 11 of dilation and evacuation. In contrast, the pamphlet names only six potential complications of vaginal delivery and eight of cesarean delivery.[20] To laypersons who have little understanding of medical risk[21] but can count complications, these tallies may imply that abortion has more complications than does childbirth. Similarly, the mortality statistics are presented as fractions with one in the numerator and with large denominators (eg, 8,475). Empiric evidence[22,23] has demonstrated that women with less formal education than a college degree have trouble comparing risks expressed in this manner. Mortality risk should be expressed as number of deaths per 100,000, which is an easier format to understand.[22,23]

Laws that compel exposure of women to such biased material thwart informed choice and contravene the ethical principle of autonomy.[24] Moreover, they put clinicians in the untenable position of having to be complicit in misleading their patients. Since the early 1970s, the public health evidence has been clear and incontrovertible: induced abortion is safer than childbirth.

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EXHIBIT H

STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
BRANCH 3

JOSH KAUL, in his official capacity as Attorney General, Wisconsin Department of Justice,
WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES,
WISCONSIN MEDICAL EXAMINING BOARD,
and
SHELDON A. WASSERMAN, M.D., in his official capacity as Chairperson of the Wisconsin Medical Examining Board

Plaintiffs,

Case No. 2022-CV-1594
Case Code: 30701

CHRISTOPHER J. FORD, KRISTIN LYERLY, and JENNIFER JURY MCINTOSH

Intervenors,

v.

JOEL URMANSKI, in his official capacity as District Attorney for Sheboygan County, Wisconsin
ISMAEL R. OZANNE, in his official capacity as District Attorney for Dane County, Wisconsin, and
JOHN T. CHISHOLM, in his official capacity as District Attorney for Milwaukee County, Wisconsin

Defendants.

AFFIDAVIT OF CHRISTOPHER J. FORD, M.D., FACEP

STATE OF WISCONSIN)
) ss
COUNTY OF MILWAUKEE)

Christopher J. Ford, M.D., being first duly sworn on oath, deposes and says:

1. I am an adult resident of the state of Wisconsin, residing in Milwaukee County.

2. I hold a Doctor of Medicine (M.D.) from the Medical College of Wisconsin.

3. I have been licensed to practice medicine in Wisconsin since 2014.

4. I am an emergency medicine physician, certified by the American Board of Emergency Medicine. I have been named a Fellow of the American College of Emergency Physicians (FACEP).

5. I currently practice emergency medicine at four hospitals in Milwaukee County. In this capacity, I treat adult and pediatric patients from throughout southeastern Wisconsin.

6. I am aware that there are numerous Wisconsin Statutes dealing with abortion and strive to comply with all of these statutes.

7. I am aware that the Wisconsin Department of Safety and Professional Services ("DSPS") receives complaints about and conducts investigations of physicians who have allegedly engaged in unprofessional conduct, which includes violations of Wisconsin law related to the practice of medicine.

8. I am aware that the Wisconsin Medical Examining Board may issue discipline to physicians as a result of DSPS investigations, including the suspension or revocation of the physician's license to practice.

9. As an emergency medicine physician, I regularly care for women of reproductive age and treat them for a variety of presentations and complications during pregnancy. It is not uncommon to care for women having serious complications of pregnancy, such as threatened, inevitable, complete, or incomplete abortions.

10. In my practice, what may be necessary to save a patient's life versus preserving her health is sometimes an extremely difficult distinction to make.

11. I often treat life-threatening conditions in pregnant patients, including hemorrhaging due to ruptured ectopic pregnancy. Conditions such as these must be treated definitively and expeditiously. In order to provide the best care to our patients in these situations, we must make very quick decisions to disposition the patient to the appropriate level of care. In emergency medicine, seconds and minutes are invaluable. Any barriers to split-second decision making can be the difference between life and death for patients.

12. At times, I must perform an abortion to preserve the health or life of the pregnant patient. For example, I see patients presenting with precipitous deliveries or miscarriages that have resulted in sepsis to the patient. In that case, the life-saving treatment that is warranted is a dilation and curettage (D&C) operation, which may be performed by my obstetrical colleagues. In the emergency department, we provide fluid resuscitation, blood products as needed, central line access if needed, and antibiotics. In more stable patients, I can elect to proceed with medications such as methotrexate to assist with the termination of a pregnancy that may jeopardize the life of the mother. I must work with my partners from obstetrics and gynecology to help facilitate operative and medical management as promptly as possible.

13. Until June 2022, I was aware that pregnant women generally had a right to obtain pre-viability abortions under United States Supreme Court decisions interpreting the United States Constitution and could do so under Wisconsin Statutes. I was

confident that I was not at risk for disciplinary action against my medical license or criminal prosecution because I performed abortions in Wisconsin.

14. Following the U.S. Supreme Court's issuance of the *Dobbs v. Jackson Women's Health Organization* decision, I learned through media coverage and discussions with colleagues that some Wisconsin prosecutors said they would prosecute medical providers who provided abortions that were inconsistent with Wis. Stat. § 940.04.

15. I am aware that Wis. Stat. § 940.04(1) states that "Any person, other than the mother, who intentionally destroys the life of an unborn child is guilty of a Class H felony." I also became aware that Wis. Stat. § 940.04(5) provides a very limited exception when a physician performs an abortion that is "necessary" or "advised by 2 other physicians as necessary" to "save the life of the mother."

16. I am aware that the penalty for a Class H felony conviction in Wisconsin includes the potential for imprisonment for up to 6 years.

17. Because of the reported statements of some Wisconsin district attorneys, I became concerned that I could face criminal prosecution for performing abortions in Wisconsin. Also because of these reported statements, I became concerned that I could face investigation from DSPS and disciplinary action from the Wisconsin Medical Examining Board for performing abortions in Wisconsin.

18. I am aware that District Attorney Urmanski has submitted an Answer in this case in which he has "aver[ed] that Wis. Stat. § 940.04(1) prohibits performing

abortions (including consensual abortions) from conception until birth," subject to the exception in Wis. Stat. § 940.04(5). (Dkt. 153, ¶ 11.)

19. I am afraid that current or future district attorneys in other Wisconsin counties (including Milwaukee County, where I currently practice) might also interpret Wis. Stat. § 940.04(1) to prohibit all abortions in Wisconsin except for those necessary to save the life of the mother.

20. I am aware that the statute of limitations for a violation of Wis. Stat. § 940.04 is 6 years. I understand this to mean that, if I perform an abortion today, it is possible that for the next 6 years, a district attorney who shares DA Urmanski's interpretation of Wis. Stat. § 940.04(1) could decide to prosecute me. Even if a current district attorney does not, I fear that a future district attorney may share DA Urmanski's interpretation.

21. I am aware that Fond du Lac County District Attorney Eric Toney, who was the Republican candidate for attorney general in 2022, said he would enforce the law as a ban on all abortions except those necessary to save the life of the mother. This adds to my fear that a future district attorney or attorney general could attempt to enforce Wis. Stat. § 940.04(1) as an abortion ban.

22. I am afraid of such criminal prosecution for multiple reasons. I am afraid that my patients' privacy could be invaded by law enforcement personnel during the course of a law enforcement investigation under Wis. Stat. § 940.04(1). I am afraid that any such investigation or prosecution would cause permanent damage to my career and reputation. I am concerned about the costs I would incur to respond to and defend

myself against any such investigation or prosecution. I am fearful of losing my liberty and going to prison.

23. My fears and concerns have impacted my medical decision making and my ability to provide necessary and appropriate medical care in Wisconsin. Instead of focusing entirely on the needs and wishes of my patient, I must consider whether her condition is so severe that an abortion is necessary to save her life. I must also consider whether I am confident that a current or future district attorney who shares DA Urmanski's interpretation of Wis. Stat. 940.04(1) will agree with my determination. Every time I decide to perform an abortion, I understand that a local law enforcement officer or prosecutor may seek to investigate or prosecute and I could risk spending six years in prison.

24. The continued uncertainty around Wis. Stat. § 940.04(1) is negatively impacting my ability to provide necessary and appropriate medical care in Wisconsin.

Christopher J. Ford, M.D., FACEP

Signed and sworn to before me
this 22nd day of August, 2023.

EChard Bienaime

Notary Public, State of Florida
My Commission expires: 07/14/2025

NOTARY PUBLIC STATE OF FLORIDA
ECHARD BIEN AIME
Notary Public - State of Florida
Commission # HH 153738
Expires on July 14, 2025

Notarized online using audio-video communication

EXHIBIT I

STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
BRANCH 3

JOSH KAUL, in his official capacity as Attorney General, Wisconsin Department of Justice,
WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES,
WISCONSIN MEDICAL EXAMINING BOARD, and
SHELDON A. WASSERMAN, M.D., in his official capacity as Chairperson of the Wisconsin Medical Examining Board

Plaintiffs,

Case No. 2022-CV-1594
Case Code: 30701

CHRISTOPHER J. FORD, KRISTIN LYERLY, and JENNIFER JURY MCINTOSH

Intervenors,

v.

JOEL URMANSKI, in his official capacity as District Attorney for Sheboygan County, Wisconsin
ISMAEL R. OZANNE, in his official capacity as District Attorney for Dane County, Wisconsin, and
JOHN T. CHISHOLM, in his official capacity as District Attorney for Milwaukee County, Wisconsin

Defendants.

AFFIDAVIT OF JENNIFER JURY MCINTOSH, DO, MS

STATE OF Wisconsin)
) ss
COUNTY OF Milwaukee)

Jennifer Jury McIntosh, DO, MS, being first duly sworn on oath, deposes and says:

1. I am an adult resident of the State of Wisconsin, residing in Milwaukee County.

2. I have a Doctor of Osteopathic Medicine (D.O.) degree and a Master of Science degree in Clinical and Translational Science.

3. I have been practicing medicine for fifteen years.

4. I have been licensed to practice medicine in Wisconsin since 2015.

5. I practice in Milwaukee County and regularly see patients from throughout southeastern Wisconsin and occasionally I see patients who have been transported from other areas of Wisconsin or out of state.

6. I am a Maternal Fetal Medicine specialist ("MFM"). I am Board certified in obstetrics and gynecology and maternal fetal medicine by the American Board of Obstetrics and Gynecology.

7. As an MFM, I take care of high-risk pregnancies. These pregnancies can be high risk for either maternal reasons, fetal reasons, or both. Our priority during this time is to balance maternal and fetal risk. Ideally, we are able to achieve the best possible outcome for both of our patients. However, realistically, this is not always possible. At times, I must perform an abortion to preserve the health and/or life of the pregnant patient.

8. As an MFM, on a regular basis, I am providing healthcare services to patients whose health, life, or both are at risk due to their pregnancies. Conditions that jeopardize the pregnant patient's life or health may include: ectopic pregnancy (ectopic could be located in fallopian tube, cesarian scar, cervix, or anywhere else outside of the uterus); previable preeclampsia; uterine bleeding or hemorrhage related to placenta previa; placenta accreta; placental abruption; previable premature rupture of

membranes; molar pregnancy; severe maternal cardiac or renal diseases where pregnancy would cause significant clinical deterioration of the cardiac or renal disease; patients who have a transplanted organ who are refractory to standard/safe in pregnancy transplant medications (e.g. where the optimal transplant medication to save the transplanted organ/patient's life would harm the fetus); sepsis related to an intrauterine infection, cardiac, renal or respiratory failure; severe hematologic disorders; and maternal cancer where standard of care treatment would be at odds with pregnancy continuation and altered cancer risk would put the mother's life at risk. There are other conditions and situations not specifically listed here that may also put a mother's life at risk.

9. I am aware that there are numerous Wisconsin Statutes dealing with abortion and strive to comply with all of these statutes.

10. I am aware that the Wisconsin Department of Safety and Professional Services ("DSPS") receives complaints about and conducts investigations of physicians who have allegedly engaged in unprofessional conduct, which includes violations of Wisconsin law related to the practice of medicine.

11. I am aware that the Wisconsin Medical Examining Board may issue discipline to physicians as a result of DSPS investigations, including the suspension or revocation of the physician's license to practice.

12. In my medical practice, what may be necessary to save a patient's life versus necessary to preserve the patient's health is often a difficult distinction to make,

and one that often must be made very quickly; delaying care may increase the risks of negative outcomes for the patient.

13. Until June 2022, I was aware that pregnant women generally had a right to obtain pre-viability abortions under United States Supreme Court decisions interpreting the United States Constitution and could do so under Wisconsin Statutes. I was confident that I was not at risk for disciplinary action against my medical license or criminal prosecution because I performed abortions in Wisconsin.

14. Following the U.S. Supreme Court's issuance of the *Dobbs v. Jackson Women's Health Organization* decision, I learned through media coverage and discussions with colleagues that some Wisconsin prosecutors said they would prosecute medical providers who provided abortions that were inconsistent with Wis. Stat. § 940.04.

15. I am aware that Wis. Stat. § 940.04(1) states that "Any person, other than the mother, who intentionally destroys the life of an unborn child is guilty of a Class H felony." I also became aware that Wis. Stat. § 940.04(5) provides an exception when a physician performs an abortion that is "necessary" or "advised by 2 other physicians as necessary" to "save the life of the mother."

16. I am aware that the penalty for a Class H felony conviction in Wisconsin includes the potential for imprisonment for up to 6 years.

17. Because of the reported statements of some Wisconsin district attorneys, I became concerned that I could face criminal prosecution for performing abortions in Wisconsin. Also because of these reported statements, I became concerned that I could

face investigation from DSPS and disciplinary action from the Wisconsin Medical Examining Board for performing abortions in Wisconsin.

18. I am aware that DA Urmanski has submitted an Answer in this case in which he has "aver[ed] that Wis. Stat. § 940.04(1) prohibits performing abortions (including consensual abortions) from conception until birth," subject to the exception in Wis. Stat. § 940.04(5). (Dkt. 153, ¶ 11.)

19. I am afraid that current or future district attorneys in other Wisconsin counties (including Milwaukee County, where I practice) may also interpret Wis. Stat. § 940.04(1) to prohibit all abortions in Wisconsin except for those necessary to save the life of the mother.

20. I am aware that the statute of limitations for a violation of Wis. Stat. § 940.04(1) is 6 years. I understand this to mean that, if I perform an abortion today, it is possible that for the next 6 years, a district attorney who shares DA Urmanski's interpretation of Wis. Stat. § 940.04(1) could decide to prosecute me. Even if a current district attorney does not, I fear that a future district attorney may share DA Urmanski's interpretation.

21. I am aware that Fond du Lac County District Attorney Eric Toney, who was the Republican candidate for attorney general in 2022, said he would enforce the law as a ban on all abortions except those necessary to save the life of the mother. This adds to my fear that a future district attorney or attorney general will enforce Wis. Stat. § 940.04(1) as an abortion ban.

22. I am afraid of such criminal prosecution for multiple reasons. I am afraid that my patients' privacy could be invaded by law enforcement personnel during the course of a law enforcement investigation under Wis. Stat. § 940.04(1). I am afraid that any such investigation or prosecution would cause permanent damage to my career and reputation. I am concerned about the costs I would incur to respond to and defend myself against any such investigation or prosecution. I am fearful of losing my liberty and going to prison.

23. My fears and concerns have impacted my medical decision making and my ability to provide necessary and appropriate medical care in Wisconsin. Instead of focusing entirely on the needs and wishes of my patient, I must consider whether her condition is so severe that an abortion is necessary to save her life. I must also consider whether I am confident that a current or future district attorney who shares DA Urmanski's interpretation of Wis. Stat. § 940.04(1) will agree with my determination. Every time I decide to perform an abortion, I understand that a local law enforcement officer or prosecutor may seek to investigate or prosecute and I could risk spending six years in prison.

24. The continued uncertainty around Wis. Stat. § 940.04(1) is negatively impacting my ability to provide necessary and appropriate medical care in Wisconsin.

Jennifer Jury McIntosh, DO, MS

County Okaloosa State Florida

Signed and sworn to before me
this 23rd day of August, 2023.
by Jennifer Jury McIntosh provided WI DL for ID

Notary Public, State of Florida
My Commission expires: 06/13/2027
OZELLA MAE MOORE Online Notary

OZELLA MAE MOORE
Notary Public - State of Florida
Commission # HH 391605
Expires on June 13, 2027

Notarized online using audio-video communication

EXHIBIT J

STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
BRANCH 3

JOSH KAUL, in his official capacity as Attorney General, Wisconsin Department of Justice,
WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES,
WISCONSIN MEDICAL EXAMINING BOARD, and
SHELDON A. WASSERMAN, M.D., in his official capacity as Chairperson of the Wisconsin Medical Examining Board

Plaintiffs,

Case No. 2022-CV-1594
Case Code: 30701

CHRISTOPHER J. FORD, KRISTIN LYERLY, and JENNIFER JURY MCINTOSH

Intervenors,

v.

JOEL URMANSKI, in his official capacity as District Attorney for Sheboygan County, Wisconsin
ISMAEL R. OZANNE, in his official capacity as District Attorney for Dane County, Wisconsin, and
JOHN T. CHISHOLM, in his official capacity as District Attorney for Milwaukee County, Wisconsin

Defendants.

AFFIDAVIT OF KRISTIN LYERLY, MD, MPH, FACOG

STATE OF ARIZONA)
) ss
COUNTY OF COCONINO)

Kristin Lyerly, MD, being first duly sworn on oath, deposes and says:

1. I am an adult resident of the state of Wisconsin, residing in Brown County.

2. I received my Doctor of Medicine (M.D.) degree and a Master of Public Health (MPH) from the University of Wisconsin-Madison.

3. I have been licensed to practice medicine in Wisconsin since 2010.

4. My area of specialty is as an obstetrician-gynecologist. I am Board certified in obstetrics and gynecology, and a Fellow of the American College of Obstetricians and Gynecologists (FACOG).

5. I currently practice full scope care in obstetrics and gynecology temporarily in Minnesota and Arizona. Previously, I practiced full scope care in obstetrics and gynecology in Sheboygan and Brown counties, Wisconsin. In that capacity, I treated patients coming from as far as three hours away from my clinics.

6. I am aware that there are numerous Wisconsin Statutes dealing with abortion, and when practicing in Wisconsin, I strive to comply with all of these statutes.

7. I am aware that the Wisconsin Department of Safety and Professional Services ("DSPS") receives complaints about and conducts investigations of physicians who have allegedly engaged in unprofessional conduct, which includes violations of Wisconsin law related to the practice of medicine.

8. I am aware that the Wisconsin Medical Examining Board may issue discipline to physicians as a result of DSPS investigations, including the suspension or revocation of the physician's license to practice.

9. As an obstetrician-gynecologist, I regularly care for women of reproductive age and treat them for a variety of presentations and complications during pregnancy. It is not uncommon to care for women having serious complications of

pregnancy, such as threatened, inevitable, complete or incomplete abortions. I also perform elective abortions.

10. Up until late June of 2022, I performed abortions in Wisconsin. I provided abortions in several counties throughout Wisconsin, including Sheboygan.

11. During that time period, I was aware that pregnant women generally had a right to obtain pre-viability abortions under United States Supreme Court decisions interpreting the United States Constitution and could do so under Wisconsin Statutes. I was confident that I was not at risk for disciplinary action against my medical license or criminal prosecution because I performed abortions in Wisconsin.

12. Following the U.S. Supreme Court's issuance of the *Dobbs v. Jackson Women's Health Organization* decision, I learned through media coverage and conversations with colleagues that Sheboygan County District Attorney Joel Urmanski ("DA Urmanski") and other Wisconsin prosecutors said they would prosecute medical providers who provided abortions that violated Wis. Stat. § 940.04. I also learned through media coverage that DA Urmanski had proactively contacted law enforcement in Sheboygan County to inform them about his interpretation that Wis. Stat. § 940.04 prohibits abortions.

13. I am aware that Wis. Stat. § 940.04(1) states that "Any person, other than the mother, who intentionally destroys the life of an unborn child is guilty of a Class H felony." I also became aware that Wis. Stat. § 940.04(5) provides an exception when a physician performs an abortion that is "necessary" or "advised by 2 other physicians as necessary" to "save the life of the mother."

14. I am aware that the penalty for a Class H felony conviction in Wisconsin includes the potential for imprisonment for up to 6 years.

15. In my practice, complications I have seen regularly include ectopic pregnancy, preterm premature rupture of membranes (PPROM), hemorrhaging, preeclampsia, molar pregnancies, and more. These are conditions in which it can be difficult to determine whether the life or health of the pregnant patient is at stake at a given moment, and can change to a life-threatening situation from minute to minute. For example, PPROM is a condition that always threatens the health of the patient, but can quickly transform into a life-threatening, emergency situation when signs of infection emerge.

16. Because of DA Urmanski's reported statements, I became concerned that I could face criminal prosecution for practicing obstetrics and gynecology, including abortion care, in Wisconsin. Also because of DA Urmanski's reported statements, I became concerned that I could face investigation from DSPS and disciplinary action from the Wisconsin Medical Examining Board for practicing obstetrics and gynecology, including abortion care, in Wisconsin.

17. I am aware that the statute of limitations for a violation of Wis. Stat. § 940.04 is 6 years. I understand this to mean that, if I perform an abortion today, it is possible that for the next 6 years, DA Urmanski or another district attorney who shares his interpretation of Wis. Stat. § 940.04(1) could decide to prosecute me. Even if a current district attorney does not, I fear that a future district attorney may share DA Urmanski's interpretation.

18. Although I would prefer to practice medicine in Wisconsin, because of my concerns and fears, I stopped performing abortions in Wisconsin and temporarily relocated my practice to Minnesota and Arizona. I was aware that abortion rights were protected under the Minnesota Constitution and was confident that performing abortions in that state would not put me at risk for disciplinary action or criminal prosecution.

19. I am aware that District Attorney Urmanski has submitted an Answer in this case in which he has "aver[ed] that Wis. Stat. § 940.04(1) prohibits performing abortions (including consensual abortions) from conception until birth," subject to the exception in Wis. Stat. § 940.04(5). (Dkt. 153, ¶ 11.)

20. I want to resume practicing medicine in Wisconsin, including in Sheboygan County. Because Sheboygan County's district attorney still maintains that Wis. Stat. § 940.04(1) prohibits all abortions in Wisconsin except for those necessary to save the life of the mother, I am concerned that resuming my medical practice in Sheboygan County could subject me to criminal prosecution.

21. I am afraid that district attorneys in other Wisconsin counties may also interpret Wis. Stat. § 940.04(1) to prohibit all abortions in Wisconsin except for those necessary to save the life of the mother. I am concerned that resuming my medical practice anywhere Wisconsin could subject me to criminal prosecution.

22. I am aware that Fond du Lac County District Attorney Eric Toney, who was the Republican candidate for attorney general in 2022, said he would enforce the law as a ban on all abortions except those necessary to save the life of the mother. This

adds to my fear that a future district attorney or attorney general will enforce Wis. Stat. § 940.04(1) as an abortion ban.

23. I am afraid of such criminal prosecution for multiple reasons. I am afraid that my patients' privacy could be invaded by law enforcement personnel during the course of a law enforcement investigation under Wis. Stat. § 940.04(1). I am afraid that any such investigation or prosecution would cause permanent damage to my career and reputation. I am concerned about the costs I would incur to respond to and defend myself against any such investigation or prosecution. I am fearful of losing my liberty and going to prison.

24. District Attorney Urmanski's statements that Wis. Stat. § 940.04(1) prohibits all abortions in Wisconsin, except those necessary to save the life of the pregnant patient prevents me from resuming my medical practice in Wisconsin.

Kristin Lyerly

Kristin Lyerly, MD, MPH, FACOG

Signed and sworn to before me
this 22 day of AUGUST, 2023.

Notary Public, State of Florida
My Commission expires: 09/05/2026

MICHAEL DE PENA
Notary Public - State of Florida
Commission # HH308451
Expires on September 5, 2026

Notarized online using audio-video communication

EXHIBIT K

Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion

Honor MacNaughton, MD, Tufts University Family Medicine Residency at Cambridge Health Alliance, Malden, Massachusetts; Tufts University School of Medicine, Boston, Massachusetts

Melissa Nothnagle, MD, MSc, Natividad Family Medicine Residency, Salinas, California; University of California San Francisco School of Medicine, San Francisco, California

Jessica Early, MD, Tufts University Family Medicine Residency at Cambridge Health Alliance, Malden, Massachusetts; Tufts University School of Medicine, Boston, Massachusetts

Medication regimens using mifepristone and misoprostol are safe and effective for outpatient treatment of early pregnancy loss for up to 84 days' gestation and for medication abortion up to 77 days' gestation. Gestational age is determined using ultrasonography or menstrual history. Ultrasonography is needed when gestational dating cannot be confirmed using clinical data alone or when there are risk factors for ectopic pregnancy. The most effective regimens for medication management of early pregnancy loss and medication abortion include 200 mg of oral mifepristone (a progesterone receptor antagonist) followed by 800 mcg of misoprostol (a prostaglandin E_1 analogue) administered buccally or vaginally. Cramping and bleeding are expected effects of the medications, with bleeding lasting an average of nine to 16 days. The adverse effects of misoprostol (e.g., low-grade fever, gastrointestinal symptoms) can be managed with nonsteroidal anti-inflammatory drugs or antiemetics. Ongoing pregnancy, infection, hemorrhage, undiagnosed ectopic pregnancy, and the need for unplanned uterine aspiration are rare complications. Clinical history, combined with serial quantitative beta human chorionic gonadotropin levels, urine pregnancy testing, or ultrasonography, is used to establish complete passage of the pregnancy tissue. (*Am Fam Physician*. 2021;103(8):473-480. Copyright © 2021 American Academy of Family Physicians.)

Medication management of early pregnancy loss and medication abortion has become increasingly common since the U.S. Food and Drug Administration (FDA) approval of mifepristone (Mifeprex) in 2000. Medication abortion now accounts for 60% of all abortions completed before 10 weeks' gestation.[1] The most effective medication regimens combine mifepristone, a progesterone receptor antagonist that causes decidual necrosis and uterine contractions, and misoprostol (Cytotec), a prostaglandin E_1 analogue that causes cervical ripening and uterine contractions. These regimens are safe and acceptable to patients and can be prescribed by primary care clinicians in the outpatient setting.[2-4] Primary care clinicians are uniquely positioned to counsel patients and provide access to medications, with their wide geographic distribution, skills in shared decision-making, and longitudinal relationships with patients; however, only 1% of abortions currently occur in clinicians' offices.[1]

CME **This clinical content** conforms to AAFP criteria for CME. See CME Quiz on page 460.

Author disclosure: No relevant financial affiliations.

Determining Eligibility

Before prescribing mifepristone and misoprostol, clinicians should determine gestational age, evaluate for contraindications, provide patient-centered counseling on management options, and assess the need for laboratory testing.

WHAT'S NEW ON THIS TOPIC

Early Pregnancy Loss and Medication Abortion

Based on a 2018 review, the National Academies of Sciences, Engineering, and Medicine concluded that medication abortion does not increase the risk of breast cancer, mental health problems, infertility, pregnancy loss, or preterm birth.

Medication abortion accounts for 60% of all abortions before 10 weeks' gestation.

SORT: KEY RECOMMENDATIONS FOR PRACTICE

Clinical recommendation	Evidence rating	Comments
Mifepristone (Mifeprex) and misoprostol (Cytotec) can be safely prescribed by primary care clinicians in the outpatient setting.[4]	C	Consensus guideline on the safety and quality of abortion care by the National Academies of Sciences, Engineering, and Medicine
Menstrual dating or ultrasonography is required to confirm gestational age prior to medication abortion; ultrasonography should be performed in patients at risk of ectopic pregnancy or if gestational age cannot be confirmed using clinical data alone.[9-11]	B	Consistent results from two prospective case series and a retrospective review
The most effective regimen for medication management of early pregnancy loss is mifepristone, 200 mg orally, followed 24 to 48 hours later by misoprostol, 800 mcg vaginally; when available, the combination should be recommended over misoprostol alone.[2,3]	A	Consistent results of randomized controlled trials demonstrating that mifepristone and misoprostol are more effective than misoprostol alone for early pregnancy loss
The recommended regimen for medication abortion up to 70 days' gestation is mifepristone, 200 mg orally, followed by misoprostol, 800 mcg administered buccally 24 to 48 hours later or vaginally 0 to 72 hours later.[6,13,23-27]	A	Systematic review of using mifepristone and misoprostol buccally and individual randomized controlled trials of using misoprostol vaginally
To increase effectiveness of medication abortion, a second dose of misoprostol four hours after the first is recommended at 71 to 77 days' gestation and should be considered at 64 to 70 days' gestation.[8,28,29]	C	Retrospective chart review and consensus guideline
Following medication management, completed early pregnancy loss or abortion is confirmed using clinical history and an 80% decline from pretreatment in serum beta human chorionic gonadotropin levels, ultrasonography documenting the absence of a previously seen gestational sac, or a negative urine pregnancy test result.[11,35]	B	Retrospective review and a systematic review of lower quality clinical trials

A = consistent, good-quality patient-oriented evidence; **B** = inconsistent or limited-quality patient-oriented evidence; **C** = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to https://www.aafp.org/afpsort.

Regimens using mifepristone and misoprostol are effective up to 84 days' gestation for early pregnancy loss,[2,3] and up to 77 days' gestation for medication abortion.[5-8] Ultrasonography is indicated to establish the diagnosis and confirm gestational dating before using medications for early pregnancy loss. Ultrasonography, if needed, or menstrual dating can establish that gestational age is less than 77 days before a medication abortion is provided.[9-11] Ultrasonography should be performed in patients at risk of ectopic pregnancy or if gestational age cannot be confirmed using clinical data alone *(Table 1)*.[9-11]

There are few contraindications to using mifepristone and misoprostol[12] *(Table 2*[4,12,13]*)*. Medication management research has excluded patients with severe hepatic, renal, respiratory, or cardiovascular disease, or with hemoglobin levels of less than 10 g per dL (100 g per L). Laboratory testing should be considered for patients with symptoms of or at risk of anemia or sexually transmitted infections. An initial quantitative beta human chorionic gonadotropin (β-hCG) level is needed if serial β-hCG will be used to confirm completed abortion. The standard of care has been to administer $Rh_o(D)$ immune globulin (Rhogam) to all patients who are Rh-negative and who are undergoing early pregnancy loss or abortion.[14] However, according to preliminary research findings, the risk of alloimmunization in early gestation may be negligible.[15] If future research confirms this finding, testing for Rh status may not be indicated when prescribing mifepristone and misoprostol in the first trimester.[16]

Providing Counseling and Consent

Patients with early pregnancy loss or unintended pregnancy should receive patient-centered counseling on all management options because patients who are included in the decision-making process and whose treatment preferences are honored have better mental health outcomes.[17,18] The risks and benefits of treatment options for early pregnancy loss (i.e., expectant management, medication management, and uterine aspiration) are reviewed at https://www.aafp.org/afp/2019/0201/p166.html. For an in-depth discussion of the options for unintended pregnancy, including parenting, adoption, and medication or aspiration abortion, see https://www.aafp.org/afp/2015/0415/p544.html. All patients should be interviewed alone to ensure they are not being coerced by a partner or anyone else to decide against their will.[19] The FDA requires patients who use mifepristone to sign a patient agreement that is available on the drug manufacturers' websites.[20,21]

TABLE 1

Indications for Ultrasonography Before Medication Abortion

Increased risk of ectopic pregnancy
Adnexal mass or tenderness on examination
History of ectopic pregnancy
History of treatment for pelvic inflammatory disease
History of tubal surgery, including sterilization
Pregnancy with intrauterine device in place
Vaginal bleeding or unilateral pelvic pain
Unable to confirm gestational age less than 11 weeks
Hormonal contraceptive use within the past two months
Last menstrual period more than 10 weeks ago
Unsure date of last menstrual period
Uterine size/date discrepancy on bimanual examination

Information from references 9-11.

TABLE 2

Contraindications to Mifepristone (Mifeprex) and Misoprostol (Cytotec) Use

Absolute contraindications
Adrenal insufficiency
Allergy to mifepristone or misoprostol
Chronic systemic glucocorticoid use
Confirmed or suspected ectopic pregnancy
Hemodynamic instability
Hemorrhagic disorder or current anticoagulant use (excluding aspirin)
Inherited porphyrias
Intrauterine device in place (remove, then proceed with medications)
Septic abortion
Relative contraindications
Hemoglobin less than 10 g per dL (100 g per L)
Inability to access emergency or follow-up services

Information from references 4, 12, and 13.

Using Mifepristone and Misoprostol

REGIMENS FOR EARLY PREGNANCY LOSS

The most effective regimen for medication management of early pregnancy loss is 200 mg of oral mifepristone followed by 800 mcg of misoprostol administered vaginally 24 to 48 hours later.[2,3] Regimens with misoprostol alone can be used if mifepristone is not available; however, rates of effectiveness are lower.[2,3] One common regimen is misoprostol, 800 mcg vaginally, with a repeat dose in 48 hours if no bleeding has occurred[22] *(Table 3*[2,5-8,21-28]*)*.

REGIMENS FOR MEDICATION ABORTION

The FDA regimen for medication abortion up to 70 days' gestation is 200 mg of oral mifepristone followed by 800 mcg of misoprostol administered buccally 24 to 48 hours later.[13,23] Evidence-based regimens, however, demonstrate safety and effectiveness up to 77 days' gestation.[7,8,28,29] Effectiveness between 64 and 77 days' gestation increases with the addition of a second dose of misoprostol, 800 mcg four hours after the first dose.[8,28,29] Other studies show that evidence-based regimens using vaginal misoprostol 0 to 72 hours after mifepristone administration are as safe, tolerable, and effective as the FDA regimen[6,24-27] *(Table 3*[2,5-8,21-28]*)*.

PRESCRIBING LOGISTICS

Mifepristone must be ordered from the manufacturer and dispensed to the patient under the supervision of a clinician. Information on

ordering mifepristone and resources for implementing medication management of early pregnancy loss or medication abortion are provided in *Table 4*. Telehealth has been shown to be a safe and effective model for providing medication abortion and may increase access.[30] The patient may swallow the mifepristone in the office or at home. Home dosing allows for more flexible timing of subsequent misoprostol use and related cramping and bleeding.

TABLE 3

Comparison of Mifepristone (Mifeprex) and Misoprostol (Cytotec) Regimens

Gestational age in days	Mifepristone dose and route	Misoprostol dose and route	Interval between mifepristone and misoprostol use	Effectiveness
Early pregnancy loss				
Up to 84	200 mg orally	800 mcg vaginally, single dose	24 hours	83.8%
Up to 84 (misoprostol alone)	Not applicable	800 mcg vaginally, single dose	Not applicable	67.1% to 70.8%
Medication abortion				
Up to 63	200 mg orally	800 mcg buccally, single dose	24 to 48 hours	96.7%
		800 mcg vaginally, single dose	0 to 72 hours	94.0% to 96.9%
64 to 70	200 mg orally	800 mcg buccally, single dose	24 to 48 hours	93.1%
		800 mcg vaginally, single dose	24 to 48 hours	94.9%
		800 mcg buccally, two doses four hours apart	24 to 48 hours	99.6%
71 to 77	200 mg orally	800 mcg buccally, single dose	24 to 48 hours	86.7%
		800 mcg buccally, two doses four hours apart	24 to 48 hours	97.7%

Information from references 2, 5-8, and 21-28.

TABLE 4

Resources for Early Pregnancy Loss and Medication Abortion

Resource	Website	Comments
National Abortion Federation 2020 Clinical Policy Guidelines for Abortion Care	https://prochoice.org/providers/quality-standards/	Clinical guideline
Reproductive Health Access Project	https://www.reproductiveaccess.org/resource/order-mifepristone/ https://www.reproductiveaccess.org/abortion/ https://www.reproductiveaccess.org/resource/miscarriage-treatment-medication/ https://www.reproductiveaccess.org/resource/mabfactsheet/	Patient handouts and provider resources
Reproductive Health Education in Family Medicine	https://rhedi.org/education/medication-abortion/	Curricular resources for medication abortion

Misoprostol is available by prescription, or it can be stocked in the office. Patients using misoprostol buccally should place two tablets between the cheek and gums on each side of the mouth and allow them to dissolve for 30 minutes before swallowing any remaining medication. Patients using misoprostol vaginally should place four pills in the vagina and lie down for 30 minutes to allow the medication to be absorbed.

MANAGING EXPECTED AND ADVERSE EFFECTS

Mifepristone is generally well tolerated, with the most common adverse effect being nausea.[23] Misoprostol causes strong uterine cramping and heavier bleeding than menses, often with blood clots. Cramping and bleeding typically begin within several hours of using misoprostol and last for three to five hours. Lighter bleeding persists for an average of nine to 16 days.[4] Pain can usually be managed with nonsteroidal anti-inflammatory drugs and a heating pad.

Clinicians should inform patients that gastrointestinal symptoms such as nausea, vomiting, and diarrhea are common with misoprostol use. Oral antiemetics may be helpful. Low-grade fever and chills are less common and can be managed with antipyretics.[23]

TABLE 5

Complication Rates of the Management of Early Pregnancy Loss and Medication Abortion

Complication	Rate
Early pregnancy loss using mifepristone (Mifeprex) and misoprostol (Cytotec)	
Need for unplanned uterine aspiration	8.8%
Hemorrhage requiring transfusion	2.0%
Pelvic infection	1.3%
Early pregnancy loss using misoprostol alone	
Need for unplanned uterine aspiration	23.5%
Hemorrhage requiring transfusion	0.7%
Pelvic infection	0.6% to 1.3%
Medication abortion using mifepristone and misoprostol	
Need for unplanned uterine aspiration for reason other than ongoing pregnancy	1.8% to 4.2%
Ongoing pregnancy	0.8%
Hemorrhage requiring transfusion	0.03% to 0.6%
Undiagnosed ectopic pregnancy	0.02%
Pelvic infection	0.01% to 0.5%

Information from references 2, 22, 23, 31, and 32.

Safety

Complications following treatment are rare and include hemorrhage, infection, ongoing pregnancy, and undiagnosed ectopic pregnancy *(Table 5)*.[2,22,23,31,32] For early pregnancy loss, the rate of unplanned aspiration attributed to persistent pain or bleeding is 8.8% when using combined regimens of mifepristone and misoprostol and 23.5% when using misoprostol alone.[2] For patients undergoing medication abortion, rates of unanticipated uterine aspiration attributed to persistent pain or bleeding range from 1.8% to 4.2%.[23] Prophylactic antibiotics are not recommended for medication management of early pregnancy loss or abortion.[33]

Patients should be instructed to call if they experience symptoms of potential complications, including heavy bleeding, no bleeding following misoprostol use, pain not relieved by analgesics, purulent vaginal discharge, or fever or feeling ill more than 24 hours after using misoprostol. The differential diagnoses and triage for these symptoms are listed in *Table 6*.

Based on a 2018 review, the National Academies of Sciences, Engineering, and Medicine concludes that medication abortion does not increase the risk of breast cancer, mental health problems, infertility, pregnancy loss, or preterm birth.[4] Long-term fertility rates and pregnancy outcomes are similar for medication compared with surgical management of early pregnancy loss.[34]

Patient Follow-up

Successful passage of pregnancy tissue after early pregnancy loss or medication abortion should be confirmed by combining clinical history with a negative urine pregnancy test result, an adequate decline in serial serum β-hCG levels, or ultrasonography documenting the absence of a previously visible gestational sac.[35] Serum β-hCG levels should fall by at least 50% in the first

24 hours or 80% by seven days after misoprostol use.[11,35] Heterogeneous echogenicity, a thickened endometrial stripe, and the presence of Doppler flow on ultrasonography are not signs of incomplete abortion and, in the absence of symptoms, do not warrant further intervention.

Patients may start oral, transdermal, or vaginal contraception any time following misoprostol use. The etonogestrel implant (Nexplanon) can be inserted on the same day mifepristone is taken without increasing the risk of ongoing pregnancy.[36] Medroxyprogesterone (Depo-Provera) and intrauterine devices may be used after confirmation of completed abortion.[37] Patients who wish to conceive again can try as soon as they feel ready.[38]

TABLE 6

Differential Diagnoses and Triage of Symptoms Following Medication Management of Early Pregnancy Loss and Medication Abortion

Symptom	Differential diagnosis	Response
Fever, purulent vaginal discharge, or feeling sick more than 24 hours after using misoprostol (Cytotec)	Endometritis Septic abortion Condition unrelated to early pregnancy loss or abortion	Assess in person
No bleeding within 24 hours of using misoprostol	Ongoing pregnancy Ectopic pregnancy	Urgent ultrasonography if intrauterine pregnancy not previously documented If ectopic pregnancy excluded, repeat dose of misoprostol
Ongoing pregnancy symptoms: nausea, vomiting, breast pain, positive urine pregnancy test, amenorrhea	Ongoing pregnancy Ectopic pregnancy Expected resolution of pregnancy symptoms Condition unrelated to early pregnancy loss or abortion	Ultrasonography, if not done, to rule out ongoing or ectopic pregnancy If ongoing pregnancy, counsel on teratogenicity of medications, offer repeat dose of medications if < 77 days' gestation or aspiration procedure Counsel that breast tenderness typically resolves in two weeks, urine pregnancy test should be negative by four weeks, menses should return in four to six weeks
Soaking through two maxi pads per hour for two hours in a row	Expected bleeding Retained products of conception Hemorrhage	If no symptoms of anemia, push oral fluids, rest, nonsteroidal anti-inflammatory drugs, and follow-up by phone in one hour If symptomatic anemia or persistent heavy bleeding, assess in person, ensure hemodynamic stability, check hemoglobin, and consider ultrasonography
Uncontrolled abdominal or pelvic pain more than 24 hours after misoprostol use	Retained products of conception Ectopic pregnancy Endometritis Condition unrelated to early pregnancy loss or abortion	Ultrasonography, if not done, to ensure intrauterine pregnancy If signs or symptoms of infection, assess in person for endometritis If persistent pain despite recommended analgesic use, assess in person for retained products of conception If retained products of conception, offer uterine aspiration or, in a stable patient, repeat dose of misoprostol, 800 mcg
Uncontrolled abdominal or pelvic pain within 24 hours of misoprostol use	Misoprostol effect Ectopic pregnancy Endometritis	Ultrasonography, if not done, to ensure intrauterine pregnancy If signs or symptoms of infection, assess in person for endometritis Ensure proper analgesic use
Vomiting after using mifepristone (Mifeprex)	Vomiting of pregnancy Adverse effect of mifepristone	Offer antiemetic Repeat dose if vomiting within 60 minutes

Data Sources: A PubMed search was completed in Clinical Queries using the following key terms: medication abortion, early pregnancy loss, mifepristone, and misoprostol. The search included meta-analysis, randomized controlled trials, clinical trials, guidelines, and reviews. Also searched were the Cochrane database, the Agency for Healthcare Research and Quality, and DynaMed. An evidence summary, generated from Essential Evidence Plus, was reviewed, and relevant studies were referenced. Search dates: August 1 to November 1, 2019; and September 28, 2020.

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EXHIBIT L

AMA Principles of Medical Ethics

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following *Principles* adopted by the American Medical Association are not laws, but standards of conduct that define the essentials of honorable behavior for the physician.

Principles

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.

II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.

III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.

IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.

V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.

VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.

VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.

VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.

IX. A physician shall support access to medical care for all people.

Adopted June 1957; revised June 1980; revised June 2001.

EXHIBIT M

Medical Principles and Practice

Review

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Principles of Clinical Ethics and Their Application to Practice

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Highlights of the Study

- Main principles of ethics, that is beneficence, nonmaleficence, autonomy, and justice, are discussed.
- Autonomy is the basis for informed consent, truth-telling, and confidentiality.
- A model to resolve conflicts when ethical principles collide is presented.
- Cases that highlight ethical issues and their resolution are presented.
- A patient care model that integrates ethics, professionalism, and cognitive and technical expertise is shown.

Keywords
Ethics · Confidentiality · Autonomy · Informed consent · Professionalism · Integrated patient care model

Abstract
An overview of ethics and clinical ethics is presented in this review. The 4 main ethical principles, that is beneficence, nonmaleficence, autonomy, and justice, are defined and explained. Informed consent, truth-telling, and confidentiality spring from the principle of autonomy, and each of them is discussed. In patient care situations, not infrequently, there are conflicts between ethical principles (especially between beneficence and autonomy). A four-pronged systematic approach to ethical problem-solving and several illustrative cases of conflicts are presented. Comments following the cases highlight the ethical principles involved and clarify the resolution of these conflicts. A model for patient care, with caring as its central element, that integrates ethical aspects (intertwined with professionalism) with clinical and technical expertise desired of a physician is illustrated.

Introduction

A defining responsibility of a practicing physician is to make decisions on patient care in different settings. These decisions involve more than selecting the appropriate treatment or intervention.

Ethics is an inherent and inseparable part of clinical medicine [1] as the physician has an ethical obligation (i) to benefit the patient, (ii) to avoid or minimize harm, and to (iii) respect the values and preferences of the patient. Are physicians equipped to fulfill this ethical obligation and can their ethical skills be improved? A goal-oriented educational program [2] (Table 1) has been shown to improve learner awareness, attitudes, knowledge, moral reasoning, and confidence [3, 4].

Ethics, Morality, and Professional Standards

Ethics is a broad term that covers the study of the nature of morals and the specific moral choices to be made. Normative ethics attempts to answer the question, "Which general moral norms for the guidance and evalu-

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Table 1. Goals of ethics education

- To appreciate the ethical dimensions of patient care
- To understand ethical principles of medical profession
- To have competence in core ethical behavioral skills
(Obtaining informed consent, assessing decision-making capacity, discussing resuscitation status and use of life-sustaining treatments, advanced care planning, breaking bad news and effective communication)
- To know the commonly encountered ethical issues in general and in one's specialty
- To have competence in analyzing and resolving ethical problems
- To appreciate cultural diversity and its impact on ethics

ation of conduct should we accept, and why?" [5]. Some moral norms for right conduct are common to human kind as they transcend cultures, regions, religions, and other group identities and constitute *common morality* (e.g., not to kill, or harm, or cause suffering to others, not to steal, not to punish the innocent, to be truthful, to obey the law, to nurture the young and dependent, to help the suffering, and rescue those in danger). *Particular morality* refers to norms that bind groups because of their culture, religion, profession and include responsibilities, ideals, professional standards, and so on. A pertinent example of particular morality is the physician's "accepted role" to provide competent and trustworthy service to their patients. To reduce the vagueness of "accepted role," physician organizations (local, state, and national) have codified their standards. However, complying with these standards, it should be understood, may not always fulfill the moral norms as the codes have "often appeared to protect the profession's interests more than to offer a broad and impartial moral viewpoint or to address issues of importance to patients and society" [6].

Bioethics and Clinical (Medical) Ethics

A number of deplorable abuses of human subjects in research, medical interventions without informed consent, experimentation in concentration camps in World War II, along with salutary advances in medicine and medical technology and societal changes, led to the rapid evolution of bioethics from one concerned about professional conduct and codes to its present status with an extensive scope that includes research ethics, public health ethics, organizational ethics, and clinical ethics.

Hereafter, the abbreviated term, ethics, will be used as I discuss the principles of clinical ethics and their application to clinical practice.

The Fundamental Principles of Ethics

Beneficence, nonmaleficence, autonomy, and justice constitute the 4 principles of ethics. The first 2 can be traced back to the time of Hippocrates "to help and do no harm," while the latter 2 evolved later. Thus, in Percival's book on ethics in early 1800s, the importance of keeping the patient's best interest as a goal is stressed, while autonomy and justice were not discussed. However, with the passage of time, both autonomy and justice gained acceptance as important principles of ethics. In modern times, Beauchamp and Childress' book on Principles of Biomedical Ethics is a classic for its exposition of these 4 principles [5] and their application, while also discussing alternative approaches.

Beneficence

The principle of beneficence is the obligation of physician to act for the benefit of the patient and supports a number of moral rules to protect and defend the right of others, prevent harm, remove conditions that will cause harm, help persons with disabilities, and rescue persons in danger. It is worth emphasizing that, in distinction to nonmaleficence, the language here is one of positive requirements. The principle calls for not just avoiding harm, but also to benefit patients and to promote their welfare. While physicians' beneficence conforms to moral rules, and is altruistic, it is also true that in many instances it can be considered a payback for the debt to society for education (often subsidized by governments), ranks and privileges, and to the patients themselves (learning and research).

Nonmaleficence

Nonmaleficence is the obligation of a physician not to harm the patient. This simply stated principle supports several moral rules – do not kill, do not cause pain or suffering, do not incapacitate, do not cause offense, and do not deprive others of the goods of life. The practical application of nonmaleficence is for the physician to weigh the benefits against burdens of all interventions and treatments, to eschew those that are inappropriately burdensome, and to choose the best course of action for the patient. This is particularly important and pertinent in difficult end-of-life care decisions on withholding and

withdrawing life-sustaining treatment, medically administered nutrition and hydration, and in pain and other symptom control. A physician's obligation and intention to relieve the suffering (e.g., refractory pain or dyspnea) of a patient by the use of appropriate drugs including opioids override the foreseen but unintended harmful effects or outcome (doctrine of double effect) [7, 8].

Autonomy

The philosophical underpinning for autonomy, as interpreted by philosophers Immanuel Kant (1724–1804) and John Stuart Mill (1806–1873), and accepted as an ethical principle, is that all persons have intrinsic and unconditional worth, and therefore, should have the power to make rational decisions and moral choices, and each should be allowed to exercise his or her capacity for self-determination [9]. This ethical principle was affirmed in a court decision by Justice Cardozo in 1914 with the epigrammatic dictum, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body" [10].

Autonomy, as is true for all 4 principles, needs to be weighed against competing moral principles, and in some instances may be overridden; an obvious example would be if the autonomous action of a patient causes harm to another person(s). The principle of autonomy does not extend to persons who lack the capacity (competence) to act autonomously; examples include infants and children and incompetence due to developmental, mental or physical disorder. Health-care institutions and state governments in the US have policies and procedures to assess incompetence. However, a rigid distinction between incapacity to make health-care decisions (assessed by health professionals) and incompetence (determined by court of law) is not of practical use, as a clinician's determination of a patient's lack of decision-making capacity based on physical or mental disorder has the same practical consequences as a legal determination of incompetence [11].

Detractors of the principle of autonomy question the focus on the individual and propose a broader concept of relational autonomy (shaped by social relationships and complex determinants such as gender, ethnicity and culture) [12]. Even in an advanced western country such as United States, the culture being inhomogeneous, some minority populations hold views different from that of the majority white population in need for full disclosure, and in decisions about life support (preferring a family-centered approach) [13].

Resistance to the principle of patient autonomy and its derivatives (informed consent, truth-telling) in non-western cultures is not unexpected. In countries with ancient civilizations, rooted beliefs and traditions, the practice of paternalism (*this term will be used in this article, as it is well-entrenched in ethics literature, although parentalism is the proper term*) by physicians emanates mostly from beneficence. However, culture (a composite of the customary beliefs, social forms, and material traits of a racial, religious or social group) is not static and autonomous, and changes with other trends over passing years. It is presumptuous to assume that the patterns and roles in physician-patient relationships that have been in place for a half a century and more still hold true. Therefore, a critical examination of paternalistic medical practice is needed for reasons that include technological and economic progress, improved educational and socioeconomic status of the populace, globalization, and societal movement towards emphasis on the patient as an individual, than as a member of a group. This needed examination can be accomplished by research that includes well-structured surveys on demographics, patient preferences on informed consent, truth-telling, and role in decision-making.

Respecting the principle of autonomy obliges the physician to disclose medical information and treatment options that are necessary for the patient to exercise self-determination and supports informed consent, truth-telling, and confidentiality.

Informed Consent

The requirements of an informed consent for a medical or surgical procedure, or for research, are that the patient or subject (i) must be competent to understand and decide, (ii) receives a full disclosure, (iii) comprehends the disclosure, (iv) acts voluntarily, and (v) consents to the proposed action.

The universal applicability of these requirements, rooted and developed in western culture, has met with some resistance and a suggestion to craft a set of requirements that accommodate the cultural mores of other countries [14]. In response and in vigorous defense of the 5 requirements of informed consent, Angell wrote, "There must be a core of human rights that we would wish to see honored universally, despite variations in their superficial aspects …The forces of local custom or local law cannot justify abuses of certain fundamental rights, and the right of self-determination on which the doctrine of informed consent is based, is one of them" [15].

As competence is the first of the requirements for informed consent, one should know how to detect incompetence. Standards (used singly or in combination) that

are generally accepted for determining incompetence are based on the patient's inability to state a preference or choice, inability to understand one's situation and its consequences, and inability to reason through a consequential life decision [16].

In a previously autonomous, but presently incompetent patient, his/her previously expressed preferences (i.e., prior autonomous judgments) are to be respected [17]. Incompetent (non-autonomous) patients and previously competent (autonomous), but presently incompetent patients would need a surrogate decision-maker. In a non-autonomous patient, the surrogate can use either a substituted judgment standard (i.e., what the patient would wish in this circumstance and not what the surrogate would wish), or a best interests standard (i.e., what would bring the highest net benefit to the patient by weighing risks and benefits). Snyder and Sulmasy [18], in their thoughtful article, provide a practical and useful option when the surrogate is uncertain of the patient's preference(s), or when patient's preferences have not kept abreast of scientific advances. They suggest the surrogate use "substituted interests," that is, the patient's authentic values and interests, to base the decision.

Truth-Telling

Truth-telling is a vital component in a physician-patient relationship; without this component, the physician loses the trust of the patient. An autonomous patient has not only the right to know (disclosure) of his/her diagnosis and prognosis, but also has the option to forgo this disclosure. However, the physician must know which of these 2 options the patient prefers.

In the United States, full disclosure to the patient, however grave the disease is, is the norm now, but was not so in the past. Significant resistance to full disclosure was highly prevalent in the US, but a marked shift has occurred in physicians' attitudes on this. In 1961, 88% of physicians surveyed indicated their preference to avoid disclosing a diagnosis [19]; in 1979, however, 98% of surveyed physicians favored it [20]. This marked shift is attributable to many factors that include – with no order of importance implied – educational and socioeconomic progress, increased accountability to society, and awareness of previous clinical and research transgressions by the profession.

Importantly, surveys in the US show that patients with cancer and other diseases wish to have been fully informed of their diagnoses and prognoses. Providing full information, with tact and sensitivity, to patients who want to know should be the standard. The sad consequences of not telling the truth regarding a cancer include depriving the patient of an opportunity for completion of important life-tasks: giving advice to, and taking leave of loved ones, putting financial affairs in order, including division of assets, reconciling with estranged family members and friends, attaining spiritual order by reflection, prayer, rituals, and religious sacraments [21, 22].

In contrast to the US, full disclosure to the patient is highly variable in other countries [23]. A continuing pattern in non-western societies is for the physician to disclose the information to the family and not to the patient. The likely reasons for resistance of physicians to convey bad news are concern that it may cause anxiety and loss of hope, some uncertainty on the outcome, or belief that the patient would not be able to understand the information or may not want to know. However, this does not have to be a binary choice, as careful understanding of the principle of autonomy reveals that autonomous choice is a right of a patient, and the patient, in exercising this right, may authorize a family member or members to make decisions for him/her.

Confidentiality

Physicians are obligated not to disclose confidential information given by a patient to another party without the patient's authorization. An obvious exception (with implied patient authorization) is the sharing necessary of medical information for the care of the patient from the primary physician to consultants and other health-care teams. In the present-day modern hospitals with multiple points of tests and consultants, and the use of electronic medical records, there has been an erosion of confidentiality. However, individual physicians must exercise discipline in not discussing patient specifics with their family members or in social gatherings [24] and social media. There are some noteworthy exceptions to patient confidentiality. These include, among others, legally required reporting of gunshot wounds and sexually transmitted diseases and exceptional situations that may cause major harm to another (e.g., epidemics of infectious diseases, partner notification in HIV disease, relative notification of certain genetic risks, etc.).

Justice

Justice is generally interpreted as fair, equitable, and appropriate treatment of persons. Of the several categories of justice, the one that is most pertinent to clinical ethics is *distributive justice*. Distributive justice refers to the fair, equitable, and appropriate distribution of health-care resources determined by justified norms that struc-

ture the terms of social cooperation [25]. How can this be accomplished? There are different valid principles of distributive justice. These are distribution to each person (i) an equal share, (ii) according to need, (iii) according to effort, (iv) according to contribution, (v) according to merit, and (vi) according to free-market exchanges. Each principle is not exclusive, and can be, and are often combined in application. It is easy to see the difficulty in choosing, balancing, and refining these principles to form a coherent and workable solution to distribute medical resources.

Although this weighty health-care policy discussion exceeds the scope of this review, a few examples on issues of distributive justice encountered in hospital and office practice need to be mentioned. These include allotment of scarce resources (equipment, tests, medications, organ transplants), care of uninsured patients, and allotment of time for outpatient visits (equal time for every patient? based on need or complexity? based on social and or economic status?). Difficult as it may be, and despite the many constraining forces, physicians must accept the requirement of fairness contained in this principle [26]. Fairness to the patient assumes a role of primary importance when there are conflicts of interests. A flagrant example of violation of this principle would be when a particular option of treatment is chosen over others, or an expensive drug is chosen over an equally effective but less expensive one because it benefits the physician, financially, or otherwise.

Conflicts between Principles

Each one of the 4 principles of ethics is to be taken as a *prima facie* obligation that must be fulfilled, unless it conflicts, in a specific instance, with another principle. When faced with such a conflict, the physician has to determine the actual obligation to the patient by examining the respective weights of the competing *prima facie* obligations based on both content and context. Consider an example of a conflict that has an easy resolution: a patient in shock treated with urgent fluid-resuscitation and the placement of an indwelling intravenous catheter caused pain and swelling. Here the principle of beneficence overrides that of nonmaleficence. Many of the conflicts that physicians face, however, are much more complex and difficult. Consider a competent patient's refusal of a potentially life-saving intervention (e.g., *instituting* mechanical ventilation) or request for a potentially life-ending action (e.g., *withdrawing* mechanical ventilation). Nowhere in the arena of ethical decision-making is conflict as pronounced as when the principles of beneficence and autonomy collide.

Beneficence has enjoyed a historical role in the traditional practice of medicine. However, giving it primacy over patient autonomy is paternalism that makes a physician-patient relationship analogous to that of a father/mother to a child. A father/mother may refuse a child's wishes, may influence a child by a variety of ways – nondisclosure, manipulation, deception, coercion etc., consistent with his/her thinking of what is best for the child. Paternalism can be further divided into *soft* and *hard*.

In *soft* paternalism, the physician acts on grounds of beneficence (and, at times, nonmaleficence) when the patient is nonautonomous or substantially nonautonomous (e.g., cognitive dysfunction due to severe illness, depression, or drug addiction) [27]. Soft paternalism is complicated because of the difficulty in determining whether the patient was nonautonomous at the time of decision-making but is ethically defensible as long as the action is in concordance with what the physician believes to be the patient's values. *Hard* paternalism is action by a physician, intended to benefit a patient, but contrary to the voluntary decision of an autonomous patient who is fully informed and competent, and is ethically indefensible.

On the other end of the scale of hard paternalism is consumerism, a rare and extreme form of patient autonomy, that holds the view that the physician's role is limited to providing all the medical information and the available choices for interventions and treatments while the fully informed patient selects from the available choices. In this model, the physician's role is constrained, and does not permit the full use of his/her knowledge and skills to benefit the patient, and is tantamount to a form of patient abandonment and therefore is ethically indefensible.

Faced with the contrasting paradigms of beneficence and respect for autonomy and the need to reconcile these to find a common ground, Pellegrino and Thomasma [28] argue that beneficence can be inclusive of patient autonomy as "the best interests of the patients are intimately linked with their preferences" from which "are derived our primary duties to them."

One of the basic and not infrequent reasons for disagreement between physician and patient on treatment issues is their divergent views on goals of treatment. As goals change in the course of disease (e.g., a chronic neurologic condition worsens to the point of needing ventilator support, or a cancer that has become refractory to treatment), it is imperative that the physician communi-

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Table 2. Application of principles of ethics in patient care

Beneficence, nonmaleficence	*Clinical assessment* Nature of illness (acute, chronic, reversible, terminal)? Goals of treatment? Treatment options and probability of success for each option? Adverse effects of treatment and does benefit outweigh harm? Effects of no medical/surgical treatment? If treated, plans for limiting treatment? Stopping treatment?
Respect for autonomy	*Patient rights and preferences* Information given to patient on benefits and risks of treatment? Patient understood the information and gave consent? Patent mentally competent? If competent, what are his/her preferences? If patient mentally incompetent, are patient's prior preferences known? If preferences unknown, who is the appropriate surrogate?
Beneficence, nonmaleficence, respect for autonomy	*Quality of life (QOL)* Expected QOL with and without treatment? Deficits – physical, mental, social – may have after treatment? Judging QOL of patient who cannot express himself/herself? Who is the judge? Recognition of possible physician bias in judging QOL? Rationale to forgo life-sustaining treatment(s)?
Distributive justice	*External forces and context* Conflicts of interests – does physician benefit financially, professionally by ordering tests, prescribing medications, seeking consultations? Research or educational considerations that affect clinical decisions, physician orders? Conflicts of interests based on religious beliefs? Legal issues? Conflicts of interests between organizations (clinics, hospitals), 3rd party payers? Public health and safety issues? Problems in allocation of scarce resources?

cates with the patient in clear and straightforward language, without the use of medical jargon, and with the aim of defining the goal(s) of treatment under the changed circumstance. In doing so, the physician should be cognizant of patient factors that compromise decisional capacity, such as anxiety, fear, pain, lack of trust, and different beliefs and values that impair effective communication [29].

The foregoing theoretical discussion on principles of ethics has practical application in clinical practice in all settings. In the resource book for clinicians, Jonsen et al. [30] have elucidated a logical and well accepted model (Table 2), along the lines of the systematic format that practicing physicians have been taught and have practiced for a long time (Chief Complaint, History of Present Illness, Past History, pertinent Family and Social History, Review of Systems, Physical Examination and Laboratory and Imaging studies). This practical approach to problem-solving in ethics involves:

- Clinical assessment (identifying medical problems, treatment options, goals of care)
- Patient (finding and clarifying patient preferences on treatment options and goals of care)
- Quality of life (QOL) (effects of medical problems, interventions and treatments on patient's QOL with awareness of individual biases on what constitutes an acceptable QOL)
- Context (many factors that include family, cultural, spiritual, religious, economic and legal).

Using this model, the physician can identify the principles that are in conflict, ascertain by weighing and balancing what should prevail, and when in doubt, turn to ethics literature and expert opinion.

Illustrative Cases

There is a wide gamut of clinical patient encounters with ethical issues, and some, especially those involving end-of-life care decisions, are complex. A few cases (Case 1 is modified from resource book [30]) are presented below as they highlight the importance of understanding

and weighing the ethical principles involved to arrive at an ethically right solution. Case 6 was added during the revision phase of this article as it coincided with the outbreak of Coronavirus Infectious Disease-2019 (COVID-19) that became a pandemic rendering a discussion of its ethical challenges necessary and important.

Case 1

A 20-year old college student living in the college hostel is brought by a friend to the Emergency Department (ED) because of unrelenting headache and fever. He appeared drowsy but was responsive and had fever (40 °C), and neck rigidity on examination. Lumbar puncture was done, and spinal fluid appeared cloudy and showed increased white cells; Gram stain showed Gram-positive diplococci. Based on the diagnosis of bacterial meningitis, appropriate antibiotics were begun, and hospitalization was instituted. Although initial consent for diagnosis was implicit, and consent for lumbar puncture was explicit, at this point, the patient refuses treatment without giving any reason, and insists to return to his hostel. Even after explanation by the physician as to the seriousness of his diagnosis, and the absolute need for prompt treatment (i.e., danger to life without treatment), the patient is adamant in his refusal.

Comment. Because of this refusal, the medical indications and patient preferences (see Table 2) are at odds. Is it ethically right to treat against his will a patient who is making a choice that has dire consequences (disability, death) who gives no reason for this decision, and in whom a clear determination of mental incapacity cannot be made (although altered mental status may be presumed)? Here the principle of beneficence and principle of autonomy are in conflict. The weighing of factors: (1) patient may not be making a reasoned decision in his best interest because of temporary mental incapacity; and (2) the severity of life-threatening illness and the urgency to treat to save his life supports the decision in favor of beneficence (i.e., to treat).

Case 2

A 56-year old male lawyer and current cigarette smoker with a pack-a-day habit for more than 30 years, is found to have a solitary right upper lobe pulmonary mass 5 cm in size on a chest radiograph done as part of an insurance application. The mass has no calcification, and there are no other pulmonary abnormalities. He has no symptoms, and his examination is normal. Tuberculosis skin test is negative, and he has no history of travel to an endemic area of fungal infection. As lung cancer is the most probable and significant diagnosis to consider, and early surgical resection provides the best prospects for cure, the physician, in consultation with the thoracic surgeon, recommends bronchoscopic biopsy and subsequent resection. The patient understands the treatment plan, and the significance of not delaying the treatment. However, he refuses, and states that he does not think he has cancer; and is fearful that the surgery would kill him. Even after further explanations on the low mortality of surgery and the importance of removing the mass before it spreads, he continues to refuse treatment.

Comment. Even though the physician's prescribed treatment, that is, removal of the mass that is probably cancer, affords the best chance of cure, and delay in its removal increases its chance of metastases and reaching an incurable stage – the choice by this well informed and mentally competent patient should be respected. Here, autonomy prevails over beneficence. The physician, however, may not abandon the patient and is obligated to offer continued outpatient visits with advice against making decision based on fear, examinations, periodic tests, and encouragement to seek a second opinion.

Case 3

A 71-year-old man with very severe chronic obstructive pulmonary disease (COPD) is admitted to the intensive care unit (ICU) with pneumonia, sepsis, and respiratory failure. He is intubated and mechanically ventilated. For the past 2 years, he has been on continuous oxygen treatment and was short of breath on minimal exertion. In the past 1 year, he had 2 admissions to the ICU; on both occasions he required intubation and mechanical ventilation. Presently, even with multiple antibiotics, intravenous fluid hydration, and vasopressors, his systolic blood pressure remains below 60 mm Hg, and with high flow oxygen supplementation, his oxygen saturation stays below 80%; his arterial blood pH is 7.0. His liver enzymes are elevated. He is anuric, and over next 8 h his creatinine has risen to 5 mg/dL and continues to rise. He has drifted into a comatose state. The intensivist suggests discontinuation of vasopressors and mechanical ventilation as their continued use is futile. The patient has no advance care directives or a designated health-care proxy.

Comment. The term "futility" is open to different definitions [31] and is often controversial, and therefore, some experts suggest the alternate term, "clinically nonbeneficial interventions" [32]. However, in this case the term futility is appropriate to indicate that there is evidence of physiological futility (multisystem organ failure in the setting of preexisting end stage COPD, and medical

interventions would not reverse the decline). It is appropriate then to discuss the patient's condition with his family with the goal of discontinuing life-sustaining interventions. These discussions should be done with sensitivity, compassion and empathy. Palliative care should be provided to alleviate his symptoms and to support the family until his death and beyond in their bereavement.

Case 4

A 67-year old widow, an immigrant from southern India, is living with her son and his family in Wisconsin, USA. She was experiencing nausea, lack of appetite and weight loss for a few months. During the past week, she also had dark yellow urine, and yellow coloration of her skin. She has basic knowledge of English. She was brought to a multi-specialty teaching hospital by her son, who informed the doctor that his mother has "jaundice," and instructed that, if any serious life-threatening disease was found, not to inform her. He asked that all information should come to him, and if there is any cancer not to treat it, since she is older and frail. Investigations in the hospital reveals that she has pancreatic cancer, and chemotherapy, while not likely to cure, would prolong her life.

Comment. In some ancient cultures, authority is given to members of the family (especially senior men) to make decisions that involve other members on marriage, job, and health care. The woman in this case is a dependent of her son, and given this cultural perspective, the son can rightfully claim to have the authority to make health-care decisions for her. Thus, the physician is faced with multiple tasks that may not be consonant. To respect cultural values [33], to directly learn the patient's preferences, to comply with the American norm of full disclosure to the patient, and to refuse the son's demands.

The principle of autonomy provides the patient the option to delegate decision-making authority to another person. Therefore, the appropriate course would be to take the tactful approach of directly informing the patient (with a translator if needed), that the diagnosed disease would require decisions for appropriate treatment. The physician should ascertain whether she would prefer to make these decisions herself, or whether she would prefer all information to be given to her son, and all decisions to be made by him.

Case 5

A 45-year-old woman had laparotomy and cholecystectomy for abdominal pain and multiple gall stones. Three weeks after discharge from the hospital, she returned with fever, abdominal pain, and tenderness. She was given antibiotics, and as her fever continued, laparotomy and exploration were undertaken; a sponge left behind during the recent cholecystectomy was found. It was removed, the area cleansed, and incision closed. Antibiotics were continued, and she recovered without further incident and was discharged. Should the surgeon inform the patient of his error?

Comment. Truth-telling, a part of patient autonomy is very much applicable in this situation and disclosure to patient is required [34–36]. The mistake caused harm to the patient (morbidity and readmission, and a second surgery and monetary loss). Although the end result remedied the harm, the surgeon is obligated to inform the patient of the error and its consequences and offer an apology. Such errors are always reported to the Operating Room Committees and Surgical Quality Improvement Committees of US Hospitals. Hospital-based risk reduction mechanisms (e.g., Risk Management Department) present in most US hospitals would investigate the incident and come up with specific recommendations to mitigate the error and eliminate them in the future. Many institutions usually make financial settlements to obviate liability litigation (fees and hospital charges waived, and/or monetary compensation made to the patient). Elsewhere, if such mechanisms do not exist, it should be reported to the hospital. Acknowledgment from the hospital, apologies from the institution and compensation for the patient are called for. Whether in US or elsewhere, a malpractice suit is very possible in this situation, but a climate of honesty substantially reduces the threat of legal claims as most patients trust their physicians and are not vindictive.

Case(s) 6

The following scenario is at a city hospital during the peak of the COVID-19 pandemic: A 74-year-old woman, residing in an assisted living facility, is brought to the ED with shortness of breath and malaise. Over the past 4 days she had been experiencing dry cough, lack of appetite, and tiredness; 2 days earlier, she stopped eating and started having a low-grade fever. A test for COVID-19 undertaken by the assisted living facility was returned positive on the morning of the ED visit.

She, a retired nurse, is a widow; both of her grown children live out-of-state. She has had hypertension for many years, controlled with daily medications. Following 2 strokes, she was moved to an assisted living facility 3 years ago. She recovered most of her functions after the strokes and required help only for bathing and dressing. She is able to answer questions appropriately but haltingly, because of respiratory distress. She has tachypnea (34/min),

tachycardia (120/min), temperature of 101°F, BP 100/60 and 90% O_2 saturation (on supplemental O_2 of 4 L/min). She has dry mouth and tongue and rhonchi on lung auscultation. Her respiratory rate is increasing on observation and she is visibly tiring.

Another patient is now brought in by ambulance; this is a 22-year-old man living in an apartment and has had symptoms of "flu" for a week. Because of the pandemic, he was observing the recommended self-distancing, and had no known exposure to coronavirus. He used saline gargles, acetaminophen, and cough syrup to alleviate his sore throat, cough, and fever. In the past 2 days, his symptoms worsened, and he drove himself to a virus testing station and got tested for COVID-19; he was told that he would be notified of the results. He returned to his apartment and after a sleepless night with fever, sweats, and persistent cough, he woke up and felt drained of all strength. The test result confirmed COVID-19. He then called for an ambulance.

He has been previously healthy. He is a non-smoker and uses alcohol rarely. He is a second-year medical student. He is single, and his parents and sibling live hundreds of miles away.

On examination, he has marked tachypnea (>40/min), shallow breathing, heart rate of 128/min, temperature of 103°F and O_2 saturation of 88 on pulse oximetry. He appears drowsy and is slow to respond to questions. He is propped up to a sitting position as it is uncomfortable for him to be supine. Accessory muscles of neck and intercostals are contracting with each breath, and on auscultation, he has basilar crackles and scattered rhonchi. His O_2 saturation drops to 85 and he is in respiratory distress despite nebulized bronchodilator treatment.

Both of these patients are in respiratory failure, clinically and confirmed by arterial blood gases, and are in urgent need of intubation and mechanical ventilation. However, only one ventilator is available; who gets it?

Comment. The decision to allocate a scarce and potentially life-saving equipment (ventilator) is very difficult as it directly addresses the question "Who shall live when not everyone can live? [5]. This decision cannot be emotion-driven or arbitrary; nor should it be based on a person's wealth or social standing. Priorities need to be established ethically and must be applied consistently in the same institution and ideally throughout the state and the country. The general social norm to treat all equally or to treat on a first come, first saved basis is not the appropriate choice here. There is a consensus among clinical ethics scholars, that in this situation, maximizing benefits is the dominant value in making a decision [37]. Maximizing benefits can be viewed in 2 different ways; in lives saved or in life-years saved; they differ in that the first is non-utilitarian while the second is utilitarian. A subordinate consideration is giving priority to patients who have a better chance of survival and a reasonable life expectancy. The other 2 considerations are promoting and rewarding instrumental value (benefit to others) and the acuity of illness. Health-care workers (physicians, nurses, therapists etc.) and research participants have instrumental value as their work benefits others; among them those actively contributing are of more value than those who have made their contributions. The need to prioritize the sickest and the youngest is also a recognized value when these are aligned with the dominant value of maximizing benefits. In the context of COVID-19 pandemic, Emanuel et al. [37] weighed and analyzed these values and offered some recommendations. Some ethics scholars opine that in times of a pandemic, the burden of making a decision as to who gets a ventilator and who does not (often a life or death choice) should not be on the front-line physicians, as it may cause a severe and life-long emotional toll on them [35, 36]. The toll can be severe for nurses and other front-line health-care providers as well. As a safeguard, they propose that the decision should rest on a select committee that excludes doctors, nurses and others who are caring for the patient(s) under consideration [38].

Both patients described in the case summaries have comparable acuity of illness and both are in need of mechanical ventilator support. However, in the dominant value of maximizing benefits the two patients differ; in terms of life-years saved, the second patient (22-year-old man) is ahead as his life expectancy is longer. Additionally, he is more likely than the older woman, to survive mechanical ventilation, infection, and possible complications. Another supporting factor in favor of the second patient is his potential instrumental value (benefit to others) as a future physician.

Unlike the other illustrative cases, the scenario of these 2 cases, does not lend itself to a peaceful and fully satisfactory resolution. The fairness of allocating a scarce and potentially life-saving resource based on maximizing benefits and preference to instrumental value (benefit to others) is open to question. The American College of Physicians has stated that allocation decisions during resource scarcity should be made "based on patient need, prognosis (determined by objective scientific measure and informed clinical judgment) and effectiveness (i.e., likelihood that the therapy will help the patient to recover), … to maximize the number of patients who will recover" [39].

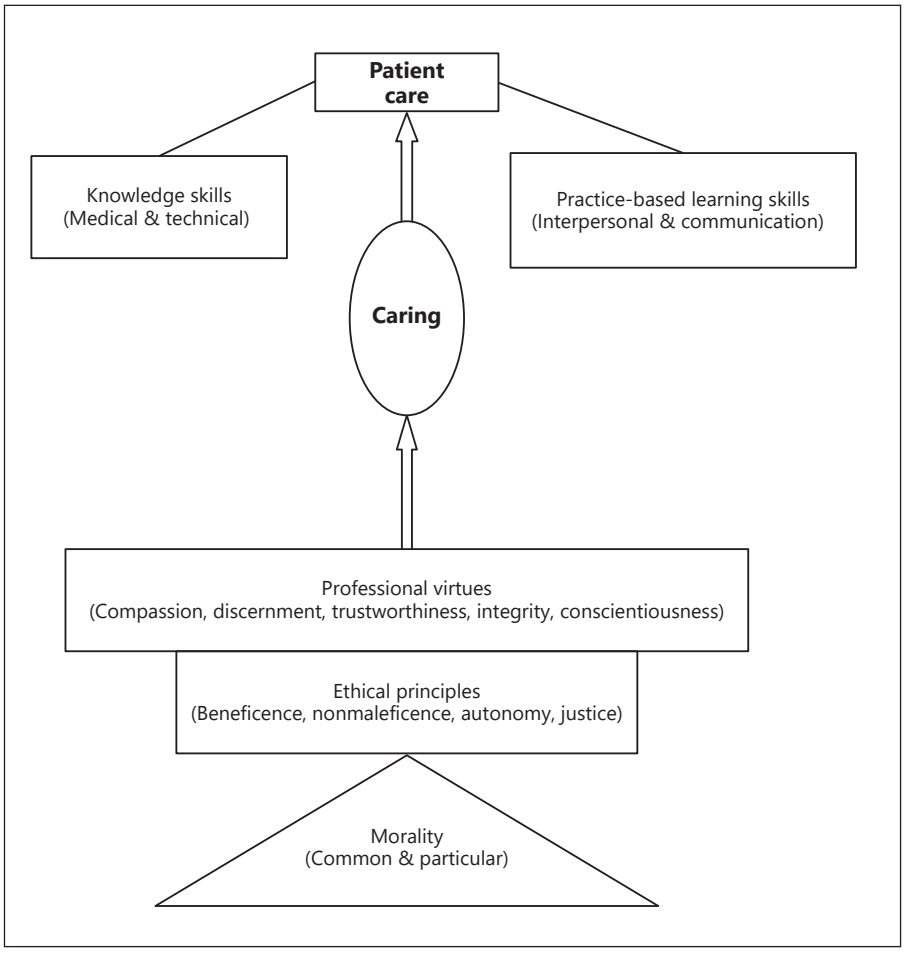

Fig. 1. Integrated model of patient care.

Conclusion

This review has covered basics of ethics founded on morality and ethical principles with illustrative examples. In the following segment, professionalism is defined, its alignment with ethics depicted, and virtues desired of a physician (inclusive term for medical doctor regardless of type of practice) are elucidated. It concludes with my vision of an integrated model for patient care.

The core of professionalism is a therapeutic relationship built on competent and compassionate care by a physician that meets the expectation and benefits a patient. In this relationship, which is rooted in the ethical principles of beneficence and nonmaleficence, the physician fulfills the elements shown in Table 3. Professionalism "demands placing the interest of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health" [26, 40].

Table 3. Physicians obligations

• Cure of disease when possible
• Maintenance or improvement of functional status and quality of life (relief of symptoms and suffering)
• Promotion of health and prevention of disease
• Prevention of untimely death
• Education and counseling of patients (condition and prognosis)
• Avoidance of harm to the patient in the course of care
• Providing relief and support near time of death (end-of-life care)

Drawing on several decades of experience in teaching and mentoring, I envisage physicians with qualities of both "heart" and "head." Ethical and humanistic values shape the former, while knowledge (e.g., by study, research, practice) and technical skills (e.g., medical and

surgical procedures) form the latter. Figure 1 is a representation of this model. Morality that forms the base of the model and ethical principles that rest on it were previously explained. Virtues are linked, some more tightly than others, to the principles of ethics. Compassion, a prelude to caring, presupposes sympathy, is expressed in beneficence. Discernment is especially valuable in decision-making when principles of ethics collide. Trustworthiness leads to trust, and is a needed virtue when patients, at their most vulnerable time, place themselves in the hands of physicians. Integrity involves the coherent integration of emotions, knowledge and aspirations while maintaining moral values. Physicians need both professional integrity and personal integrity, as the former may not cover all scenarios (e.g., prescribing ineffective drugs or expensive drugs when effective inexpensive drugs are available, performing invasive treatments or experimental research modalities without fully informed consent, any situation where personal monetary gain is placed over patient's welfare). Conscientiousness is required to determine what is right by critical reflection on good versus bad, better versus good, logical versus emotional, and right versus wrong.

In my conceptualized model of patient care (Fig. 1), medical knowledge, skills to apply that knowledge, technical skills, practice-based learning, and communication skills are partnered with ethical principles and professional virtues. The virtues of compassion, discernment, trustworthiness, integrity, and conscientiousness are the necessary building blocks for the virtue of caring. Caring is the defining virtue for all healthcare professions. In all interactions with patients, besides the technical expertise of a physician, the human element of caring (one human to another) is needed. In different situations, caring can be expressed verbally and non-verbally (e.g., the manner of communication with both physician and patient closely seated, and with unhurried, softly spoken words); a gentle touch especially when conveying "bad news"; a firmer touch or grip to convey reassurance to a patient facing a difficult treatment choice; to hold the hand of a patient dying alone). Thus, "caring" is in the center of the depicted integrated model, and as Peabody succinctly expressed it nearly a hundred years ago, "The secret of the care of the patient is caring for the patient" [41].

Conflict of Interest Statement

The author declares that he has no conflicts of interest.

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EXHIBIT N

Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014

Rachel K. Jones, PhD, and Jenna Jerman, MPH

Objectives. To assess the prevalence of abortion among population groups and changes in rates between 2008 and 2014.

Methods. We used secondary data from the Abortion Patient Survey, the American Community Survey, and the National Survey of Family Growth to estimate abortion rates. We used information from the Abortion Patient Survey to estimate the lifetime incidence of abortion.

Results. Between 2008 and 2014, the abortion rate declined 25%, from 19.4 to 14.6 per 1000 women aged 15 to 44 years. The abortion rate for adolescents aged 15 to 19 years declined 46%, the largest of any group. Abortion rates declined for all racial and ethnic groups but were larger for non-White women than for non-Hispanic White women. Although the abortion rate decreased 26% for women with incomes less than 100% of the federal poverty level, this population had the highest abortion rate of all the groups examined: 36.6. If the 2014 age-specific abortion rates prevail, 24% of women aged 15 to 44 years in that year will have an abortion by age 45 years.

Conclusions. The decline in abortion was not uniform across all population groups. (*Am J Public Health.* 2017;107:1904–1909. doi:10.2105/AJPH.2017.304042)

See also Foster, p. 1860.

Abortion is a common medical procedure and an important component of public health.[1,2] In 2014, 926 190 abortions were performed in the United States; the abortion rate was 14.6 abortions per 1000 women aged 15 to 44 years, meaning that in that year 1.5% of women of reproductive age had an abortion.[3] In 2008, it was estimated that 30% of women aged 15 to 44 years would have an abortion by age 45 years if the prevailing rate continued,[4] and this figure is often used to demonstrate the commonality of abortion.[2,5] However, the abortion rate has declined substantially since that time—14% between 2011 and 2014 alone[3]—and it is likely that the estimate of the lifetime incidence of abortion has also declined.

In addition to fewer women having abortions, the characteristics of the women who obtained them has changed. In 2014, 49% of abortion patients had family incomes below 100% of the federal poverty level, a significant increase from 42% in 2008.[6] Adolescents accounted for a significantly smaller share of abortion patients: 12% in 2014 compared with 18% in 2008. Low-income and younger women have traditionally been at increased risk for unintended pregnancy and, in turn, abortion. Changes in the prevalence of abortion for these and other groups, as measured by the abortion rate, could inform strategies to reduce disparities in access to family planning services and other types of reproductive health care.

We combined information on abortion rates and the characteristics of women who have abortions to determine if declines in abortion were experienced by all populations of women. Specifically, we estimated abortion rates in 2014 according to age, income, race and ethnicity, and other characteristics, and we also examined changes in population rates since 2008, the last year these measures were generated. Finally, we provide an updated estimate of the lifetime incidence of abortion.

METHODS

We used secondary data from multiple sources to construct 2 measures: population group abortion rates, for comparisons between 2008 and 2014, and the lifetime incidence of abortion for 2014. We relied on 3 data sets to calculate these estimates: the Guttmacher Institute's 2014 Abortion Patient Survey (APS), the American Community Survey (ACS), and the National Survey of Family Growth (NSFG). We used Stata 14.2 (StataCorp, College Station, TX) to analyze these data. The US federal government makes ACS and NSFG publicly available. The APS is currently available only to the study team and provides information about a hard-to-reach population; thus, we have summarized the data collection, and we provide more detailed information in Appendix A (available as a supplement to the online version of this article at http://www.ajph.org).

The 2014 APS provides information on the characteristics of US women obtaining abortions (including both medical and surgical) in that year. This was the Guttmacher Institute's fifth national survey of abortion patients. As in past surveys, patients at facilities that reported fewer than 30 abortions in 2011 were excluded because of the high likelihood that these facilities would perform few or no abortions during the survey period. Their exclusion can cause little bias

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because these facilities accounted for less than 1% of all reported procedures in 2014.[3] The 2014 APS used the same methodology as previous surveys with 1 exception: it did not include patients obtaining abortions at hospital facilities. We excluded these facilities because of past recruitment and logistical challenges. In 2014, hospitals with caseloads of 30 or more abortions accounted for 4% of all abortions.[3]

The 2014 APS survey design randomly sampled 113 US nonhospital facilities selected from a database of all clinics and physician's offices where abortions were known to be performed in 2011,[7] with updates for new facilities known to have started providing abortion services between 2011 and 2014. We stratified the database by provider type (clinics and private physicians' offices) and caseload (30–399; 400–1999; 2000–4999; and 5000 or more abortions) and then listed them by census region and state within each stratum to ensure that the sample was geographically representative. Every nth facility was sampled. Facilities were asked to administer the questionnaire to all women who obtained an abortion during the fielding period, which ranged from 2 to 12 weeks. If a facility declined to participate or did not obtain usable questionnaires from at least half of the target population, it was replaced by the next facility in its stratum, which was usually in the same state or in a neighboring state in the same region. Between April 2014 and June 2015, 87 facilities participated in the study.

The survey collected information directly from abortion patients, using a 4-page, paper-and-pencil, self-administered questionnaire available in English and Spanish. Envelopes were provided so that staff could not see patients' responses.

Participating facilities reported performing 11 024 abortions during the sampling period; usable data were collected from 8380 women, for a response rate of 76%. We constructed weights to correct for any bias produced by patient nonresponse and deviation from the original sampling plan. We used survey items on age, union status, race and ethnicity, foreign-born status, education, number of previous births, and poverty.

Information on the characteristics of all women aged 15 to 44 years comes from 2 surveys: the ACS and the NSFG. The ACS is a monthly government survey of more than 2 million households conducted by the US Census Bureau, and the sample is selected to represent the civilian noninstitutional population.[8] We used the 2014, 1-year supplemental file of the ACS to estimate distributions of age group, race and ethnicity, education (among women aged 20 years and older), foreign-born status, and poverty for US women aged 15 to 44 years. We used the 2013 to 2015 NSFG to estimate union status and number of previous births because this information was not available in the ACS. The NSFG, which is overseen by the National Center for Health Statistics, collected data on pregnancy, childbearing, and related measures from a nationally representative sample of 5699 US women aged 15 to 44 years between July 2013 and July 2015.[9]

We applied weights to the APS, ACS, and NSFG data to generate frequency distributions. We applied these patient and population characteristics to the total number of abortions and total number of US women aged 15 to 44 years. Estimates of the total number of abortions in 2014 come from the Guttmacher Institute, which conducts a periodic census of all known abortion providers.[3] Population figures for the total number of women aged 15 to 44 years come from the US Census Bureau July 1, 2014, estimates.[10]

We calculated population group abortion rates by dividing the number of abortions in a specific group by the number of women in that group in the US population; we then multiplied this figure by 1000. We rounded population figures for both abortion patients and all women to the nearest tenth.

Our analysis focused on changes in abortion rates by demographic characteristic for the period between 2008 and 2014, because 2008 was the next most recent APS. Abortion rates for 2008 were published,[4] but we adjusted them to be comparable with the 2014 analysis. The previous study relied on the 2008 Current Population Survey to estimate population characteristics. However, the ACS is now considered more accurate than the Current Population Survey, so we reestimated population characteristics used to construct the 2008 abortion rates using the 2008 ACS. Additionally, on the basis of the 2010 Census, the Census Bureau retrospectively adjusted population totals for the years 2006 through 2010; thus, we relied on the updated 2008 count of women aged 15 to 44 years. Finally, the 2008 APS included hospital abortion patients, and the 2014 survey did not. To make the data comparable, we excluded the 402 patients in the 2008 APS (4.2% of the sample) obtaining abortions at hospitals.

As a sensitivity analysis, we compared the demographic profiles of hospital and nonhospital patients in 2008 to determine whether their exclusion appeared to bias the sample (Table A, available as a supplement to the online version of this article at http://www.ajph.org). The 2 groups differed significantly on 2 of the 8 characteristics we examined. Relative to patients obtaining abortions at clinics and physicians' offices, a larger proportion of hospital patients were aged 25 to 29 years (28.2% compared with 24.2%). They were also less educated: 22.7% had not graduated from high school compared with 11.9% of nonhospital abortion patients. Despite these differences, the nonhospital sample was very similar to the full sample on these 2 characteristics, and it is unlikely that the exclusion of the hospital patients biased the sample.

To estimate the lifetime incidence of abortion, or the proportion of women of reproductive age who will have an abortion by age 45 years, we adopted the methodology developed by Forrest.[11] We used data from the 2014 APS to determine the proportion of women who were obtaining first abortions in each of the following age groups: younger than 15, 15 to 17, 18 to 19, 20 to 24, 25 to 29, 30 to 34, 35 to 39, and 40 years and older. Because first abortion rates for the youngest abortion patients are traditionally lower than are those for older adolescents, we estimated age-specific abortion rates separately for adolescents younger than 15 years.

Although standard demographic analyses restrict the population denominator to women aged 15 to 44 years, this component of the analysis estimates abortion rates for adolescents younger than 15 years, using those aged 14 years as the denominator. (We did not calculate an overall abortion rate for those younger than 15 years because this group is so small.) We applied these proportions to the age-specific abortion rates to obtain age-specific first abortion rates.

We obtained the cumulative first abortion rate, or proportion of women estimated to have had an abortion by the time they reach the end of a specified age range, by multiplying each age-specific first abortion rate by the number of years in that age group (e.g., the 15–17 years age group had a multiplier of 3) and summing all age groups up to that age group.

RESULTS

Between 2008 and 2014 the national abortion rate declined 25%, from 19.4 to 14.6 abortions per 1000 women aged 15 to 44 years (Table 1). Abortion rates decreased among all groups of women examined in the analysis. However, the degree of change within and among groups varied considerably.

When examined by age group, women aged 20 to 24 years accounted for the largest share of abortions and also had the highest abortion rate: 28.0 per 1000. The second highest abortion rate was among those aged 25 to 29 years: 22.8 per 1000. The drop in abortion rates between 2008 and 2014 was particularly marked for individuals aged 15 to 19 years, declining 56% among those aged 15 to 17 years and 41% among women aged 17 to 19 years.

When examined by union status, never married women accounted for the largest proportion of abortions in 2014 (45.9%) and had an abortion rate of 16.9 per 1000. Women cohabiting with but not married to their partners had the highest abortion rate: 31.0 per 1000. Between 2008 and 2014, declines in abortion were most pronounced for cohabitating women (39%) and lowest for married women (21%), although the latter group had a low abortion rate in both periods.

White women accounted for the largest share of abortions among the 4 racial and ethnic groups examined (38.7%), although they had the lowest abortion rate: 10.0 per 1000. Black women were overrepresented among abortion patients and had the highest abortion rate: 27.1 per 1000. The decline in the abortion rate among non-Hispanic Black women (32%) was greater than that for that non-Hispanic White women (14%); declines were also substantial for Hispanic women (36%) and non-Hispanic women who

TABLE 1—Number of US Abortions and Population Characteristics of Women Aged 15–44 Years in 2014 and Estimated Abortion Rates and Percentage Change in Estimated Rates Between 2008 and 2014: United States

Characteristic	Abortions in 2014		All Women in 2014, No. (%)	No. Abortions per 1000 Women		
	No.	% (95% CI)		2008[a]	2014	% Change
Total	926 190		63 397 514	19.4	14.6	–25
Age group, y						
< 15	2 220	0.2 (0.2, 0.4)	NA	NA	NA	NA
15–19	108 360	11.7 (10.9, 13.0)	10 333 790 (16.3)	19.4	10.5	–46
15–17	31 610	3.4 (3.0, 3.9)	6 086 160 (9.6)	11.8	5.2	–56
18–19	76 360	8.2 (7.5, 9.0)	4 247 630 (6.7)	30.3	18.0	–41
20–24	310 980	33.6 (32.3, 34.9)	11 094 560 (17.5)	39.9	28.0	–30
25–29	245 260	26.5 (25.4, 27.5)	10 777 580 (17.0)	28.8	22.8	–21
30–34	147 450	15.9 (14.9, 16.9)	10 714 180 (16.9)	17.2	13.8	–20
35–39	84 060	9.1 (8.2, 10.0)	10 016 810 (15.8)	9.5	8.4	–11
≥ 40[b]	28 300	3.1 (2.7, 3.5)	10 460 590 (16.5)	3.2	2.7	–16
Union status						
Married	132 540	14.3 (13.2, 15.5)	24 167 130 (38.1)	7.0	5.5	–21
Cohabiting, not married	287 120	31.0 (29.8, 32.3)	9 256 040 (14.6)	50.9	31.0	–39
Never married, not cohabiting	425 210	45.9 (44.2, 47.7)	25 175 150 (39.7)	23.1	16.9	–27
Previously married, not cohabiting	81 500	8.8 (7.9, 9.7)	4 803 000 (7.6)	23.4	17.0	–28
Race/ethnicity						
Non-Hispanic White	358 810	38.7 (34.6, 43.0)	36 009 790 (56.8)	11.6	10.0	–14
Non-Hispanic Black	255 630	27.6 (23.6, 32.1)	9 446 230 (14.9)	39.8	27.1	–32
Non-Hispanic other	81 960	8.8 (7.7, 10.1)	5 033 760 (7.9)	26.6	16.3	–39
Hispanic	229 790	24.8 (20.8, 29.3)	12 679 500 (20.0)	28.4	18.1	–36
Foreign-born						
No	776 800	83.9 (81.5, 86.1)	52 493 140 (82.8)	19.7	14.8	–25
Yes	149 390	16.1 (13.9, 18.5)	10 904 370 (17.2)	19.0	13.7	–28
Hispanic and foreign-born	73 910	8.0 (6.4, 9.8)	5 078 140 (8.0)	16.5	14.6	–12
Education[c]						
< high school	71 700	8.8 (7.6, 10.1)	5 041 050 (9.5)	21.2	14.2	–33
High school graduate or GED	227 920	27.9 (26.4, 29.6)	11 408 700 (21.5)	23.6	20.0	–15
Some college or associate degree	337 930	41.4 (39.8, 43.1)	19 209 070 (36.2)	21.5	17.6	–18
≥ college graduate	178 550	21.9 (20.0, 23.9)	17 351 840 (32.7)	13.4	10.3	–23
Previous births						
0	376 770	40.7 (38.1, 43.2)	29 086 780 (45.9)	17.3	13.0	–25
1	242 750	26.2 (25.0, 27.5)	11 031 170 (17.4)	32.0	22.0	–31
≥ 2	306 660	33.1 (31.1, 35.2)	23 273 230 (36.7)	17.3	13.2	–24
Family income as % of federal poverty level						
< 100	457 070	49.4 (46.6, 52.1)	12 489 310 (19.7)	49.5	36.6	–26
100–199	237 730	25.7 (24.5, 26.8)	12 463 960 (19.7)	28.0	19.1	–32
≥ 200	231 360	25.0 (22.6, 27.4)	38 482 290 (60.7)	9.4	6.0	–36

Note. CI = confidence interval; GED = general equivalency diploma; NA = not available.
[a]On the basis of previously published abortion rates (Jones and Kavanaugh[4]) and adjusted to account for updated population figures and to exclude nonhospital abortions.
[b]Denominator is women aged 40–44 years.
[c]Among women aged 20 years and older.

identified with a race other than Black or White (39%).

The majority of abortions in 2014 (83.9%) were obtained by women born in the United States. Foreign-born women had an abortion rate that was slightly lower than that of US-born women, 13.7 and 14.8 per 1000, respectively, and rates for both groups declined approximately the same amount. The abortion rate for foreign-born Hispanic women, 14.6 per 1000, was lower than was the abortion rate for all Hispanic women, 18.1 per 1000.

In 2014, 1 in 5 abortion patients (aged 20 years and older) had a college degree, and this group had the lowest abortion rate, 10.3 per 1000, compared with 14.2 to 20.0 per 1000 for the other education groups. Declines in abortion were steepest for women aged 20 years and older who had not graduated from high school (33%).

The majority of abortion patients in 2014 had previously given birth. Women with only 1 previous birth had a higher abortion rate, 22.0 per 1000, than did both women with more than 1 previous birth, 13.2 per 1000, and nulliparous women, 13.0 per 1000. The decline in abortion among women with 1 child (31%) was slightly higher than was that for women with no (25%) or 2 or more children (24%).

Women with family incomes less than 100% the federal poverty level accounted for almost half of all abortion patients in 2014, and this group had the highest abortion rate of all groups we examined; 36.6 per 1000. As income levels increased, the abortion rate decreased; women in the highest income group had an abortion rate less than half the national rate: 6.0 per 1000. Although abortion declined for all income groups between 2008 and 2014, poor women experienced the smallest decline (26%), and the declines grew greater with income.

We used age-specific first abortion rates to estimate the lifetime incidence of abortion (Table 2). In 2014, almost all abortion patients younger than 15 years were obtaining a first abortion (96.1%) and, the first abortion rate was the same as their age-specific abortion rate: 1.1 per 1000 (Figure A, available as a supplement to the online version of this article at http://www.ajph.org). The overwhelming majority of adolescents aged 15 to 17 years were also obtaining their first abortion (93.1%), resulting in a first abortion rate that was only slightly lower than was their age-specific abortion rate (4.8 compared with 5.2 [per 1000]). We obtained the cumulative first abortion rate for those aged 15 to 17 years by multiplying their first abortion rate by 3 (to account for the 3 years in the age group) and adding this to the first abortion rate for adolescents younger than 15 years.

Women aged 40 years and older had a cumulative first abortion rate of 236.7 per 1000, meaning that an estimated 23.7% of women aged 15 to 44 years in 2014 will have an abortion by age 45 years if the 2014 abortion rates continue throughout their reproductive lives. Correspondingly, an estimated 4.6% of women will have had an abortion by age 20 years and 19% by aged 30 years.

TABLE 2—Abortion Rate, Percentage of First Abortions, First Abortion Rate, and Cumulative First Abortion Rate of Women Aged 15–44 Years, All by Age: United States, 2014

Age at Outcome, Years	No. Abortions per 1000 Women	% Obtaining First Abortion (95% CI)	No. First Abortions per 1000 Women	Cumulative First Abortion Rate
< 15[a]	1.1	96.1 (77.5, 99.4)	1.1	1.1
15–17	5.2	93.1 (89.8, 95.5)	4.8	15.6
18–19	18.0	84.7 (81.8, 87.2)	15.2	46.0
20–24	28.0	61.9 (59.2, 64.5)	17.4	132.8
25–29	22.8	47.0 (44.3, 49.6)	10.7	186.2
30–34	13.8	41.2 (38.3, 44.2)	5.7	214.6
35–39	8.4	39.9 (35.4, 44.7)	3.4	231.3
≥ 40[b]	2.7	39.9 (32.9, 47.3)	1.1	236.7
Total	14.6	55.0 (53.2, 56.9)	8.0	236.7

Note: CI = confidence interval.
[a]Denominator is women aged 14 years.
[b]Denominator is women aged 40–44 years.

DISCUSSION

The US abortion rate fell 25% between 2008 and 2014, but this decline was not uniform across all population groups.

The decline in the abortion rate was largest, 46%, for young women aged 15 to 19 years. This parallels the 23% drop in the adolescent birth rate over the same period.[12,13] Recent research suggests that most of the decline in adolescent fertility between 2007 and 2012 was a result of changes in contraceptive use, including increased reliance on long-acting reversible contraception (LARC) such as the IUD (intrauterine device) and implants.[14]

Changes in contraceptive use were likely an important factor behind the steep drop in abortion among adult women, as well.[15] Reliance on LARC among all contraceptive users increased 130% between 2007 and 2009 and continued into 2011, although at a slower pace.[16] Between 2011 and 2014, LARC use increased 48% among clients at federally funded family planning clinics,[17] and this pattern may apply to all women of reproductive age. A recent study found that, for the first time in 2 decades, typical use failure rates for condoms improved.[18] This may also have contributed to the decline in abortion because it is the second most common reversible contraceptive method.[19]

For the first time in 2 decades, the abortion rate declined among women with incomes less than 100% the federal poverty level.[20] Still, the abortion rate for this group was the highest of all the groups examined, and the decrease in abortion was less pronounced than was that for higher income women. Between 2008 and 2014, the number of state abortion restrictions increased,[21] and research suggests that some of these restrictions made abortion more difficult for women to access in at least some states.[3,22–24] We might expect these types of laws to

have the greatest impact on low-income women, resulting in even more of a decline in abortion for this group relative to others. That this was not the case may be because of several factors. The most recent research available suggests that in 2009 through 2012 reliance on LARC was as common for women with family incomes less than 100% the federal poverty level as for higher income women.[16] However, if LARC or other highly effective contraceptive methods became less accessible to low-income women in recent years, this could have led to differential declines in unintended pregnancy and abortion.

Another factor potentially contributing to the trends in abortion by income is health reform. Although federal Medicaid can be used to pay for abortion only under very limited circumstances, 15 states use their own funds to pay for abortions for women with coverage.[6] All but 2 of these 15 states expanded Medicaid eligibility under the Affordable Care Act. Previous research using the 2014 APS found that Medicaid coverage increased among abortion patients in states where Medicaid covers abortion, and the proportion using Medicaid to pay for the procedure also increased significantly: from 44% in 2008 to 52% in 2014.[6] It is possible that more poor women in states where Medicaid pays for abortion acquired coverage and were able to use it to pay for their procedures. This, in turn, could have increased access to abortion for economically disadvantaged women in these states.

We found that White women had the lowest abortion rate of all the racial and ethnic groups examined, although the decline in abortion was greater for women of color. It is possible that increased reliance on LARC and more consistent use of condoms were more pronounced for non-White women. For example, previous research found that the increase in LARC use was significantly higher among Latina (but not Black) women than among Whites.[16] Alternately, the decline could reflect reduced access to care. For example, a disproportionate share of women of color may have lived in states where abortion restrictions successfully reduced access to care,[3,22,23] or they may have been disproportionately affected by restrictions in those and other states. If this was the case, the larger decline in abortion would actually be an indicator of racial and ethnic disparities. More research is needed to better understand the dynamics behind these declines.

The proportion of women expected to have an abortion by age 45 years declined from 30% in 2008 to 24% in 2014. This pattern parallels, but was less pronounced than, the decline in the abortion rate during that same period. That nearly 1 in 4 women is anticipated to have an abortion during her reproductive years demonstrates that it is not an uncommon experience.

Limitations

Our study has several limitations. The APS data contain some amount of measurement error. For example, imputation was used to assign values on key demographic measures when they were not provided by respondents. Social desirability may have affected responses to survey items about family income, previous abortion, and other measures. Owing, in part, to the fact that patients of similar racial and ethnic backgrounds tend to be concentrated within facilities, estimates for this characteristic were more imprecise and had larger confidence intervals. Thus, the abortion numbers and rates we calculated should be considered estimates and not precise measures.

The information from patients did not include women who obtained abortions in a hospital setting. Our analysis of the 2008 APS suggests that their exclusion did not bias the findings, but it is possible that we would have detected differences between these 2 populations in 2014 had we been able to make the same comparisons. Our estimate of the lifetime incidence of abortion is on the basis of patients' reports of previous terminations. Underreporting of abortions is common in nationally representative surveys.[25,26] Because the study questionnaire was filled out by women obtaining abortions, we expect that underreporting was less common. Still, if some women obtaining abortions failed to report previous abortions, this would mean that the estimate of the lifetime incidence of abortion is artificially high.

Conclusions

Disparities in abortion rates correspond with disparities in unintended pregnancy.[15] Not only do women of color and those with family incomes less than 100% of the federal poverty level have higher rates of abortion than do White women and those with higher incomes, but they also have higher rates of unintended birth. Equitable access to wide-range family planning and contraceptive services would better allow women in underserved populations to avoid unintended pregnancy, but these efforts alone will not eliminate these disparities. Efforts should also be devoted to making sure that women who want abortions are able to have them without having to overcome financial and logistical barriers.

Laws and policies that make abortion more difficult to access have a disproportionate impact on groups overrepresented among abortion patients, particularly those who are poor or low income. Future research and interventions focused on abortion and unintended pregnancy should seek to understand the underlying causes of disparities in these outcomes, because this information could inform a comprehensive set of policies and programs that benefit all women. AJPH

CONTRIBUTORS

R. K. Jones was the lead analyst and drafted the article. J. Jerman oversaw data collection and contributed to the writing and editing of the article.

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HUMAN PARTICIPANT PROTECTION

The Abortion Patient Survey questionnaire and survey procedures were approved by the Guttmacher Institute's federally registered institutional review board; no approval was needed for our analyses because we relied on secondary data.

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EXHIBIT O

CAUSE NO. D-1-GN-23-008611

KATE COX; JUSTIN COX; and DAMLA KARSAN, M.D., on behalf of herself, her staff, nurses, pharmacists, agents, and patients,

Plaintiffs,

v.

STATE OF TEXAS; ATTORNEY GENERAL OF TEXAS, KEN PAXTON, in his official capacity as Attorney General of Texas; TEXAS MEDICAL BOARD; and STEPHEN BRINT CARLTON, in his official capacity as Executive Director of the Texas Medical Board,

Defendants.

IN THE DISTRICT COURT OF

TRAVIS COUNTY, TEXAS

200TH, DISTRICT COURT
_____ JUDICIAL DISTRICT

PLAINTIFFS' ORIGINAL VERIFIED PETITION FOR DECLARATORY JUDGMENT AND APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PERMANENT INJUNCTION

Plaintiffs file this Original Verified Petition for Declaratory Judgment and Application for Temporary Restraining Order and Permanent Injunction. The immediate threat of enforcement of Texas's abortion bans, codified at Tex. Health & Safety Code §§ 170A.001-002 (the "Trigger Ban"), Tex. Health & Safety Code §§ 171.002(3), 171.203-205 ("S.B. 8"), and 1925 Tex. Penal Code arts. 1191-96 (the "pre-*Roe* Ban"), is causing irreparable injury to Plaintiffs, Plaintiff's patients, and Plaintiff's staff, nurses, pharmacists, and agents. **Plaintiffs respectfully urge the Court to rule expeditiously on the requested relief.**

INTRODUCTION

1. **Kate Cox needs an abortion, and she needs it now.** Ms. Cox is currently 20 weeks pregnant,[1] and she has been to three different emergency rooms in the last month due to severe

[1] Consistent with standard medical practice, gestational ages as used in this petition are dated from the first day of the patient's last menstrual period ("LMP"), which is typically approximately two weeks before the estimated date of fertilization of a pregnancy.

cramping and unidentifiable fluid leaks. For weeks, Ms. Cox's physicians have been telling her that early screening and ultrasound tests suggest that her pregnancy is unlikely to end with a healthy baby. Because Ms. Cox has had two prior cesarean surgeries ("C-sections"), continuing the pregnancy puts her at high risk for severe complications threatening her life and future fertility, including uterine rupture and hysterectomy. Ms. Cox understands that a dilation and evacuation ("D&E") abortion is the safest option for her health and her best medical option given that she wants to have more children in the future. Yet because of Texas's abortion bans, Ms. Cox's physicians have informed her that their "hands are tied" and she will have to wait until her baby dies inside her or carry the pregnancy to term, at which point she will be forced to have a third C-section, only to watch her baby suffer until death.

2. On November 28, 2023, Ms. Cox received the results of an amniocentesis which confirmed prior prenatal testing—her third pregnancy has full trisomy 18, meaning her pregnancy may not survive to birth, and, if it does, her baby would be stillborn or survive for only minutes, hours, or days. November 28, 2023 is the same day that the Texas Supreme Court heard oral argument in a similar case filed in this Court in March, *Zurawski v. State of Texas*, Cause No. D-1-GN-23-000968 (353th Judicial Dist., Travis Cty.). Because of the unusual confluence of events and the specific progression of her medical condition, Ms. Cox both heard about the case and was able to reach out to Plaintiffs' counsel for help. Most Texans will not be so lucky.

3. Over the months that *Zurawski* has been pending, the state defendants have refused to provide any clarification of the law or even their own interpretation of its meaning. Before the Supreme Court of Texas, the state defendants conceded that a physician could provide an abortion to a patient with a fatal fetal diagnosis if there was "some evidence" of "substantial impairment of

a major bodily function." But the state defendants have never said what evidence nor what condition would be enough. All the while, pregnant Texans like Ms. Cox have continued to suffer.

4. Because Ms. Cox cannot wait for the Texas Supreme Court to issue its ruling, nor for the stay of proceedings in *Zurawski* to be lifted, she files this separate action, with the physician who could provide her a D&E abortion if Texas law was not standing in the way, to seek a temporary restraining order authorizing her physician to provide her with the abortion she needs to preserve her life and her fertility.

DISCOVERY CONTROL PLAN

5. Plaintiffs request that this case be conducted as a Level 3 case for the purposes of discovery in accordance with Texas Rule of Civil Procedure 190.4. In addition, pursuant to Texas Rule of Civil Procedure 47(c)(5), Plaintiffs state that they seek non-monetary relief only.

PARTIES

I. PLAINTIFFS

A. Kate Cox

6. Kate Cox is 31 years old and lives in the greater Dallas-Fort Worth metroplex in Texas.

7. Ms. Cox is a mother of two, a 3-year-old daughter and a 1-and-a-half-year-old son, and she and her husband hope to have more children. Ms. Cox's prior deliveries were not easy, and both of her children were delivered via cesarean surgery ("C-section").

8. Ms. Cox learned she was pregnant for the third time in August 2023. She was still breastfeeding her son, and so she was not tracking her cycle precisely, but she and her husband had been hoping for a third. Her whole family was thrilled.

9. In October 2023, Ms. Cox provided a blood sample for noninvasive prenatal blood testing ("NIPT"), which can be done between 10 and 13 weeks to screen for some fetal conditions

as well as reveal the sex of the pregnancy. Ms. Cox was excited to learn the sex of her baby so early,[2] as she had for her older children. When Ms. Cox's OB/GYN called her with the results, however, Ms. Cox immediately knew something was wrong. She had never received NIPT results directly from her doctor before.

10. Ms. Cox's OB/GYN informed her that the NIPT indicated that her baby was at high risk for trisomy 18, a condition with a very high likelihood of miscarriage or stillbirth and low survival rates. Because the test is not diagnostic, her OB/GYN recommended further testing and referred her to a maternal-fetal medicine ("MFM") specialist. Ms. Cox and her husband were deeply concerned but tried to remain hopeful.

11. At her first appointment with the specialist later in October, she received a detailed ultrasound that showed Ms. Cox's baby had a single umbilical artery where there should be two and a "spine abnormality." The specialist recommended amniocentesis testing at 16 weeks and continued ultrasound testing in the meantime.

12. Over the next 5 weeks, Ms. Cox received weekly ultrasounds to monitor her baby's growth. At each ultrasound, the prognosis worsened. The ultrasounds revealed multiple serious conditions including: a single artery in the umbilical cord; a protrusion from the baby's abdomen, likely an umbilical hernia; a twisted spine likely due to spina bifida, a neural tube defect; clubbed or "rocker-bottom" foot; intrauterine growth restriction; and irregular skull and heart development. The appointments were devastating for Ms. Cox and her husband. Many of the conditions, including the twisting of their baby's spine, were clearly visible on the ultrasound, and at each visit, the chances of a third healthy baby felt more and more remote. Ms. Cox's specialist told her

[2] This petition describes pregnancy using medical terminology, unless describing a particular patient's pregnancy, in which case, consistent with principles of medical ethics, it adopts the terminology preferred by the individual patient.

and her family that given the results of the ultrasound alone, their baby was likely to pass in utero, be stillborn, or only live for a week at most.

13. Ms. Cox's physicians informed her that continuing the pregnancy would pose risks to her health as well. In October, Ms. Cox did a screening test for gestational diabetes that revealed elevated glucose. Ms. Cox also had elevated glucose in a prior pregnancy. Due to these results and other underlying health conditions, she is at increased risk of gestational hypertension, gestational diabetes, fetal macrosomia, cesarean delivery, post-operative infections, and anesthesia complications.

14. At the beginning of November, when Ms. Cox was 16 weeks, she underwent an amniocentesis procedure and was told it would take several weeks to receive the complete results. Ms. Cox was given the option to pay extra to receive preliminary results using fluorescence in situ hybridization ("FISH") within 48 hours. The FISH results again suggested that her baby had trisomy 18.

15. On November 17, Ms. Cox went to the emergency room due to severe cramping and diarrhea that had been going on for several days. She had been experiencing intermittent cramping throughout the pregnancy, but when the cramps became worse, Ms. Cox worried that her baby was in distress. An ultrasound in the emergency room once again revealed irregular growth, particularly around the baby's spine. But without other signs of maternal or fetal distress, Ms. Cox was sent home.

16. On November 25, after two days of painful cramping, Ms. Cox again went to the emergency room. She was also concerned she was leaking amniotic fluid, as her underwear was wet, and she did not know why. An ultrasound revealed the presence of "endocervical mild fluid" in her vaginal canal, and Ms. Cox was transferred to another hospital for additional testing. When

medical staff at the second hospital were unable to determine the source of the leaking fluid, Ms. Cox was eventually sent home.

17. Ms. Cox finally received the official results of the amniocentesis on November 28, 2023, the same day the Texas Supreme Court heard argument in *Zurawski*. The diagnosis was confirmed: their baby has full trisomy 18. Ms. Cox and her family were devastated.

18. Ms. Cox's physicians explained that some families with a trisomy 18 diagnosis choose to continue their pregnancies, while others choose abortion. She was told that in her case, there was virtually no chance that their baby would survive to birth or long afterwards, so Ms. Cox asked about termination. Ms. Cox was shocked when her physician told her that due to Texas's abortion bans, as long as her baby had a heartbeat, she would not be able to obtain an abortion in Texas. All they could do was continue to monitor the baby for cardiac activity. If the baby's heartbeat stopped, they could offer her a labor induction, but because of her prior C-sections, induction carries a serious risk of uterine rupture. If the baby survived to term, Ms. Cox could receive an induction or C-section, but it was clear to Ms. Cox that C-section was the safer option for her health because of the risk of uterine rupture with induction given her prior two C-Sections. Yet Ms. Cox's physicians also explained that a C-section at full term would make subsequent pregnancies higher risk and make it less likely she would be able to carry a third child in the future.

19. The safest option to protect Ms. Cox's health and future fertility was to get a D&E abortion. But Ms. Cox's physicians told her that because of Texas's abortion laws, there was likely no one in the state who could provide her the procedure.

20. After much discussion with her husband and her family, Ms. Cox decided that terminating this pregnancy is the right decision for her family. In her own words: "It is not a matter of *if* I will have to say goodbye, but *when*. I do not want to continue the pain and suffering that has

plagued this pregnancy. I do not want to put my body through the risks of continuing this pregnancy. I do not want to continue until my baby dies in my belly or I have to deliver a stillborn baby or one where life will be measured in hours or days, full of medical tubes and machinery. Trisomy 18 babies that survive birth often suffer cardiac or respiratory failure. I do not want my baby to arrive in this world only to watch her suffer a heart attack or suffocation. I desperately want the chance to try for another baby and want to access the medical care now that gives me the best chance at another baby."

21. For these reasons, Ms. Cox wants a D&E abortion to protect her life, health, and future fertility.

22. Ms. Cox researched her options online and because of the fortuitous timing, came across multiple news stories about the Texas Supreme Court argument in *Zurawski*. Ms. Cox reached out to Plaintiffs' counsel on November 30, 2023.

23. Ms. Cox wants to receive an abortion as soon as possible, and she does not want to have to leave her state to obtain this necessary medical care.

24. Ms. Cox's claims are capable of repetition but evading review. Ms. Cox sues on her own behalf.

B. Justin Cox

25. Justin Cox is 34 years old and lives in the greater Dallas-Fort Worth metroplex in Texas. Mr. Cox is married to Ms. Cox.

26. If permitted by law and/or court order, Mr. Cox hopes to assist his wife in obtaining the abortion she needs to preserve her life and future fertility.

27. Mr. Cox's claims are capable of repetition but evading review. Mr. Cox sues on his own behalf.

C. Dr. Damla Karsan

28. Plaintiff Damla Karsan, M.D, is a board-certified OB/GYN in private practice at Comprehensive Women's Healthcare in Houston, Texas, who is licensed to practice medicine in the state of Texas.

29. Dr. Karsan has practiced obstetrics and gynecology in Houston since 2001. As part of her practice, Dr. Karsan provides gynecological care, prenatal care, and obstetric care to her patients and to her colleagues' patients when she is on-call at the hospital where she has admitting privileges.

30. She is also trained to provide abortion care, and before S.B. 8, she routinely provided abortions to her patients as part of their comprehensive reproductive health care needs.[3]

31. Over her career, Dr. Karsan has personally treated pregnant patients with a wide variety of obstetrical and other health complications that develop during pregnancy, including but not limited to: miscarriage; ectopic pregnancy; management of fetal demise; complications of pregnancy, including cervical insufficiency, previable preterm premature rupture of membranes ("PPROM"), bleeding, preeclampsia, hyperemesis gravidarum; maternal comorbidities such as hypertension, diabetes, heart disease, kidney disease, cancer, rheumatologic disorders, psychiatric conditions, including those that may lead to suicide; complicated twin pregnancies; lethal fetal anomalies; various genetic diagnoses, including trisomy 13, 18, and 21; structural fetal abnormalities; and molar pregnancy. Dr. Karsan consults with specialists in the care of such patients—including but not limited to emergency medicine hospitalists, cardiologists, oncologists, anesthesiologists, and maternal fetal medicine doctors—and actively participates in the care of her

[3] Before S.B. 8, Texas law generally permitted physicians to provide a limited number of abortions per year up to 18 weeks LMP in their private practices, or up to 22 weeks LMP in a hospital or ambulatory surgical center. *See* Tex. Health & Safety Code §§ 171.004, 171.045, 245.004.

patients who are treated for emergent health conditions during their pregnancies. Dr. Karsan intends to continue providing the full scope of care to her pregnant patients in the future.

32. Since S.B. 8 took effect, Dr. Karsan has seen the devastating impact of Texas's abortion bans on her practice and on that of her colleagues. In Dr. Karsan's experience, widespread fear and confusion regarding the scope of Texas's abortion bans have chilled the provision of necessary obstetric care, including abortion care. Dr. Karsan and her colleagues fear that prosecutors and politicians will target them personally and threaten the state funding of the hospitals where they work if they provide abortion care to pregnant people with emergent medical conditions.

33. Dr. Karsan has seen that physicians in Texas are even afraid to speak out publicly about this issue for fear of retaliation. Dr. Karsan feels she is only able to speak out publicly because she is in private practice and not directly employed by a state-funded hospital.

34. Dr. Karsan has also personally treated pregnant patients with emergent medical conditions since S.B. 8 took effect and consulted with colleagues about the care of such patients. In Dr. Karsan's experience, an emergent condition or emergency situation cannot be formulaically defined and will always depend on the patient's unique situation.

35. Since *Roe v. Wade* was overturned, Dr. Karsan has treated patients with emergent medical conditions, including patients carrying pregnancies with lethal fetal conditions who needed treatment for complications like kidney stones, bipolar disorder, and hemorrhage, and patients diagnosed with PPROM. Before S.B. 8, Dr. Karsan would have offered abortion care to these patients. Now, Dr. Karsan instead has had to give them information about where to seek abortion care out of state.

36. Dr. Karsan has met Ms. Cox, reviewed her medical records, and discussed Ms. Cox's case with her hospital administration. If the Plaintiffs receive a temporary restraining order from this Court saying that Ms. Cox's abortion is authorized by Texas law, Dr. Karsan may be able to provide her with a D&E abortion.

37. Dr. Karsan sues on her own behalf, on behalf of herself, her staff, nurses, pharmacists, agents, and patients.

II. DEFENDANTS

38. Defendant the State of Texas is responsible for the enforcement of Texas laws, including its abortion bans. The State of Texas includes private citizens that could potentially enforce S.B. 8.

39. Defendant Ken Paxton is the Attorney General of Texas. As Attorney General, he is empowered to institute an action for a civil penalty against physicians licensed in Texas who violate or threaten to violate any provision of the Texas Medical Practice Act, including provisions triggered by a violation of the Trigger Ban. Tex. Occ. Code § 165.101; *id.* § 164.053. The Attorney General is additionally empowered to file a civil action against any person who violates the Trigger Ban, seeking a civil penalty of at least $100,000, plus attorney's fees and costs. Tex. Health & Safety Code § 170A.005. Defendant Paxton has threatened that he will "strictly enforce" the Trigger Ban.[4] Defendant Paxton is sued in his official capacity and may be served with process at 300 West 15th Street, Austin, Texas 78701.

40. Defendant Texas Medical Board ("TMB") is the state agency mandated to regulate the practice of medicine by licensed doctors in Texas. TMB must initiate disciplinary action

[4] Ken Paxton, Tex. Att'y Gen., *Advisory on Texas Law Upon Reversal of* Roe v. Wade (June 24, 2022), https://www.texasattorneygeneral.gov/sites/default/files/images/executive-management/Post-Roe%20Advisory.pdf.

against licensees who violate any provision of the Texas Medical Practice Act or Chapter 171 of the Texas Health and Safety Code. Tex. Occ. Code § 165.001; *id.* § 164.055. TMB may impose discipline on a doctor who violates any state law "connected with the physician's practice of medicine" because such violation constitutes per se "unprofessional or dishonorable conduct." Tex. Occ. Code § 164.053(a)(1); *id*. § 164.052(a)(5); *see also id.* § 164.053(b) (making clear that "[p]roof of the commission of the act while in the practice of medicine . . . is sufficient" for discipline). TMB "shall" also "revoke the license, permit, registration, certificate, or other authority" of a physician who violates the Trigger Ban. Tex. Health & Safety Code § 170A.007. TMB may be served with process at 1801 Congress Avenue, Suite 9.200, Austin, Texas 78701.

41. Defendant Stephen Brint Carlton is the Executive Director of TMB and in that capacity serves as the chief executive and administrative officer of TMB. Tex. Occ. Code § 152.051. Mr. Carlton is sued in his official capacity and may be served with process at 1801 Congress Avenue, Suite 9.200, Austin, Texas 78701.

JURISDICTION AND VENUE

42. Plaintiffs have standing to bring this action. The state defendants acknowledged as much before the Texas Supreme Court in the *Zurawski* case. There, the state defendants told the Supreme Court that, "for example," a patient-plaintiff who is currently pregnant and receives a fatal fetal diagnosis, "bringing a lawsuit in that specific circumstance [of a fetal diagnosis] to challenge whether or not the statute encompasses that [diagnosis and accompanying health conditions]" against "either the attorney general or the executive director of TMB" would suffice for standing purposes.[5] The state defendants made similar statements regarding a physician-

[5] Oral Arg., *State of Texas v. Zurawsk*i, at 12:24–13:28 (Tex. Nov. 28, 2023), https://www.youtube.com/watch?v=Ult-iWTMNl4.

plaintiff who needs to bring suit for clarity on a specific patient's case.[6]

43. This action is brought pursuant to Texas Rules of Civil Procedure 680 to 693, Texas Civil Practice and Remedies Code Chapter 65, and the common law of Texas to obtain declaratory and injunctive relief against Defendants.

44. This Court has jurisdiction over this matter, pursuant to the Texas Uniform Declaratory Judgments Act, Texas Civil Practice and Remedies Code § 37.001, *et seq.* ("UDJA"), Sections 24.007 and 24.008 of the Texas Government Code, and Texas Constitution, Article V, § 8.

45. Further, this Court has jurisdiction over Plaintiffs' request for declaratory and injunctive relief against Defendants because the UDJA waives sovereign and governmental immunity for challenges to the validity of statutes.

46. The Court also has jurisdiction over the Defendants sued in their official capacity because the *Ultra Vires* Doctrine permits claims brought against state officials for nondiscretionary acts unauthorized by law. *See* Tex. Civ. Prac. & Rem. Code §§ 37.003, 37.004, 37.006; *Tex. Lottery Comm'n v. First State Bank of DeQueen*, 325 S.W.3d 628, 634-635 (Tex. 2010); *Tex. Dep't of Transp. v. Sefzik*, 355 S.W.3d 618, 621-22 (Tex. 2011).

47. The state defendants acknowledged before the Texas Supreme Court in the *Zurawski* case that a court "could get to the merits" in a lawsuit identical to this one. There, the state defendants told the Texas Supreme Court that a patient-plaintiff in circumstances identical to Ms. Cox's "would sue either the Attorney General or the Executive Director of TMB, perhaps under an *ultra vires* theory."[7] "That might be a way you could get to the merits there."[8] Likewise,

[6] *See, e.g.*, *id.* at 11:23–12:20.

[7] *Id.* at 13:07–35.

[8] *Id.*

when pressed, the state defendants acknowledged that "I think if a doctor had a specific circumstance in front of them, they could perhaps bring that lawsuit."[9] That would be a lawsuit "under the UDJA" that names "either the TMB or the Attorney General."[10]

48. Finally, Texas's abortion bans are enforced through civil means, including steep civil penalties and disciplinary sanctions. *See, e.g.*, Tex. Occ. Code §§ 165.001, 164.052(a)(5), 164.053(a), 164.055; Tex. Health & Safety Code §§ 170A.005, 170A.007. This Court has jurisdiction to render a declaratory judgment regarding a civil enforcement scheme.

49. Although there are also potential criminal penalties for providing a prohibited abortion in Texas, this Court has jurisdiction to enter declaratory and injunctive relief because of the bans' civil penalties. Additionally, the Court has jurisdiction to enter declaratory and injunctive relief because criminal enforcement threatens irreparable injury to physicians' vested property interests in their medical licenses and liberty interests in pursuit of their chosen profession. *See Tex. Propane Gas Ass'n v. City of Houston*, 622 S.W.3d 791, 798–99 (Tex. 2021) (holding that district court had jurisdiction to render declaratory judgment regarding municipal criminal ordinances because the ordinances threatened irreparable injury to the plaintiff's property rights); *TitleMax of Tex., Inc. v. City of Austin*, 639 S.W.3d 240, 248 (Tex. Ct. App. 2021) (same). This Court also has jurisdiction because application of the abortion bans is causing pregnant people to face death, sustain physical injury, and endure extreme mental anguish, which is unconstitutional and threatens irreparable injury to Physician Plaintiffs' and their patients' rights. *State v. Morales*, 869 S.W.2d 941, 942 (Tex. 1994).

[9] *Id.* at 13:36–14:04.

[10] *Id.* at 11:30–50.

50. Venue is proper in Travis County because Defendants State of Texas, Paxton, TMB, and Carlton reside or have their principal office in Travis County. Tex. Civ. Prac. & Rem. Code § 15.002(a).

51. Plaintiffs' request for prospective relief is specifically authorized as a request for a declaratory judgment under the UDJA. An action for a declaratory judgment is neither legal nor equitable but is sui generis—that is, of its own kind. *Tex. Liquor Control Bd. v. Canyon Creek Land Corp.*, 456 S.W.2d 891, 895 (Tex. 1970). Without such declaratory judgment, Plaintiffs have no meaningful remedy for their state law claims in accordance with Texas Constitution Article I, § 13.

FACTUAL ALLEGATIONS

I. BACKGROUND

A. Abortion is Health Care

52. Every major mainstream medical organization, including the American Medical Association ("AMA"), the American College of Obstetricians and Gynecologists ("ACOG"), the American College of Emergency Physicians ("ACEP"), and the Society for Maternal-Fetal Medicine ("SMFM"), recognizes that abortion is necessary health care. These organizations are all opposed to governmental interference into patient-physician relationships. Such interference is contrary to the appropriate exercise of professional judgment that medical professionals need to exercise to protect patients' well-being. As Ms. Cox's experience demonstrates, abortion bans are a paradigmatic example of such governmental interference.

53. The vast majority of abortions in the United States at 20 weeks of pregnancy or later are accomplished through an outpatient procedure. Procedural abortions are possible throughout pregnancy and involve a two-step process where the medical provider first partially dilates the patient's cervix (using medications and/or mechanical or osmotic dilators), then

evacuates the uterus using suction aspiration, instruments, or some combination. Dilation is done either the same day or the day before, and the evacuation phase of a procedural abortion typically takes around 5 minutes in the first trimester of pregnancy and 10-20 minutes in the second trimester, depending on the patient's response to the procedure and the complexity of the case.[11] Starting at approximately 15 weeks, a procedural abortion is typically referred to as a dilation and evacuation or D&E abortion.

54. The only other medically proven abortion method is induction abortion, where a physician uses medication to induce labor and delivery of a non-viable fetus. Induction of labor accounts for only about 2% of second-trimester abortions nationally. Induction abortions must be performed in a hospital or similar facility that has the capacity to monitor a patient overnight and provide pain management (e.g., epidural). Induction abortions can last anywhere from five hours to three days; are extremely expensive; entail more pain, discomfort, and recovery time for the patient—similar to giving birth—than procedural abortion; and are medically contraindicated for some patients.[12]

55. All pregnancy care, including abortion, is time sensitive. Medically unnecessary delays in access to abortion care always harm pregnant people. Yet pregnancy can lead to any number of urgent or emergent conditions, if not outright medical emergencies, where especially prompt termination of pregnancy is necessary to preserve the life, health, and/or future fertility of the pregnant person. The American Board of Emergency Medicine ("ABEM") defines "emergent" conditions as cases where the "[p]atient presents with symptoms of an illness or injury that may

[11] *See The Safety and Quality of Abortion Care in the United States*, Nat'l Acads. of Sci., Eng'g, & Med. (2018) at 51-65.

[12] *See id.* at 5-8, 66-68.

progress in severity or result in complications with a high probability for morbidity if treatment is not begun quickly."[13]

B. Texas's Abortion Bans

56. Texas has several abortion bans, each of which contains a medical exception to preserve patients' lives and health (collectively, the "Emergent Medical Condition Exception").

1. Texas's Definition of Abortion

57. Texas law does not define "abortion" using the medical definition. Rather, Texas law states: "'Abortion' means the act of using or prescribing an instrument, a drug, a medicine, or any other substance, device, or means with the intent to cause the death of an unborn child of a woman known to be pregnant. The term does not include birth control devices or oral contraceptives. An act is not an abortion if the act is done with the intent to: (A) save the life or preserve the health of an unborn child; (B) remove a dead, unborn child whose death was caused by spontaneous abortion; or (C) remove an ectopic pregnancy." Tex. Health & Safety Code § 245.002(1).

58. Texas law defines "ectopic pregnancy" as "the implantation of a fertilized egg or embryo outside of the uterus." Tex. Health & Safety Code § 245.002(4-a).

59. While there is no express definition, it is generally understood that in the context of Texas's definition of abortion, "dead" means that there is no cardiac activity present in the embryo or fetus. *See, e.g.*, Tex. Health & Safety Code §§ 171.201-203 (emphasizing importance of a "fetal heartbeat" or "cardiac activity" to "unborn life").

[13] Michael S. Beeson et al., *The 2019 Model of the Clinical Practice of Emergency Medicine*, 59 J. of Emergency Med. 96 (2020), https://www.jem-journal.com/article/S0736-4679(20)30154-2/fulltext.

60. Abortions done to "save the life or preserve the health of *an* unborn child" are not considered abortions under Texas law. Tex. Health & Safety Code § 245.002(1)(A) (emphasis added); *see also* Tex. Health & Safety Code § 170A.002(b) (applying exception to abortion ban where "the person performs, induces, or attempts the abortion in a manner that, in the exercise of reasonable medical judgment, provides the best opportunity for the unborn child to survive unless, in the reasonable medical judgment, that manner would create . . . a serious risk of substantial impairment of a major bodily function of the pregnant female.").

61. Texas's abortion bans cite back to Texas's definition of abortion, meaning that neither medical care involving removal of an ectopic pregnancy, nor removal of pregnancy tissue where no cardiac activity is present, is an abortion under Texas law.

2. Trigger Ban

62. Texas's criminal ban on abortion is often referred to as the Trigger Ban because, while signed into law in 2021, it specified a contingent effective date and did not take effect until August 25, 2022, 30 days after the Supreme Court issued its judgment overturning *Roe v. Wade*.[14]

63. The Trigger Ban states that "[a] person may not knowingly perform, induce, or attempt an abortion," citing to Texas's longstanding definition of abortion. Tex. Health & Safety Code §§ 170A.001(a), 170A.002(a).

64. There are both criminal and civil penalties for violations of the Trigger Ban.

[14] Defendant Paxton published an "Advisory on Texas Law" after the U.S. Supreme Court issued its opinion in *Dobbs v. Jackson Women's Health Org.*, Case No. 19-1392, on June 24, 2022, that correctly noted the effective date of the Trigger Ban as 30 days after issuance of the "judgment" in *Dobbs*. Ken Paxton, Tex. Att'y Gen., *Advisory on Texas Law Upon Reversal of* Roe v. Wade (June 24, 2022), https://www.texasattorneygeneral.gov/sites/default/files/images/executive-management/Post-Roe%20Advisory.pdf. Defendant Paxton later published an "Updated Advisory on Texas Law" upon issuance of the *Dobbs* judgment that confirmed that the Trigger Ban would take effect August 25, 2022. Ken Paxton, Tex. Att'y Gen., *Updated Advisory on Texas Law Upon Reversal of* Roe v. Wade (July 27, 2022), https://texasattorneygeneral.gov/sites/default/files/images/executive-management/Updated%20Post-Roe%20Advisory%20Upon%20Issuance%20of%20Dobbs%20Judgment%20(07.27.2022).pdf.

65. A person can be charged with either a first- or second-degree felony for violating the Trigger Ban. Tex. Health & Safety Code § 170A.004. First-degree felonies are subject to imprisonment for life, or a term of between 5 and 99 years. Tex. Penal Code § 12.32. Second-degree felonies are punishable by imprisonment for a term of between 2 and 20 years. Tex. Penal Code § 12.33.

66. Further, the Trigger Ban states that the relevant licensing authority, the Texas Medical Board, "shall revoke the license, permit, registration, certificate, or other authority of a physician or other health care professional who performs, induces, or attempts an abortion in violation" of the Trigger Ban. Tex. Health & Safety Code § 170A.007.

67. Finally, any person who violates the Trigger Ban "is subject to a civil penalty of not less than $100,000 for each violation," and "[t]he attorney general shall file an action to recover a civil penalty assessed under this section and may recover attorney's fees and costs incurred in bringing the action." Tex. Health & Safety Code § 170A.005.

68. The only exception to the Trigger Ban is an abortion performed by a physician on a patient with an emergent medical condition (*see infra* ¶ 82).

3. Senate Bill 8

69. Senate Bill 8 of 2021 prohibits physicians from providing an abortion in Texas if the embryo or fetus has detectible cardiac activity. Tex. Health & Safety Code §§ 171.201-204. S.B. 8 took effect in September of 2021 and creates additional civil penalties for physicians who perform abortions prohibited by S.B. 8.

70. Violations of S.B. 8 are subject to a bounty-hunting civil enforcement scheme allowing any individual to seek "statutory damages in an amount of not less than $10,000 for each

abortion that the defendant performed" and "injunctive relief sufficient to prevent the defendant from violating" S.B. 8 in the future. Tex. Health & Safety Code §§ 171.207-211.

71. Like the Trigger Ban, the only exception to S.B. 8's ban on abortion in pregnancies with detectible cardiac activity is an abortion performed by a physician on a patient with an emergent medical condition (discussed in detail below).

72. S.B. 8 also created new state documentation and reporting requirements that apply to all abortions performed under the Emergent Medical Condition Exception. As of September 1, 2021, all abortions performed under the Emergent Medical Condition Exception must be documented in detail by the treating physician. Specifically, the physician must "execute a written document": (1) that "certifies the abortion is necessary due to a medical emergency;" (2) that "specifies the medical condition the abortion is asserted to address;" (3) that "provides the medical rationale for the physician's conclusion that the abortion is necessary to address the medical condition;" (4) "place the document . . . in the pregnant woman's medical record" (5) and "maintain a copy of the document . . . in the physician's practice records." Tex. Health & Safety Code §§ 171.008, 171.205.

73. S.B. 8 also requires physicians who perform abortions at abortion facilities to report all abortions performed under the Emergent Medical Condition Exception to the state. Tex. Health & Safety Code § 245.011(c)(10), (11) (requiring reporting to include "whether the abortion was performed or induced because of a medical emergency and any medical condition of the pregnant woman that required the abortion").

4. Pre-Roe Ban

74. The Texas abortion ban at issue in *Roe v. Wade* (the "pre-*Roe* Ban")[15] also contained an exception for the life of the pregnant person.[16] After the pre-*Roe* Ban was held unconstitutional in 1973, it was removed from the Texas Penal Code and Texas Civil Code. The Texas Legislature then enacted a comprehensive statutory scheme permitting and regulating abortion. In light of those later enactments, the Fifth Circuit held that the pre-*Roe* Ban was impliedly repealed. *McCorvey v. Hill*, 385 F.3d 846 (5th Cir. 2004).[17]

75. On June 24, 2022, for the first time, the text of the pre-*Roe* Ban was placed on the Texas Legislature's website, with the note that the relevant statutes were "held to have been impliedly repealed in *McCorvey v. Hill*, 385 F.3d 846 (5th Cir. 2004)."[18] Despite that holding and subsequent litigation regarding the pre-*Roe* Ban, Defendant Paxton took the position that the pre-*Roe* Ban was immediately enforceable after *Roe v. Wade* was overturned. Courts addressing this issue after *Roe* was overturned, however, largely disagree. *See* Order at 1, *Fund Tex. Choice v. Paxton*, No. 1:22-CV-859-RP (W.D. Tex. Feb. 24, 2023), ECF No. 120 ("[T]he Court finds that the pre-*Roe* laws have been repealed by implication . . . ."); *Texas v. Becerra*, No. 5:22-CV-185-

[15] "If any person shall designedly administer to a pregnant woman or knowingly procure to be administered with her consent any drug or medicine, or shall use towards her any violence or means whatever externally or internally applied, and thereby procure an abortion, he shall be confined in the penitentiary not less than two nor more than five years; if it be done without her consent, the punishment shall be doubled. By 'abortion' is meant that the life of the fetus or embryo shall be destroyed in the woman's womb or that a premature birth thereof be caused." 1925 Tex. Crim. Stat. 1191.

[16] "By medical advice. Nothing in this chapter applies to an abortion procured or attempted by medical advice for the purpose of saving the life of the mother." 1925 Tex. Crim. Stat. 1196.

[17] *See also Whole Woman's Health v. Paxton*, Civil Cause No. 2022-38397, 2022 WL 2314499 (Harris Cnty. Dist. Ct. June 27, 2022), *injunction lifted by In re Paxton*, No. 22-0527, 2022 WL 2425619 (Tex. July 1, 2022), *case dismissed* (Harris Cnty. Dist. Ct. Oct. 5, 2022); *Texas v. Becerra*, No. 5:22-cv-185-H, 2022 WL 3639525 (N.D. Tex. Aug. 23, 2022), *appeal docketed*, No. 22-11037 (5th Cir. Oct. 25, 2022); Order, *Fund Tex. Choice v. Paxton*, No. 1:22-cv-00859 (W.D. Tex. Feb. 24, 2023), ECF No. 120.

[18] Vernon's Tex. Civ. Stats. ch. 6-1/2 (last updated Dec. 14, 2022), https://statutes.capitol.texas.gov/Docs/SDocs/VERNON'SCIVILSTATUTES.pdf.

H, 2022 WL 3639525, at *2 (N.D. Tex. Aug. 23, 2022) (treating the pre-Roe Ban as enforceable but noting that the Trigger Ban "reflects a more recent, more specific regulation of abortion and, normally, a more recent enactment governing the same subject supersedes prior enactments").

5. House Bill 3058 of 2023

76. In 2023, Texas passed House Bill 3058, a bill that creates a limited affirmative defense for "medical treatment" provided to pregnant Texans with preterm premature rupture of membranes ("PPROM"), a condition where a patient's water breaks prematurely before fetal viability. The law does not amend either abortion ban or add new exceptions. Instead, it: amends medical-malpractice tort law to create an affirmative defense for civil lawsuits brought under the Trigger Ban, but not S.B.8, Tex. Civ. Prac. & Rem. Code § 74.552(a); amends the Medical Practice Act to restrict TMB from disciplining a physician who "exercised reasonable medical judgment in providing medical treatment" to a patient with PPROM, Tex. Occ. Code § 164.055(c); and provides a justification defense in criminal prosecutions for physicians who reasonably provide "medical treatment" to a patient with PPROM, Tex. Penal Code § 9.35.

77. As the *Zurawski* district court noted, an affirmative defense is "vastly less protective than an exception" because it shifts the burden to the defendant to prove the defense. Moreover, H.B. 3058 may generate further physician confusion because singling out PPROM, but not other common pregnancy complications, incorrectly suggests that PPROM does not fall within the Trigger Ban's medical exception. In other words, H.B. 3058 does not appear to put physicians in any position different from where they were already.

C. Exception to Texas's Abortion Bans for Emergent Medical Conditions

78. Texas's abortion laws have long recognized that providing abortion care to pregnant people with emergent medical conditions is exempted from the state's various restrictions

on the provision of abortion. Yet inconsistencies in the language of these provisions, the use of non-medical terminology, and sloppy legislative drafting have resulted in understandable confusion throughout the medical profession regarding the scope of the exception.

1. History of the Emergent Medical Condition Exception

79. Texas's Emergent Medical Condition Exception first appeared in the Texas Code in 2011, when Texas updated its informed consent requirements for abortion and created certain exceptions for cases of so-called "medical emergency." It defined "medical emergency" as "a life-threatening physical condition aggravated by, caused by, or arising from a pregnancy that, as certified by a physician, places the woman in danger of death or a serious risk of substantial impairment of a major bodily function unless an abortion is performed." Tex. Health & Safety Code § 171.002(3) (hereinafter the "Definition Provision").

80. Over the last ten years, Texas has added numerous requirements to its abortion code that, utilizing this definition, have exceptions for "medical emergencies."[19] For example, in 2017 Texas passed a ban on "dismemberment abortion"—essentially a ban on dilation and evacuation ("D&E") abortions—that has an exception for "medical emergencies." Tex. Health & Safety Code § 171.152(a).

81. S.B. 8 is another example. The only exception to S.B. 8's abortion ban and its associated civil penalties is for patients where "a physician believes a medical emergency exists." Tex. Health & Safety Code § 171.205.

82. The same language in the Definition Provision appears as the sole exception to the

[19] *See* Tex. Health & Safety Code § 171.0124 (informed consent); Tex. Fam. Code §§ 33.002, 33.0022 (informed consent for minors); Tex. Ins. Code §§ 1218.001, 1696.001 (insurance coverage); Tex. Gov't Code § 2273.002 (facility licensing); Tex. Health & Safety Code § 171.152(a) (ban on "dismemberment abortions"); Tex. Occ. Code § 164.052 (physician licensing).

Trigger Ban. Specifically, Texas's criminal ban on abortion "does not apply if: (1) the person performing, inducing, or attempting the abortion is a licensed physician; (2) in the exercise of reasonable medical judgment, the pregnant female on whom the abortion is performed, induced, or attempted has a life-threatening physical condition aggravated by, caused by, or arising from a pregnancy that places the female at risk of death or poses a serious risk of substantial impairment of a major bodily function unless the abortion is performed or induced; and (3) the person performs, induces, or attempts the abortion in a manner that, in the exercise of reasonable medical judgment, provides the best opportunity for the unborn child to survive unless, in the reasonable medical judgment, that manner would create: (A) a greater risk of the pregnant female's death; or (B) a serious risk of substantial impairment of a major bodily function of the pregnant female." Tex. Health & Safety Code § 170A.002(b).

83. Texas law has several other abortion restrictions that utilize virtually the same definition of "medical emergency" used in S.B. 8 and the Trigger Ban, and thus do not apply to a patient who falls within the Emergent Medical Condition Exception. These laws include: a ban on abortion procedures performed using D&E, Tex. Health & Safety Code § 171.152; a law requiring certain biased counseling before abortion and a 24-hour mandatory delay, Tex. Health & Safety Code § 171.0124; and a law prohibiting the use of tax revenue for abortions, Tex. Health & Safety Code § 285.202.

2. Physician Discretion Under the Emergent Medical Condition Exception

84. Courts have long recognized that where an abortion ban provides an exception for patients in certain circumstances, a good faith standard, rather than a reasonable person standard, must apply. *See, e.g.*, *Colautti v. Franklin*, 439 U.S. 379, 395-96 (1979) ("Because of the absence of a scienter requirement in the provision directing the physician to determine whether the fetus is

or may be viable, the statute is little more than 'a trap for those who act in good faith'" (quoting *United States v. Ragen*, 314 U.S. 513, 524 (1942))); *Women's Med. Prof'l Corp. v. Voinovich*, 130 F.3d 187, 205 (6th Cir. 1997) ("The determination of whether a medical emergency or necessity exists . . . is fraught with uncertainty and susceptible to being subsequently disputed by others. . . . In an area as controversial as abortion, . . . where there is such disagreement, it is unlikely that the prosecution could not find a physician willing to testify that the physician did not act reasonably. Under the Act, a physician who performs a post-viability abortion under either the medical emergency or medical necessity exception may be held liable, even if the physician believed he or she was acting reasonably, and in accordance with his or her best medical judgment, as long as others later decide that the physician's actions were nonetheless unreasonable.").

85. The Emergent Medical Condition Exception's language, which appears five times in the Texas abortion code, contains conflicting language across the different sections regarding physician discretion and intent. This leaves physicians uncertain whether the treatment decisions they make in good faith, based on their medical judgment, will be respected or will be later disputed.

86. For example, the Trigger Ban defines "reasonable medical judgment" as "a medical judgment made by a reasonably prudent physician, knowledgeable about a case and the treatment possibilities for the medical conditions involved." Tex. Health & Safety Code § 170A.001(4).

87. Yet the Trigger Ban also prohibits a physician from "knowingly" providing a prohibited abortion. Thus, a physician does not violate the Trigger Ban by providing an abortion in reliance on the exception unless the physician subjectively *knows* that in the exercise of reasonable medical judgment, the patient does *not* have a condition qualifying for the exception. When a physician relies on the exception in good faith, the physician does not know that the

exception does not apply. Stated differently, a physician cannot knowingly violate the ban if she acts in good faith reliance on the exception.

88. Meanwhile, the Definition Provision's language, which applies to S.B. 8, does not explicitly mention intent. Instead, the language "as certified by a physician" modifies the exception language, suggesting that the treating physician's good faith certification, buttressed by the documentation and reporting requirements for medical emergencies added to the code by S.B. 8, governs the assessment of a patient's circumstances.

89. Physicians confronted with the question of whether or not a patient qualifies for the Emergent Medical Condition Exception must consider not only their ethical responsibilities as physicians and potential medical malpractice liability if they do not follow the standard of care, but the risk of loss of liberty and prison sentence they will face, Tex. Health & Safety Code § 170A.004, Tex. Penal Code §§ 12.32-12.33, and the potential loss of their license to practice medicine and pursue their chosen profession if they are found guilty of violating an abortion ban, Tex. Occ. Code §§ 165.001, 164.052(a)(5), 164.053(a), 164.055; Tex. Health & Safety Code § 170A.007.

90. Understandable confusion regarding physicians' level of discretion under Texas's abortion bans and fear for the legal consequences if they are wrong, is leading to physicians denying care to patients—including patients presenting with emergent conditions—even when such care likely would fall within the exception. As Plaintiffs' experiences show, because of the laws' uncertainty, physicians are over-complying with the laws to the detriment of their patients' lives and health.

91. Texas's abortion bans can and should be read to ensure that physicians have wide discretion to determine the appropriate course of treatment, including abortion care, for their

patients who present with emergent medical conditions—without being second guessed by the Attorney General, the Texas Medical Board, a prosecutor, or a jury.

3. Conditions Included in the Emergent Medical Condition Exception

92. In addition to the conflicting language regarding physician intent, Texas law provides scant guidance for what the rest of the language in the Emergent Medical Condition Exception means. Nowhere in the code does Texas law define any of the following distinctions: "risk" versus "serious risk"; "insubstantial impairment" versus "substantial impairment"; or "minor bodily function" versus "major bodily function." Nor does Texas law define what it means to have "a serious risk of a substantial impairment" or "a substantial impairment of a major bodily function."

93. None of this terminology has standardized meaning in the medical profession, leaving physicians to guess at how to translate it into clinical practice. The lack of clarity is preventing medical professionals from providing the care that their patients need.

94. The best reading of Texas law's plain text in the context of supporting patient and physician autonomy requires, at a minimum, that: (1) measurement of risk is left to physician judgment; (2) impairment of a "major bodily function" includes harm to reproductive functions and fertility (3) acute risk need not be already present or imminent; and (4) the patient's condition need not be presently "life-threatening."

95. A condition placing the pregnant person at "risk" or "serious risk" includes any condition that, in the physician's judgment, merits intervention to prevent "death" or "substantial impairment of a major bodily function," given the patient's symptoms, medical history, and the physician's experience and training.

96. While "major bodily function" is not defined in the Texas Health and Safety Code, the Texas Labor Code defines the term to include "reproductive functions." Tex. Labor Code § 21.002(11-a) ("[M]ajor bodily function, includ[es], but [is] not limited to, functions of the immune system, normal cell growth, and digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions.").

97. Accordingly, any physical condition that presents a serious risk of substantially impairing the patient's future fertility falls within the exception. This includes any condition that poses a serious risk of substantial impairment or loss of the patient's uterus, ovaries, or other reproductive organs.

98. The exception does not require that any of the risks to the pregnant person be imminent. To the contrary, the exception only requires that a physician certify that the patient is "in danger of death" *or* has a condition that creates "a serious risk of substantial impairment of a major bodily function."

99. Nor does the best reading of the exception require that the pregnant person have a condition that is imminently and/or definitively "life-threatening." While the exception references a "life-threatening physical condition," this phrase must be read together with the full language of the exception, which permits physicians to provide an abortion if the patient's condition would pose a serious risk to her health (specifically, a "serious risk of substantial impairment of a major bodily function") if left untreated.

4. Legislative Intent Regarding the Scope of the Emergent Medical Condition Exception

100. According to the lead and primary sponsors of the Texas Abortion Bans, the legislative intent was that it would be "the determination of the physician and the woman" whether

the woman has "a physical condition" that meets the requirements of the Emergent Medical Condition Exception.[20]

101. Representative Giovanni Capriglione, the primary sponsor of the Trigger Ban in the House, responded to a reporter's questions about exceptions to the ban by saying "if a qualified doctor, a physician *believes* that the pregnant mother's life is at risk, then they would be able to make a medical decision in that particular instance."[21]

102. In 2013, then-Representative Jodie Laubenberg was one of the primary sponsors on a bill banning abortion after 20 weeks of pregnancy that also contained the Emergent Medical Condition Exception. During a debate on the House floor regarding the bill, Representative Laubenberg described the exception as "very broad" *eight times*.[22]

103. Yet the legislators who supported these bills and other politicians in Texas who championed them have largely remained silent since S.B. 8 took effect and *Roe* was overturned.

104. Meanwhile, confusion among the medical profession over the last year and a half regarding the scope and meaning of the exception has been widely reported, showing that Plaintiffs' experiences are the norm, not the exception.

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[20] *Senate Session*, 87th Leg., Reg. Sess. (Tex. Mar. 29, 2021) (floor debate on Senate Bill 9, the companion bill to House Bill 1280, the Trigger Ban), https://tlcsenate.granicus.com/MediaPlayer.php?view_id=49&clip_id=15566 (beginning at 4:47:18); *House Session*, 83d Leg., 2d Called Sess., House Journal Suppl. S4–S6 (Tex. July 9, 2013) (floor debate on House Bill 2), https://journals.house.texas.gov/HJRNL/832/PDF/83C2DAY02SUPPLEMENTFINAL.PDF (House Bill 2 "gives the physician full authority to know what condition his patient is in and to have that authority to make that determination.").

[21] *Texas' 'Trigger Law' on Abortion Set to Go into Effect in 30 Days*, KLTV (June 24, 2022), https://www.kltv.com/2022/06/24/texas-trigger-law-abortion-set-go-into-effect-30-days/ (emphasis added).

[22] *See id.* ("This bill does give the physician the full autonomy and full authority to take care of his patient."), *id.* (The exception language "places the physician at the center of this [determination]," so that "[i]t will be his judgment" whether the patient has met the threshold for an abortion under the exception.), *id.* (The bill "gives the physician full control" over determining whether the "threshold" for the emergent medical condition exception is met.), *id.* ("By this language, we're allowing whatever the physician determines to be the condition that would impair the physical life of the woman" to control.), *id.* ("[T]his language actually gives broad coverage by allowing the physician, the physician, to have that authority."), *id.* ("Actually, it's not [tying the physician's hands]" because "[i]t's very broad to give that physician the authority."), *id.* ("It's whatever the doctor believes is in the best interest for the health of the pregnant mom."), *id.* ("I would not want to limit the physician's authority.").

105. Shortly after *Roe v. Wade* was overturned, the Texas Medical Association ("TMA") asked state regulators to provide guidance to the state's physicians on the scope of the exception. Public reporting indicates that in July 2022, TMA sent a letter to the Texas Medical Board ("TMB") saying it had received complaints that hospitals, administrators, and their attorneys are prohibiting doctors from providing abortion services to patients with major pregnancy complications for fear of violating Texas's abortion bans. The letter, which is not public, is said to have asked the TMB to "swiftly act to prevent any wrongful intrusion into the practice of medicine."[23]

106. Upon information and belief, to date, the TMB has not responded to TMA.

107. Similarly, Texas Senator Bryan Hughes, the author of S.B. 8, sent a letter to the TMB on August 4, 2022, regarding reported complaints that hospitals "may be wrongfully prohibiting or seriously delaying physicians from providing medically appropriate and possibly life saving services to patients who have various pregnancy complications. These complaints arise from confusion or disregard of the law in Texas since [*Roe* was overturned] and must be corrected." Letter from Bryan Hughes to Executive Director Brint Carlton (Aug. 4, 2022) (attached hereto as Exhibit A).[24] Senator Hughes's Letter concludes by saying, "Texas law makes it clear that a mother's life and major bodily function should be protected." Ex. A at 2.

108. Upon information and belief, to date, the TMB has not responded to Senator Hughes's letter.

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[23] Allie Morris, *Texas Hospitals Fearing Abortion Law Delay Pregnant Women's Care, Medical Association Says*, Dallas Morning News (July 14, 2022), https://www.dallasnews.com/news/politics/2022/07/14/texas-hospitals-fearing-abortion-law-delay-pregnant-womens-care-medical-association-says/.

[24] The letter was made public in a news report regarding Texas's interpretation of EMTALA after *Roe* was overturned. Dan Vergano, *The Federal Law Against Patient Dumping—EMTALA—Is the Latest Front in the Abortion Battle*, Grid (Aug. 29, 2022), https://www.grid.news/story/science/2022/08/29/the-federal-law-against-patient-dumping-emtala-is-the-latest-front-in-the-abortion-battle.

109. When Governor Greg Abbott was asked about the Emergent Medical Condition Exception during his re-election campaign for governor, he said the following: "[S]omething that really does need to be done and that is clarify what it means to protect the life of the mother. . . . But that said, I've even seen some other situations that some women are going through where they're not getting the health care they need to protect their life. . . . [T]he point is this, our goal is to make sure we protect the lives of both the mother and the baby. And there's been too many allegations that have been made about ways in which the lives of the mother are not being protected. And so that must be clarified."[25]

110. When Jonathan Mitchell, a former Texas Solicitor General who helped draft S.B. 8, was asked if he was concerned about the patient stories told in this case, he said the following: "It concerns me, yeah, because the statute was never intended to restrict access to medically necessary abortions, and the statute specifically says that it's not restricting access to medically necessary abortions. So that shouldn't be happening. The statute was written to draw a clear distinction between abortions that are medically necessary and abortions that are purely elective. Only the purely elective abortions are unlawful under SB 8."[26] Mitchell was sitting next to Senator Hughes in Senator Hughes's office when he made this statement.

111. Defendant Paxton sued Secretary of Health and Human Services Xavier Becerra over legal guidance that the Biden administration's HHS issued after *Roe v. Wade* was overturned. That guidance reiterated that the federal EMTALA law obligates hospitals and physicians to provide abortion care to a patient who presents to the hospital's emergency department if a physician or other qualified medical provider determines that the patient has an emergency medical

[25] Michael McCardel, *Race for Texas Governor: Full interview with Governor Greg Abbott*, WFAA (Oct. 16, 2022) at 1:42-2:26, https://www.wfaa.com/article/news/politics/inside-politics/texas-politics/inside-texas-politics-governor-greg-abbott-full-interview/287-e3aa0d2f-d204-46a9-8d4e-7dc442e5e6fa.

condition and that an abortion is needed to prevent serious jeopardy to the patient's health. The guidance states that physicians and hospitals have a legal obligation to follow EMTALA even if doing so involves providing treatment—including abortion—that is prohibited in the state where the hospital is located. After receiving a preliminary injunction blocking part of the guidance in Texas, Paxton issued a press release lauding the decision, stating: "We're not going to allow left-wing bureaucrats in Washington to transform our hospitals and emergency rooms into walk-in abortion clinics" and "I will fight back to defend our pro-life laws and Texas mothers and children."[27]

112. As Ms. Cox's experience shows, Texas law is not "pro-life" when it comes to pregnant people's lives, and the State of Texas has failed to give physicians any meaningful guidance on how to interpret its laws consistent with that goal.

D. *Zurawski v. Texas*

113. On March 6, 2023, *Zurawski v. Texas* was originally filed by five women and two obstetrician-gynecologists ("OB/GYNs") against the State of Texas and its officials and agencies that enforce Texas's abortion bans, seeking clarification regarding the medical exceptions to Texas's bans. Since then, the case has grown to 22 plaintiffs.

114. On August 4, 2023, a Travis County District Court entered a temporary injunction providing a statutory interpretation regarding the scope of the abortion statutes and, in the alternative, concluding that as-applied to Texans with life- or health-threatening pregnancy complications, the abortion bans likely violated the Texas Constitution. The same day, the State

[27] Ken Paxton, Tex. Att'y Gen., *Paxton Secures Victory Against Biden Administration, Blocks HHS from Forcing Healthcare Providers to Perform Abortions in Texas* (Aug. 24, 2022), https://www.texasattorneygeneral.gov/news/releases/paxton-secures-victory-against-biden-administration-blocks-hhs-forcing-healthcare-providers-perform.

defendants filed a notice of appeal, automatically staying both the district court's order and the district court's proceedings pending appeal.

115. Dr. Ingrid Skop, a board-certified OB/GYN licensed to practice medicine in Texas, was Defendants' testifying expert and sole witness in the District Court, and largely agreed with the *Zurawski* Plaintiffs' positions.

116. Dr. Skop testified that Texas law clearly allows an abortion for a maternal life-threatening condition without requiring that the threat to the patient's life be immediate. She testified that Texas law allows doctors to use their judgment in determining whether the medical exception applies.

117. Dr. Skop testified that in her view, Texas's abortion laws do not change anything about how doctors are allowed to treat patients in the hospital. If a doctor would have intervened to terminate a pregnancy before the abortion laws took effect, the current abortion laws allow them to intervene in the same way they always have.

118. Dr. Skop testified that Texas's abortion laws allow doctors to practice according to the standard of care. And when a woman's pregnancy threatens her life, the standard of care is to offer termination of pregnancy, which could be through inducing labor, a Caesarean section, or induced abortion like a D&E.

119. Dr. Skop testified that if the termination of pregnancy is done before fetal viability and is done to protect the pregnant patient's life or to prevent serious irreversible injury to an organ system, then Texas law allows the termination, regardless of the method of termination, including D&E abortion, suction aspiration, or medication abortion.

120. Dr. Skop also testified that if a physician induces labor before fetal viability and does so with the intent to save the pregnant person's life, then it is not an abortion at all under Texas law.

121. Dr. Skop testified that even though she believes the Texas abortion laws are clear and that nothing should change regarding how doctors treat patients in the hospital, she is aware that doctors have, in fact, changed the way that they have practiced. Dr. Skop testified that many doctors are confused about when they can provide abortion. In fact, doctors are not just confused, they are frightened because they do not understand the law. She testified that doctors are afraid of committing a felony or risking losing their certification from the TMB.

122. Dr. Skop testified that at one of the medical systems where she practices, she has seen that doctors have changed how they have provided care to their patients from before and after *Dobbs*. She testified: "The doctors are frightened. They're misinformed. They don't—they have not read the law in many cases. It is the blind leading the blind on the ground." She testified she has seen doctors refusing to intervene even though they know it is not the standard of care, and they justify it by saying, "I'm not going to risk a felony. I'm not going to risk losing my board certification."

123. Texas has failed to provide clarification or guidance on the meaning of the exception, despite being asked repeatedly.

124. Even Dr. Skop placed the blame for the confusion and fear in part on Defendant TMB: "The Texas Medical Board—obviously, if someone were to lose their board certification, it would come through the Texas Medical Board. The Texas Medical Board has provided the doctors with no reassurance that it's not going to take their board certification if it disagrees with their management, and so, unfortunately, the substandard care that's occurring is because the doctors

don't understand the law." Dr. Skop testified about her awareness that doctors are not just confused, they are frightened because they do not understand the law. She testified that doctors are afraid of committing a felony or risking losing their certification from the TMB.

125. Dr. Skop testified that she had reached out to members of the medical executive board at her hospital begging for clarification because she had seen confusion.

126. Dr. Skop has also written that one of the reasons doctors are confused about what they are allowed to do is that "[g]overnment agencies and medical organizations that have historically cleared up confusion when laws were misunderstood have remained eerily silent." In the same writing, Dr. Skop wrote that doctors in Texas are "fearful." Almost a year after S.B. 8 took effect, she wrote that "[c]onfusion abounds in Texas today because 10 months have passed since the Texas Human Life Protection Act was implemented, and the organizations that usually helped to clarify laws for physicians remain uncharacteristically silent."

127. Dr. Skop wrote that Defendant TMB "could educate and reassure physicians by reminding them that they can and should practice according to the standard of care. They have previously offered guidance to help physicians understand confusing laws." She continued: "Yet they have remained silent and not provided needed clarification to help physicians and avoid confusion."

128. On November 28, 2023, the Texas Supreme Court heard argument in the *Zurawski* Defendants' appeal of the district court's entry of a temporary injunction and denial of their plea to the jurisdiction.

II. APPLICATION OF TEXAS'S ABORTION BANS TO MS. COX

A. D&E Abortion is Medically Necessary for Ms. Cox

129. The longer Ms. Cox stays pregnant, the higher the risks to her life and health, including her fertility.

130. While Ms. Cox's life may not be imminently at risk, she is at high risk for many serious medical conditions that pose risks to her future fertility and can become suddenly and unexpectedly life-threatening.

131. Ms. Cox understands that the safest medical option to preserve her life and future fertility is a D&E abortion. If Ms. Cox is unable to receive a D&E abortion, she will receive either 1) a labor induction at term or earlier, if her baby's heartbeat stops, or 2) a C-section at full term. Both are associated with significantly higher mortality and morbidity than abortion and both pose significant risks to her future fertility.

132. Induction of labor after C-section carries the risk of uterine rupture. In patients where risk of uterine rupture is especially high, including where they have had recent and repeat C-sections, major medical associations like ACOG recommend against induction.[28]

133. A C-section is major surgery that becomes risker each time it is repeated. The risks of repeat C-sections include placenta problems such as placenta previa, blood transfusion, uterine rupture, damage to the bladder, infection, and hysterectomy.[29]

B. Mr. Cox Fears Liability Under S.B. 8

134. Mr. Cox is extremely concerned for his wife's life and wants to help her get the healthcare she needs to protect her life and ensure that they can have more children in the future.

135. Without court intervention, Mr. Cox fears liability under S.B. 8 for assisting his wife in obtaining medically necessary abortion care in Texas.

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[28] *See Vaginal Birth After Cesarean Delivery: Frequently Asked Questions*, ACOG, https://www.acog.org/womens-health/faqs/vaginal-birth-after-cesarean-delivery.

[29] *See Cesarean Birth: Frequently Asked Questions*, ACOG, https://www.acog.org/womens-health/faqs/cesarean-birth; Nicole E. Marshall, et al., *Impact of Multiple Cesarean Deliveries on Maternal Morbidity: A Systematic Review*, 2011 Am. J. of Obstetrics & Gynecology, Sept. 205(3): 262.e1-8, https://www.ajog.org/article/S0002-9378(11)00763-0/fulltext.

C. Dr. Karsan Cannot Provide Ms. Cox with an Abortion Under Texas Law without Court Authorization.

136. Dr. Karsan has reviewed Ms. Cox's medical records. The risks of trisomy 18 pregnancy combined with Ms. Cox's medical history and comorbidities indicate that Ms. Cox's life, health, and fertility are at risk if she continues the pregnancy. In Dr. Karsan's medical opinion, a D&E abortion is the best medical option to preserve Ms. Cox's life, health, and fertility.

137. Like its abortion bans, certain of Texas's abortion restrictions do not apply in cases of "medical emergencies." Texas's prohibition on D&E procedures, for example, has an exception for "medical emergencies" that uses the same definition of the term that applies for S.B. 8. *See* Tex. Health & Safety Code § 171.152(a). Various other abortion restrictions do not apply in cases of "medical emergencies," including Texas's biased counseling and 24-hour mandatory delay, Tex. Health & Safety Code § 171.0124, and Texas's law prohibiting the use of tax revenue for abortions, Tex. Health & Safety Code § 285.202.

138. Dr. Karsan has met Ms. Cox, reviewed her medical records, and believes in good faith, exercising her best medical judgment, that a D&E abortion is medically recommended for Ms. Cox.

139. It is also Dr. Karsan's good faith belief and medical recommendation that that the Emergent Medical Condition Exception to Texas's abortion bans and laws permits an abortion in Ms. Cox's circumstances, as Ms. Cox has a life-threatening physical condition aggravated by, caused by, or arising from her current pregnancy that places her at risk of death or poses a serious risk of substantial impairment of her reproductive functions if a D&E abortion is not performed.

140. Dr. Karsan is unsure how close to death her patients need to be before abortion is permitted under Texas law. As has been the case with prior patients over the last two years, Dr.

Karsan is unsure if Ms. Cox's current medical condition counts as close enough to death under Texas law for the Emergent Medical Condition Exception to apply.

141. Without authorization from the Court to provide Ms. Cox a medically indicated abortion, Dr. Karsan cannot risk loss of her medical license, life in prison, and massive civil fines.

142. Dr. Karsan has consulted with the administration of the hospital where she regularly practices and has been told that if she obtains court authorization to protect her and any medical staff who would assist her in performing an abortion from liability under Texas's abortion bans, the hospital will allow her to perform a D&E abortion for Ms. Cox.

III. THE TEXAS CONSTITUTION PROTECTS PREGNANT PEOPLE WITH EMERGENT MEDICIAL CONDITIONS AND THEIR PHYSICIANS FROM STATE DEPRIVATION OF THEIR RIGHTS

A. Pregnant People and their Families Have Fundamental and Equal Rights Under the Texas Constitution

143. The Supreme Court may have stripped pregnant people of their federal constitutional right to abortion, *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), but that does not mean that Plaintiffs are without Constitutional Rights.

144. The Texas Constitution guarantees its citizens certain fundamental rights, specifically: "[n]o citizen of this State shall be deprived of life, liberty, property, privileges, or immunities, or in any manner disfranchised, except by the due course of the law of the land." Tex. Const. art. I, § 19. People do not lose these rights simply because they are pregnant. Moreover, Texas law cannot demand that a pregnant person sacrifice their life, their fertility, or their health for any reason, let alone in service of "unborn life," particularly where a pregnancy will not or is unlikely to result in the birth of a living child with sustained life.

145. The Texas Constitution also prohibits Texas law from excluding pregnant people with certain kinds of emergent conditions—for example, pregnant people whose health risks are not imminently "life-threatening"—from receiving appropriate and/or life-saving medical care.

146. The Texas Constitution also guarantees "equal rights" under the law and prohibits the law from "den[ying] or abridg[ing rights] because of sex." Tex. Const. art. I, §§ 3, 3a. To deny a "woman known to be pregnant" equal access to life-saving and health-preserving medical care, simply because she is pregnant, would violate this foundational premise of equality under Texas law.

147. The Texas Constitution also states that "Excessive bail shall not be required, nor excessive fines imposed, nor cruel or unusual punishment inflicted. All courts shall be open, and every person for an injury done him, in his lands, goods, person or reputation, shall have remedy by due course of law." Tex. Const. art. I, § 13. To deny pregnant people access to abortion when necessary to preserve their lives, health, or fertility, or to deny individuals the ability to aid or abet pregnant people in accessing such abortion care, would violate this provision of the Texas Constitution.

148. The state cannot force its citizens to continue pregnancies that will need to be delivered by C-section when the pregnancy will not produce a child with sustained life. *See In re A.C.*, 573 A.2d 1235, 1261–63 (D.C. 1990) (en banc); *In re Baby Boy Doe*, 632 N.E.2d 326, 402 (Ill. App. Ct. 1994).

149. To the extent Texas's abortion bans bar the provision of abortion to pregnant people to treat medical conditions that pose a risk to the pregnant person's life or a significant risk to their health, and prevent individuals from aiding or abetting pregnant people in accessing such abortion,

the bans violate pregnant people's fundamental rights under §§ 13, 19 and their rights to equality under the law under §§ 3, 3a.

150. Indeed, Texas's abortion bans fail any level of constitutional review when applied to such pregnant people. "If the Texas [pre-*Roe* ban] statute were to prohibit an abortion even where the mother's life is in jeopardy, I have little doubt that such a statute would lack a rational relation to a valid state objective under the test stated in *Williamson* . . . ." *Roe v. Wade*, 410 U.S. 113, 173 (1973) (Rehnquist, J., dissenting). Because the abortion bans force pregnant people with emergent medical conditions to surrender their lives, health, and/or fertility, they have no rational relationship to protecting life, health, or any other legitimate state interest.

B. Texas-Licensed Physicians Have Liberty and Property Rights to Provide Care to Pregnant People with Emergent Conditions

151. The Texas Constitution guarantees that "[n]o citizen of this State shall be deprived of life, liberty, property, privileges, or immunities, or in any manner disfranchised, except by the due course of the law of the land." Tex. Const. art. I, § 19. The threatened enforcement of the abortion bans against physicians who in good faith provide abortions for pregnant people suffering emergent medical conditions infringes this constitutional guarantee.

152. Section 19 guarantees Texas-licensed physicians the right to practice their profession by providing abortion to their pregnant patients to treat emergent medical conditions that the physician determines poses a risk to the patient's life or health.

153. To fulfill this guarantee, physicians must be able to exercise their good faith judgment in the care of their patients with emergent conditions without threat that the state will take their license and/or liberty if a prosecutor or jury second guesses their medical judgment.

154. Texas law authorizes Defendant TMB to institute disciplinary and licensing proceedings against any physician who performs an abortion that the TMB determines did not

meet the Emergent Medical Condition Exception. *See, e.g.*, Tex. Occ. Code §§ 165.001, 164.052(a)(5), 164.053(a), 164.055; Tex. Health & Safety Code § 170A.007. These proceedings may result in a provider losing their license to practice medicine. *See, e.g.*, Tex. Health & Safety Code § 170A.007.

155. Disciplinary actions are reported to the National Practitioner Data Bank[30] and can have collateral consequences on a physician's ability to practice in other U.S. states.[31] Defendant TMB, for example, requires physicians to make timely reports of any disciplinary actions taken by other jurisdictions against the physician, 22 Tex. Admin. Code § 173.3, and has taken disciplinary action against physicians based on conduct occurring in other states.[32] Upon information and belief, disciplinary sanctions may also result in loss of employment.

156. Physicians must make a substantial investment to obtain a medical license in Texas.

157. According to the TMB, to be eligible for a physician's license in Texas, individuals must: graduate from an accredited medical school, having gained admission through a highly competitive application process which often necessitates incurring significant amounts of debt (in 2019, an average of between $94,399 and $142,797 for students at medical schools in Texas);[33] complete at least one continuous year of graduate medical training or a fellowship; pass rigorous

[30] *See* 42 U.S.C. § 11132 (requiring state medical boards to report all revocations or suspensions of physician licenses); *see also* Nat'l Practitioner Data Bank, *Guidebook*, at Ch. E: Reports, Table E-1 (Oct. 2018), https://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp (explaining state medical boards and hospitals have mandatory reporting obligations).

[31] *See, e.g.*, Tex. Admin. Code § 173.3(d) (requiring reporting within 30 days of any actions issued by another state); Tex. Med. Bd. Press Release at 4-5, *TMB Disciplines 27 Physicians at June Meeting, Adopts Rule Changes* (June 30, 2022), https://www.tmb.state.tx.us/dl/2B28AF92-02B2-0425-2295-86E2DEAD1C51 (describing "other states' [disciplinary] actions").

[32] Tex. Med. Bd. Press Release at 4-5, *TMB Disciplines 27 Physicians at June Meeting, Adopts Rule Changes* (June 30, 2022), https://www.tmb.state.tx.us/dl/2B28AF92-02B2-0425-2295-86E2DEAD1C51.

[33] *See, e.g.*, *Medical School Debt Keeps Climbing,* Tex. Med. Ass'n (April 2020), https://app.texmed.org/tma.archive.search/files/53049/april_20_tm_educationinfographic.pdf.

state examinations; practice medicine full-time for one year; and, *inter alia*, have no relevant disciplinary or criminal history. 22 Tex. Admin Code § 163.2.

158. If physicians meet these requirements and incur the substantial associated costs, they are eligible for full licensure in Texas for which they must apply. 22 Tex. Admin Code §§ 163.2, 163.4. Once granted, a physician may practice medicine within Texas and has a vested property interest in their license.

159. Revoking or suspending a physician's license based on a flawed interpretation of the Emergent Medical Condition Exception is improper interference with the physician's vested property interest in their license.

160. Further, sending a physician to prison for up to 99 years for providing timely and appropriate medical care to a pregnant person with an emergent medical condition is improper interference with the physician's liberty.

161. Physicians have constitutional rights under § 19 of the Texas Constitution including rights to liberty, property, and substantive due course of law. Even for laws that only touch on economic rights, § 19 requires a rational relationship to the purpose of the law.

162. As applied to pregnant people with emergent medical conditions and the physicians treating them, Texas's abortion bans fail to comply with the Texas Constitution. They do not serve a proper legislative purpose because far from furthering life, they harm pregnant people's lives, and the lives of their children, without furthering potential life at all. Texas law also demands that there be a real and substantial connection between a legislative purpose and the language of the law as it functions in practice. For pregnant people with emergent medical conditions, there is none. Further, for patients with emergent conditions, Texas's abortion bans work an excessive

burden on physicians treating such patients relative to their purported purpose. *See, e.g.*, *Patel v. Tex. Dep't of Licensing & Reg.*, 469 S.W.3d 69, 80-81 (Tex. 2015).

CLAIMS

CLAIM I: DECLARATORY JUDGMENT

163. The allegations in paragraphs 1 through 162 above are incorporated as if fully set forth herein.

164. Plaintiffs hereby petition the Court pursuant to the UDJA.

165. Section 37.002 of the UDJA provides that it is remedial and its purpose is to settle and to afford relief from uncertainty and insecurity with respect to rights, status, and other legal relations; and it is to be liberally construed and administered.

166. Under Section 37.003 of the UDJA, a court of proper jurisdiction has the power to declare rights, status, and other legal relations, whether or not further relief is or could be claimed. The declaration may be either affirmative or negative in form and effect and the declaration has the force and effect of a final judgment or decree.

167. Plaintiffs thus seek a declaratory judgment that the exception to Texas's abortion bans and laws, codified at Tex. Health & Safety Code §§ 170A.001-002, 171.002(3), 171.203-205, 171.152, 171.0124, 285.202, permits physicians to provide a pregnant person with abortion care when the physician determines, in their good faith judgment and in consultation with the pregnant person, that the pregnant person has a physical emergent medical condition that poses a risk of death or a risk to their health (including their fertility).

168. Plaintiffs also seek a declaratory judgment that, at a minimum, Texas's abortion bans do not preclude a physician from providing abortion care where, in the physician's good faith judgment and in consultation with the pregnant person, a pregnant person has: a physical medical condition or complication of pregnancy that poses a risk of infection, bleeding, or otherwise makes

continuing a pregnancy unsafe for the pregnant person; a physical medical condition that is exacerbated by pregnancy, cannot be effectively treated during pregnancy, or requires recurrent invasive intervention; and/or a fetal condition where the fetus is unlikely to survive the pregnancy and sustain life after birth.

169. Plaintiffs have sued the State and the relevant state agencies, and that they seek to have this Court determine the validity of Texas's abortion bans as applied in circumstances arising from emergent medical conditions. Therefore, the State and its agencies are necessary parties to this suit and governmental immunity does not apply.

CLAIM II: ULTRA VIRES

170. The allegations in paragraphs 1 through 169 above are incorporated as if fully set forth herein.

171. A state office may not act without legal authority. *See, e.g.*, *City of El Paso v. Heinrich*, 284 S.W.3d 366, 372 (Tex. 2009).

172. Any official's enforcement of Texas's abortion bans against 1) any physician who provides an abortion to a pregnant person after determining that, in the physician's medical judgment, the pregnant person has a physical emergent medical condition for which abortion would prevent or alleviate a risk of death or risk to their health (including their fertility), or 2) any individual aiding or abetting a pregnant person in obtaining such an abortion, would be inconsistent with the Emergent Medical Condition Exception to Texas's abortion bans and therefore would be *ultra vires*.

173. Plaintiffs have sued the Defendant state officials in their official capacities, and they seek prospective relief other than the recovery of monetary damages. Therefore, governmental immunity does not apply.

CLAIM III: SECTION 19 RIGHTS OF PREGNANT PEOPLE

174. The allegations in paragraphs 1 through 173 above are incorporated as if fully set forth herein.

175. Under the Texas Constitution, "[n]o citizen of this State shall be deprived of life, liberty, property, privileges, or immunities, or in any manner disfranchised, except by the due course of the law of the land." Tex. Const. art. I, § 19.

176. To the extent Texas's abortion bans bar the provision of abortion to pregnant people to treat emergent medical conditions that pose a risk to pregnant people's lives or health (including their fertility), the bans violate pregnant people's fundamental rights under Article I, § 19 of the Texas Constitution.

177. To the extent Texas's abortion bans force pregnant people to continue pregnancies that will need to be delivered by C-section when the pregnancy will not produce a child with sustained life, the bans violate pregnant people's fundamental rights under Article I, § 19 of the Texas Constitution.

178. Thus applied, Texas's abortion bans do not serve a compelling or important state interest and are not sufficiently tailored to serve any compelling interest.

179. Thus applied, Texas's abortion bans also lack any rational relationship to protecting life, health, or any other legitimate state interest.

180. Plaintiffs seek a declaratory judgment that Article I, § 19 of the Texas Constitution guarantees a pregnant person the right to an abortion where the pregnant person has an emergent medical condition that poses a risk of death or risk to their health (including their fertility), and an abortion would prevent or alleviate such risk.

181. Any official's enforcement of Texas's abortion bans as applied to a pregnant person with an emergent medical condition for whom an abortion would prevent or alleviate a risk of

death or risk to their health (including their fertility) would be inconsistent with Article I, § 19 of the Texas Constitution and therefore would be *ultra vires*.

CLAIM IV: EQUAL RIGHTS FOR PREGNANT PEOPLE AND SUPPORTERS OF ABORTION

182. The allegations in paragraphs 1 through 181 above are incorporated as if fully set forth herein.

183. Under the Texas Constitution, "[a]ll freemen, when they form a social compact, have equal rights, and no man, or set of men, is entitled to exclusive separate public emoluments, or privileges, but in consideration of public services." Tex. Const. art. I, § 3.

184. Texas does not prevent non-pregnant people or people unable to get pregnant from accessing critical medical treatment nor force them to unnecessarily suffer severe illnesses and injuries and undergo mental anguish.

185. To the extent Texas's abortion bans bar or delay the provision of abortion to a pregnant person with an emergent medical condition that poses a risk of death or risk to their health (including their fertility), while allowing non-pregnant people and people unable to get pregnant to access medical treatment for emergent medical conditions, Texas's abortion bans violate pregnant people's right to equal rights.

186. S.B. 8 also singles out people who "aid or abet" or intent to "aid or abet" pregnant people seeking such abortion, and then treats this category of people differently from all other defendants in civil litigation in Texas.

187. S.B. 8 alters the procedural rules and limits the substantive defenses and arguments available in S.B. 8 enforcement proceedings to skew those proceedings and harm those sued under S.B. 8 in violation of the constitutional guarantee of equal protection. The statute's venue and fee-

shifting provisions, its openness to claimants without any connection to an abortion, and its evisceration of defenses and arguments, all work together to disadvantage supporters of abortion.

188. Thus applied, Texas's abortion bans do not serve a compelling or important state interest and are not sufficiently tailored to serve any compelling interest.

189. Thus applied, Texas's abortion bans also lack any rational relationship to protecting life, health, or any other legitimate state interest.

190. Plaintiffs seek a declaratory judgment that Article I, § 3 of the Texas Constitution guarantees a pregnant person the right to an abortion where the pregnant person has an emergent medical condition that poses a risk of death or risk to their health (including their fertility), and an abortion would prevent or alleviate such risk.

191. Plaintiffs seek a declaratory judgment that, to the extent S.B. 8 prevents an individual from aiding or abetting a pregnant person in obtaining an abortion necessary to preserve their life or health (including their fertility), S.B. 8 violates Article I, § 3 of the Texas Constitution.

192. Any official's enforcement of Texas's abortion bans as applied to 1) a pregnant person with an emergent medical condition for whom an abortion would prevent or alleviate a risk of death or risk to their health (including their fertility), or 2) an individual aiding or abetting a pregnant person in obtaining such an abortion, would be inconsistent with Article I, § 3 of the Texas Constitution and therefore would be *ultra vires*.

CLAIM V: EQUALITY BASED ON SEX FOR PREGNANT PEOPLE

193. The allegations in paragraphs 1 through 192 above are incorporated as if fully set forth herein.

194. Under the Texas Constitution, "[e]quality under the law shall not be denied or abridged because of sex, race, color, creed, or national origin." Tex. Const. art. I, § 3a.

195. To the extent Texas's abortion bans bar or delay the provision of abortion to a "woman known to be pregnant" to treat an emergent medical condition that poses a risk of death or risk to their health (including their fertility), while allowing other people to access medical treatment for emergent medical conditions, Texas's abortion bans deny pregnant women equality because of sex.

196. To the extent the Texas's abortion bans are based on gender stereotypes that a woman's primary role is to birth children and be a mother, they constitute discrimination because of sex.

197. Thus applied, Texas's abortion bans do not serve a compelling or important state interest and are not sufficiently tailored to serve any compelling interest.

198. Thus applied, Texas's abortion bans also lack any rational relationship to protecting life, health, or any other legitimate state interest.

199. Plaintiffs seek a declaratory judgment that Article I, § 3a of the Texas Constitution guarantees a pregnant person the right to an abortion where the pregnant person has an emergent medical condition that poses a risk of death or risk to their health (including their fertility), and an abortion would prevent or alleviate such risk.

200. Any official's enforcement of Texas's abortion bans as applied to a pregnant person with an emergent medical condition for whom an abortion would prevent or alleviate a risk of death or risk to their health (including their fertility) would be inconsistent with Article I, § 3a of the Texas Constitution and therefore would be *ultra vires*.

CLAIM VI: SECTION 13 RIGHTS FOR PREGNANT PEOPLE AND SUPPORTERS OF ABORTION

201. The allegations in paragraphs 1 through 200 above are incorporated as if fully set forth herein.

202. The Texas Constitution states that "Excessive bail shall not be required, nor excessive fines imposed, nor cruel or unusual punishment inflicted. All courts shall be open, and every person for an injury done him, in his lands, goods, person or reputation, shall have remedy by due course of law." Tex. Const. art. I, § 13.

203. To the extent that S.B. 8 prevents a pregnant person from obtaining an abortion to preserve their life or health (including their fertility) or prevents an individual from aiding or abetting a pregnant person in obtaining such an abortion, it violates Article I, Section 13.

204. Plaintiffs seek a declaratory judgment that Article I, § 13 of the Texas Constitution guarantees a pregnant person the right to an abortion where the pregnant person has an emergent medical condition that poses a risk of death or risk to their health (including their fertility), and an abortion would prevent or alleviate such risk.

205. Plaintiffs seek a declaratory judgment that, to the extent S.B. 8 prevents an individual from aiding or abetting a pregnant person in obtaining an abortion necessary to preserve their life or health (including their fertility), S.B. 8 violates Article I, § 13 of the Texas Constitution.

206. Any official's enforcement of Texas's abortion bans as applied to 1) a pregnant person with an emergent medical condition for whom an abortion would prevent or alleviate a risk of death or risk to their health (including their fertility), or 2) an individual aiding or abetting a pregnant person in obtaining such an abortion, would be inconsistent with Article I, § 13 of the Texas Constitution and therefore would be *ultra vires*.

CLAIM VII: SECTION 19 RIGHTS OF PHYSICIANS

207. The allegations in paragraphs 1 through 206 above are incorporated as if fully set forth herein.

208. Under the Texas Constitution, "[n]o citizen of this State shall be deprived of life, liberty, property, privileges, or immunities, or in any manner disfranchised, except by the due course of the law of the land." Tex. Const. art. I, § 19.

209. Section 19 guarantees Texas-licensed physicians the right to practice their profession by providing abortion to their pregnant patients to treat emergent medical conditions that the physician determines pose a risk to the pregnant person's life or health (including their fertility).

210. To the extent Texas's abortions bans bar or delay physicians from providing abortion to treat emergent medical conditions that pose a risk to a pregnant person's life or health (including their fertility), Texas's abortion bans violate Texas-licensed physicians' rights under Section 19.

211. Thus applied, Texas's abortion bans do not serve a proper legislative purpose, there is no real and substantial connection between a legislative purpose and the language of the abortion bans as those bans function in practice for patients with emergent medical conditions, and Texas's abortion bans work an excessive burden on Texas-licensed physicians treating such patients relative to their purpose.

212. Thus applied, Texas's abortion bans also lack any rational basis.

213. Plaintiffs seek a declaratory judgment that Article I, § 19 of the Texas Constitution guarantees Texas-licensed physicians the right to provide an abortion to a pregnant person to treat an emergent medical condition that the physician determines poses a risk to the pregnant person's life or health (including their fertility).

214. Any official's enforcement of Texas's abortion bans as applied to a Texas-licensed physician who provides an abortion to a pregnant person to treat an emergent medical condition that the physician determines poses a risk to the pregnant person's life or health (including their fertility) would be inconsistent with Article I, § 19 of the Texas Constitution and therefore would be *ultra vires*.

CLAIM VIII: APPLICATION FOR TEMPORARY RESTRAINING ORDER

215. The allegations in paragraphs 1 through 214 above are incorporated as if fully set forth herein.

216. Pursuant to Texas Civil Practice and Remedies Code Section 65.011 *et seq.*, Plaintiffs are entitled to a temporary restraining order against Defendants, their officers, agents, servants, employees, and attorneys, and upon those persons in active concert or participation with them, prohibiting enforcement of Texas's abortion bans and laws, codified at Tex. Health & Safety Code §§ 170A.001-002, 171.002(3), 171.203-205, 171.152, 171.0124, 285.202, against Plaintiffs Ms. and Mr. Cox and Dr. Karsan and her staff, nurses, pharmacists, agents, and patients, for purposes of terminating Ms. Cox's current pregnancy.

217. Defendants' threatened enforcement of Texas's abortion bans is causing imminent, irreparable injury to Plaintiffs.

218. Plaintiffs are likely to prevail on the merits of this case and receive the requested declaratory judgment, as well as equitable relief.

219. Plaintiffs also have no adequate remedy at law for Defendants' threatened actions. Specifically, money damages are insufficient to redress the threatened injury to Plaintiffs.

220. The threatened injury to Plaintiffs far outweighs any possible damages to Defendants. Ms. Cox needs a time-sensitive medically necessary abortion procedure to preserve

her life, health, and fertility, which Dr. Karsan cannot provide without equitable relief from this Court. There is no state interest that can outweigh the harm caused to Ms. Cox, Mr. Cox, and their family by being denied or delayed in accessing abortion.

221. Accordingly, to preserve the status quo, Plaintiffs request that Defendants be cited to appear, and further request that the Court enter a temporary restraining order pursuant to Texas Rule of Civil Procedure 680 *et seq.* and Texas Civil Practice and Remedies Code Section 65.011 *et seq*.

222. Plaintiffs are willing to post a bond for any temporary restraining order if ordered to do so by the Court, but request that the bond be minimal because Defendants are acting in a governmental capacity, have no pecuniary interest in the suit, and no monetary damages can be shown. Tex. R. Civ. P. 684.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask this Court:

A. To enter a judgment against Defendants granting appropriate declaratory relief to clarify the scope of the exception to Texas's abortion bans and laws consistent with the Texas Constitution;

B. To enter a judgment against the Defendant state officials that enforcing Texas's abortion bans and laws contrary to the Court's declaration regarding their scope would be *ultra vires*;

C. To enter a judgment that Texas's abortion bans and laws, as applied to pregnant people with emergent medical conditions and Texas-licensed physicians treating such patients, violate the Texas Constitution;

D. To issue temporary injunctive relief as soon as possible and permanent injunctive relief that restrains Defendants, their agents, servants, employees, attorneys, and

any persons in active participation or concert with Defendants, from enforcing Texas's abortion bans and laws or instituting disciplinary actions related to alleged violations of the abortion bans in a manner violating the court's judgment;

E. To retain jurisdiction after judgment for the purposes of issuing further appropriate injunctive relief if the Court's declaratory judgment is violated; and

F. To such other and further relief as the Court deems just and proper.

Dated: December 5, 2023

Respectfully submitted,

/s/ Austin Kaplan

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Attorneys for Plaintiffs

* Pro hac vice application pending
** Pro hac vice applications forthcoming

Exhibit A

THE TEXAS SENATE

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AUSTIN, TEXAS 78701
512.463.0101

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SUITE 207
TYLER, TEXAS 75702
903.581.1776

BRYAN HUGHES

COMMITTEES ON:
STATE AFFAIRS, CHAIR
EDUCATION
JURISPRUDENCE
NATURAL RESOURCES &
ECONOMIC DEVELOPMENT
NOMINATIONS
REDISTRICTING

August 4, 2022

Executive Director Brint Carlton, JD
Texas Medical Board
333 Guadalupe Street
Tower 3, Suite 610
Austin, Texas 78701

Re: Concerns over allegations received involving the potential corporate practice of medicine and patients experiencing pregnancy complications

Dear Executive Director Carlton:

It has come to my attention that the Texas Medical Association has received and notified the Texas Medical Board of complaints alleging potential violations of Texas' prohibition on the corporate practice of medicine.[1] Such complaints include the allegations that hospitals, their administrators, or even their lawyers may be wrongfully prohibiting or seriously delaying physicians from providing medically appropriate and possibly life saving services to patients who have various pregnancy complications.[2] These complaints arise from confusion or disregard of the law in Texas since the ruling by the United States Supreme Court on *Dobbs v. Jackson Women's Health Organization* and must be corrected.

One mentioned example involves the interference by at least two hospitals of care for premature ruptures of membranes and forcing these patients to be sent home to miscarry without proper pain management or care being provided at the hospital. Another egregious example involves the allegation that a hospital instructed a physician to turn away a pregnant mother diagnosed with an ectopic pregnancy until it ruptured. These disturbing allegations of the prohibited practice of medicine by laypersons and malpractice by acquiescent physicians must be investigated and if they are occurring, stopped.

Pregnancy complications such as these should be swiftly and reasonably treated to prevent or address a medical emergency determined by the physician.[3] "Medical emergency" is defined under Texas Health and Safety Code 171.002(3) to mean "a life-threatening physical condition aggravated by, caused by, or arising

---

[1] See, e.g., 22 TAC §177.17(a) stating, in part, "The corporate practice of medicine doctrine is a legal doctrine, which generally prohibits corporations, entities, or non-physicians from practicing medicine. The prohibition on the corporate practice of medicine is based on numerous provisions of the Medical Practice Act, including §§155.001, 155.003, 157.001, 164.052(a)(8), (13), and 165.156."

[2] Letter sent to the Texas Medical Board on behalf of the Texas Medical Association on July 13, 2022 notifying the Board of these complaints.

[3] Other pregnancy complication that a physician could determine rise to the level of a "medical emergency" are ectopic pregnancies, preterm premature rupture of membranes, pre-eclampsia, hemorrhaging, strain on the mother's heart, or peripartum cardiomyopathy. This is a non-exhaustive list.

from a pregnancy that, as certified by a physician, places the woman in danger of death or a serious risk of substantial impairment of a major bodily function unless an abortion is performed." This definition has not changed.

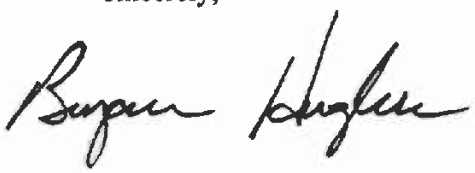
Senate Bill 8, The Heartbeat Act, expressly allows for a physician to perform or induce an abortion "if a physician believes that a medical emergency exists...."[4] House Bill 1280, the Trigger Bill, also provides an express exemption to prosecution where a physician "in the exercise of reasonable medical judgment, the pregnant female on whom the abortion is performed, induced, or attempted has a life-threatening physical condition aggravated by, caused by, or arising from a pregnancy that places the female at risk of death or poses a serious risk of substantial impairment of a major bodily function unless the abortion is performed or induced."[5]

The definition of abortion also provides guidance as to what is not a violation of Texas law: "The term does not include birth control devices or oral contraceptives. An act is not an abortion if the act is done with the intent to save the life or preserve the health of an unborn child; remove a dead, unborn child whose death was caused by spontaneous abortion; or remove an ectopic pregnancy."[6]

Texas law makes it clear that a mother's life and major bodily function should be protected. Any deviation, such as these allegations, should be investigated as potential malpractice and a non-physician (including hospitals) instructing a physician to act should be investigated as a prohibition on the corporate practice of medicine.

I respectfully request that the Texas Medical Board issue guidance on this issue and investigate these allegations.

Sincerely,



Bryan Hughes

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[4] Texas Health and Safety Code Sec. 171.205(a), SB 8, 87th Leg.
[5] Texas Health and Safety Code Sec. 170A.002, HB 1280, 87th Leg.
[6] Under Texas Health and Safety Code Sec. 245.002(1): "Abortion" means the act of using or prescribing an instrument, a drug, a medicine, or any other substance, device, or means with the intent to cause the death of an unborn child of a woman known to be pregnant. The term does not include birth control devices or oral contraceptives. An act is not an abortion if the act is done with the intent to:

(A) save the life or preserve the health of an unborn child;
(B) remove a dead, unborn child whose death was caused by spontaneous abortion; or
(C) remove an ectopic pregnancy.

VERIFICATION

STATE OF ~~TEXAS~~ Florida §

COUNTY OF Saint Lucie §

Before me, the undersigned notary public, on this day personally appeared Kate Cox, who declares and states that she is authorized to make this affidavit, that she has read the Verified Petition for Declaratory Judgment and Application for Temporary Restraining Order and Permanent Injunction against Defendants ("Petition") and knows the contents thereof; and, unless otherwise stated, that the factual statements contained in the Petition are based upon her personal knowledge, or obtained from others with personal knowledge or from documents, and are, to the best of her knowledge, true and correct.

Katelynn Cox

Kate Cox

Sworn to and subscribed before me, the undersigned, this 4 day of December 2023.

ECHARD BIEN-AIME
Notary Public - State of Florida
Commission # HH 153738
Expires on July 14, 2025

Echard bien-aime

Notary Public, State of ~~Texas~~ Florida
Commission Expires on 07/14/2025

Notarized online using audio-video communication

VERIFICATION

STATE OF TEXAS ~~XXXX~~ Florida §

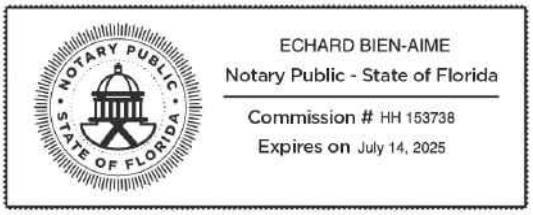
COUNTY OF Saint Lucie §

Before me, the undersigned notary public, on this day personally appeared Justin Cox, who declares and states that he is authorized to make this affidavit, that he has read the Verified Petition for Declaratory Judgment and Application for Temporary Restraining Order and Permanent Injunction against Defendants ("Petition") and knows the contents thereof; and, unless otherwise stated, that the factual statements contained in the Petition are based upon his personal knowledge, or obtained from others with personal knowledge or from documents, and are, to the best of his knowledge, true and correct.

Justin T Cox

Justin Cox

Sworn to and subscribed before me, the undersigned, this 4 day of December 2023.



Echard bien-aime

Notary Public, State of ~~Texas~~ Florida

Commission Expires on 07/14/2025

Notarized online using audio-video communication

VERIFICATION

STATE OF TEXAS §
COUNTY OF HARRIS **§**

Before me, the undersigned notary public, on this day personally appeared Damla Karsan, M.D., who declares and states that she is authorized to make this affidavit, that she has read the Verified Petition for Declaratory Judgment and Application for Temporary Restraining Order and Permanent Injunction against Defendants ("Petition") and knows the contents thereof; and, unless otherwise stated, that the factual statements contained in the Petition are based upon her personal knowledge, or obtained from others with personal knowledge or from documents, and are, to the best of her knowledge, true and correct.

Damla Karsan

Sworn to and subscribed before me, the undersigned, this 5th day of December 2023.

Irene Del Rosario Rivas
My Commission Expires
2/17/2026
Notary ID
4927841

Notary Public, State of Texas
Commission Expires on 2/17/2025

CAUSE NO. _____

KATE COX; JUSTIN COX; and DAMLA KARSAN, M.D., on behalf of herself, her staff, nurses, pharmacists, agents, and patients,	IN THE DISTRICT COURT OF
Plaintiffs,	TRAVIS COUNTY, TEXAS
v.	_____ JUDICIAL DISTRICT
STATE OF TEXAS; ATTORNEY GENERAL OF TEXAS, KEN PAXTON, in his official capacity as Attorney General of Texas; TEXAS MEDICAL BOARD; and STEPHEN BRINT CARLTON, in his official capacity as Executive Director of the Texas Medical Board,	
Defendants.	

[PROPOSED] TEMPORARY RESTRAINING ORDER

On the ___ day of December, 2023, the Court considered Plaintiffs Kate Cox, Justin Cox, and Dr. Damla Karsan's Application for Temporary Restraining Order ("Application") seeking to restrain Defendants State of Texas, Attorney General of Texas, Ken Paxton, Texas Medical Board, and Stephen Brint Carlton ("Defendants"), their agents, servants, employees, attorneys, and all persons in active concert and participation with Defendants from enforcing Texas's abortion bans and laws, codified at Tex. Health & Safety Code §§ 170A.001-002 (the "Trigger Ban"), Tex. Health & Safety Code §§ 171.002(3), 171.203-205 ("S.B. 8"), and 1925 Tex. Penal Code arts. 1191-96 (the "pre-*Roe* Ban"), and certain Texas abortion laws utilizing the same medical exception, Tex. Health & Safety Code §§ 170A.001-002, 171.002(3), 171.203-205, 171.152, 171.0124, 285.202, against Plaintiffs Kate and Justin Cox and Plaintiff Dr. Karsan and her staff, nurses, pharmacists, agents, and patients. After consideration of the Application and pursuant to the Texas Rule of Civil Procedure 680, the Court hereby finds:

FINDINGS

The Court finds that Ms. Cox's life, health, and fertility are currently at serious risk, and she needs a dilation and evacuation ("D&E") abortion immediately to preserve her life, health, and fertility. Ms. Cox's circumstances meet the medical exception to Texas's abortion bans and laws.

Ms. Cox is currently 20 weeks pregnant. Ms. Cox has two young children already, both delivered by cesarean surgery ("C-section"). Her third child has been diagnosed with full trisomy 18. After multiple screenings, ultrasounds, and diagnostic testing, Ms. Cox's physicians have confirmed that her baby may not survive to birth and, if so, will only live for minutes, hours, or days.

The longer Ms. Cox stays pregnant, the greater the risks to her life. Ms. Cox has already been to three emergency rooms with severe cramping, diarrhea, and leaking unidentifiable fluid. If she is forced to continue this pregnancy, Ms. Cox is at a particularly high risk for gestational hypertension, gestational diabetes, fetal macrosomia, post-operative infections, anesthesia complications, uterine rupture, and hysterectomy, due to her two prior C-sections and underlying health conditions. If she is forced to carry this pregnancy to term, she will likely need a third C-section. Undergoing a third C-section would make subsequent pregnancies higher risk and make it less likely that Ms. Cox would be able to carry another child in the future.

Dr. Karsan has met Ms. Cox, reviewed her medical records, and believes in good faith, exercising her best medical judgment, that a D&E abortion is medically recommended for Ms. Cox and that the medical exception to Texas's abortion bans and laws permits an abortion in Ms. Cox's circumstances. Dr. Karsan, however, cannot risk liability under Texas's abortion bans and laws for providing Ms. Cox's abortion absent intervention from the Court confirming that doing so will not jeopardize Dr. Karsan's medical license, finances, and personal liberty.

Mr. Cox is married to Ms. Cox and is the father of her children. He is ready to assist Ms. Cox in obtaining an abortion in Texas but needs assurances from this Court that doing so will not violate Texas's abortion bans and laws.

The Court finds that (1) Dr. Karsan is a Texas-licensed physician, and (2), consistent with Dr. Karsan's good faith belief and medical recommendation, that Ms. Cox has a life-threatening physical condition aggravated by, caused by, or arising from her current pregnancy that places her at risk of death or poses a serious risk of substantial impairment of her reproductive functions if a D&E abortion is not performed. Ms. Cox's circumstances thus fall within the medical exception to Texas's abortion bans and laws. Texas law therefore permits Dr. Karsan to perform, induce, or attempt an abortion for Ms. Cox, and permits Mr. Cox to assist Ms. Cox in obtaining that abortion.

This Court further finds that a D&E abortion is the method of abortion medically necessary to preserve Ms. Cox's life, health, and future fertility, and poses far fewer risks than an induction or a C-section.

The Court further finds that the risks to Ms. Cox's life, health, and fertility do not arise from a claim or diagnosis that Ms. Cox would engage in conduct that might result in her own death or self-harm.

Money damages are insufficient to remedy the injuries to Plaintiffs that will result if Defendants are not enjoined from instituting civil, criminal, or disciplinary investigations or actions under Texas's abortion bans and laws related to the abortion Ms. Cox is currently seeking. Conversely, Defendants will not be harmed if the Court restrains them and anyone in active participation or concert with them from enforcing Texas's abortion bans and laws as applied to the abortion Ms. Cox is currently seeking.

Defendants are responsible for enforcing Texas's abortion bans and laws. Defendant State of Texas enforces all Texas laws and includes persons acting under color of state law who could potentially enforce S.B. 8 and the pre-*Roe* ban. Defendants Attorney General Paxton, the Texas Medical Board, and Stephen Brint Carlton are statutorily empowered to assess civil penalties and disciplinary sanctions against anyone who violates the Trigger Ban and other Texas abortion laws. Defendants have not disavowed enforcement of these laws in circumstances like Ms. Cox's, nor have they provided any clarity as to how physicians like Dr. Karsan or persons like Mr. Cox should interpret the medical exception to Texas's abortion bans and laws that Defendants enforce. Violations of Texas's abortion bans and laws are subject to heavy penalties, including lifetime imprisonment, hundreds of thousands of dollars in fines and penalties, and loss of professional license. The Court finds that Plaintiffs are reasonably chilled from performing or aiding in the performance of an abortion for Ms. Cox without issuance of temporary relief restraining Defendants.

Defendants were provided notice of the cause of action, the Application, and the hearing conducted. Unless Defendants are restrained, Plaintiffs face an imminent threat of irreparable harm under Texas's abortion bans and laws. Judicial intervention is necessary to preserve Plaintiffs' legal right to obtain, provide, aid, or abet the abortion Ms. Cox is currently seeking.

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

A. A Temporary Restraining Order is entered enjoining Defendants, their officers, agents, servants, employees, and attorneys, and those persons in active participation or concert with them, from enforcing Texas's abortion bans and laws, codified at Tex. Health & Safety Code §§ 170A.001-002, 171.002(3), 171.203-205, 171.152, 171.0124, 285.202 against Plaintiffs and their staff, nurses, pharmacists, agents, and patients, as applied to Ms. Cox's current pregnancy.

B. Defendants shall provide notice of this Temporary Restraining Order to their officers, agents, servants, employees, and attorneys, and all other persons in active participation or concert with them.

C. The matter is scheduled for a permanent injunction hearing on the ___ day of _____, 2024, at _____.

D. Plaintiffs' bond is set at _____. A law firm check or credit card is sufficient to post bond. Upon the filing of the bond required herein, the Clerk of this Court shall issue a Temporary Restraining Order in conformity with the law and the terms of this Order Granting Plaintiffs' Application for Temporary Restraining Order.

E. All parties may be served with notice of this Temporary Restraining Order and of the hearing on the request for Permanent Injunction in any matter provided under Rule 21a of the Texas Rules of Civil Procedure.

F. This Temporary Restraining Order shall expire on _____, 2023, at 5:00 p.m.

SIGNED this _____ day of _____, 2023, at _____ a.m./p.m.

_____

PRESIDING JUDGE

Automated Certificate of eService

This automated certificate of service was created by the efiling system. The filer served this document via email generated by the efiling system on the date and to the persons listed below. The rules governing certificates of service have not changed. Filers must still provide a certificate of service that complies with all applicable rules.

Christie Coffey on behalf of Austin Kaplan
Bar No. 24072176
ccoffey@kaplanlawatx.com
Envelope ID: 82235994
Filing Code Description: Petition
Filing Description: PLAINTIFFS' ORIGINAL VERIFIED PETITION FOR DECLARATORY JUDGMENT AND APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PERMANENT INJUCTION
Status as of 12/5/2023 3:39 PM CST

Case Contacts

Name	BarNumber	Email	TimestampSubmitted	Status
Austin HKaplan		akaplan@kaplanlawatx.com	12/5/2023 10:14:11 AM	SENT
Christie Coffey		ccoffey@kaplanlawatx.com	12/5/2023 10:14:11 AM	SENT

EXHIBIT P

JHR
THE JOURNAL OF HUMAN RESOURCES

Research Article | Articles

Education and Labor Market Consequences of Teenage Childbearing

Evidence Using the Timing of Pregnancy Outcomes and Community Fixed Effects

Jason M. Fletcher and Barbara L. Wolfe

Journal of Human Resources, March 2009, 44 (2) 303-325; DOI: https://doi.org/10.3368/jhr.44.2.303

Abstract

The question of whether giving birth as a teenager has negative economic consequences for the mother remains controversial despite substantial research. In this paper, we build upon existing literature, especially the literature that uses the experience of teenagers who had a miscarriage as the appropriate comparison group. We show that miscarriages are not random events, but rather are likely correlated with (unobserved) community-level factors, casting some doubt on previous findings. Including community-level fixed effects in our specifications lead to important changes in our estimates. By making use of information on the timing of miscarriages as well as birth control choices preceding the teenage pregnancies we construct more relevant control groups for teenage mothers. We find evidence that teenage childbearing likely reduces the probability of receiving a high school diploma by 5 to 10 percentage points, reduces annual income as a young adult by $1,000 to $2,400, and may increase the probability of receiving cash assistance and decrease years of schooling.

Received November 2007.

Accepted January 2008.

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31 Mar 2009
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PRESS

EXHIBIT Q

THE JOURNAL OF PEDIATRICS • www.jpeds.com ORIGINAL ARTICLES

Effects of Carrying an Unwanted Pregnancy to Term on Women's Existing Children

Diana Greene Foster, PhD[1], Sarah E. Raifman, MSc[1], Jessica D. Gipson, PhD[2], Corinne H. Rocca, PhD[1], and M. Antonia Biggs, PhD[1]

Objective To examine how receiving or being denied a wanted abortion affects the subsequent development, health, caregiving, and socioeconomics of women's existing children at time of seeking abortion.

Study design The Turnaway Study is a 5-year longitudinal study with a quasi-experimental design. Women were recruited from January 2008 to December 2010 from 30 abortion facilities throughout the US. We interviewed women regarding the health and development of their living children via telephone 1 week after seeking an abortion and semiannually for 5 years. We compare the youngest existing children younger than the age 5 years of women denied abortion because they presented for care beyond a facility's gestational limit (Turnaway group) with those of women who received the abortion (Abortion group). We used mixed-effects regression models to test for differences in outcomes of existing children of women in the Turnaway group (n = 55 children) compared with existing children of women in the Abortion group (n = 293 children).

Results From 6 months to 4.5 years after their mothers sought abortions, existing children of women denied abortions had lower mean child development scores (adjusted β –0.04, 95% CI –0.07 to –0.00) and were more likely to live below the Federal Poverty Level (aOR 3.74, 95% CI 1.59-8.79) than the children of women who received a wanted abortion. There were no significant differences in child health or time spent with a caregiver other than the mother.

Conclusions Denying women a wanted abortion may have negative developmental and socioeconomic consequences for their existing children. *(J Pediatr 2019;205:183-9).*

Approximately 60% of women in the US who have abortions are already mothers.[1] Approximately one-third of women seeking an abortion say that their reason for wanting to terminate the pregnancy is to care for children they already have.[2,3]

The Turnaway Study was designed to examine the consequences of terminating an unwanted pregnancy vs carrying it to term. We followed 956 women for 5 years, all of whom sought an abortion at 1 of 30 abortion facilities across the country. Some of the women in the study received the abortion, and some were denied the wanted abortion. Other findings from this study have indicated that being denied an abortion places women at greater risk of anxiety, stress, and low self-esteem at the time of being denied an abortion; however, mental health symptoms improve over time whether or not the woman received the abortion.[4-7] Women from this study who were denied abortions were more likely to live in poverty,[8] to raise children alone, to stay tethered to an abusive partner,[9] and were less likely to have and achieve aspirational plans for the future,[10] compared with women who obtained the wanted abortion. These factors may affect the home environment and resources available to children in the family and therefore may affect the well-being of existing children in the home. In this article, we investigate the effect of being denied an abortion on the health and development of women's existing children at the time of abortion-seeking by comparing the outcomes of existing children of women who received vs were denied a wanted abortion.

Methods

The Turnaway Study is a 5-year, longitudinal telephone-interview study of the effects of receiving vs being denied abortion on women's physical health, mental health, and socioeconomic well-being, as well as those of their children. Details have been published previously.[11] The study was approved by the Committee for Human Research at the University of California, San Francisco.

Study participants included English- and Spanish-speaking women aged 15 or older, with no known fetal anomalies or demise, presenting for abortion care between

PEDS:DM	Parents' Evaluation of Developmental Status: Developmental Milestones
TANF	Temporary Assistance to Needy Families program

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2008 and 2010 at 30 facilities throughout the US. Recruitment facilities were selected based on the criterion that they had the latest gestational limit of any other facility within 150 miles. We identified facilities using the National Abortion Federation directory and contacts within the abortion research community. Women were recruited into 1 of 3 designated study groups in a 2:1:1 ratio based on the gestational age limit of the facility: 1) women receiving an abortion up to 2 weeks under a facility's gestational limit, 2) women who received a first-trimester abortion, and 3) women who were denied an abortion with gestations up to 3 weeks over a facility's limit.

For this analysis, we compared the outcomes of the existing children of all women in the study who received an abortion (Abortion group) regardless of original study group with the outcomes of existing children whose mothers were denied the abortion and carried the pregnancy to term (Turnaway group). Women in the Turnaway group who went on to have an abortion elsewhere were included in the Abortion group. Previous analyses have shown that women who received an abortion elsewhere after being turned away were, on average, a month earlier in pregnancy[8]; they were less likely to be Latina and also less likely to have had a difficult time deciding to have the abortion than women in the Turnaway group who carried their pregnancies to term.[12] Women were interviewed by telephone 8 days after seeking the abortion and then every 6 months for 5 years.

Measures

We collected data on child development, health, socioeconomic well-being, and caregiving of women's youngest living child younger than age 5 years at 1 week after abortion-seeking and every 6 months through 4 years. Child development was assessed using the Parents' Evaluation of Developmental Status: Developmental Milestones (PEDS:DM) instrument.[13] The PEDS:DM is a parent-reported screening and surveillance tool for children ages birth to 8 years to assess 6 age-specific measures of child development: fine motor, receptive language, expressive language, gross motor, self-help, and social emotional. We used longitudinal reports from mothers to assess whether the child achieved each milestone (yes/no), as well as an overall percentage across the 6 milestones. Child health included any diagnoses and recent attacks of asthma, physical disabilities, and injuries severe enough to consider seeking medical attention. Caregiving was assessed by asking whether the child lived with the mother; hours per week the child spent with other caregivers; and, for children ages 3 and 4 years, whether they attended preschool. Finally, measures to assess child's socioeconomic well-being included questions about the mother and the household: whether the mother lived with adult family members, with a male partner, or on her own (without a male partner or adult family members) and whether the mother received public assistance from the Women, Infants, and Children program, Temporary Assistance for Needy Families (TANF), and Supplemental Nutritional Assistance Program, also known as food stamps. We calculated poverty based on each survey calendar year's federal poverty threshold, the number of people sharing expenses in the household, and the total household income, including public assistance. We measured subjective poverty by asking the woman whether she had enough money to meet basic living needs, such as food, housing, and transportation in the previous month. We dichotomized this outcome to indicate women who reported that they did not always have enough money to cover basic living expenses.

Our primary independent variable was analytic group (Turnaway vs Abortion). We also included baseline covariates that could confound the relationship between the analytic group and child outcomes. Child-specific covariates included birth order (first, second, third, and fourth or greater), sex, presence of a physical disability at baseline, and a time-varying measure of child age. Maternal covariates were all measured at baseline and included age, self-reported race/ethnicity (white, black, Hispanic/Latina, and other), education (less than high school, high school/General Educational Development, and more than high school/General Educational Development), and union status (married, cohabitating, never married and not cohabiting, previously married and not cohabiting).

Statistical Analyses

We used mixed-effects linear and logistic regression to test for baseline analytic group differences in mothers' and youngest existing children's characteristics at the time of abortion-seeking, with random effects for site. We assessed differences in child development, health, caregiving, and socioeconomic status over the 5-year study period by analytic group (existing children in the Turnaway vs Abortion group). Specifically, we compared outcomes of the youngest existing child to each woman beginning at the 6-month interview (after mothers in the Turnaway group gave birth) and continuing at each subsequent interview until the last existing child reached age 5 years. We present the results of the adjusted analyses for all outcomes, with the exception of physical disabilities, because the number of children with physical disabilities was too small to fit adjusted models. All analyses accounted for clustering by site and multiple observations per child over time with random effects. Analyses were performed using Stata 14 (StataCorp, College Station, Texas).[14] Statistical tests are reported at $P < .10$ and $P < .05$ using 2-tailed tests. For models in which the adjusted model showed significant differences between the Abortion and Turnaway groups, we report marginal predicted probabilities generated from the adjusted model.

For all analyses, we omitted existing children whose mother did not complete more than the first interview (n = 26) and existing children (n = 50) from 1 site where nearly all women who were turned away went on to get an abortion elsewhere (**Figure**). Given the unique health risks for twin births,[15] we also excluded twins (n = 14). In the main analyses, we also excluded existing children of women in the Turnaway group who reported that they had a miscarriage (n = 4) or who placed the new child for adoption (n = 7). As a sensitivity check, we tested whether there were substantive differences in the results if we separated the Abortion group into Near-Limit, First Trimester, and Turnaways who did not give birth (those who placed the child for adoption, miscarried, or went on to receive an abortion elsewhere).

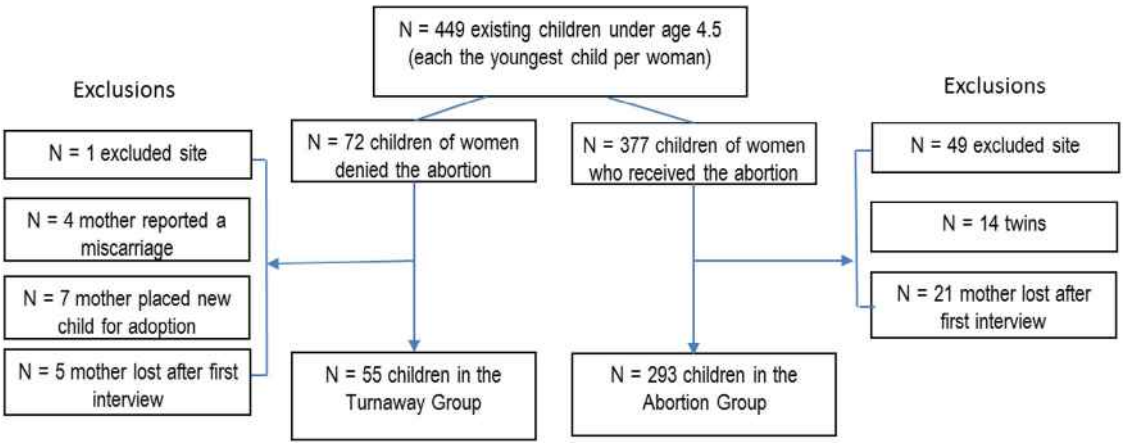

Figure. Existing children by analytic group and reason for exclusion.

Results

A total of 37.5% (1132/3016) of eligible participants approached consented to participate. Overall, 956 women seeking abortions completed baseline interviews between January 2008 and December 2010. At the time of seeking abortion, 603 (63%) women reported at least one living existing child, and 449 were younger than age 5 years. Among the 210 mothers in the Turnaway group who were interviewed, 44 (21%) received an abortion elsewhere. The final sample of observations of existing children in this analysis includes 1944 semiannual data points for 348 children. This includes 293 children of mothers in the Abortion group (180 from the Near-Limit group, 14 from women who were initially denied an abortion but received one elsewhere, and 99 from First-Trimesters) and 55 children of mothers in the Turnaway group.

Baseline Characteristics

At the time of the baseline survey, 8 days after receipt or denial of abortion, the average age of youngest existing children at or younger than age 4.5 years was 2.1 years (range 4 months to 4.5 years) (**Table I**). Forty-three percent were only children, 29% were the second child, and 28% had a higher birth order. There were no statistically significant baseline differences by analytic group in any child demographic characteristics, child development, child health, caregiving, and most socioeconomic outcomes, except mothers in the Turnaway group were more likely than mothers in the Abortion group to report that they did not always have enough money to pay for food, housing, and transportation ($P < .05$).

Differences by Analytic Group from 6 Months to 5 Years Postabortion-Seeking

By 6 months, all women in the Turnaway group had given birth. The mean child development score from 6 months to 5 years among existing children in the Turnaway group was 4 percentage points lower than that of the existing children of women in the Abortion group (73% vs 77% of milestones achieved, aβ −0.04, 95% CI −0.07 to −0.003) (**Table II**). Self-help was the only 1 of the 6 individual child development domains that was significantly different by analytic group in adjusted models: existing children of women in the Turnaway group were less likely to achieve self-help milestones compared with existing children of women in the Abortion group (59% vs 93%, aOR 0.71, 95% CI 0.52-0.97).

In terms of the existing child's health, we found no significant differences in frequency of reported injuries or in episodes of asthma by analytic group in adjusted analyses (**Table II**). In unadjusted analyses, the proportions of existing children with physical disabilities were not significantly different by group.

There were no differences by analytic group in the odds that existing children lived with their mothers or in hours spent with other caregivers. Among 3- and 4-year-old children, existing children of women in the Turnaway group were more likely to attend preschool (56% vs 45%, aOR 2.25, 95% CI 1.02-4.95) than children of mothers in the Abortion group.

We found significant differences in socioeconomic well-being by analytic group (**Table II**). Existing children of women in the Turnaway group had more than 3 times greater odds of living in a household that received assistance from the Women, Infants, and Children program (aOR 3.66, 95% CI 1.97-6.79) and TANF (19% vs 10% receiving TANF, aOR 5.34, 95% CI 1.64-17.42,) and also greater odds of living in a household below the Federal Poverty Level (72% vs 55%, aOR 3.74, 95% CI 1.59-8.79) compared with children of women who received an abortion. The household income relative to Federal Poverty Level was lower among children of women in the Turnaway group (115% vs 83% of the Federal Poverty Level, aβ −0.32, 95% CI −0.54 to −0.10) than among children of women who received the abortion. Existing children were more likely to live in a household in which their mother reported not having enough money to pay for food, housing, and transportation if their mother was denied vs received the abortion (87% vs 70%, aOR 6.13, 95% CI 2.47-15.22).

Table I. Characteristics of mothers and existing children by analytic group 1 week after abortion-seeking

Characteristics	Turnaway group N = 55	Abortion group N = 293	Total N = 348
Mother's characteristics			
Age, y, mean (SD)	24.3 (4.7)	25.0 (4.5)	24.9 (4.6)
Race/ethnicity, %			
White (reference)	15	27	25
Black	40	37	38
Hispanic/Latina	27	20	21
Other	18	16	16
Highest level of education, %			
Less than high school (reference)	22	19	19
High school or GED	35	35	35
More than high school/GED	44	46	46
Union status, %			
Married (reference)	20	12	14
Cohabitating	15	21	20
Never married, not cohabiting	56	53	53
Previously married, not cohabiting	9	14	13
Child's characteristics			
Age, y, mean (SD)	2.1 (1.1)	2.0 (1.2)	2.1 (1.2)
Female sex, %	42	52	51
Birth order, %			
First child (reference)	40	44	43
Second child	33	28	29
Third child	15	18	17
Fourth child or higher	13	11	11
Child's development			
Expressive language, %	94	89	90
Fine motor, %	85	87	87
Gross motor, %	75	75	75
Receptive language, %	85	83	84
Social emotional, %	83	90	89
Self-help, %	75	75	75
Overall percentage, mean (SD)	83 (21)	83 (23)	83 (23)
Child's health			
Experienced injury in past 6 mo, %	5	9	8
Has asthma, %	18	11	12
Has a physical disability, %	2	1	1
Caregiving			
Lives with mother, %	93	96	95
Time with caregiver other than mother, h/wk, mean (SD)	15.6* (20.6)	22.0 (25.3)	21.0 (24.7)
Preschool attendance (among 3 and 4 years old, n = 85), %	31	42	40
Socioeconomics			
Mother lives on her own, %	31	39	38
Mother lives with family, %	36	29	30
Mother lives with male partner, %	33	32	32
Household receives assistance from WIC, %	38†	27	28
Household receives TANF, %	24	16	17
Household receives food stamps, %	56	45	47
Household income below the Federal Poverty Level, %	58	63	62
Percent of the Federal Poverty Level, mean (SD)	95 (72)	101 (86)	100 (84)
Missing household income, %	35*	22	24
Not enough money to cover basic living expenses, %	96†	83	85

GED, General Educational Development; *WIC*, Women, Infants, and Children.
Reference group: Abortion group. Statistical significance is based on mixed-effects regression analyses accounting for clustering by site. Tests for differences compare the Turnaway group with the Abortion group (the reference group). For categorical variables with more than 2 categories (race/ethnicity, parity, and marital status), we used an omnibus postestimation test to accommodate multiple category associations.
*$P < .10$.
†$P < .05$.

Results from sensitivity analyses, in which we examined the original abortion study groups (Near-Limits and First-Trimesters) separately instead of combining them into 1 Abortion group were similar in direction, magnitude, and significance for all but 2 outcomes (**Table III**; available at www.jpeds.com). Although analytic group differences for self-help and overall mean child development were similar in direction, the differences were no longer statistically significant at a $P < .05$ level ($P = .067$ and $P = .074$, respectively).

Discussion

Women's concerns that having another child may affect their ability to care for existing children are supported by a limited,

Table II. Differences in outcomes between existing children of mothers in the Turnaway group compared with those in the Abortion group

Outcomes	Measurement	Unadjusted estimate	*P* value	95% CI	Adjusted* estimate	*P* value	95% CI
Child development							
Expressive language	OR	0.55†	.029	(0.32-0.94)	0.67	.135	(0.40-1.13)
Fine motor	OR	0.57‡	.052	(0.33-1.00)	0.63	.104	(0.35-1.10)
Gross motor	OR	0.76‡	.055	(0.57-1.01)	0.73‡	.060	(0.52-1.01)
Receptive language	OR	0.81	.206	(0.58-1.12)	0.93	.691	(0.66-1.32)
Social emotional	OR	0.92	.627	(0.64-1.31)	1.02	.932	(0.70-1.49)
Self help	OR	0.70†	.017	(0.52-0.94)	0.71†	.033	(0.52-0.97)
Overall percentage PEDS:DM	β	–0.05†	.004	(–0.09 to –0.02)	–0.04†	.030	(–0.07 to 0.00)
Child health							
Injury in the past 6 mo	OR	0.78	.508	(0.37-1.64)	0.72	.368	(0.35-1.48)
Asthma	OR	§			2.92	.259	(0.45-18.73)
Physical disability	OR	3.73	.193	(0.51-27.19)	§		
Caregiving							
Hours with caregivers other than mother	β	–2.97	.220	(–7.71 to 1.78)	–2.59	.269	(–7.19 to 2.01)
Preschool attendance (among 3 and 4 years old)	OR	1.92‡	.062	(0.97-3.82)	2.25†	.045	(1.02-4.95)
Socioeconomic							
Mother lives on her own	OR	0.74	.560	(0.27-2.04)	0.91	.847	(0.37-2.26)
Mother lives with family	OR	1.53	.422	(0.54-4.34)	1.28	.603	(0.50-3.28)
Mother lives with male partner	OR	0.96	.952	(0.28-3.35)	0.84	.731	(0.30-2.30)
Household receives WIC	OR	3.76†	.000	(2.03-6.97)	3.66†	.000	(1.97-6.79)
Household receives TANF	OR	4.90†	.008	(1.52-15.86)	5.34†	.005	(1.64-17.42)
Household receives food stamps	OR	1.66	.209	(0.75-3.63)	1.51	.294	(0.70-3.24)
Household income below the Federal Poverty Level	OR	3.99†	.003	(1.58-10.10)	3.74†	.002	(1.59-8.79)
Percent of the Federal Poverty Level	β	–0.37†	.003	(–0.62 to –0.13)	–0.32†	.004	(–0.54 to –0.10)
Not enough money to cover basic living expenses	OR	5.59†	.000	(2.30-13.63)	6.13†	.000	(2.47-15.22)

β, beta coefficient.
Reference group: Abortion group.
*Adjusted models include age, education, race/ethnicity and union status of mother at recruitment, birth order, sex, and time varying age of child at interview and include site and child random effects.
†$P < .05$.
‡$P < .10$.
§Not available; model would not converge.

yet growing body of empirical evidence demonstrating adverse effects of unintended childbearing, both for the child resulting from an unintended pregnancy, as well as for older siblings.[16-21] This study prospectively assessed the effects of access to wanted abortion care on women's existing children. We found slightly lower child development scores and poorer socioeconomic well-being for the existing children of women denied abortions compared with children whose mothers received an abortion. These 2 major findings may be linked. Diminished resources may lead to slowed development, as is supported by the resource-dilution model.[22-24] A mother who is stressed may invest less in her children, emotionally and financially. That existing children of women denied abortion were more likely to live in poorer households is commensurate with previous research from this same study on the effects of abortion denial on women.[8] Although increases in preschool attendance among existing children in the Turnaway group may help to counterbalance some of the effect of diminished financial well-being on their development, we find that any such benefit is not sufficient to keep development scores on par with the children of women who received an abortion.

This study has several limitations. The sample size of existing children at time of abortion-seeking is small in this study and did not allow us to examine how outcomes varied over time. We only collected data on the youngest existing child, which limits our ability to detect effects on other children in the family. We may not have been sufficiently powered to detect differences in all the outcomes we measured. Further, we test many outcomes within 4 domains—socioeconomic, development, health, and caregiving—raising the possibility of a type I error. However, the consistency of findings within the socioeconomic and development domains are reassuring. Our measure of child development, the PEDS:DM, is primarily used as a screening tool in clinic settings, rather than in research, and we do not know whether the small measured differences in development are good indicators of these children's long-term well-being. The apparent differences in subjective poverty at the baseline interview may be due to the fact that the first interview took place 1 week after the woman learned that she was going to have a/another child, so she may have had a heightened sense of inadequate income. Yet, given the small number of children under study, our significant findings on child development and poverty are particularly striking. Future study should include all existing children and follow more women to examine whether the results vary by age of the existing child or are concentrated in specific ages.

There are 2 mechanisms by which older siblings may be affected by a subsequent unintended pregnancy carried to term. The resource-dilution model posits that parents' time, money, and energy are finite, so as the number of children in a family increases, resources allocated to any one child decline,

ultimately impacting outcomes of all children in the household.[22-24] A second mechanism suggests that apart from the effects of family size, the occurrence of an unintended pregnancy carried to term may negatively impact the woman. These impacts may result from the woman's greater stress or depression associated with the unintended pregnancy measured during the pregnancy,[25,26] in the perinatal period,[27] or beyond.[20,28] These adverse effects have been shown to extend beyond the woman to the child resulting from the unintended pregnancy, as well as her existing children, via lower-quality mother–child relationships[20,29,30] more physical punishment of children,[20] a deterioration of the home environment,[31] and an increase in behavioral problems among boys whose younger sibling was unintended.[31]

Efforts to examine the extent of the effects of unintended childbearing on existing children, however, have been hampered by 3 main methodologic challenges. First, to isolate the effect of being born from unintended pregnancies, these children often are compared with children born from intended pregnancies. However, the differences in child well-being resulting from this comparison could be confounded by factors such as the pregnant woman's circumstances—financial, health, or relationship status, for example, that might lead to both poor child outcomes, as well as to the increased likelihood of having an unintended pregnancy or of retrospectively reporting a pregnancy as unintended.

Second, efforts to control for these confounding factors have compared siblings, one from an unintended pregnancy and one from an intended pregnancy, within the same family. This approach, however, may underestimate the effect of unintended pregnancy if there are negative spillover effects from the unintended pregnancy to the other children in the family.[19,31] If other children in the family are negatively affected by the unintended pregnancy, what is perceived as a family effect may actually be a consequence of the unintended pregnancy. To prevent spillover effects, in this study we compared existing children, otherwise similar, who did and did not experience an additional sibling from an unintended pregnancy.

Lastly, "unintended pregnancy"—the broad term including both unwanted and mistimed pregnancy and most often used in previous studies—is an inherently complex phenomenon to measure. Women may have mixed or ambivalent feelings toward pregnancy,[32,33] and these feelings may change over the course of pregnancy and after childbirth.[34] Despite its complexity, many studies examining unintended pregnancy rely on crude, retrospective measures that are likely to lead to misclassification of "unintended" pregnancy and underestimate any associated consequences. This small study has overcome these methodologic challenges to detect an effect on existing children by whether their mother received or was denied a wanted abortion. This study shows that the effect of a birth following an unwanted pregnancy may not just redound to the child born from that pregnancy; there may also be negative effects on existing children. These findings support the legitimacy of women's concerns about the effect of carrying an unwanted pregnancy to term on the well-being of their existing children.

Until now, research on the effects of denial of wanted abortion has focused on women and the child born as a result of abortion denial.[17,35] This study, in contrast, highlights the potential negative effects on existing children of women who are denied a wanted abortion, underscoring women's own concerns about the well-being of their families when faced with the prospect of carrying an unintended pregnancy to term. We find small negative effects on existing children's development and an increased chance of living in poverty among children whose mothers were denied rather than obtained a wanted abortion. ■

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Table III. Differences in outcomes between existing children of mothers in the Turnaway group compared with those in the Abortion group (all abortion vs by study group)

		Parent in Turnaway group compared with all Abortion group (original model)			T-Parent in Turnaway group compared with near limit (sensitivity model)		
Outcomes	**Measurement**	**OR/β**	***P* value**	**95% CI**	**OR/β**	***P* value**	**95% CI**
Child development							
Expressive language	OR	0.67	.135	(0.40-1.13)	0.71	.222	(0.42-1.23)
Fine motor	OR	0.63	.104	(0.35-1.10)	0.65	.151	(0.36-1.17)
Gross motor	OR	0.73*	.06	(0.52-1.01)	0.74*	.089	(0.52-1.05)
Receptive language	OR	0.93	.691	(0.66-1.32)	0.97	.857	(0.68-1.39)
Social emotional	OR	1.02	.932	(0.70-1.49)	1.04	.838	(0.70-1.55)
Self help	OR	0.71†	.033	(0.52-0.97)	0.74*	.067	(0.53-1.02)
Overall percentage PEDS:DM	β	–0.04†	.03	(–0.07 to 0.00)	–0.03*	.074	(–0.07 to 0.00)
Child health							
Injury in the past 6 months	OR	0.72	.368	(0.35-1.48)	0.74	.420	(0.35-1.55)
Asthma	OR	2.92	.259	(0.45-18.73)	‡		
Physical disability	OR	‡			‡		
Caregiving							
Hours with caregivers other than mother	β	–2.59	.269	(–7.19 to 2.01)	–2.39	.329	(–7.18 to 2.40)
Preschool attendance (among 3 and 4 years old)	OR	2.25†	.045	(1.02-4.95)	2.92†	.010	(1.29-6.64)
Socioeconomic							
Mother lives on her own	OR	0.91	.847	(0.37-2.26)	1.03	.948	(0.41-2.62)
Mother lives with family	OR	1.28	.603	(0.50-3.28)	0.92	.864	(0.35-2.40)
Mother lives with male partner	OR	0.84	.731	(0.30-2.30)	0.97	.947	(0.34-2.74)
Household receives WIC	OR	3.66†	0	(1.97-6.79)	3.80†	.000	(1.98-7.30)
Household receives TANF	OR	5.34†	.005	(1.64-17.42)	3.38†	.045	(1.03-11.13)
Household receives food stamps	OR	1.51	.294	(0.70-3.24)	1.39	.414	(0.63-3.09)
Household income below the Federal Poverty Level	OR	3.74†	.002	(1.59-8.79)	3.50†	.005	(1.46-8.44)
Percent of the Federal Poverty Level	β	–0.32†	.004	(–0.54 to –0.10)	–0.31†	.008	(–0.54 to –0.08)
Not enough money to cover basic living expenses	OR	6.13†	0	(2.47-15.22)	5.21†	.001	(2.14-13.28)

Adjusted models include maternal age, education, race/ethnicity and union status at recruitment, and child's birth order, sex, and time varying age at interview. Models include site and child random effects.

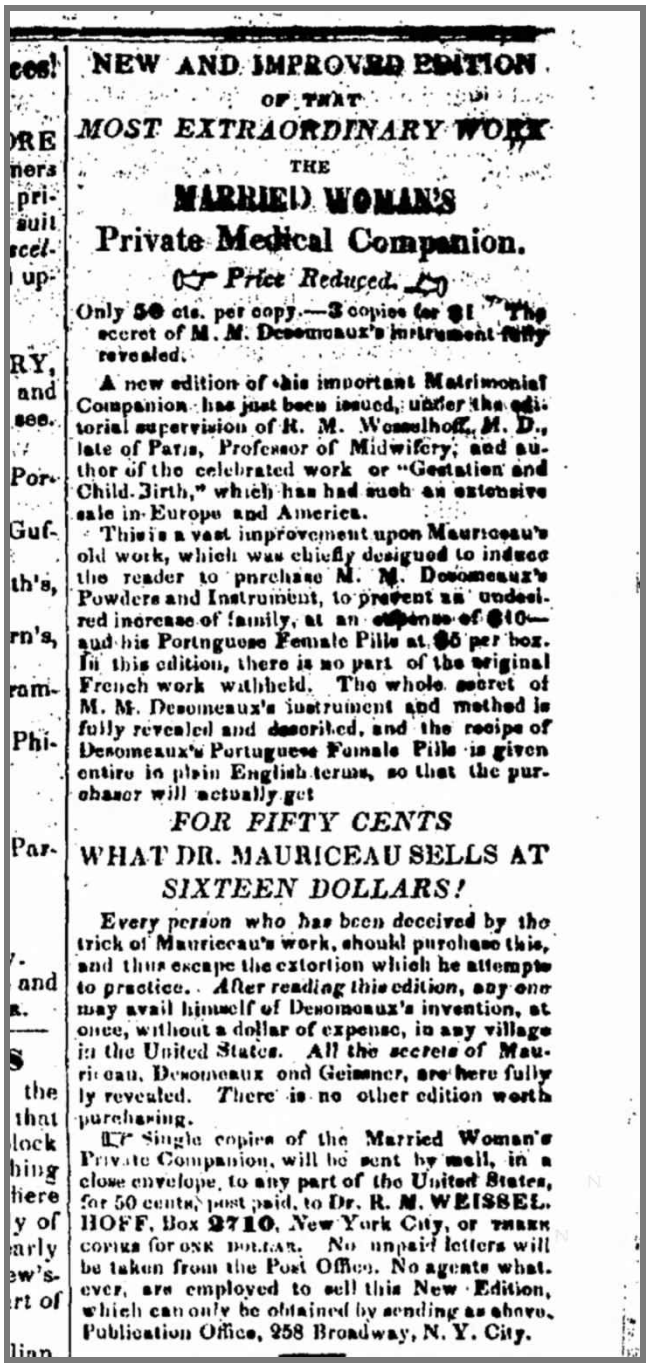
*$P < .10$.

†$P < .05$.

‡Not available; model would not converge.

EXHIBIT R

Wisconsin Express (Madison, Wisconsin) · Tue, Jan 9, 1849 · Page 4



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THE
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WHAT DR. MAURICEAU SELLS AT
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Every person who has been deceived by the trick of Mauriceau's work, should purchase this, and thus escape the extortion which he attempts to practice. *After reading this edition, any one* may avail himself of Desomeaux's invention, at once, without a dollar of expense, in any village in the United States. *All the secrets of Mauriceau, Desomeaux and Geissner, are here fully* ly revealed. *There is no other edition worth* purchasing.

☞ Single copies of the Married Woman's Private Companion, will be sent by mail, in a close envelope, to any part of the United States, for 50 cents, post paid, to Dr. R. M. WEISSELHOFF, Box 2710, New York City, or THREE copies for ONE DOLLAR. No unpaid letters will be taken from the Post Office. No agents whatever, are employed to sell this New Edition, which can only be obtained by sending as above. Publication Office, 258 Broadway, N. Y. City.

EXHIBIT S

The Wisconsin Standard (Lake Geneva, Wisconsin) · Sat, Jul 7, 1849 · Page 4

executed with dispatch. jy22 A. W. HATCH & CO.

S. JOHNSON, Wholesale and Retail

dealer in DRUGS, MEDICINDS, PAINTS, OILS, DYE STUFS, GLASS, PUTTY, SASH; also dealer in *School Books, Sttaionery, Blank Books, Fancy Articles, &c.*— Racine Wn.

S. JOHNSON now offers for sale a large and well selected stock of drugs, medicines, paints, oils varnishes, glass, putty, patent and Thomsonian medicines, fresh herbs and extracts, chemicals, etc.

S. JOHNSON is agent for the following popular medicines:

Osgoods Indian Cholagogue	McAlister's all healing salve
Wistars balsam wild cherry	Moffatt's Olasaonian
Folger's Olasaonian	" phœnix bitters
Buchan's Hung'n balsam	Branderth's Pills
Fish's lilly syrup	Lee's do
Jayne's hair tonic	Hooper's female pills
" expectorant	Resurrection do
Wyncoops tonic mixture	Hastings' do
Fahenstock's vermlfuge	Hibbard's do
Indian tonic	Sugar coated do
Bristol's sarsaparilla,	Indian vegetable do
Sand's "	Sherman's lozenges
Comstock's "	Jew David's plaster
Eagans' "	Edson's tonic mixture,
Rowed's tonic mixture	Moor's essence life
Thompson's eye water	Phiney's pills

PAINTS AND OILS.

Pure ground lead in oil	Linseed oil
No 1 " "	Lamp "
Pure dry lead	Sperm "
No 1 " "	Tanner "
Venetian red	Sweet "
Spanish brown	Castor "
Yellow ochre,	Spirits turpentine
Chrome yellow	Gold bronze
American vermillion	" leaf
Chinese "	Umber
Chrome green	Kera de sieni
Red lead	Blue, bl'k green smalts
Litherage	White vitrial
Sugar lead	Prussian blue
Lamp black	Putty
Verdigres	Pomice stone

Also a large quantity of window glass of all sizes, from 7 by 9 to 12 by 20. Sash of all sizes, etc., for sale by

jy22 1y S. JOHNSON.

BRUSHES.—Paint Brushes, all sizes.

EXHIBIT T

THE COMPOSITION OF CERTAIN SECRET REMEDIES.*

VIII.—"FEMALE MEDICINES."

NONE of the groups of proprietary medicines which we have hitherto dealt with in this series of reports contains anything like so large a number as the present. These preparations are put forward ostensibly for the relief and cure of painful or deficient menstruation, but in the majority of instances more or less obvious hints are given that they will be of service in averting unwelcome pregnancy, and it is impossible to doubt that they are very largely taken with this object. Certain of them, including some two or three of those dealt with below, appear to be advertised and recommended in a way which is no more objectionable than the advertisements of any other nostrums, but these are the exception, as we shall show. The media selected for advertising most of these articles, and the character of the advertisements in the same paper, are a sufficient indication of what it is desired to convey by the advertisements without using words that might lead to the interference of the police. On one page of the advertisement portion of a weekly "comic" paper before us, six of these preparations figure interspersed among seven advertisements of "surgical rubber goods," eight advertisements of photographs delicately hinted to be of the pornographic variety, together with treatises on "Manhood! How lost, how regained"; "Words of wisdom for our wives" (advertised by a rubber company); "The Malthusian" (advertised by a firm of "surgical instrument and appliance makers"), and other announcements scarcely to be found in respectable publications.

In the majority of cases, when the medicine advertised is supplied, it is accompanied by a circular recommending some "special" or "extra strong" form for obstinate cases, a higher price being charged for these "extra strong" medicines. Sometimes three or even four grades are supplied at ascending prices; several of these special forms are described below.

Many of the nostrums here reported on are pills, and in almost every case they contain one or more drugs or galenical preparations of a complex and variable nature, which it is not possible therefore to determine quantitatively with accuracy. In one or two cases also an ingredient occurs which it has not been possible to identify satisfactorily, and seeing that the makers of these articles can draw at pleasure on the animal, vegetable, and mineral kingdoms, this need be no matter for surprise. It is desirable, therefore, to repeat the caution which was expressed in an earlier article, that the formulae given must be taken in many cases as approximations only.

TOWLE'S PENNYROYAL AND STEEL PILLS.

Prepared by E. T. Towle and Co., Ltd., 66, Long Row, Nottingham. Price 1s. 1½d. per box, containing twenty-six pills.

The following extract is taken from a circular enclosed with the box:

The irregularities and obstructions to which so many ladies are subject, and from which they suffer great inconvenience, calls for a reliable remedy that would correct the system and assist nature in her work. Towle's Pennyroyal and Steel Pills have proved invaluable to thousands of women the wide world over, for upwards of 80 years. They are looked upon as a necessity to the proper fulfilment of a woman's duties. After suffering from various distressing complaints, and regaining strength, healthfulness, and brightness of spirits, she gladly admits that Towle's Pills are blessings in disguise. For the prevention and removal of Sick Headache, Whites, Eruptions, and Sallowness of the Skin, Depression of Spirits, Languor, Lassitude, Hysteria, and kindred complaints, they are particularly recommended.

The directions are "2 to be taken 3 times a day."

The pills were coated with French chalk and sugar; after removal of the coating the average weight was slightly over 2 grains. Enough oil of pennyroyal was present to give a not very marked odour of the drug, and estimation of the quantity showed about 0.02 grain in each pill; iron sulphate was present, in amount corresponding to 6.7 per cent. of the official exsiccated salt. About 43 per cent. of the pill consisted of powdered capsicum, and no other active ingredient was found, the remainder being excipient and moisture. The formula is thus, approximately:

Dried sulphate of iron...	14 grains
Powdered capsicum	86 ,,
Oil of pennyroyal	3 minims
Excipient	q.s.
In 100 pills.	

Estimated cost of the drugs, for twenty-six pills, one-eighth of a penny.

Two other circulars were enclosed with the pills, one being an advertisement of

Towle's Extra Strong Pennyroyal and Steel Pills. Specially prepared for obstinate cases. To be obtained direct from the sole proprietors only,

the smallest box of these being 4s. 6d. The other circular gives a list of specialities prepared by E. T. Towle and Co., Ltd., and includes Towle's Soluble Quinine Pessaries, "The wife's friend," double strength; Towle's Antiseptic Tablets, for syringing, etc., with other articles. A further note states:

All kinds of surgical appliances and rubber goods kept in stock.

DR. JOHN HOOPER'S FEMALE PILLS.

These pills are stated to be prepared under letters patent granted to Dr. John Hooper in 1743; neither on the label of the box nor on the circular in which it is wrapped is the name of the person or firm now preparing them given. An additional slip or coupon is enclosed, however, promising cash prizes to the persons sending in the largest numbers of such coupons, and this is headed "Dr. John Hooper's Female Pills Co., Ltd.," while the coupons are directed to be sent to Messrs. May, Roberts and Co., 9, Clerkenwell Road, London, E.C. Price 1s. 1½d. per box containing forty-one pills.

The uses of the pills are set forth in a paragraph from which the following extracts are taken:

These pills, by long experience in private Practice, have been found the most useful Remedy against those general Complaints the Female Sex are subject to. . . . They are the best Medicine ever discovered for Young Women of a pale, sallow Complexion, or when bilious, or afflicted with that what is commonly called Chlorosis, or Green Sickness, which two or three Boxes seldom fail of curing. They are also excellent for Palpitation of the Heart, Giddiness, Loathing of Food, bad Digestion, Pains of the Stomach, Beating of the Arteries of the Neck, Short Breath upon every little Motion, Sinking of the Spirits, a dejected Countenance, and Dislike to Exercise and Conversation. For all which Disorders they are a most excellent and successful Remedy, and are to be given from seven years old and upwards. They are also equally proper for Married Women, and ought always to be taken one month after Delivery; for they cleanse the Body, and purge off those gross Humours which, when retained, generate numerous Diseases, and render Women unhealthy all their lives. They should also be taken by Women at that period which is usually called "The Turn of Life," to prevent those Complaints which often attend them at that time.

Directions for their Use.—Take Two or Three Pills every other Night going to Bed, from Ten years old to Fifteen, and those above that Age are to take Three or Four after the same manner.

Examination of the letters patent granted in 1743 showed that a patent for pills was taken out in that year by a Dr. John Hooper; in those days, however, so-called "specifications" appear to have been accepted which specified practically nothing, and no hint is given as to the composition of the pills, except that they are composed of "the best purging stomatick and antihysterical ingredients." The results of examination of the pills showed them to have an average weight of 1.2 grains, and to contain sulphate of iron (equivalent to 8.4 per cent. of the exsiccated salt), aloes, powdered senna, jalap, and canella bark, with a trace of oil of pennyroyal. A similar pill is given by the following formula:

Dried sulphate of iron...	10 grains
Powdered senna...	48 ,,
Powdered canella	27 ,,
Powdered jalap	17 ,,
Aloes	13 ,,
Oil of pennyroyal	2 drops
Excipient	q.s.
In 100 pills.	

Estimated cost of the drugs, for forty-one pills, one-fifth of a penny.

* Previous articles of this series were published in the following issues of the BRITISH MEDICAL JOURNAL: 1904, vol. ii, p. 1585; 1906, vol. ii, pp. 27, 1645; 1907, vol. i, p. 213; vol. ii, pp. 24, 150, 209, 393, 530.

KEARSLEY'S ORIGINAL WIDOW WELCH'S FEMALE PILLS.

Prepared by C. and G. Kearsley, 42, Waterloo Road, London, S.E. Price 1s. 1½d. per box containing twenty pills.

In a circular enclosed with the box the pills are described as

A medicine known for OVER A CENTURY as a certain remedy for removing those obstructions to which Young Women are so frequently subject at puberty, and in regulating that function so important to female health up to a certain period of life, and which is apt to become deranged from such various and slight causes.

Then follows a paragraph devoted to

The most prominent symptoms of disturbed health from the derangement of this function.

The circular continues:

These Pills contain neither Pennyroyal nor other deleterious or irritating drug, and they may therefore be taken with PERFECT SAFETY by all; they act on the system and general health, and are EQUALLY EFFICACIOUS in treating the ABSENCE, EXCESS, or IRREGULARITY, as well as every other variety of derangement to which this function is liable.

Directions. Begin with three Pills on going to bed; afterwards four, and continue that number every night till the cure be accomplished.

The pills had an average weight of 3.8 grains, and were found to contain sulphate of iron (equal to 29 per cent. of the exsiccated salt), sulphur (2.7 per cent.), with powdered liquorice, powdered turmeric, maize starch, and excipient. The vegetable powders were estimated to be present in the amounts given in the following formula:

Dried sulphate of iron	120 grains
Precipitated sulphur	12 ,,
Powdered liquorice	65 ,,
Powderic turmeric	34 ,,
Excipient	q.s.
In 100 pills.	

Estimated cost of drugs, for twenty pills, one-twentieth of a penny.

DR. DAVIS'S FAMOUS FEMALE PILLS.

An address, but no maker's name, is given on the label; in the enclosed circular also no maker's name is given, but it is stated that the pills can be obtained from chemists and patent medicine vendors or from the proprietor, 309, Portobello Road, Notting Hill, W. The following also appears:

Dr. Davis's Famous Female Remedies have been established for over twenty-five years, and warn the public that this Establishment is not connected with any other firm, and have no other address than 309, Portobello Road, Notting Hill, London, W.

A second circular enclosed, quoted below, manifests an even greater reluctance on the part of the manufacturer to declare his identity. In this connexion it is pertinent to recall that in 1901 Henry Davis, of 309, Portobello Road, Notting Hill, was prosecuted for illegally representing himself as a qualified medical practitioner, and was fined after some severe comments from the court.[1]

The price of the pills is 1s. 1½d. per box, containing twenty-three. In the circular already quoted from, it is stated that:

Dr. Davis's Famous Female Pills have been known and acknowledged as a boon to womankind for over Twenty-five Years, they are largely recommended by Medical men as an excellent and an effective remedy for Anaemia, Giddiness, Fullness and Swelling after Meals, Loss of Appetite, Palpitation of the Heart, Debility, Depression, Weakness, Irregularity, and all Female Ailments.

The pills were found to be coated with French chalk; after removal of the coating the average weight was 2.7 grains. Examination showed the presence of sulphate of iron (equal to 16 per cent. of exsiccated salt) powdered savin (about 57 per cent.), and a bitter substance; it was not possible to determine whether a bitter extract, such as extract of gentian, had been used as excipient, or whether a small quantity of extract of colocynth was contained in the pill. If the latter, the formula is approximately

Dried sulphate of iron	46 grains.
Powdered savin	154 ,,
Extract of colocynth...	3 ,,
Excipient	q.s.
In 100 pills.	

Estimated cost of drugs, in twenty-three pills, one-sixth of a penny.

[1] BRITISH MEDICAL JOURNAL, February 23rd, 1901, p. 476.

The circular already quoted gives prices of (among other things) Dr. Davis's Quinine Safety Cones and Dr. Davis's Compound Quinine Injection; also advice to every one whose income is small to read "Dr. Davis's Little Book for Married Ladies."

A second circular also enclosed not only does not give the name and address of the maker of the pills, but carefully avoids naming even the pills. The entire circular reads as follows:

THE MOST RELIABLE REMEDY KNOWN. For more than twenty-five years Thousands of Ladies have derived successful benefit from these Pills. PREVENTION is the most important question of the day, to every one whose income is limited. These pills are absolutely the most effective preventative that can be used, no other remedy can approach them, and no other medicine can produce such rapid results. The most obstinate and long-standing cases of Irregularities, Suppressions, and Obstructions incident to the female constitution gives way before this unique treatment. Extra Strong, 11s. and 22s. These Pills will not injure the most delicate constitution.

Another specimen of this circular gives the prices as "Extra Strong, 11s., Special Strength, 22s."

DR. DAVIS'S FAMOUS FEMALE MIXTURE.

This is described on the label as "Prepared by the Proprietor at 309, Portobello Rd., Notting Hill." The same circulars are enclosed as with the pills just described. Price 2s. 9d. per bottle, containing two fluid ounces.

Directions—One Teaspoonful to be taken Four Times a Day.

The principal ingredient found was oil of pennyroyal, of which about 0.8 per cent. was present, with 9 per cent. of alcohol (by volume), and about 4 per cent. of glycerine. The mixture also contained 0.8 per cent. of undissolved substance; this contained a trace of magnesia (no doubt employed in mixing in the oil of pennyroyal); the insoluble and dissolved substances gave evidence of the presence of extract of gossypium, but as this contains no definite active principle, and there is no standard method for preparing it, the quantity could not be determined. The whole of the drug extractive present did not appear to be derived from gossypium, but the other ingredient could not be identified with any ordinary drug, after comparison with a considerable number. A trace of some alkaloidal substance (under 0.01 per cent.) was also present.

JEFFERSON DODD'S CORRECTIVE.

Prepared by Jefferson Dodd, for Jefferson Dodd, Ltd., 34, James Street, Oxford Street, London, W. Price 2s. 9d. per bottle, containing 4 fluid ounces.

The following extracts are from a circular enclosed with the bottle:

Dodd's Female Remedies are recognized by the most eminent Medical Authorities in London on Diseases of Women as being the safest and most beneficial Medicines that science, skill, and long years of practice have been able to discover for the cure and relief of complaints peculiar to the Female Sex.

This MIXTURE is specially recommended to be taken with or without the FEMALE PILLS. It gives most prompt relief in all cases.

Directions.—Two teaspoonfuls to be taken three or four times a day, with one or more of Dodd's Female Pills, night and morning, until relief is effected.

Examination of the mixture showed the presence of the constituents of decoction of aloes, except saffron, together with a small quantity of chloroform; the alcohol, however, only amounted to 5.3 per cent. (by volume). A "concentrated decoction of aloes, without saffron," is largely sold as a cheaper substitute for the official preparation; the latter, however, whether with or without the saffron, cannot properly be prepared of the concentration commonly employed (1 = 4) on account of the amount of tincture of cardamoms, and the alcohol is therefore diminished in the concentrated preparation, and may consequently vary in the preparations of different makers. The following formula:

Concentrated decoction of aloes without saffron (1 to 3), 1 part;
Chloroform water, 2 parts;
Water to 8 parts (all by measure),

gave a mixture agreeing in all respects, except the amount of alcohol present, with the one under examination.

Estimated cost of ingredients of 4 ounces, nine-tenths of a penny.

JEFFERSON DODD'S FEMALE PILLS.

Price 1s. 1½d. per box, containing thirty-six.

In the same circular as has been quoted above these are referred to as follows:

Dodd's female pills . . . are the safest and most effectual pills for all ailments peculiar to women. In cases of Hysteria, Anaemia, Loss of Appetite, Sallow Complexion, Pains in the Limbs, Nervousness, Headache, Neuralgia, Faintness, Palpitation, Depressed Spirits, Cold Feelings, Fatigue, Functional Amenorrhoea, and all Nervous Affections they are most beneficial.

Directions.—One or two pills night and morning, or one three times a day.

The pills were found to be coated with French chalk, and after removal of the coating had an average weight of 3.4 grains. Analysis showed sulphate of iron to be present (equal to 8.9 per cent. of exsiccated salt), with aloes and powdered liquorice, the remainder being excipient and moisture. The following formula gave a similar pill:

Dried sulphate of iron	34 grains
Powdered liquorice	72 ,,
Barbadoes aloes	142 ,,
Excipient	q.s.

In 100 pills.

Estimated cost of drugs for thirty-six pills, one-sixth of a penny.

MARTIN'S APIOL AND STEEL PILLS.

Proprietor, William Martin, High Street, Southampton. Price 4s. 6d. per bottle, containing forty-nine pills.

The directions on the label are as follows:

One or two night and morning, a few days before the period is due, or if passed, take for three or four days, then discontinue and commence taking a few days before the next period. Ten to twenty drops of the special essence of pennyroyal may be taken each night at bedtime in a little warm gin and water during the time the pills are being taken.

The pills were coated with French chalk, coloured pink with eosin; after removal of the coating the average weight was 3.8 grains. Iron was found to be present in the metallic state to the extent of 2 per cent.; powdered cinnamon, powdered cardamom, and aloes were also found, and about 3 per cent. of apiol; estimation of the amounts of the drugs and comparison with pill-masses prepared for the purpose indicated the following formula:

Reduced iron	10 grains
Barbadoes aloes	150 ,,
Apiol	12 ,,
Powdered cinnamon	75 ,,
Powdered cardamom	55 ,,
Excipient	qs.

In 100 pills.

Estimated cost of ingredients, for forty-nine pills, three farthings. Enclosed with the pills is a circular, which refers first to the "Special Essence of Pennyroyal" mentioned in the directions, and continues:

If the Pills are not sufficiently strong, the strongest preparation sold is Fournier's Hygienique Mixture. Price eleven shillings post free. Take a few days before the periods are due. A long walk or a good cycle ride also helps nature.

At the foot of the circular appears "Proprietor—William Martin, Pharmaceutical Chemist, opposite General Post Office, Southampton."

FOURNIER'S HYGENIQUE MIXTURE FOR FEMALES (EXTRA STRONG).

Price 11s. 0d. per bottle holding twenty fluid ounces.

The mixture was obtained from W. Martin, as above, but the name on the label is "Fournier et Cie., London, Paris and New York."

"Dose: Two tablespoonfuls to be taken three times a day half an hour after meals."

Examination showed the mixture to consist of compound decoction of aloes, with the addition of a very small quantity of iron; the amount of the latter corresponded to 0.45 per cent. of the crystalline ferrous sulphate, or two grains in a dose. A further difference between this mixture and the official decoction of aloes was that this only contained 3.9 per cent. of alcohol, against 18 per cent. in the preparation of the *Pharmacopoeia*.

Estimated cost of ingredients for twenty fluid ounces, 1s. 1d.

DUMAS'S PARIS PILLS.

Supplied by Adeline Dumas, 217, Graham Road, London, N.E.

These pills are advertised in the following terms:

"To Married Ladies.
Try the French Remedy.
Not a Dangerous Drug, but a wonderful Secret Invention.
Never Fails. Particulars Free to all Applicants.
Address,
M.D., 217, Graham Road, London, N.E."

"M.D." may, of course, stand for Madame Dumas, but it can hardly be doubted that it is intended to suggest that the "secret invention" is supplied by a Doctor of Medicine.

In a circular referring to the pills and giving testimonials, etc., they are described as follows:

"Dumas' Paris Pills.
The Combination Remedy (Protected).

WHAT IS MEANT BY A COMBINATION REMEDY?

Dumas's Combination Remedy, The Paris Pill (Pilule de Paris) is in reality a carefully selected combination of the most powerful drugs known to Medical and Botanical Sciences, whereby a maximum certainty of producing the desired effect is absolutely assured, the explanation of this remarkable result being as follows: If any specific drug contained in the Paris Pill be not actively suitable for a particular female organization, there are other active ingredients present, which, from their varied and searching nature, are in every way calculated to at once grapple with and overcome the most obstinate case. In the face, therefore, of such a remedy as here described, it can be well understood that there need be no fear of a failure of effect.

Dumas's Paris Pills, secret, and powerful ingredients (protected by Government stamp) act with instant certainty, in all cases of Irregularities and Suppression of the Menses, incidental to females.

"Dumas's Paris Pills are sold at 4s. 6d. per box. Special and Extra Strong, 11s. per box."

Another pamphlet from the same source is—

"The Pocket Price List of Appliances (Hygienic and Surgical) to be obtained at Dumas's Laboratory and Dépôt, 217, Graham Road, London, N.E." This gives particulars of the following articles, among others: "Soluble Pessaries," "Preventive Sponge," "The 'Special' Malthus Sheath," "Dumas' Preventive Powders," and "Dumas' French Remedy (known as the 'anti-geniture,'—protected) a wonderful secret invention, for use by married ladies, for the prevention of conception."

The box of pills examined was obtained by post from the address given. It bore no name on the package or label, the entire wording of the latter being as follows:

Not to be taken in cases of pregnancy. Caution. One pill only to be taken night and morning. Alcoholic stimulants should be discontinued whilst taking the Pills.

The box contained forty-six pills; these were coated with French chalk, and after removal of the coating had an average weight of 2.9 grains. Examination showed the presence of sulphate of iron, aloes, canella, liquorice, jalap, ginger, wheat-flour, and a trace of oil of pennyroyal. Estimation of the amounts of these ingredients indicated the following formula:

Dried sulphate of iron...	38 grains
Powdered canella	22 ,,
Powdered liquorice	22 ,,
Powdered jalap	12 ,,
Powdered ginger	6 ,,
Barbadoes aloes	46 ,,
Flour	12 ,,
Oil of pennyroyal	2 minims
Excipient	q.s.

In 100 pills.

Estimated cost of ingredients for forty-six pills, one-fifth of a penny.

MONAID TABLETS.

Prepared by C. I. Hood and Co., Lowell, Mass., U.S.A., and 34, Snow Hill, London, E.C.

Price 2s. 9d. per box containing fifty-nine tablets.

The following extracts are taken from a circular enclosed with the box:

MONAID TABLETS.

An agreeable, convenient, and absolutely safe specific for Painful Menstruation. Knowing that women and girls generally—especially tired and worn-out mothers, girls in mills, shops, stores, and offices, girls in school and at college—suffer during the menstrual period—some of them so intensely that the monthly process is an ordeal—and also knowing that we had a remedy that would give immediate relief without producing any ill effect whatsoever, we felt it our bounden duty to make this remedy known in every city, town, village, and hamlet throughout the length and breadth of our land.

This we are now undertaking to do, not by the ordinary advertising methods, but by such methods as seem to us to be the least open to criticism in point of delicacy.

Monaid Tablets are composed of warming, soothing, comforting remedies, and do not contain a particle of opium or any of its derivatives, or any other narcotic whatsoever.

The directions are given as follows:

Dose: Four tablets with a draught of water, repeat every half hour until the pain is relieved. Generally speaking the first dose relieves, but a cup of hot water adds materially to the effect of the Tablets and should be taken with the second dose.

The tablets are described as "chocolate coated;" in reality they were coated with sugar coloured to a chocolate-brown with iron oxide. After removal of the coating, the average weight of one was 2.2 grains. They contained neither iron, aloes, pennyroyal, or any powdered vegetable drug, and no alkaloid. Oleo-resin of capsicum was present to a rather considerable extent, and almost the whole of the remaining material of the tablets consisted of a substance agreeing in all respects with caulophyllin; the two were compared by various tests, but as there are no definite reactions for caulophyllin, and it possesses no characteristic smell, taste, etc., it cannot be quite positively asserted that this was the substance present. Enough oil of caraway was present to give a slight odour, and small quantities of flour and kaolin; there was some indication of another substance, but nothing further could be identified.

Nurse Powell's Remedies.

Supplied by the Powell Remedy Co., Replingham Road, Wandsworth, London, S.W.

These are advertised in the following terms:

Free Offer to Ladies.

Our recent offer of a Free Sample of Nurse Powell's Popular Pellets met with such striking success that we have decided to repeat the offer. Ladies should write for free box, enclosing stamp for postage. Delay is dangerous; write at once and obtain relief.—Nurse F. Powell Remedy Co., Replingham Road, Wandsworth, London.

An application for a free box as advertised brought a small box containing three white-coated pills, together with a letter, from which the following extracts are taken:

Owing to their proved superiority they have now come to be looked upon as The Leading Woman's Medicine—a proof of which is that in thousands of homes to-day a box is *always* to be found, ready for any emergency which may arise. They are composed of ingredients which are Perfectly Harmless, and will not injure the most delicate constitution, nor disturb one's usual occupations, yet they Fully Carry Out All that is claimed for them. We shall be glad if you will try this sample at once, and let us know the result. In many cases this small quantity has brought about relief and health. We would ask you Not to Expect Too Much from it, however, but to obtain more and take them regularly Each Day until you obtain a beneficial result. They have cured thousands of suffering women who have been on the verge of despair, and we are confident that if you will only persevere with them, and give them a thorough trial They Will Relieve You.

The pills were stated to be 1s. 1½d. per box, and this amount was sent with a request for a box. This brought a box containing twenty-four white-coated pills, bearing on the label the words "Nurse Powell's Popular Pellets cure Anaemia, Debility, Constipation, Headache, and all Female Ailments"; the words "Poplets, Registered," were printed across the label in red ink. A circular was enclosed on which it was stated—

It should be particularly noted that the pellets are prepared in Two Forms to meet the requirements of the case. The Ordinary Pellets (Price 1s. 1½d. and 2s. 9d.) are prepared as a remedy for Nervousness, Headache, Constipation, Anaemia, Debility, Sleeplessness, Hysteria, Lack of Energy, Wind, Biliousness, Indigestion, Sick Headache, and a general run-down state of the system, and Menstrual Troubles of a slight nature. The Special Pellets (Price 4s. 6d. per box) are expressly compounded for use in all Severe Menstrual Troubles, and should be ordered for Suppression of the Menses, Irregular and Painful Menstruation, Painful Urination, Change of Life, Dragging or Bearing Down Pains, Leucorrhoea (whites), Excessive Flow of the Menses, and all kindred ailments

A box of the "special pellets" was therefore obtained; these were compressed tablets with a bright purple coating, and were labelled "Nurse Powell's Popular Pellets for all Female Ailments (Special)," and also bore the words "Poplets, Registered," in red ink across the label.

Another circular was now enclosed, from which the following extracts are taken:

Special notice!

There are many cases of female irregularities which require special treatment, and which cannot be met by the remedies which cure more ordinary ailments. This fact is well known to the Physician who has made a special study of the female system, and has his own special prescriptions which he applies to the various stages of the ailments as occasion demands.

Whilst it is quite true that Nurse Powell's Popular Pellets cure all but the more obstinate cases, we find it occasionally necessary that a stronger treatment is required. For this purpose, we supply two preparations prepared from the prescriptions of a celebrated physician, and which he relied upon to cure where every other means had been unavailing. These remedies are prepared in the form of a pill and a mixture, either of which will be found effective, but in order to obtain the very best results, by far the best method is to take the pills and mixture in alternate doses.

These exceedingly valuable preparations we recommend with the utmost confidence. They are prepared by fully qualified chemists from the purest ingredients obtainable, and most beneficial results are obtained after a few doses.

The price of these remedies is necessarily higher than the ordinary preparations, but compared with the results the cost is small.

Prices { Corrective Pills, 11s. per box;
Corrective Mixture, 13s. per bot.;
or the two preparations, 21s.

Supplies of both these were obtained.

In a little book sent with the earlier supply, entitled *Woman's Home Doctor*, appears the following:

Advice to Sufferers Free.

Many women are in doubt as to the nature of their ailment and the best means to obtain a cure. To all such, we offer our Experienced Advice Free if full particulars are given to us in a letter. If Nurse Powell's Popular Pellets will be of no use in your particular case you will be at once told so. Address all letters asking for advice to the Manageress, and mark them "Private" in the top left hand corner. They will then receive immediate attention and will be treated in the strictest confidence.

In sending for each of these preparations nothing was said with regard to the case for which they were supposed to be intended, but after a short interval a typed letter was received, from which the following extracts are taken:

Dear Madam,—In reply to your communication of a few days ago, we looked carefully into your case, and advised you to persevere with our remedy. It seemed to us that your ailment was similar in almost all respects to many other cases which we have had, and in practically all of these the treatment we advise has been taken with entire success, as the grateful letters we have received plainly show. . . . . With all good wishes, and again assuring you of our sympathy and aid, we remain, dear Madam, yours faithfully, The Nurse Powell Remedy Co.

As the "ordinary" pellets turned out (*after* they were bought) to be chiefly intended for indigestion and constipation they were not analysed. The other three preparations were examined with the following results:

Nurse Powell's Popular Pellets (Special).

Price 4s. 6d. per box, containing forty-five tablets. The label gives no directions for taking, but one of the circulars includes the following:

For all menstrual troubles, suppression, obstruction, and irregularity. Take two to three Special Pellets three times daily after meals, according to the nature of the case. Bathe the feet in hot water each night until regular flow is established. Then follow by one Special Pellet night and morning for three days.

The tablets were coated with sugar, dyed externally to a bright purple; the average weight after removing the coating was 2.8 grains. Analysis showed the presence of sulphate of iron, aloes, canella, ginger, oil of pennyroyal, with starch and kaolin. Estimation of the various ingredients indicated the following formula:

Dried sulphate of iron	40 grains.
Socotrine aloes	67 ,,
Powdered canella	56 ,,
Powdered ginger	8 ,,
Oil of pennyroyal	12 minims.
Maize starch	16 grains.
Kaolin	50 ,,
Excipient	q.s.

In 100 tablets.

Estimated cost of ingredients of forty-five tablets, one halfpenny.

NURSE POWELL'S CORRECTIVE PILLS.

Price 11s. per box, containing forty-two pills.

The box bears no label, and the only indication of the identity of the article was a seal showing the initial "P" on the outer case.

Stamped on the lid of the box are the following directions: "Dose, 3—3 times daily after meals."

The pills were greyish-black, and proved to be coated with French chalk and graphite; after removal of the coating the average weight was 4.6 grains. Analysis showed the presence of sulphate of iron, aloes, oil of pennyroyal, jalap, starch, and powdered liquorice; another vegetable substance was present, which agreed in its histological characters with powdered olive stones, a material largely employed in adulterating the cheaper grades of powdered liquorice. Estimation of the various ingredients indicated the following formula:

Dried sulphate of iron	100 grains
Socotrine aloes	140 ,,
Powdered jalap...	14 ,,
Powdered liquorice (adulterated)...	80 ,,
Oil of pennyroyal	10 minims
Starch	10 grains
Excipient	q.s.

In 100 pills.

Estimated cost of ingredients for forty-two pills, one-third of a penny.

NURSE POWELL'S CORRECTIVE MIXTURE.

Price 13s. per bottle, containing eight fluid ounces.

Directions for use. Take two tablespoonfuls night and morning—after meals. Bathe the feet each night in hot water.

Examination of the liquid showed it to be of the nature of compound decoction of aloes, without saffron, with a trace of chloroform; it was, however, much darker than the official decoction of corresponding strength; no additional drug, however, could be detected, and by adding burnt sugar to the decoction made without saffron, a very similar liquid was obtained. Only 4.7 per cent. (by volume) of alcohol was present, instead of the 18 per cent. of the official decoction.

Estimated cost of ingredients of eight fluid ounces, 3d.

SANOL CONES.

This article is advertised in the following terms:

LADIES

Should send stamped addressed envelope for Full Particulars of a harmless and purely medicinal remedy for all ailments incidental to the sex. No Pills or Mixtures.

The Most Reliable Remedy ever discovered.

Address Mrs. Hilda D. Manners,
257, High Holborn, London, W.C.

Application by post to the address given brought a booklet entitled "Woman's Key to Health," and a multiple-type-written letter, from which it appeared that the remedy in question consisted of "Sanol Cones," or rectal suppositories. In the letter it is stated that—

They act like magic, and are TEN TIMES MORE EFFICACIOUS THAN ANY MEDICINE CAN POSSIBLY BE as they undergo no change by passing through the system as medicines have to do, but act direct in their full strength and activity. . . . "Sanol Cones" are packed in boxes price 4s. 6d., and "Special" Cones (strongly recommended) price 11s. each, and are sent entirely free from all observation with full directions and a special letter of advice.

The following extracts are from the "Woman's Key to Health":

Ninety-nine out of every hundred women are afflicted with some complaint in greater or lesser degree. It is to these that rectal treatment, as represented by Sanol Cones, so strongly appeals.

Some may naturally ask, is it a fact that remedies are absorbed rapidly when introduced into the rectum? To this we answer, unquestionably so! The skin, and the mucous membrane to a much greater degree, have the singular power of absorbing substances applied to them. . . .

Compare this simple treatment with ordinary medication, which usually consists of the introduction of powerful drugs into the stomach. These drugs have to undergo an elaborate preparation in the stomach; and not only do they corrode and weaken that organ, but they are themselves often neutralised by the various juices of the stomach and intestines, and so rendered inert and useless, hence remedies as exemplified by SANOL CONES used by the rectum are more rapidly absorbed in a purer and more active state into the circulation and do their work more effectually than stomach medicines can possibly do. . . . SANOL CONES are a certain, safe, and speedy Remedy for: Anaemia, Leucorrhoea, Change of Life, Hysteria, Female Weakness, Painful or Excessive Menstruation, General Debility, Depression of Spirits, Lassitude, Loss of Energy, Nervous Irritability, Suppression, and all Ailments Incidental to the Female System without taking Stomach Medicines.

A page in this booklet is devoted to "Pessaires Contraconceptifs," "or Improved Soluble Quinine Pessaries." Two boxes of cones were obtained, each one being accompanied by a letter, typed, like the first, by a multiple copy machine; the first gave directions as follows: "insert one cone up the rectum (which is the back passage leading to the bowels) three times daily," and urges the necessity of perseverance; the second recommends "sanol cascara tablets" if any inclination to constipation exists. After an interval a further letter was received, as follows:

Dear Madam,—I have been anxiously waiting to hear from you as to how the "Sanol Cones" I sent you some time ago have acted. I sincerely trust that in this case no news is good news, and that you have derived great benefit from their use.

As I think I told you before, some complaints are naturally much more difficult to cure than others, and require longer perseverance, but I honestly and truly do not believe they ever fail to benefit when used as directed and persevered with.

I assure you I should be the last to induce you to spend money unless I honestly thought and believed that the cones would benefit you; but if you are not yet cured I think it is only my duty to strongly urge you to persevere with the treatment, and if you hesitate to do so owing to the money being a consideration to you, I am willing to meet you as far as I possibly can; and will send you on a further supply of "Sanol Cones" at half the ordinary price, namely, either a 4s. 6d. box for 2s. 3d., or an 11s. box of the "Special" Cones for 5s. 6d.

I am offering you this very great reduction in price as I am most anxious that you should be restored to health as I am quite certain that you will be if you persevere steadily.

Do not be afraid of troubling me by writing me fully as to how the treatment has affected you, as I can assure you that I am quite as anxious to cure as you yourself are to be cured, and I take a special interest in your case.

Trusting soon to hear from you,
Yours truly, HILDA MANNERS.

A box of the "Special" Cones was also obtained, and both kinds were analysed.

SANOL CONES (ORDINARY). Price 4s. 6d. per box, containing sixteen cones. The "cones" were small suppositories rounded at one end and tapering towards the other; they were of an average weight of 13.2 grains. They contained sulphate of iron corresponding to 1.5 per cent. of the exsiccated salt, quinine corresponding to 6.6 per cent. of the ordinary sulphate, and about 2 per cent. of a vegetable powder, which proved to be gentian root; the remainder consisted of oil of theobroma. The formula is thus:

Dried sulphate of iron	22 grains
Sulphate of quinine	87 ,,
Powdered gentian	26 ,,
Cacao butter	1,200 ,,

In 100 cones.

Estimated cost of ingredients of sixteen cones, under three halfpence.

SANOL CONES (SPECIAL). Price 11s. per box, containing thirty-six cones. These were similar in size and shape to the preceding, but differed in being of a green colour. Analysis showed the presence of quinine sulphate, 5 5 per cent., and powdered gentian about 4 per cent.; the base was oil of theobroma. No other medicament could be detected; the green colouring matter was small in quantity and dissolved in the fat, a similar product being obtained by colouring cacao butter with commercial chlorophyll. The formula is thus:

Sulphate of quinine	72 grains
Powdered gentian	52 ,,
Cacao butter (tinted green)...	...1,200 ,,

In 100 cones.

Estimated cost of ingredients in thirty-six cones, 3d.

I.R.S. COMPOUND GOLDEN TABLETS.

Supplied by the I R.S. Company (also calling themselves the Irristum Company), 145 Stockwell Road. London, S.W.

Price 1s. 1½d. per box, containing twenty-four.

"Dose—One four times a day."

These are advertised in the following terms:

The I.R.S. Golden Compound Tablets are of priceless value to all ladies. They afford relief in every instance—frequently in a few hours. Coated with Gold, prepared with drugs worth their weight in Gold, they are far superior to

Bitter Apple, Steel, and Pennyroyal, etc., and all similar preparations.

A letter was sent with the pills, which ran as follows:

Dear Madam, I am sending Tablets as requested, with every confidence in their efficacy, and I have no doubt they will very soon relieve you of all your present uncomfortable feelings; we have many patients who NEVER require anything stronger. On the other hand there are ladies upon whom liquid medicine acts more promptly; we therefore beg to enclose you particulars of our "Irristum" in its liquid form, in case you require very speedy relief, or your constitution is a very stubborn one. Take these Tablets after Meals. Assuring you of my personal and immediate attention, I am, dear Madam, Faithfully yours, THE LADY MANAGER.

The "tablets" were ovoid pills, coated with French chalk, "gilded" on the surface; the "gilding" showed the composition of so-called gold paint, containing copper but no gold. After removal of the coating the average weight of the pills was 2 grains; analysis showed them to contain sulphate of iron equivalent to 48 per cent. of the exsiccated salt, and sodium carbonate, producing ferrous carbonate on addition of water; the other ingredients were starch, gum, and moisture. The amounts of ferrous sulphate and sodium carbonate were not properly adjusted for converting the whole of the former to ferrous carbonate, but the composition was variable. One specimen showed 48 per cent. of dried ferrous sulphate, one-fourth of which was converted to ferrous carbonate on treatment with water; another gave only 37 per cent. of dried ferrous sulphate, two-fifths of which formed ferrous carbonate. The formula is thus approximately:

Dried sulphate of iron	86 grains
Dried sodium carbonate	25 ,,
Excipient	q.s.
In 100 pills.	

Estimated cost of ingredients of twenty-four pills, one-fifteenth of a penny.

IRRISTUM.

The "particulars of our 'Irristum' in its liquid form," referred to in the letter quoted above, were in the form of a small book, from which the following extracts are taken:

The "Irristum" medicine is an ABSOLUTELY SAFE AND CERTAIN REMEDY FOR AMENORRHOEA, CHLOROSIS, DYSMENORRHOEA, LEUCORRHOEA, ANAEMIA, AND ALL IRREGULARITIES AND OBSTRUCTIONS EVEN OF THE MOST OBSTINATE AND STUBBORN CHARACTER, and unquestionably if one curse stands out prominently above all the other misfortunes of womankind, it is a disregard of the laws of health. The mind and the body—the mental and the physical—are so intimately and so wonderfully co-mingled in the human frame that it is impossible for the most self-denying and amiable woman to maintain that equanimity and sweetness of demeanour without which conjugal felicity is out of the question, if there exists a hidden or secret sorrow, or if the inscrutable laws of health are not fulfilling their proper functions. *Thousands upon thousands are daily suffering, and hour by hour anxiously enquiring how this great law of health is best to be regulated*, and this applies to women more than to men, in a proportion that can scarcely be approximated. . . .

"IRRISTUM" *is unquestionably one of the most priceless blessings of the nineteenth century.* . . .

"IRRISTUM" *never fails, that is the marvel of it.* On "Irristum" is stamped the seal of unequivocal success. To it women may turn with the *brightest confidence and hope*, assured of health and happiness, instead of that wretched depression of animal spirits, and possibly *life-long misery*, which accrue from a blind confidence in the *nostrums of unscrupulous quacks.* . . .

Nothing conceivable can be worse or more contemptible than for confiding and suffering women to be the dupes of plausible and unscrupulous adventurers. Not merely is it the pocket, but the paramount question of life-long health which may be imperilled; and here it is that the *never-failing efficacy, the privacy, the simplicity and the rapidity of action characteristic of the "Irristum" medicine, come as a challenge to the world in this most important branch of the healing art.* . . .

We do not profess to work wonderful miracles; we only state, with *absolute confidence*, that if *you*, who read this, feel the need of such a preparation, you will never do better than send to us *at once*. It would of course be untrue to say a second bottle is *never* required. It sometimes happens that a lady has to send for another supply, but in 19 cases out of 20 the *whole* of the second one is not required. . . .

It will be sent you by return, securely packed from observation, for 4s. 9d., including postage.

Extra strong (for immediate effect), 10s.; by post, 10s. 6d. This is specially recommended to ladies who desire speedy and certain relief, and is truly described as a "marvellous preparation."

The "extra strong" preparation was obtained for analysis. A letter which was sent with it promised some tablets free of charge with a second bottle, if more were required; but these tablets were not procured. The 10s. bottle of the medicine contained six and three-quarters ounces. On the label it is stated—

This medicine is purely an EMMENOGOGUE *(sic)*, of a powerful nature, and is a SAFE and CERTAIN REMEDY for anaemia and all female ailments. Contains no abortifacient properties.

A further label gives the dose as "one tablespoonful to be taken three times a day."

Analysis showed it to be an acid syrup of phosphate of iron with quinine; it also contained 5 per cent. by volume of alcohol, which may have been added in the form of a colouring tincture; the colouring matter appeared to be cudbear. Determination of the quantities of the various ingredients gave the following formula:

Quinine sulphate	9 grains.
Ferrous phosphate	10 ,,
Dilute phosphoric acid ...	6 fl. drachms.
Sugar	3 oz.
Rectified spirit	220 minims.
Cudbear	q.s
Water to	6.75 fl. oz.

Estimated cost of ingredients, twopence.

INFANTILE MORTALITY.

THE HUDDERSFIELD SCHEME.

THE principal object of the Huddersfield scheme for checking infantile mortality is to help the mother to nurse her infant herself in her own home. In order to do this the following plan is followed:

1. Notifications of birth reach the medical officer of health within forty-eight hours of the time of birth.
2. Two lady assistant medical officers of health visit the home, inquire, advise, and help.
3. The notifications are sent every Monday to voluntary workers—ladies who supervise, visit at intervals, and help in the homes.
4. If the baby does not thrive, and is not under medical care, the case is referred to the medical officer of health and appropriate action taken.

The official staff to carry out the above consists of the medical officer of health and two assistant medical officers of health, who are fully qualified and registered medical women. Nearly their whole time is given to the work in connexion with infant mortality, and the medical officer of health exercises a general direction and supervision of their proceedings. There is also a voluntary association called the Huddersfield and District Public Health Union. It is worked by upwards of 100 ladies. There is a close and intimate relation between the municipal and voluntary portions of the work.

By a special Act, which has been in operation since November 1st, 1906, the Corporation has power to require compulsory notification of births to the medical officer of health within forty-eight hours. The notifications within the time limit have been 94 per cent. of the total births. Immediately upon receipt of the notification one or other of the lady assistant medical officers of health proceeds to the address given and verifies it. If the case is one where help or advice is likely to be of use this visit affords the opportunity. Cards and leaflets of advice on the care of infants, very carefully thought out, are generally left. Wherever practicable breast feeding is urged, and if there is any difficulty in this respect help and advice are proffered. This first visit by the lady doctors is followed by repeated visits in all cases where the circumstances call for them. It is at this point that the utility of the Public Health Union comes into play. For the purpose of this association the borough is divided up into separate districts, corresponding as far as possible with the wards, but taking as a basis for a separate district the number of births; about 150 births per annum is the approximate number for one district. Over each of these districts is appointed a lady superintendent, and with her are associated a group of lady helpers, varying in number in proportion to the number of babies likely to be born; it is not reckoned that any one lady helper should have more than 15 to 20 babies on her list.

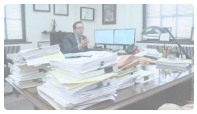
After the first visit of the assistant medical officer of health, the lists of babies are divided up into the districts

EXHIBIT U

NEWS > LOCAL NEWS

Sheboygan County D.A. says he'll prosecute providers accused of performing abortions in violation of state law

Sheboygan County's district attorney says he will prosecute abortion providers if there's probable cause an alleged abortion violates state law.

By: Ben Jordan

Posted at 5:23 PM, Jun 28, 2022 and last updated 2:45 PM, Jun 29, 2022

SHEBOYGAN, Wis. — Sheboygan County's district attorney says he will prosecute abortion providers if there's probable cause an alleged abortion violates state law.

Sheboygan County District Attorney Joel Urmanski says he prosecutes laws based on how they are written and he plans to do the same when it comes to the state's abortion laws.

Recent Stories from tmj4.com

Car crashes into Milwaukee day care; two injured including child

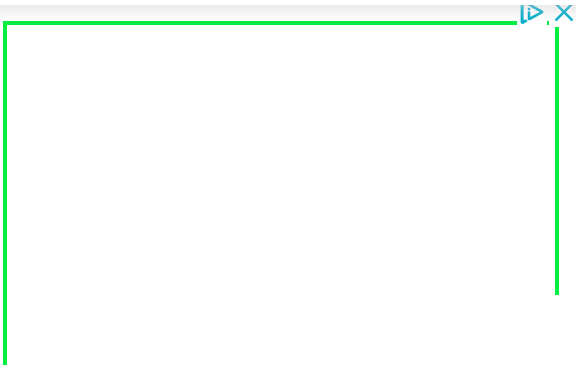
"If law enforcement forwards an investigation to us and there's a violation of law, we will prosecute it," he said. "Our job as prosecutors, in my opinion, is we're upholding the law. We're not legislators, we're not passing laws, we're not voting on laws, we're enforcing those laws. I'm not going to go out there and say, 'go ahead and commit this crime, do this, do that'. It's not how I feel about the law. It's not my intentions or thoughts about any particular law. We enforce that law. So if there's a violation here, we'll enforce it."

There are four abortion clinics in Wisconsin. One of them is a Planned Parenthood in Sheboygan. All four clinics halted abortion procedures last Friday after the U.S. Supreme Court struck down Roe v. Wade.

TMJ4

Now, a law established in 1849 is back in effect. It bans abortions unless it's deemed necessary to save the mother's life. The law states two other physicians would have to verify that's the case before legally proceeding.

"Do you think a law that sat dormant for 49 years and was enacted 173 years ago is the will of the people in 2022?" Reporter Ben Jordan asked. "If you look at the law itself, there has been legislative action on that law much more recent than that," D.A. Urmanski responded. "I think in 1985 there was some action that occurred with that statute and even afterwards. Regardless, take that aside. You're now seeing multiple states across the country that are enforcing or creating new laws dealing with abortion. So to suggest this is an old antiquated law and it's not the way that people see the law or how it should be followed or that it shouldn't be followed, that's just not accurate."



D.A. Urmanski says he’s unaware at this point if local law enforcement agencies in Sheboygan County will investigate alleged criminal violations of state abortion law.

"I don't have that answer, it's new,” he said. “I can tell you that I reached out to law enforcement in this county letting them know the decision that came about, sharing with them the abortion statute that we have on the books so our law enforcement is aware of it."

Sheboygan Co. District Attorney Joel Urmanski says he'll prosecute providers accused of performing abortions in violation of state law. 1 of 4 abortion clinics in Wisconsin is in Sheboygan. Full report airs tonight at 6 on @TMJ4.

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“What will you say to your assistant district attorneys who may have a different position on this?” TMJ4's Ben Jordan asked.

"I say that our job is to enforce the law and that's what we do,” D.A. Urmanski responded. “If I have a prosecutor that says morally or otherwise, they do not believe that they can handle a prosecution, then I, myself, or someone else in the office may have to step in and take that particular case."

Meanwhile in Milwaukee County, District Attorney John Chisholm has joined about 80 other prosecutors across the country in saying they will not criminally charge abortion providers who have been investigated and allegedly found in violation of state law. A day after the U.S. Supreme Court’s majority draft

"We have unbelievable demands being made on us right now to try to address the surge in violence, overdose deaths, reckless driving," D.A. Chisholm said. "They have already taxed law enforcement and court and prosecutorial and defense resources to the max. Now you're asking us to, again, insert what? Police officers are going to investigate doctors?"

Back in Sheboygan County, D.A. Urmanski acknowledged each county may function differently in the short term on this law. But he believes his position represents the will of the people in the county he was elected to serve.

"Can I say that we are a busy place and we need more prosecutors and we need more help? Yes, but to go out there and take a stance of, 'I'm not going to prosecute a certain crime'. That's not a position I'm going to take," D.A. Urmanski said.

You can read Wisconsin's 1849 law on abortion below or by clicking here.

(5) This section does not apply to a therapeutic abortion which:

(a) Is performed by a physician; and

(b) Is necessary, or is advised by 2 other physicians as necessary, to save the life of the mother; and

(c) Unless an emergency prevents, is performed in a licensed maternity hospital.

(6) In this section "unborn child" means a human being from the time of conception until it is born alive.

History: 2001 a. 109; 2011 a. 217.

Aborting a child against a father's wishes does not constitute intentional infliction of emotional distress. Przybyla v. Przybyla, 87 Wis. 2d 441, 275 N.W.2d 112 (Ct. App. 1978).

Sub. (2) (a) proscribes feticide. It does not apply to consensual abortions. It was not impliedly repealed by the adoption of s. 940.15 in response to *Roe v. Wade*. State v. Black, 188 Wis. 2d 639, 526 N.W.2d 132 (1994).

The common law "year-and-a-day rule" that no homicide is committed unless the victim dies within a year and a day after the injury is inflicted is abrogated, with prospective application only. State v. Picotte, 2003 WI 42, 261 Wis. 2d 249, 661 N.W.2d 381, 01-3063.

This section is cited as similar to a Texas statute that was held to violate the due process clause of the 14th amendment, which protects against state action the right to privacy, including a woman's qualified right to terminate her pregnancy. Roe v. Wade, 410 U.S. 113 (1973).

The state may prohibit first trimester abortions by nonphysicians. Connecticut v. Menillo, 423 U.S. 9 (1975).

The viability of an unborn child is discussed. Colautti v. Franklin, 439 U.S. 379 (1979).

Poverty is not a constitutionally suspect classification. Encouraging childbirth except in the most urgent circumstances is rationally related to the legitimate governmental objective of protecting potential life. Harris v. McRae, 448 U.S. 297 (1980).

Abortion issues are discussed. Akron v. Akron Center for Reproductive Health, 462 U.S. 416 (1983); Planned Parenthood Assn. v. Ashcroft, 462 U.S. 476 (1983); Simopoulas v. Virginia, 462 U.S. 506 (1983).

The essential holding of *Roe v. Wade* allowing abortion is upheld, but various state restrictions on abortion are permissible. Planned Parenthood v. Casey, 505 U.S. 833, 120 L. Ed. 2d 674 (1992).

Wisconsin's abortion statute, s. 940.04, Stats. 1969, is unconstitutional as applied to the abortion of an embryo that has not quickened. Babbitz v. McCann, 310 F. Supp. 293 (1970).

When U.S. supreme court decisions clearly made Wisconsin's antiabortion statute unenforceable, the issue in a physician's action for injunctive relief against enforcement became mooted, and it no longer presented a case or controversy over which the court could have jurisdiction. Larkin v. McCann, 368 F. Supp. 1352 (1974).

Wisconsin State Legislature

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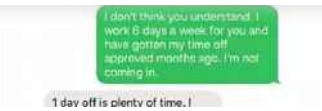

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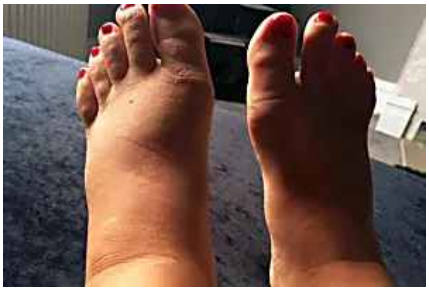

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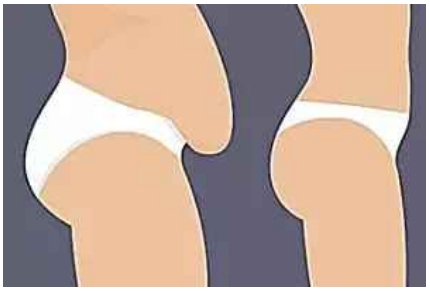

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EXHIBIT V

STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
BRANCH ___

JOSH KAUL, in his official capacity
as Attorney General,
Wisconsin Department of Justice
17 West Main Street
Madison, WI 53703

WISCONSIN DEPARTMENT OF
SAFETY AND PROFESSIONAL
SERVICES
4822 Madison Yards Way
Madison, WI 53705

WISCONSIN MEDICAL EXAMINING
BOARD
4822 Madison Yards Way
Madison, WI 53705

and

SHELDON A. WASSERMAN, M.D., in
his official capacity as Chairperson of
the Wisconsin Medical Examining Board
4822 Madison Yards Way
Madison, WI 53705

Plaintiffs,

v.

Case No. 2022-CV-
Declaratory Judgment: 30701

CHRIS KAPENGA, in his official capacity
as President of the Wisconsin Senate and
Co-Chair of the Joint Committee on
Legislative Organization
Wisconsin State Capitol, Room 220 South
Madison, WI 53702

DEVIN LEMAHIEU, in his official capacity as the Majority Leader of the Wisconsin Senate,
Wisconsin State Capitol, Room 211 South
Madison, WI 53702

and

ROBIN VOS, in his official capacity as the Speaker of the Wisconsin Assembly and Co-Chair of the Joint Committee on Legislative Organization
Wisconsin State Capitol, Room 217 West
Madison, WI 53702

Defendants.

SUMMONS

THE STATE OF WISCONSIN,

To each person named above as a Defendant:

You are hereby notified that the Plaintiffs named above have filed a lawsuit or other legal action against you. The Complaint, which is attached, states the nature and basis of the legal action.

Within 45 days of receiving this Summons, you must respond with a written answer, as that term is used in chapter 802 of the Wisconsin Statutes, to the Complaint. The Court may reject or disregard an answer that does not follow the requirements of the statutes. The answer must be sent or delivered to the Court, whose address is Dane County Clerk of Courts, Dane County

Courthouse, 215 South Hamilton St., Madison, Wisconsin 53703, and to Assistant Attorney General Hannah S. Jurss, Plaintiffs' attorney, whose address is Wisconsin Department of Justice, Special Litigation and Appeals Unit, 17 West Main Street, Post Office Box 7857, Madison, Wisconsin 53707-7857. You may have an attorney help or represent you.

If you do not provide a proper answer within 45 days, the Court may grant judgment against you for the award of money or other legal action requested in the Complaint, and you may lose your right to object to anything that is or may be incorrect in the Complaint. A judgment may be enforced as provided by law. A judgment awarding money may become a lien against any real estate you own now or in the future, and may also be enforced by garnishment or seizure of property.

Dated this 28th day of June 2022.

Respectfully submitted,

JOSHUA L. KAUL
Attorney General of Wisconsin

Electronically signed by:

Hannah S. Jurss
HANNAH S. JURSS
Assistant Attorney General
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STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
BRANCH ___

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4822 Madison Yards Way
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4822 Madison Yards Way
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SHELDON A. WASSERMAN, M.D., in
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Wisconsin State Capitol, Room 211 South
Madison, WI 53702

and

ROBIN VOS, in his official capacity as the Speaker of the Wisconsin Assembly and Co-Chair of the Joint Committee on Legislative Organization
Wisconsin State Capitol, Room 217 West
Madison, WI 53702

Defendants.

COMPLAINT

INTRODUCTION

The Wisconsin statutes contain two sets of criminal laws that directly conflict with each other if both are applied to abortion. In these circumstances, it is well settled that the older law cannot be enforced. Specifically, Wis. Stat. § 940.04—which originated in the mid-1800s, at a time when Wisconsin women did not even have the right to vote—has been superseded and cannot be enforced as applied to abortions.

Wisconsin Stat. § 940.04 states a very broad ban, without exceptions that are now widely accepted as appropriate and necessary. It provides that it is a criminal felony to destroy the life of an unborn child at any point after

conception unless necessary to save the pregnant woman's life. Nationally, these broad bans were rarely, and disparately, enforced historically and not enforced at all after the Supreme Court's decision in *Roe v. Wade*. Subsequently, the Wisconsin Legislature enacted different criminal laws applicable to abortion after the point of viability and with broader exceptions for the pregnant woman's health. In addition, the Legislature passed various other laws with specific parameters under which physicians may lawfully provide abortions after conception.

The pre-*Roe* and post-*Roe* Wisconsin laws thus directly conflict if both were applied to abortion. Either it is lawful to provide a pre-viability abortion, or it is not. Either it is lawful to provide an abortion to preserve the mother's health, or it is not. These are exactly the circumstances where courts hold that the older law may not be enforced—particularly when that law imposes criminal sanctions.

Wisconsin abortion providers cannot be held to two sets of diametrically opposed laws, and the Wisconsin people deserve clarity. This Court should hold that Wis. Stat. § 940.04 has been superseded and cannot be enforced as applied to abortions.

JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of this dispute pursuant to Wis. Const. art. VII, § 8, and Wis. Stat. § 753.03, which provide for subject-matter jurisdiction over all civil matters within this State.

2. Defendants, as state officers, are subject to this Court's jurisdiction. *See Lister v. Bd. of Regents of Univ. of Wis. Sys.*, 72 Wis. 2d 282, 303, 240 N.W.2d 610 (1976).

3. Venue is proper in Dane County because all defendants are state officers. Wis. Stat. § 801.50(3)(a).

PARTIES

4. Plaintiff Josh Kaul sues in his official capacity as the Wisconsin Attorney General, the elected constitutional officer under Wis. Const. art. VI, § 1, who directs the activities of the Wisconsin Department of Justice. *See* Wis. Stat. § 15.25. The Department of Justice consults with and advises agencies and officers in Wisconsin on the application and potential enforcement of Wisconsin's criminal laws. *See* Wis. Stat. § 165.25. The Department of Justice also provides training and guidance to law enforcement officers about Wisconsin's criminal laws. Wis. Stat. § 165.86. Thus, the Department of Justice should have clarity about the applicability of abortion laws in Wisconsin. The Attorney General sues in his official capacity as the Attorney General and

director and supervisor of the Department, with an address of 17 West Main Street, Madison, WI, 53703.

5. The Wisconsin Department of Safety and Professional Services (DSPS) conducts investigations of physicians for unprofessional conduct that includes violations of law. Wis. Stat. §§ 448.02(3), (8), 440.03(3m) ("The department may investigate complaints made against a person who has been issued a credential"). That includes "a violation . . . of any laws or rules of this state . . . substantially related to the practice of medicine and surgery." Wis. Admin. Code Med §§ 10.03(1)(a), (3)(i). Attached to DSPS is the Wisconsin Medical Examining Board, which may discipline licenses of doctors based on such investigations. Wis. Stat. §§ 448.02, 448.03. Thus, DSPS may be called upon to investigate or gather information pertaining to alleged violations of any applicable abortion laws. DSPS is located at 4822 Madison Yards Way, Madison, WI, 53705.

6. Plaintiff Wisconsin Medical Examining Board is created by Wis. Stat. § 15.405(7) and, pursuant to Wis. Stat. ch. 448, subchapter II, has duties that include issuing licenses to practice medicine and surgery. The Board's duties also include considering allegations of unprofessional conduct and issuing discipline, which may include alleged violations of Wisconsin laws regarding abortions. *See* Wis. Stat. § 448.02; Wis. Admin. Code Med

§§ 10.03(1)(a), (3)(i). The Board's address is 4822 Madison Yards Way, Madison, WI, 53705.

7. Plaintiff Sheldon A. Wasserman, M.D., sues in his official capacity as Chairperson of the Wisconsin Medical Examining Board. In that official capacity, his address is 4822 Madison Yards Way, Madison, WI, 53705.

8. Pursuant to Wis. Stat. § 165.25(1m) and Wis. Stat. § 14.11(1), the Governor has requested that the Department of Justice appear for and represent these state entities and officials in the prosecution of this action.

9. Defendant Chris Kapenga is President of the Wisconsin Senate and Co-Chair of the Joint Committee on Legislative Organization and is sued in his official capacity. The Legislature, over which President Kapenga exercises leadership duties, has passed a series of laws regarding abortion that are in conflict. After *Roe v. Wade* rendered Wis. Stat. § 940.04 unconstitutional, the Legislature failed in its duty to enact a revisor's correction bill eliminating the law as unconstitutional, *see* Wis. Stat. § 13.92(2)(L), or to otherwise affirmatively repeal the law in light of directly conflicting statutes passed post-*Roe*. Further, the Legislature and/or its members or committees have repeatedly sought to intervene, and in some cases have intervened, in cases under Wis. Stat. § 803.09(2m) on behalf of the Wisconsin Legislature, Wisconsin Senate, or Wisconsin Assembly pursuant to Wis. Stat. § 13.365, where the enforceability of state law was at issue. For such official capacity

claims, President Kapenga's address is Wisconsin State Capitol, Room 220 South, Madison, WI, 53702.

10. Defendant Devin LeMahieu is the Majority Leader of the Wisconsin Senate and is sued in his official capacity. The Legislature, over which Majority Leader LeMahieu exercises leadership duties, has passed a series of laws regarding abortion that are in conflict. After *Roe v. Wade* rendered Wis. Stat. § 940.04 unconstitutional, the Legislature failed in its duty to enact a revisor's correction bill eliminating the law as unconstitutional, *see* Wis. Stat. § 13.92(2)(L), or to otherwise affirmatively repeal the law in light of directly conflicting statutes passed post-*Roe*. Further, the Legislature and/or its members or committees have repeatedly sought to intervene, and in some cases have intervened, in cases under Wis. Stat. § 803.09(2m) on behalf of the Wisconsin Legislature, Wisconsin Senate, or Wisconsin Assembly pursuant to Wis. Stat. § 13.365, where the enforceability of state law was at issue. For such official capacity claims, Majority Leader LeMahieu's address is Wisconsin State Capitol, Room 211 South Madison, WI, 53702.

11. Defendant Robin Vos is the Speaker of the Wisconsin Assembly and Co-Chair of the Joint Committee on Legislative Organization and is sued in his official capacity. The Legislature, over which Speaker Vos exercises leadership duties, has passed a series of laws regarding abortion that are in conflict. After *Roe v. Wade* rendered Wis. Stat. § 940.04 unconstitutional, the

Legislature failed in its duty to enact a revisor's correction bill eliminating the law as unconstitutional, *see* Wis. Stat. § 13.92(2)(L), or to otherwise affirmatively repeal the law in light of directly conflicting statutes passed post-*Roe*. Further, the Legislature and/or its members or committees have repeatedly sought to intervene, and in some cases have intervened, in cases under Wis. Stat. § 803.09(2m) on behalf of the Wisconsin Legislature, Wisconsin Senate, or Wisconsin Assembly pursuant to Wis. Stat. § 13.365, where the enforceability of state law is at issue. For such official capacity claims, Speaker Vos's address is Wisconsin State Capitol, Room 217 West, Madison, WI, 53702.

12. To the extent that it has application here, compliance with Wis. Stat. § 893.825 will occur with service of the Complaint on the above defendants.

FACTUAL ALLEGATIONS

13. The Wisconsin Legislature enacted the first version of the statute that today is listed as Wis. Stat. § 940.04(1) in 1849. It prohibited the administering of substances to, or use of instruments on, a woman pregnant with a "quick child" with the intent to destroy the quick child unless "necessary to preserve the life of [the] mother." Wis. Stat. ch. 133, § 11 (1849).

14. At the time, "quickening" was generally understood to mean the time at which the pregnant woman first detects fetal movement, which

typically occurs during either the fourth or fifth month of pregnancy. Reva Siegel, *Reasoning from the Body: A Historical Perspective on Abortion Regulations and Questions*, 44 Stan. L. Rev. 261, 281–82 (1992); Samuel W. Buell, *Criminal Abortion Revisited*, 66 N.Y.U. L. Rev. 1774, 1780–81 (1991).

15. In 1858, the Wisconsin Legislature amended the 1849 statute (Wis. Stat. ch. 133, § 11 (1849)) to remove the word "quick" such that the statute applied to prohibit the intentional destruction of a pregnant woman's "child" unless "necessary to preserve the life of [the] mother." *See* Wis. Stat. ch. 164, § 11 (1858). That year, the Wisconsin Legislature also added a related provision prohibiting the administering of substances or use of instruments on a pregnant woman with the intent to procure "the miscarriage of any such woman." Wis. Stat. ch. 169, § 58 (1858).

16. By the end of the nineteenth century, most states had laws prohibiting abortion during all phases of pregnancy with "therapeutic exceptions" for abortions to save the life of the pregnant woman. Buell, *Criminal*, 66 N.Y.U. L. Rev. at 1784–85.

17. These mid-19th century laws generally remained listed in state statute books subject to only minor amendments until the 1950s and 1960s. Buell, *Criminal*, 66 N.Y.U. L. Rev. at 1795–96.

18. Though these mid-19th century laws criminalizing abortion at any stage of pregnancy remained "on the books" for all that time, they were rarely

enforced. Buell, *Criminal*, 66 N.Y.U. L. Rev. at 1789–90; Mark A. Graber, *Rethinking Abortion: Equal Choice, The Constitution, and Reproductive Politics* at 42–53 (1996).

19. Scholars estimate that between 1900 and 1970, one of every three to five pregnancies ended in abortion. Graber, *Rethinking* at 41–42. Married women obtained the vast majority of those abortions. *Id.* at 42.

20. Scholars also estimate that during the 1950s and 1960s, each year, approximately one million abortions that violated listed criminal statutes occurred. Graber, *Rethinking* at 42; Buell, *Criminal*, 66 N.Y.U. L. Rev. at 1789.

21. In *Babbitz v. McCann*, 310 F. Supp. 293 (E.D. Wis. 1970), a federal district court declared that Wis. Stat. § 940.04(1) was unconstitutionally overbroad as it purported to prohibit pre-quickening abortions. *Id.* at 302.

22. In its 1973 decision in *Roe v. Wade*, the United States Supreme Court declared unconstitutional statutes criminalizing abortion at any stage of pregnancy except when necessary to save the life of the pregnant woman. *Roe v. Wade*, 410 U.S. 113 (1973).

23. *Roe* specifically listed Wis. Stat. § 940.04 as one such statute. *Id.* at 118 n.2. At the time, Wis. Stat. § 940.04 stated that it prohibited the "intentional[]" destruction of the life of an "unborn child" unless necessary to "save the life of the mother," and it defined "unborn child" as a "human being from the time of conception until it is born alive."

24. Following *Roe*, the Wisconsin Legislature passed laws prohibiting abortion either after 20 weeks or after viability, and also passed a network of laws providing specific parameters for how physicians should perform abortions.

25. The United States Supreme Court overturned *Roe* in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. ____ (2022), on June 24, 2022.

CLAIMS FOR RELIEF

COUNT I

Wisconsin Stat. § 940.04 is unenforceable as applied to abortions because subsequent enactments have superseded any such application.

(Declaratory Relief Sought)

26. Plaintiffs reallege and incorporate herein by reference the foregoing paragraphs of this Complaint as if set forth here in full.

27. Any court of record in this State is authorized to enter a declaratory judgment declaring that a statutory provision, or an application of a statutory provision, is unenforceable. *See* Wis. Stat. § 806.04(1).

28. Over many decades, Wisconsin has created a statutory regime for abortion regulation that sets parameters for the providing of lawful abortions in our State.

29. This extensive, longstanding statutory regime is fundamentally inconsistent with a broad ban against abortions in Wisconsin.

30. Wisconsin Stat. § 940.15, enacted in 1985, criminalizes an abortion only after the point of "viability," which means "that stage of fetal development when, in the medical judgment of the attending physician based on the particular facts of the case before him or her, there is a reasonable likelihood of sustained survival of the fetus outside the womb, with or without artificial support."

31. Wisconsin Stat. § 940.15's prohibition of abortions after "viability" does not apply "if the abortion is necessary to preserve the life or health of the woman, as determined by reasonable medical judgment of the woman's attending physician." Wis. Stat. § 940.15(3). Wisconsin Stat. § 940.15 further states that "[n]othing in this subsection requires a physician performing an abortion to employ a method of abortion which, in his or her medical judgment based on the particular facts of the case before him or her, would increase the risk to the woman." Wis. Stat. § 940.15(6).

32. Relatedly, Wis. Stat. § 253.107 prohibits a physician from providing an abortion only after the "probable postfertilization age of the unborn child is 20 or more weeks," and offers an exception in the case of a "medical emergency." It defines "medical emergency" as a "condition, in a physician's reasonable medical judgment, that so complicates the medical condition of a pregnant woman as to necessitate the immediate abortion of her pregnancy to avert her death or for which a 24-hour delay in performance or

inducement of an abortion will create serious risk of substantial and irreversible impairment of one or more of the woman's major bodily functions." Wis. Stat. §§ 253.107, 253.10(2)(d).

33. In addition to Wis. Stat. § 940.15 and Wis. Stat. § 253.107, Wisconsin law contains a broad regulatory framework that regulates the circumstances under which lawful abortions may be provided and obtained.

34. For example, Wis. Stat. § 253.095(2) provides that "[n]o physician may perform an abortion, as defined in s. 253.10(2)(a), unless he or she has admitting privileges in a hospital within 30 miles of the location where the abortion is to be performed" and imposes a civil forfeiture for a violation. Chapter 253 also contains various other provisions that regulate legal abortions, including informed consent, a waiting period, the use of ultrasound, how abortion-inducing drugs are administered, and later-term abortions, among other things.

35. These many statutes providing the parameters for when an abortion may be performed are incompatible with a statute that would broadly criminalize abortion at any stage of pregnancy unless necessary to save the pregnant woman's life.

36. Yet, that is exactly what Wis. Stat. § 940.04 would purport to do if applied to abortion. Wisconsin Stat. § 940.04, the pre-*Roe* 19th century prohibition, contains a subsection (1) that provides that "[a]ny person, other

than the mother, who intentionally destroys the life of an unborn child is guilty of a Class H felony."

37. Wisconsin Stat. § 940.04 also contains a subsection (2) that provides that "[a]ny person, other than the mother, who does either of the following is guilty of a Class E felony:" "(a) Intentionally destroys the life of an unborn quick child." In *State v. Black*, 188 Wis. 2d 639, 646, 526 N.W.2d 132 (1994), the Wisconsin Supreme Court held that Wis. Stat. § 940.04(2)(a) "is not an abortion statute," but rather "proscribes the intentional criminal act of feticide."[1]

38. Wisconsin Stat. § 940.04(5) provides that "[t]his section does not apply to a therapeutic abortion which: (a) Is performed by a physician; and (b) Is necessary, or is advised by 2 other physicians as necessary, to save the life of the mother; and (c) Unless an emergency prevents, is performed in a licensed maternity hospital."

39. Wisconsin Stat. § 940.04(6) provides that "unborn child" means "a human being from the time of conception until it is born alive."

40. Wisconsin Stat. § 940.15, enacted in 1985, and the nineteenth-century statute listed as Wis. Stat. § 940.04 would directly conflict in two main respects if Wis. Stat. § 940.04 were applied to abortion.

[1] When Plaintiffs use the term "abortion" in this complaint, it does not include the crime of "feticide" as articulated in *Black*.

41. First, Wis. Stat. § 940.15 prohibits abortion only "after the fetus or unborn child reaches viability" but Wis. Stat. § 940.04(1) would prohibit any abortion "from the time of conception."

42. Second, Wis. Stat. § 940.15 recognizes exceptions where an abortion is necessary to preserve the life *or health* of the pregnant woman. But Wis. Stat. § 940.04 would only make an exception when necessary to save the pregnant woman's life.

43. Wisconsin Stat. § 940.04 would also directly conflict with Wis. Stat. § 253.107 if Wis. Stat. § 940.04 were applied to abortion. Wisconsin Stat. § 253.107 prohibits abortion only after the "probable postfertilization age of the unborn child is 20 or more weeks," and offers an exception in the case of a "medical emergency." But Wis. Stat. § 940.04(1) would prohibit any abortion "from the time of conception" and would make an exception only when necessary to save the pregnant woman's life.

44. Similarly, chapter 253's broad regulatory framework for the conditions under which physicians may lawfully provide abortions also directly conflicts with Wis. Stat. § 940.04 if Wis. Stat. § 940.04 were applied to abortions. That framework establishes that physicians act lawfully when they comply with the extensive regulatory provisions for their medical practice.

45. Later-enacted laws impliedly repeal earlier-enacted laws where the earlier-enacted law conflicts with the later-enacted law or where the later-

enacted laws are intended as a substitute. *Posadas v. Nat'l City Bank of New York*, 296 U.S. 497, 503 (1936); *Wisth v. Mitchell*, 52 Wis. 2d 584, 589, 190 N.W.2d 879 (1971); *State v. Dairyland Power Co-Op.*, 52 Wis. 2d 45, 51, 187 N.W.2d 878 (1971); *Tennessee Wine & Spirits Retailers Ass'n v. Thomas*, 139 S. Ct. 2449, 2462 (2019); Scalia & Garner, *Reading Law*, 331 (2012).

46. The principle that laws cannot directly conflict is particularly true with regard to criminal laws. Criminal statutes are unconstitutionally vague in violation of due process if they fail to afford proper notice of the conduct they seek to proscribe or if they encourage arbitrary and erratic arrests and convictions. *County of Kenosha v. C&S Management, Inc.*, 223 Wis. 2d 373, 392, 588 N.W.2d 236 (1999). Penal statutes therefore are strictly construed against enforcement where there is doubt as to the statutory scheme. *State v. Christensen*, 110 Wis. 2d 538, 546, 329 N.W.2d 382 (1983).

47. Similarly, under the specific/general rule of statutory construction, where two conflicting statutes apply to the same subject, the more specific controls. *State ex rel. Hensley v. Endicott*, 2001 WI 105, ¶ 19, 245 Wis. 2d 607, 629 N.W.2d 686.

48. Moreover, the Wisconsin Supreme Court has already held that Wis. Stat. § 940.15 is incompatible with interpreting another subsection of Wis. Stat. § 940.04 as a broad ban against abortion. The court there ruled that "[s]ection 940.04(2)(a) cannot be used to charge for a consensual abortive type

of procedure." *Black*, 188 Wis. 2d at 646. It ruled that doing so "would be inconsistent with the newer sec. 940.15." *Id.*

49. Enforcement of Wis. Stat. § 940.04(1) against abortion providers also would create a direct conflict with multiple other, later-enacted Wisconsin statutes that enumerate conditions and parameters under which lawful abortions may be provided.

50. This Court therefore should declare that Wis. Stat. § 940.04 is unenforceable as applied to abortions.

COUNT II

Additionally, Wis. Stat. § 940.04 is unenforceable as applied to abortions because of its disuse and in light of reliance on *Roe v. Wade* and its progeny.

(Declaratory Relief Sought)

51. Plaintiffs reallege and incorporate herein by reference the foregoing paragraphs of this Complaint as if set forth here in full.

52. Wisconsin Stat. § 940.04 has not been enforced against abortions for many decades.

53. Even pre-*Roe*, such laws were sparingly, and disparately, enforced, despite the fact that pre-"quickening" abortions remained relatively common. Buell, *Criminal*, 66 N.Y.U. L. Rev. at 1789–90; Graber, *Rethinking* at 42–53.

54. Wisconsin's post-*Roe* statutes and regulations reflect the prevailing acceptance in the law of early-stage abortions, under certain restrictions, as opposed to the broad ban in Wis. Stat. § 940.04.

55. Further, Wisconsin citizens have relied on the long existence of *Roe v. Wade*. While *Roe* was in force, there was no need to take action to advocate for the direct repeal of Wis. Stat. § 940.04, which was unenforceable as a matter of federal constitutional law.

56. Where society has long relied on the existence of a constitutional civil liberty protecting against enforcement of a law, where a law has long fallen out of common usage, or where custom—as embodied in modern practice—has evolved, a long obsolete and unused law may become unenforceable based on notions of fairness or reliance.

57. Indeed, a law that has been deemed a violation of a constitutionally protected civil liberty for nearly half a century and has not subsequently again been enacted as law cannot be said to continue to have the consent of the governed.

58. This Court therefore should declare that Wis. Stat. § 940.04 cannot be enforced as applied to abortions until and unless new legislation is enacted into law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask this Court to enter a judgment in their favor and against Defendants, consisting of:

(a) A declaratory judgment pursuant to Wis. Stat. § 806.04, declaring that Wis. Stat. § 940.04 is unenforceable as applied to abortions; and

(b) Any such other relief as the Court may deem just and proper.

Dated this 28th day of June 2022.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that in compliance with Wis. Stat. § 801.18(6), I electronically filed the Complaint with the clerk of court using the Wisconsin Circuit Court Electronic Filing System, which will accomplish electronic notice and service for all participants who are registered users.

I further certify that, unless personal service is waived, a copy of the above document will be personally served on:

Chris Kapenga
Wisconsin State Capitol, Room 220 South
Madison, WI 53702

Devin LeMahieu
Wisconsin State Capitol, Room 211 South
Madison, WI 53702

Robin Vos
Wisconsin State Capitol, Room 217 West
Madison, WI 53702

Dated this 28th day of June 2022.

Electronically signed by:

Hannah S. Jurss
HANNAH S. JURSS
Assistant Attorney General

EXHIBIT W

BY THE COURT:

DATE SIGNED: December 5, 2023

Electronically signed by Diane Schlipper
Circuit Court Judge

STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
BRANCH 3

JOSH KAUL, et al.,

Plaintiffs,

and

CHRISTOPHER J. FORD, et al.,

Intervenors,

v. Case No. 22 CV 1594

JOEL URMANSKI, et al.,

Defendants.

DECISION AND ORDER

INTRODUCTION

This Court recently determined that there is no such thing as an "1849 Abortion Ban" in Wisconsin. Specifically, this Court held that Wis. Stat. § 940.04 does not apply to consensual abortions, but to feticide, consistent with the Wisconsin Supreme Court's decision in *State v. Black*, 188 Wis. 2d 639, 526 N.W.2d 132 (1994). In light of this Court's determination that § 940.04 does not apply to abortions, the Wisconsin Attorney General and several state agencies who oversee medical licensing ("the State Agencies"), and doctors who perform abortions in

Wisconsin ("the Doctors") seek both a declaration that § 940.04 does not apply to consensual abortions and an injunction in support of the same.

Defendant Joel Urmanski, the District Attorney for Sheboygan County, opposes the Doctors' and State Agencies' motions. He asks the Court to reconsider its prior decisions that the State Agencies have standing to bring a declaratory action and that § 940.04 only prohibits feticide. Accordingly, he urges the Court to deny the State Agencies' and the Doctors' motions.

For the reasons set forth below, the Court denies Urmanski's motion for reconsideration and grants summary judgment for the Doctors. The Court declares Wis. Stat. § 940.04 does not prohibit abortions. Having now awarded the plaintiffs the ultimate relief they sought, the Court denies the Doctors' motion for an injunction and also denies the State Agencies' motion for judgment on the pleadings as moot.

I. BACKGROUND

A. Brief Procedural History.

The State Agencies plaintiffs are the Wisconsin attorney general and several other state officials and entities. They commenced this action against three district attorneys seeking a declaration that Wis. Stat. § 940.04 is unenforceable as applied to abortions. Amend. Compl., dkt. 34. Shortly thereafter, the Court allowed three Wisconsin physicians—the Doctors—to intervene in the action. Decision and Order (November 18, 2022), dkt. 80.

Sheboygan County District Attorney Joel Urmanski, a named defendant, moved to dismiss the State Agencies' and Intervenor Doctors' complaints. Urmanski Mot. to Dismiss, dkt. 89-90. In a written order ("the Dismissal Order") the Court granted Urmanski's motion in part by dismissing any claims that were "premised on the assertion that Wis. Stat. § 940.04 prohibits abortions." Decision and Order (July 7, 2023); dkt. 147:21. This was because the Court determined that §

940.04 did not apply to abortions, but only applied to feticide, consistent with the supreme court's holding in *State v. Black*, 188 Wis. 2d 639.[1] Dismissal Order, dkt. 147:20 The Court allowed the Doctors and State Agencies to proceed with their remaining claims for declaratory relief. *Id.* at 21.

The State Agencies and Doctors subsequently moved for judgment on the pleadings and summary judgement, respectively.[2]

B. Factual Background.

The following facts are undisputed.

The Doctors are a group of physicians who practice emergency medicine, obstetrics and gynecology, and maternal fetal medicine. They each treat pregnant patients experiencing serious complications with their pregnancies, and at times perform abortions. Int. Compl., dkt. 75:7. The State Agencies are comprised of the Attorney General, the Wisconsin Department of Safety and Professional Services, the Wisconsin Medical Examining Board and its chairperson. Pl. Amend. Compl., dkt. 34.

The State Agencies and Doctors brought these actions for declaratory relief against district attorneys in three Wisconsin counties where abortions were performed prior to the reversal of *Roe*. Amend. Compl., dkt. 34; Int. Compl., dkt. 75. They ask the Court to declare § 940.04 unenforceable as applied to abortions. *Id.* Additionally, the Doctors seek an injunction to support the declaration. Int. Compl., dkt. 75:15.

District Attorney Urmanski has the authority to prosecute crimes in Sheboygan County. Answer to Int. Compl., ¶ 11, dkt. 153. He has publicly interpreted § 940.04(1) as prohibiting

[1] A more comprehensive view of Wisconsin's history of abortion regulation is provided in the July 7 Dismissal Order. Dkt. 147. Additionally, this Court will not repeat the parties' arguments or the Court's rationale in determining the meaning of § 940.04—they, too, can be found in the Dismissal Order. Dkt. 147.

[2] The Doctors originally moved for judgment on the pleadings, but since they provided affidavits as evidence in support of their motion, the Court converted their motion to a motion for summary judgment. Dkt. 158; dkt. 160.

abortions (including consensual abortions) from conception until birth, subject to the exceptions in § 940.04(5) to save the life of the mother. Answer to Int. Compl., ¶¶ 11, 21-22, 24, 31-34, 36, 28, 41-43, dkt. 153.

Given his interpretation, Urmanski has said he will prosecute abortions that he believes violate § 940.04(1). Int. Compl, ¶ 11, dkt. 75; Answer to Int. Compl., ¶ 11, dkt. 153. In a public interview, Urmanski stated that he would enforce § 940.04 in cases of consensual medical abortions if referred, and he further stated he had reached out to law enforcement offices in Sheboygan County regarding his interpretation of the statute.[3] Ben Jordan, *Sheboygan County D.A. says he'll prosecute providers accused of performing abortions in violation of state law,* (June 29, 2022). https://www.tmj4.com/news/local-news/sheboygan-county-d-a-says-hell-prosecute-providers-accused-of-performing-abortions-in-violation-of-state-law; Emilee Fannon, *Wisconsin DA plans to prosecute doctors accused of performing abortions*, (June 30, 2022), https://abc7chcago.com/abortion-wisconsin-sheboygan-county-district-attorney/12006862/.

Though Urmanski voiced his intention to enforce § 940.04 as applied to consensual abortions, Defendant District Attorneys Chisholm and Ozanne from Milwaukee and Dane Counties, respectively, have taken no position on whether § 940.04(1) applies to consensual abortions. Chisholm and Ozanne ask this Court to deny the Doctors' motion for injunctive relief, claiming it interferes with their discretion to charge criminal cases. Chisholm Resp. Br., dkt. 167; Ozanne Resp. Br., dkt. 168. All three district attorneys agree they will abide by any order this Court issues regarding the meaning of § 940.04. *Id*.; Chisholm Resp. Br., dkt. 167; Urmanski Aff., ¶¶ 6-7, dkt. 171.

[3] This Court will take judicial notice of Urmanski's statements under Wis. Stat. § 902.01(2)(b), as they are public and recorded. The statements are capable of accurate and ready determination by resort to watching the video that cannot be reasonably questioned.

One of the Doctors, Dr. Kristin Lyerly, is licensed as a physician in Wisconsin and resides in Brown County. Lyerly Aff., ¶ 1, dkt. 164. She practiced as an obstetrician-gynecologist throughout the state, including Sheboygan County, and provided full scope care to women who may become pregnant, are pregnant, or may be experiencing complications with their pregnancies. Lyerly Aff. ¶¶ 1,3-5, 9, dkt. 164. Due to some of these complications, at times she performed abortions in Sheboygan County and elsewhere in Wisconsin, up until late June 2022. *Id.* ¶¶ 9-10.

In June 2022, as Dr. Lyerly was aware, the Supreme Court reversed *Roe v. Wade*, holding that there is no federal constitutional right to abortion at any stage and that "the Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. __, 142 S. Ct. 2228, 2284 (2022); Lyerly Aff., ¶ 12, dkt. 164. In reversing *Roe,* the Supreme Court placed abortion regulation back in the hands of the states. *Id.*

Prior to the Supreme Court's decision in *Dobbs,* Dr. Lyerly practiced medicine in Sheboygan County without fear of criminal prosecution. Lyerly Aff., ¶ 11, dkt. 164. After *Roe* was reversed, Dr. Lyerly learned through various media outlets that Sheboygan County District Attorney Joel Urmanski intended to prosecute abortion providers under § 940.04(1) if the cases were referred to his office by law enforcement agencies. *Id.* ¶12. Dr. Lyerly was so concerned about her continued practice in Sheboygan County and Wisconsin generally, that she temporarily relocated her medical practice to Minnesota and Arizona, where she knew she did not face criminal prosecution. *Id.* ¶¶ 16-23.

II. LEGAL STANDARDS

The State Agencies and the Doctors seek similar relief—a declaration that § 940.04 does not apply to consensual abortions—but they rely on two different procedures. The State Agencies move for judgment on the pleadings. "A judgment on the pleadings is essentially a summary

judgment decision without affidavits and other supporting documents." *McNally v. Capital Cartage, Inc.*, 2018 WI 46, ¶ 23, 381 Wis. 2d 349, 912 N.W.2d 35. Courts "[d]etermine first whether the complaint has stated a claim." *Id.* If so, courts "next examine the responsive pleading to ascertain whether an issue of material fact exists." *Id.* "Judgment on the pleadings is proper only if there are no genuine issues of material fact." *Id.*

The Doctors move for summary judgment because, unlike the State Agencies, they have provided supporting affidavits. A party is entitled to summary judgement if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *Everson v. Lorenz*, 2005 WI 51, ¶ 9, 280 Wis. 2d 1, 695 N.W.2d 298; Wis. Stat. § 802.08(2).

The power of the courts to issue a declaration is broad in scope. *Loy v. Bunderson*, 107 Wis. 2d 400, 407, 320 N.W.2d 175 (1982). Section 806.04(1) gives courts the authority to "declare rights, status, and other legal relations whether or not further relief is or could be claimed." Any interested person whose rights, status or other legal action are affected by, among other things, a statute, may have determined any question of construction or validity arising from the statute and obtain a declaration of rights. Wis. Stat. § 806.04(2).

Declaratory judgments allow courts to "anticipate and resolve identifiable, certain disputes between adverse parties." *Olson v. Town of Cottage Grove*, 2008 WI 51, ¶ 28, 309 Wis. 2d 365, 749 N.W.2d 211 (citations omitted). Courts may use declarations to settle justiciable controversies prior to the time that a wrong has been threatened or committed, providing "a remedy which is primarily anticipatory or preventative in nature." *Lister v. Bd. of Regents of Univ. Wisconsin Sys.*, 72 Wis. 2d 282, 307, 240 N.w.2d 610 (1976). A controversy is justiciable when the following factors are present:

(1) A controversy in which a claim of right is asserted against one who has an interest in contesting it.

(2) The controversy must be between persons whose interests are adverse.

(3) The party seeking declaratory relief must have a legal interest in the controversy—that is to say, a legally protectable interest.

(4) The issue involved in the controversy must be ripe for judicial determination.

Olson, 2008 WI 51, ¶29 (citing *Loy*, 107 Wis. 2d at 410).

Finally, in addition to declaratory relief, the Doctors also seek to permanently enjoin the prosecution of abortions under § 940.04. Permanent injunctions should not be issued lightly. *Pure Milk Prod. Co-op v. Nat'l Farmers Org.*, 90 Wis. 2d 781, 800, 280 N.W.2d 691 (1979). "To obtain an injunction, a plaintiff must show a sufficient probability that future conduct of the defendant will violate a right of will and injure the plaintiff." *Id.* The Plaintiff must establish the injury is irreparable. *Id.* The court must reconcile competing interests and be satisfied that on balance, equity favors issuing an injunction. *Id.*

III. ANALYSIS

To summarize, the State Agencies seek judgment on the pleadings, the Doctors seek summary judgment, and Urmanski opposes both motions arguing that the Court must reconsider its conclusions in the Dismissal Order. The Court need not address each of the arguments raised by each of these three motions, however, because Urmanski concedes that one of the Doctors, Dr. Lyerly, presents a justiciable controversy. Urmanski Resp. Br., dkt. 170:14. What this means is that, if the Court denies part of Urmanski's motion to reconsider—that is, if the Court concludes it did not commit a manifest error of law by concluding § 940.04 does not prohibit abortions—then the Court must also conclude that Dr. Lyerly has satisfied her burden to show there is no genuine issue of material fact and that she is entitled to judgment as a matter of law. In other words, given Urmanski's concession, this Court need not consider whether the State Agencies or all three of the Doctors present a justiciable claim—one doctor is enough.

A. The Court Stands by its Interpretation of § 940.04.

Urmanski's argument in opposition to Dr. Lyerly's motion for summary judgment relies entirely on the Court reconsidering the Dismissal Order. The Wisconsin Supreme Court explains the standard for reconsideration as follows:

> [A] circuit court possesses inherent discretion to entertain motions to reconsider "nonfinal" pre-trial rulings. To succeed, a reconsideration movant must either present newly discovered evidence or establish a manifest error of law or fact.
>
> Newly discovered evidence is not new evidence that could have been [submitted earlier]. Similarly, a "manifest error" must be more than disappointment or umbrage with the ruling; it requires a heightened showing of wholesale disregard, misapplication, or failure to recognize controlling precedent. Simply stated, a motion for reconsideration is not a vehicle for making new arguments or submitting new evidentiary materials that could have been submitted earlier after the court has decided a motion ….

Bauer v. Wisconsin Energy Corp., 2022 WI 11, ¶¶ 13-14, 400 Wis. 2d 592, 970 N.W.2d 243 (citations, some quotation marks, and original alterations omitted).

Urmanski says the Court made several errors in the Dismissal Order's analysis. Urmanski Reply Br., dkt. 170. To explain why, Urmanski essentially repackages all of the arguments that he made in his motion to dismiss. Dkt. 111. Reconsideration "requires a heightened showing of wholesale disregard, misapplication, or failure to recognize a controlling precedent." *Bauer*, 2022 WI 11, ¶14. This kind of heightened showing does not mean re-submitting the same arguments that a court has already rejected. This Court understands the need to preserve issues for appeal, but will not restate its rationale for deciding that § 940.04 applies to feticide and not abortions. That has been fully fleshed out in the Dismissal Order. Dkt. 147.

Urmanski continues to argue that "*Black* is objectively wrong …" for several reasons. Urmanski Resp. Br., dkt. 170:26-29. This is not a reason to reconsider the Dismissal Order because the supreme court is the "only state court with the power to overrule, modify or withdraw language

from a previous supreme court case." *Cook v. Cook*, 208 Wis. 2d 166, 189, 560 N.W.2d 246. (1997). As such, this Court has no authority to overrule *State v. Black*.

In sum, Urmanski fails to make any "heightened showing of wholesale disregard, misapplication, or failure to recognize controlling precedent." *Bauer,* 2022 WI 11, ¶ 14. Accordingly, the Court denies Urmanski's motion for reconsideration.

B. Dr. Lyerly Presents a Justiciable Claim and is Entitled to a Declaratory Judgment that § 940.04 does not Prohibit Abortions.

Dr. Lyerly fears that she may be subjected to criminal investigation or prosecution based on some prosecutors' public statements that § 940.04 could be used to prosecute abortion providers. Lyerly Aff., ¶¶ 16-17, dkt. 164. The threat of prosecution, even for abortions that may preserve the health and well-being of a pregnant patient, has caused her to stop caring for pregnant patients in Wisconsin. *Id.* ¶¶ 12-13, 16-18, 20-21, 24.

It is undisputed that Sheboygan County District Attorney Urmanski, like all district attorneys in Wisconsin, has the authority to prosecute criminal actions within his county. Answer to Int. Compl., ¶ 11, dkt. 153. Urmanski holds the position that § 940.04 prohibits performing abortions (including consensual abortions) from conception to birth (subject to specified exceptions). *Id.* ¶¶ 11, 21-22, 24, 31-34, 36, 38, 41-43.

Following the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* decision, Dr. Lyerly learned through the media and conversations with colleagues, that DA Urmanski and other Wisconsin prosecutors stated that they would prosecute medical providers who provided abortions that violated Wis. Stat. § 940.04. Lyerly Aff., ¶¶ 16-17, dkt. 164. Additionally, she learned through media coverage that Urmanski "proactively contacted law enforcement in Sheboygan County to inform them about his interpretation that Wis. Stat. § 940.04 prohibits abortions." Lyerly Aff., ¶ 12, dkt. 164.

As a result, Dr. Lyerly moved her obstetrics practice out of Sheboygan County and out of Wisconsin altogether in June 2022, though she still resides in Wisconsin. Lyerly Aff. ¶¶ 1, 18, dkt. 164. She regularly cared for women who presented with complications during pregnancy and it was not uncommon for those women to have abortions. Prior to June 2022 and the reversal of *Roe*, she also provided elective abortions. *Id.* ¶¶ 9-10, dkt. 164.

Based on Urmanski's comments, Dr. Lyerly fears criminal prosecution if she continues her medical practice in Wisconsin. Lyerly Aff., ¶¶ 16-23, dkt. 164. This continuing threat of prosecution infringes on her right to practice medicine in the best interest of patients without fear of an unfounded investigation, prosecution, and potential conviction. Dr. Lyerly wishes to resume her practice in Wisconsin but believes she cannot do so until there is certainty about § 940.04. *Id.*. She reasonably fears that district attorneys could try to enforce § 940.04 as an abortion ban. *Id.*.

It is well settled that a proper case for declaratory judgment is presented when requested by the party threatened by the application of penal law. *State ex rel. Lynch v. Conta*, 71 Wis. 2d 662, 671, 239 N.W.2d 313 (1976) *superseded on other grounds via statute as stated in State ex rel. Newspapers, Inc. v. Showers*, 135 Wis. 2d 77, 398 N.W.2d 154 (1987). Though Urmanski has not threatened her directly, it is well established that "potential defendants may seek a construction of a statute … without subjecting themselves to forfeitures or prosecution." *Miller Brands-Milwaukee, Inc. v. Case*, 162 Wis. 2d 684, 695, 470 N.W.2d 290 (1991). It is not a prerequisite for Dr. Lyerly to suffer an actual injury. A matter must be sufficiently developed to allow a conclusive adjudication. *Milwaukee Dist. Council 48 v. Milwaukee Cnty.*, 2001 WI 65, ¶ 41, 244 Wis. 2d 333, 627 N.W.2d 866.

Dr. Lyerly presents evidence to satisfy each of the four elements of a justiciable controversy. Specifically, Dr. Lyerly claims a right to perform abortions in compliance with

applicable state law, without being subject to criminal prosecution for the misapplication of § 940.04. Additionally, her interests are adverse to Urmanski. As the district attorney in Sheboygan County, Urmanski has the authority to prosecute criminal actions. Answer to Int. Compl., ¶ 11, dkt. 153. Accordingly, his interpretation of § 940.04(1) as prohibiting consensual abortions is adverse to Dr. Lyerly's claim of right to perform lawful abortions. Answer to Int. Compl., ¶¶ 11, 21-22, 24, 31-34, 36, 38, 41-43, dkt. 153. Finally, Dr. Lyerly has a legally protectable interest in this case. Her fear of enforcement of § 940.04 as applied to abortions has caused her to stop performing abortions in Sheboygan County and in Wisconsin in general.

Urmanski agrees. He "does not dispute that Lyerly presents a justiciable controversy with respect to her claims that § 940.04(1) does not apply to abortions." Urmanski Br., dkt. 170:15. Therefore, the Court need not further address any other plaintiffs' claims. It is enough that Dr. Lyerly presents a justiciable claim that is ripe for judicial determination and that there are no genuine disputes over material facts.

For all of the reasons above, this Court GRANTS the Doctors' motion for summary judgment and declares that § 940.04 does not apply to abortions.

C. The Doctors' Request for an Injunction is Denied.

In addition to declaratory relief, the Doctors also seek an order enjoining any prosecution for consensual abortion under § 940.04. In support of the Doctors' request for an injunction, the State Agencies argue that this case "presents 'unique issues of interest to this state,' reflecting the importance of complete clarity for all Wisconsinites." Pl. Br., dkt. 157:21 (quoting *State ex rel. Lynch,* 71 Wis. 2d at 668).[4] This Court has discretion to grant injunctive relief in aid of a declaratory judgment, "where necessary or proper to make the judgment effective." *Town of*

[4] The State Agencies do not seek injunctive relief in the Amended Complaint and only address an injunction in support of the Doctors' claims. Compl., dkt. 34; Pl. Br., dkt. 157:20.

Blooming Grove v. City of Madison, 275 Wis. 328, 336, 81 N.W.2d 713 (1957) (citing *Morris v. Ellis*, 221 Wis. 307, 315, 266 N.W. 921 (1936)).

1. The Doctors have Not Satisfied this Court of an Irreparable Injury.

While true that this case presents unique issues of interest for Wisconsin, the Doctors must show "a sufficient probability that future conduct of the defendant will violate a right or will and injure the plaintiff" and the injury is irreparable. *Pure Milk Prods.*, 90 Wis. 2d at 800. They have not satisfied this Court that the future conduct of the defendants, here three Wisconsin district attorneys, will violate a right or will and injure the plaintiff.

Each of the three defendants claims they will abide by the Court's order in this matter. Urmanski has filed an affidavit that acknowledges that if the Court issues a declaration that § 940.04 does not apply to consensual abortions, this would be binding on the parties to this case. Urmanski Aff., ¶¶ 6-7, Dkt. 171. Similarly, Chisholm agrees that after the Court's July 7 Decision and Order, interpreting § 940.04 as applying to feticide and not consensual abortion, "there is no basis to prosecute medical consensual abortion under § 940.04." Chisholm Resp. Br., dkt. 167:5. Likewise, Ozanne "intends to await the Court's declaration of Wisconsin law, and to abide as the Court declares it to be." Ozanne Resp. Br., dkt. 168:3. The defendants in this action, as parties, admit that they are bound by the Court's declaration.

The Doctors argue that although declaratory judgments should be the functional equivalent of injunctions when applied to government parties, this is not always the case. Int. Resp. Br., dkt. 163:20. They point to Chief Justice Abrahamson's dissent in *Madison Teachers., Inc. v. Walker*, for the premise that the supreme court's decision essentially "authorizes the executive to disobey the declaratory judgments of the judiciary," and strips the circuit courts of the ability to protect those judgments. 2013 WI 91, ¶ 24, 351 Wis. 2d 237, 839 N.W.2d 388 (Abrahamson, C.J.

dissenting). In that case, the circuit court declared that certain statutory provisions were unconstitutional. *Id.* ¶¶ 3, 19. After a government party ignored the court's order and "just forged ahead enforcing a law that had been declared null and void," the circuit court ultimately held the party in contempt and granted injunctive relief. *Id.* ¶¶ 10, 20.

The Doctors urge the Court to grant an injunction because they think *Madison Teachers* opened the door for a governmental actor to argue that a declaratory judgment does not have the same legal effect as an injunction. Int. Br., dkt. 163:21. Merely opening the door to the possibility that a government actor may disregard a declaratory judgment does not reach the level of a sufficient probability that the future conduct of the defendants will violate a right and injure the doctors—especially in light of their statements otherwise. Because government actors in a separate case, ten years ago, ignored the circuit court's order, does not mean that there is a sufficient probability that these defendants will do the same.

Simply put, the Defendants all say they will abide by this Court's order. The Doctors do not show any reason why these district attorneys would renege on that promise. Accordingly, the Doctors do not satisfy their burden to show an irreparable injury.

2. Equity Does Not Favor Issuing an Injunction.

The Court must then reconcile competing interests and the Doctors must satisfy the Court that on balance equity favors issuing the injunction. *Pure Milk Prods.,* 90 Wis. 2d at 800.

Here, there are several competing interests to consider. Urmanski correctly points out that any order to enjoin the conduct of the parties would only grant injunctive relief against three particular district attorneys, and potentially their successors—not all Wisconsin district attorneys. Urmanski Resp. Br., dkt. 170:39. Subject to some exceptions that have not been presented here, injunctions are binding only on parties to the action. *Dalton v. Meister*, 84 Wis. 2d 303, 311-12,

267 N.W.2d 326 (1978). Therefore, to grant the injunction would mean that only three Wisconsin district attorneys, and their successors, would be enjoined from unlawfully enforcing § 940.04. Though they are the district attorneys in the three counties where abortion clinics existed prior to the overturning of *Roe*, the Doctors do not show why it would be equitable to enjoin only these Defendant prosecutors, subjecting them to penalties not faced by other district attorneys.

In conclusion, the Doctors do not satisfy their burden to show future conduct of the Defendants will irreparably injure the Doctors and, after balancing the equity factors as explained above, this Court DENIES the Doctors' motion for injunctive relief.

ORDER

For the reasons stated,

The Court GRANTS Dr. Kristin Lyerly's motion for summary judgment. The Court DECLARES that Wis. Stat. § 940.04 does not apply to abortions.

The Court DENIES all other pending motions.

This is a final order for purpose of appeal. Wis. Stat. § 808.03(1).

EXHIBIT X

Query: WISH, Wisconsin Population Module (Wisconsin 1990 - 2022)

- ***((Year=2022))***

Use the drill-down variable tool to amend the current query Year

Wisconsin Population

Age	Sex		
	All Selected	Male	Female
All	5,892,539	2,955,306	2,937,233
0 - 14	1,015,827	520,511	495,316
15 - 44	2,272,325	1,164,241	1,108,084
45 - 64	1,502,268	759,240	743,028
65+	1,102,119	511,314	590,805

When using drill-down, Return to previous drill-down level.

Estimates for age and sex categories may not sum to totals shown due to rounding.

To save or copy these results:
Highlight the output you want to save.
Select EDIT, COPY.
PASTE the output into your word processing or spreadsheet program.

Next Query | Data Source | Interpretation | Help

WISH (Wisconsin Interactive Statistics on Health)
Office of Health Informatics
Division of Public Health
Wisconsin Department of Health Services
WISH is available at https://dhs.wisconsin.gov/wish/index.htm

Suggested citation: Wisconsin Dept. of Health Services, Division of Public Health, Office of Health Informatics. Wisconsin Interactive Statistics on Health (WISH) data query system, https://www.dhs.wisconsin.gov/wish/index.htm. Population Module, accessed 11/22/2023.

EXHIBIT Y

WISCONSIN DEPARTMENT OF
SAFETY AND PROFESSIONAL SERVICES
LICENSE COUNTS* AS OF 01/31/2024
Includes Temp. Licenses/*F=Firms; I=Individuals

			In State			Out of State			Totals		
Entity*	**Reg.**	**Profession**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**
I	1	Certified Public Accountant	9,844	11,266	21,110	1,615	4,999	6,614	11,459	16,265	27,724
F	3	Accounting Firm	379	874	1,253	55	170	225	434	1,044	1,478
I	4	Licensed Appraiser	221	1,798	2,019	17	269	286	238	2,067	2,305
I	5	Architect	1,609	1,275	2,884	3,535	5,518	9,053	5,144	6,793	11,937
I	6	Professional Engineer	7,171	10,757	17,928	9,119	18,269	27,388	16,290	29,026	45,316
I	7	Designer of Engineering Systems	823	1,394	2,217	44	145	189	867	1,539	2,406
I	8	Professional Land Surveyor	712	1,097	1,809	404	729	1,133	1,116	1,826	2,942
I	9	Certified Residential Appraiser	598	1,039	1,637	190	426	616	788	1,465	2,253
I	10	Certified General Appraiser	333	464	797	414	1,622	2,036	747	2,086	2,833
F	11	Architectural or Engineering Corp - Certificate of Authorization	476	1,542	2,018	1,452	1,501	2,953	1,928	3,043	4,971
I	12	Chiropractic	2,288	1,196	3,484	248	1,367	1,615	2,536	2,563	5,099
I	13	Professional Geologist	337	274	611	296	575	871	633	849	1,482
I	14	Landscape Architect	230	251	481	184	220	404	414	471	885
I	15	Dentistry	3,429	3,611	7,040	989	3,508	4,497	4,418	7,119	11,537
I	16	Dental Hygiene	5,007	2,886	7,893	512	2,116	2,628	5,519	5,002	10,521
I	17	Anesthesiologist Assistant	183	36	219	24	18	42	207	54	261
I	18	Perfusionist	120	54	174	91	41	132	211	95	306
I	19	Physical Therapist Assistant	2,097	891	2,988	160	331	491	2,257	1,222	3,479
I	20	Medicine and Surgery	15,639	13,082	28,721	10,276	24,479	34,755	25,915	37,561	63,476
I	21	Medicine and Surgery	1,793	725	2,518	1,086	1,480	2,566	2,879	2,205	5,084
I	23	Physician Assistant	3,635	905	4,540	1,146	1,007	2,153	4,781	1,912	6,693
I	24	Physical Therapist	6,203	2,420	8,623	1,025	3,817	4,842	7,228	6,237	13,465
I	25	Podiatric Medicine and Surgery	284	262	546	111	375	486	395	637	1,032
I	26	Occupational Therapist	3,755	2,300	6,055	458	1,327	1,785	4,213	3,627	7,840
I	27	Occupational Therapy Assistant	1,197	1,834	3,031	79	391	470	1,276	2,225	3,501
I	28	Respiratory Care Practitioner	2,937	1,624	4,561	722	933	1,655	3,659	2,557	6,216
I	29	Certified Dietitian	1,822	1,463	3,285	587	501	1,088	2,409	1,964	4,373
I	30	Registered Nurse	100,033	57,615	157,648	18,960	63,307	82,267	118,993	120,922	239,915
I	31	Licensed Practical Nurse	10,010	39,493	49,503	664	10,409	11,073	10,674	49,902	60,576
I	32	Nurse - Midwife	268	100	368	47	98	145	315	198	513

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WISCONSIN DEPARTMENT OF
SAFETY AND PROFESSIONAL SERVICES
LICENSE COUNTS* AS OF 01/31/2024
Includes Temp. Licenses/*F=Firms; I=Individuals

			In State			Out of State			Totals		
Entity*	**Reg.**	**Profession**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**
I	33	Advanced Practice Nurse Prescriber	8,496	1,712	10,208	2,312	1,786	4,098	10,808	3,498	14,306
I	35	Optometry	927	671	1,598	334	1,113	1,447	1,261	1,784	3,045
I	36	Art Therapist	60	80	140	8	11	19	68	91	159
I	37	Dance Therapist	7	12	19	0	3	3	7	15	22
I	38	Music Therapist	106	123	229	13	22	35	119	145	264
I	39	Athletic Trainer	1,198	956	2,154	202	387	589	1,400	1,343	2,743
I	40	Pharmacist	6,732	3,443	10,175	3,148	3,096	6,244	9,880	6,539	16,419
I	41	Pharmacy Technicians	11,275	2	11,277	673	0	673	11,948	2	11,950
F	42	Pharmacy	1,415	3,252	4,667	50	21	71	1,465	3,273	4,738
F	43	Pharmacy	7	2	9	1,420	1,844	3,264	1,427	1,846	3,273
F	44	Manufacturer	79	195	274	13	26	39	92	221	313
F	45	Wholesale Distributor of Prescription Drugs	103	576	679	743	1,845	2,588	846	2,421	3,267
I	46	Massage Therapist Or Bodyworker	0	1,624	1,624	0	369	369	0	1,993	1,993
I	47	Massage Therapist Or Bodyworker	0	266	266	0	36	36	0	302	302
F	48	Home Medical Oxygen Provider	99	71	170	88	86	174	187	157	344
I	49	Licensed Midwife	128	116	244	59	69	128	187	185	372
I	52	Auctioneer	342	1,458	1,800	160	791	951	502	2,249	2,751
F	53	Auction Company	72	308	380	36	129	165	108	437	545
I	55	Acupuncturist	441	211	652	112	327	439	553	538	1,091
I	57	Psychologist	1,787	1,044	2,831	503	927	1,430	2,290	1,971	4,261
I	58	Private Practice of School Psychology	34	315	349	0	39	39	34	354	388
F	59	School of Aesthetics	9	13	22	0	0	0	9	13	22
I	60	Hearing Instrument Specialist	253	1,159	1,412	39	258	297	292	1,417	1,709
I	61	Genetic Counselors	197	9	206	252	1	253	449	10	459
F	62	Private Detective Agency	211	2,354	2,565	143	568	711	354	2,922	3,276
I	63	Private Detective	493	6,655	7,148	266	1,413	1,679	759	8,068	8,827
I	64	Firearms Certifier	57	181	238	12	35	47	69	216	285
I	65	Nursing Home Administrator	691	2,440	3,131	122	747	869	813	3,187	4,000
F	69	Aesthetics Establishment	622	1,876	2,498	5	2	7	627	1,878	2,505
F	70	Electrology Establishment	60	687	747	0	0	0	60	687	747

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			In State			Out of State			Totals		
Entity*	**Reg.**	**Profession**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**
F	71	Manicuring Establishment	944	5,201	6,145	1	4	5	945	5,205	6,150
I	72	Aesthetics Instructor	56	29	85	2	7	9	58	36	94
I	73	Electrology Instructor	4	5	9	2	1	3	6	6	12
I	74	Manicuring Instructor	52	40	92	2	3	5	54	43	97
I	75	Funeral Director Excluding Embalming	0	69	69	0	2	2	0	71	71
I	76	Funeral Director in Good Standing	0	513	513	0	282	282	0	795	795
I	77	Funeral Director	1,003	1,576	2,579	141	302	443	1,144	1,878	3,022
F	78	Funeral Establishment	480	1,682	2,162	8	1	9	488	1,683	2,171
I	79	Funeral Director Embalming Only	0	5	5	0	6	6	0	11	11
F	80	Cosmetology Establishment	7,320	35,060	42,380	48	110	158	7,368	35,170	42,538
I	81	Cosmetology Manager	0	29,523	29,523	0	3,181	3,181	0	32,704	32,704
I	82	Cosmetologist	24,860	57,627	82,487	1,301	10,891	12,192	26,161	68,518	94,679
I	83	Cosmetology Instructor	758	1,053	1,811	51	167	218	809	1,220	2,029
I	84	Electrologist	125	605	730	8	163	171	133	768	901
I	85	Manicurist	4,221	6,160	10,381	477	1,883	2,360	4,698	8,043	12,741
I	86	Aesthetician	3,547	2,352	5,899	237	545	782	3,784	2,897	6,681
F	87	School of Cosmetology	23	141	164	0	2	2	23	143	166
F	88	School of Electrology	4	10	14	0	0	0	4	10	14
F	89	School of Manicuring	7	46	53	0	0	0	7	46	53
I	90	Real Estate Broker	7,408	43,313	50,721	999	4,915	5,914	8,407	48,228	56,635
F	91	Real Estate Business Entity	2,160	8,431	10,591	449	1,071	1,520	2,609	9,502	12,111
I	93	Timeshare Salesperson	287	2,932	3,219	26	297	323	313	3,229	3,542
I	94	Real Estate Salesperson	16,640	58,437	75,077	2,345	6,821	9,166	18,985	65,258	84,243
F	95	Cemetery Authority - Licensed	64	105	169	27	8	35	91	113	204
I	96	Cemetery Salesperson	121	2,010	2,131	2	91	93	123	2,101	2,224
I	97	Athlete Agent	6	28	34	52	161	213	58	189	247
F	98	Crematory Authority	67	118	185	9	1	10	76	119	195
F	99	Cemetery Association	112	1	113	0	0	0	112	1	113
F	101	Cemetery Preneed Seller	100	1,329	1,429	32	75	107	132	1,404	1,536
F	102	Cemetery Authority-Religious	406	33	439	0	0	0	406	33	439

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Entity*	**Reg.**	**Profession**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**
F	104	Cemetery Warehouse	0	4	4	0	4	4	0	8	8
I	106	Home Inspector	645	2,597	3,242	78	283	361	723	2,880	3,603
I	107	Agent For Burial Agreements	976	6	982	53	1	54	1,029	7	1,036
I	108	Private Security Person	8,629	59,774	68,403	468	5,004	5,472	9,097	64,778	73,875
I	109	Wisconsin Registered Interior Designer	195	457	652	25	57	82	220	514	734
I	110	Peddler	51	1	52	0	0	0	51	1	52
I	111	Professional Hydrologist	55	114	169	15	18	33	70	132	202
I	112	Professional Soil Scientist	42	125	167	8	32	40	50	157	207
I	113	Chiropractic Radiological Technician	287	611	898	6	12	18	293	623	916
I	114	Chiropractic Technician	1,092	2,805	3,897	14	56	70	1,106	2,861	3,967
F	115	Mobile Dentistry Program Registrant	25	32	57	4	2	6	29	34	63
F	116	Expanded Function Dental Auxiliary	0	1	1	2	0	2	2	1	3
I	118	Juvenile Martial Arts Instructor	55	96	151	2	4	6	57	100	157
I	120	Social Worker	4,436	8,194	12,630	195	1,047	1,242	4,631	9,241	13,872
I	121	Advanced Practice Social Worker	3,999	4,433	8,432	247	939	1,186	4,246	5,372	9,618
I	122	Independent Social Worker	177	808	985	45	125	170	222	933	1,155
I	123	Licensed Clinical Social Worker	3,910	3,212	7,122	698	895	1,593	4,608	4,107	8,715
I	124	Licensed Marriage and Family Therapist	786	455	1,241	239	181	420	1,025	636	1,661
I	125	Licensed Professional Counselor	5,210	2,904	8,114	796	691	1,487	6,006	3,595	9,601
I	126	Professional Counselor Training Certificate	0	530	530	0	52	52	0	582	582
I	127	Social Worker Training Certificate	245	3,182	3,427	8	143	151	253	3,325	3,578
I	128	Marriage and Family Therapist Training Certificate	0	92	92	0	10	10	0	102	102
I	130	Substance Abuse Counselor-in-Training	1,133	5,031	6,164	34	347	381	1,167	5,378	6,545
I	131	Substance Abuse Counselor	683	1,327	2,010	27	100	127	710	1,427	2,137
I	132	Clinical Substance Abuse Counselor	1,589	1,349	2,938	96	340	436	1,685	1,689	3,374
I	133	Clinical Supervisor-in-Training	227	742	969	5	56	61	232	798	1,030
I	134	Intermediate Clinical Supervisor	125	283	408	4	25	29	129	308	437
I	135	Independent Clinical Supervisor	369	211	580	22	43	65	391	254	645
I	136	Prevention Specialist-in-Training	2	176	178	0	10	10	2	186	188
I	137	Prevention Specialist	50	92	142	4	10	14	54	102	156

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I	140	Behavior Analyst	501	83	584	90	72	162	591	155	746
I	142	Licensed Radiographer	5,944	2,552	8,496	1,001	829	1,830	6,945	3,381	10,326
I	144	Limited X-Ray Machine Operator Permit	17	54	71	2	8	10	19	62	81
I	146	Massage Therapist or Bodywork Therapist	4,566	3,881	8,447	329	652	981	4,895	4,533	9,428
I	150	Sign Language Interpreter	0	249	249	5	302	307	5	551	556
I	151	Sign Language Interpreter- Restricted	1	157	158	0	11	11	1	168	169
I	154	Speech-Language Pathology	2,257	2,243	4,500	424	1,096	1,520	2,681	3,339	6,020
I	156	Audiology	404	186	590	84	142	226	488	328	816
I	157	Sign Language Interpreter - Intermediate Hearing	39	134	173	11	9	20	50	143	193
I	158	Sign Language Interpreter - Advanced Hearing	212	87	299	475	322	797	687	409	1,096
I	159	Sign Language Interpreter - Intermediate Deaf	1	8	9	0	0	0	1	8	9
I	160	Sign Language Interpreter - Advanced Deaf	8	1	9	8	4	12	16	5	21
I	161	Sign Language Interpreter - Temporary Exemption	0	3	3	0	0	0	0	3	3
F	180	Barbering Establishment	272	447	719	1	1	2	273	448	721
I	181	Barbering Manager	0	670	670	0	34	34	0	704	704
I	182	Barber	639	686	1,325	32	80	112	671	766	1,437
I	183	Barbering Instructor	6	5	11	1	1	2	7	6	13
F	184	Transportation Network Companies	2	6	8	5	0	5	7	6	13
F	187	School of Barbering	8	2	10	0	0	0	8	2	10
F	195	Cemetery Authority - Registered	28	50	78	0	0	0	28	50	78
I	197	Registered Sanitarian	210	450	660	11	55	66	221	505	726
F	201	Geology Firm	19	38	57	22	31	53	41	69	110
F	202	Hydrology Firm	4	6	10	2	4	6	6	10	16
F	203	Soil Science Firm	6	7	13	1	6	7	7	13	20
I	220	Administrative Medicine and Surgery	0	2	2	0	8	8	0	10	10
I	221	Administrative Medicine and Surgery	0	0	0	1	1	2	1	1	2
I	226	Professional Counselor Training License	1,723	4,145	5,868	61	346	407	1,784	4,491	6,275
I	228	Marriage and Family Therapist Training License	217	626	843	5	79	84	222	705	927
F	245	Third-Party Logistics Provider	1	0	1	0	0	0	1	0	1
F	261	Amateur Boxing Club	0	17	17	0	0	0	0	17	17

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F	262	Professional Boxing Club	0	18	18	0	0	0	0	18	18
I	263	Boxing Contestant	23	243	266	70	496	566	93	739	832
F	264	Professional Boxing Contest	15	5	20	7	3	10	22	8	30
I	265	Second	226	926	1,152	249	1,299	1,548	475	2,225	2,700
F	266	Professional Boxing Promoter	0	12	12	0	3	3	0	15	15
I	267	Mixed Martial Arts Judge	11	11	22	6	17	23	17	28	45
I	268	Mixed Martial Arts Referee	3	6	9	5	8	13	8	14	22
I	270	Matchmaker	10	31	41	2	16	18	12	47	59
I	271	Ringside Physician	7	15	22	2	12	14	9	27	36
I	272	Timekeeper	6	10	16	0	6	6	6	16	22
I	274	Boxing Judge	5	8	13	6	4	10	11	12	23
I	275	Boxing Referee	1	2	3	4	3	7	5	5	10
I	276	Mixed Martial Arts Amateur Contestant	154	862	1,016	56	419	475	210	1,281	1,491
I	277	Mixed Martial Arts Professional Contestant	29	262	291	41	378	419	70	640	710
F	278	Mixed Martial Arts Professional Club	0	1	1	0	0	0	0	1	1
F	279	Professional Mixed Martial Arts Contest	1	72	73	0	13	13	1	85	86
F	280	Professional Mixed Martial Arts Promoter	0	19	19	0	9	9	0	28	28
F	281	Unarmed Combat Sports Promoter	9	12	21	4	5	9	13	17	30
F	282	Unarmed Combat Sports Contest	0	45	45	1	9	10	1	54	55
I	283	Kickboxing Amateur Contestant	39	127	166	9	60	69	48	187	235
I	284	Kickboxing Professional Contestant	3	9	12	0	11	11	3	20	23
I	285	Muay Thai Amateur Contestant	0	4	4	0	0	0	0	4	4
I	287	Kickboxing Judge	5	3	8	2	7	9	7	10	17
I	288	Muay Thai Judge	0	2	2	0	0	0	0	2	2
I	289	Kickboxing Referee	2	1	3	3	4	7	5	5	10
I	290	Muay Thai Referee	0	1	1	0	0	0	0	1	1
I	320	Medicine and Surgery	64	24	88	2,626	1,245	3,871	2,690	1,269	3,959
I	321	Medicine and Surgery	10	7	17	434	176	610	444	183	627
F	401	Tanning Facility	115	2,049	2,164	1	18	19	116	2,067	2,183
I	403	Tattooist	1,831	3,066	4,897	353	998	1,351	2,184	4,064	6,248

The count of INACTIVE LICENSES includes the following:
1)Licenses not renewed and expired, 2)Deceased licensees, 3)Revoked licenses, 4)Voluntarily surrendered licenses, 5)Suspended licenses, 6)Licenses denied due to tax delinquencies, and 7)Licenses issued in error.
We maintain the information on inactive licenses because complaints may be filed against these licenses and we may need the information for future investigations.

WISCONSIN DEPARTMENT OF
SAFETY AND PROFESSIONAL SERVICES
LICENSE COUNTS* AS OF 01/31/2024
Includes Temp. Licenses/*F=Firms; I=Individuals

			In State			Out of State			Totals		
Entity*	**Reg.**	**Profession**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**	**Active**	**Inactive**	**Total**
I	404	Body Piercer	237	1,026	1,263	22	72	94	259	1,098	1,357
I	450	SUA-Analytical Laboratory	48	23	71	1	0	1	49	23	72
I	451	SUA-Humane Society	62	26	88	0	0	0	62	26	88
I	452	SUA-Narcotic Dog Training	171	70	241	0	0	0	171	70	241
I	453	SUA-Animal Translocation	4	0	4	0	0	0	4	0	4
I	454	SUA-Research	286	217	503	2	0	2	288	217	505
I	455	SUA-Law Enforcement Animal Control Officer	1	2	3	0	0	0	1	2	3
I	456	SUA-Industrial/Commercial Processing	8	6	14	2	2	4	10	8	18
I	457	SUA-Instructional Activities	12	4	16	0	0	0	12	4	16
I	458	SUA-Drug Movement for Training Purposes	1	1	2	0	0	0	1	1	2
I	500	Engineer In Training	1,882	2,050	3,932	507	1,199	1,706	2,389	3,249	5,638
I	600	Cosmetology Apprentice	239	7,277	7,516	7	152	159	246	7,429	7,675
I	601	Barber Apprentice	51	149	200	1	5	6	52	154	206
I	700	Funeral Director Apprentice	305	2,270	2,575	3	65	68	308	2,335	2,643
I	850	Temporary Education Training Permit	0	3,081	3,081	0	2,154	2,154	0	5,235	5,235
I	851	Resident Educational License	1,440	2,550	3,990	575	896	1,471	2,015	3,446	5,461
I	875	Special Permits	216	15,524	15,740	813	8,444	9,257	1,029	23,968	24,997
I	876	Special Licenses	6	2	8	0	4	4	6	6	12
F	900	Appraisal Management Company	5	1	6	76	37	113	81	38	119
GRAND TOTALS			349,730	611,344	961,074	82,998	229,718	312,716	432,728	841,062	1,273,790

The count of INACTIVE LICENSES includes the following:
1)Licenses not renewed and expired, 2)Deceased licensees, 3)Revoked licenses, 4)Voluntarily surrendered licenses, 5)Suspended licenses, 6)Licenses denied due to tax delinquencies, and 7)Licenses issued in error.
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EXHIBIT Z

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Society for Maternal-Fetal Medicine

OBSTETRIC CARE CONSENSUS

Interpregnancy Care

Number 8

This document is endorsed by the American College of Nurse-Midwives and the National Association of Nurse Practitioners in Women's Health. This document was developed by the American College of Obstetricians and Gynecologists and the Society for Maternal–Fetal Medicine in collaboration with Judette Marie Louis MD, MPH; Allison Bryant, MD, MPH; Diana Ramos, MD, MPH; Alison Stuebe, MD, MSc; and Sean C. Blackwell, MD.

ABSTRACT: Interpregnancy care aims to maximize a woman's level of wellness not just in between pregnancies and during subsequent pregnancies, but also along her life course. Because the interpregnancy period is a continuum for overall health and wellness, all women of reproductive age who have been pregnant regardless of the outcome of their pregnancies (ie, miscarriage, abortion, preterm, full-term delivery), should receive interpregnancy care as a continuum from postpartum care. The initial components of interpregnancy care should include the components of postpartum care, such as reproductive life planning, screening for depression, vaccination, managing diabetes or hypertension if needed, education about future health, assisting the patient to develop a postpartum care team, and making plans for long-term medical care. In women with chronic medical conditions, interpregnancy care provides an opportunity to optimize health before a subsequent pregnancy. For women who will not have any future pregnancies, the period after pregnancy also affords an opportunity for secondary prevention and improvement of future health.

Background

Efforts to reduce maternal morbidity have led to an increased focus on improving maternal health before a future pregnancy and across the lifespan. One proposed intervention is improving interpregnancy care. Long understood as an intervention to improve neonatal outcomes, the role of interpregnancy care recently has been recognized for its role in maternal health. This document reviews the existing data on interpregnancy care and offers guidance on providing women with interpregnancy care.

Prepregnancy, Postpartum, Interpregnancy, and Well-Woman Care: The Intersection

Prepregnancy, postpartum, interpregnancy, and well-woman care are interrelated and can be defined by their relationship to the timing of pregnancy (Fig. 1). For women who become pregnant, pregnancy is recognized as a window to future health because complications during pregnancy, such as gestational diabetes mellitus, gestational hypertension, preeclampsia, and fetal growth restriction, are associated with risk of health complications later in life (1–4). The interpregnancy period is an opportunity to address these complications or medical issues that have developed during pregnancy, to assess a woman's mental and physical well-being, and to optimize her health along her life course. The yield of this effort is improved maternal health at the start of the next pregnancy, which leads to improved health outcomes for the infant. The proposed long-term yield is improved long-term health for the woman. Therefore, interpregnancy care aims to maximize a woman's level of wellness not just in between pregnancies and during subsequent pregnancies, but also along her life course. Because the interpregnancy period is a continuum for

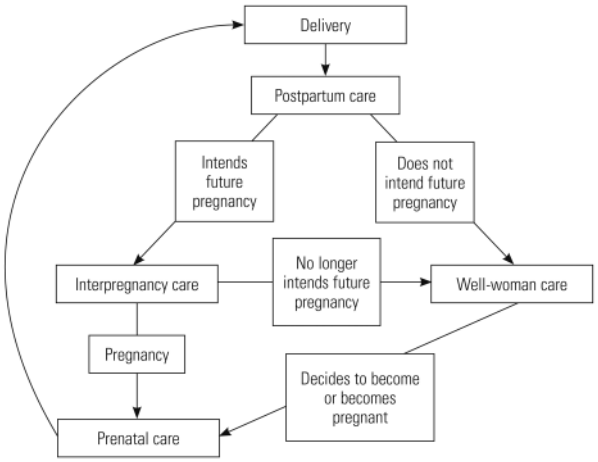

Figure 1. Interpregnancy Care Within the Continuum of Care.

overall health and wellness, all women of reproductive age who have been pregnant regardless of the outcome of their pregnancies (ie, miscarriage, abortion, preterm, full-term delivery), should receive interpregnancy care as a continuum from postpartum care (see the American College of Obstetricians and Gynecologists' [ACOG] Committee Opinion *Optimizing Postpartum Care* or the For More Information section). However, it should be acknowledged that not all women will want to or will have subsequent pregnancies or children.

The health care providers of that care for women of reproductive age include obstetrician–gynecologists, primary care providers, subspecialists who treat chronic illnesses, advanced practice professionals, and mental health providers. Some models have included pediatricians and dentists caring for the infant or other children. Creative partnerships such as these as well as policies that promote access to and coverage of interpregnancy care can ensure that the woman's health is addressed.

Definition of Interpregnancy and Well-Woman Care

Interpregnancy care is the care provided to women of childbearing age who are between pregnancies with the goal of improving outcomes for women and infants (5). When reviewing international recommendations for birth spacing, the World Health Organization identified four intervals: 1) "interpregnancy interval" indicates the time a woman is not pregnant between one live birth or pregnancy loss and the next pregnancy; 2) "birth-to-birth interval" is the time between a live birth and the subsequent live birth (this interval does not take into account any pregnancy losses in between births); 3) "interoutcome interval" describes the time between the outcome of one pregnancy and the outcome of the previous pregnancy; and 4) "birth-to-conception interval" is the time between a live birth and the start of the next pregnancy (6). This document discusses *interpregnancy care*, defined here as the care that addresses a woman's health care needs during the interval between one live birth or pregnancy loss and the start of the next pregnancy; specifically, it will focus on this interval after a woman has transitioned from postpartum care.

Existing Recommendations

The concept of interpregnancy care is well established and multiple organizations have put forth their own distinct set of interpregnancy care recommendations (5, 7–9). However, many of these recommendations are focused solely on improving neonatal outcomes of future pregnancies. This document will focus on interpregnancy care to improve maternal and neonatal outcomes of future pregnancies, as well as long-term women's health outcomes.

Clinical Considerations and Management

To optimize interpregnancy care, anticipatory guidance should begin during pregnancy with the development of a postpartum care plan that addresses the transition to parenthood and interpregnancy or well-woman care (4) (Table 1). The initial components of interpregnancy care should include the components of postpartum care (10), such as reproductive life planning, screening for depression, vaccination, managing diabetes or hypertension if needed, education about future health, assisting the patient to develop a postpartum care team, and making plans for long-term medical care (Box 1). Timing of visits should consider any changes in insurance coverage anticipated after delivery.

► ***What Are the Clinical Components of Interpregnancy Care?***

Breastfeeding and Maternal Health

Health care providers should routinely provide anticipatory guidance and support to enable women to breastfeed as an important part of interpregnancy health (11, 12). Multiple studies have shown that longer duration of breastfeeding is associated with improved maternal health, including lower risks of diabetes (13–15), hypertension (15, 16), myocardial infarction (17), ovarian cancer (15, 18), and breast cancer (15, 19). For women with gestational diabetes, longer duration of breastfeeding is associated with decreased risk of metabolic syndrome (20) and type 2 diabetes (21). A recent simulation study found that if 90% of women were to breastfeed optimally, this would prevent 5,023 cases of breast cancer, 12,320 cases of type 2 diabetes, 35,982 cases of hypertension, and 8,487 cases of myocardial infarction (22).

Although ACOG recommends exclusive breastfeeding for the first 6 months of life, obstetrician–gynecologists and other health care providers should support each woman's informed decision about whether to initiate or continue breastfeeding (11), recognizing that she is uniquely qualified to decide whether exclusive

Table 1. Interpregnancy Care Recommendations

Recommendation	Grade of Recommendation
General	
To optimize interpregnancy care, anticipatory guidance should begin during pregnancy with the development of a postpartum care plan that addresses the transition to parenthood and interpregnancy or well-woman care.	Best Practice
Breastfeeding and Maternal Health	
Health care providers should routinely provide anticipatory guidance and support to enable women to breastfeed as an important part of interpregnancy health.	1A Strong recommendation, high-quality evidence
Interpregnancy Interval	
Women should be advised to avoid interpregnancy intervals shorter than 6 months.	1B Strong recommendation, moderate-quality evidence
Women should be counseled about the risks and benefits of repeat pregnancy sooner than 18 months.	2B Weak recommendation, moderate-quality evidence
Family planning counseling should begin during prenatal care with a conversation about the woman's interest in future childbearing.	Best Practice
Depression	
All women should be screened for depression in the postpartum period, and then as part of well-woman care during the interpregnancy period. Such screening should be implemented with systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up.	1B Strong recommendation, moderate-quality evidence
Postpartum depression screening also may occur at the well-child visit with procedures in place to accurately convey the information to the maternal care provider.	1B Strong recommendation, moderate-quality evidence
Other Medical Conditions	
Women should be encouraged to reach their prepregnancy weight by 6–12 months postpartum and ultimately to achieve a normal BMI (calculated as weight in kilograms divided by height in meters squared) of 18.5–24.9.	2B Weak recommendation, moderate-quality evidence
Health care providers should offer specific, actionable advice regarding nutrition and physical activity using proven behavioral techniques.	1A Strong recommendation, high-quality evidence
Nonpregnant adult smokers should be offered smoking cessation support through behavioral interventions and U.S. Food and Drug Administration-approved pharmacotherapy.	1A Strong recommendation, high-quality evidence
In the interpregnancy period, all women should be routinely asked about their use of alcohol and drugs, including prescription opioids, marijuana, and other medications used for nonmedical reasons and referred as indicated. Substance use disorder and relapse prevention programs also should be made available.	Best Practice

(*continued*)

Table 1. Interpregnancy Care Recommendations (*continued*)

Recommendation	Grade of Recommendation
Health care providers should consider patient navigators, trained medical interpreters, health educators, and promotoras to facilitate quality interpregnancy care for women of low-health literacy, with no or limited English proficiency, or other communication needs.	2C Weak recommendation, low-quality evidence
Women of childbearing age should be screened for intimate partner violence, such as domestic violence, sexual coercion, and rape, and referred for intervention services if they screen positive.	2B Weak recommendation, moderate-quality evidence
Women with histories of sexually transmitted infections before or during pregnancy should have thorough sexual and behavioral histories taken to determine risk of repeat infection or current or subsequent infection with HIV or viral hepatitis.	1A Strong recommendation, high-quality evidence
All women should be encouraged to engage in safe sex practices; partner screening and treatment should be facilitated as appropriate.	1A Strong recommendation, high-quality evidence
As part of interpregnancy care, women at high risk of STIs should be offered screening, including for HIV, syphilis, and hepatitis. Screening should follow guidance set forth by the CDC.	1A Strong recommendation, high-quality evidence
History of High-Risk Pregnancy	
Women with prior preterm births should be counseled that short interpregnancy intervals may differentially and negatively affect subsequent pregnancy outcomes and, as such, the birth spacing recommendations listed in the section "Interpregnancy Interval" are particularly important.	1B Strong recommendation, moderate-quality evidence
Given insufficient evidence of benefit, screening and treating asymptomatic genitourinary infections in the interpregnancy period in women at high risk of preterm birth is not recommended.	1B Strong recommendation, moderate-quality evidence
For women who have had pregnancies affected by congenital abnormalities or genetic disorders, health care providers should review postnatal or pathologic information with the women and offer genetic counseling, if appropriate, to estimate potential recurrence risk.	1C Strong recommendation, low-quality evidence
All women who are planning a pregnancy or capable of becoming pregnant should take 400 micrograms of folic acid daily. Supplementation should begin at least 1 month before fertilization and continue through the first 12 weeks of pregnancy.	1A Strong recommendation, high-quality evidence
All women planning a pregnancy or capable of becoming pregnant who have had a child with a neural tube defect should take 4 mg of folic acid daily. Supplementation should begin at least 3 months before fertilization and continue through the first 12 weeks of pregnancy.	1A Strong recommendation, high-quality evidence
A thorough review of all prescription and nonprescription medications and potential teratogens and environmental exposures should be undertaken before the next pregnancy.	1A Strong recommendation, high-quality evidence

(*continued*)

Table 1. Interpregnancy Care Recommendations (*continued*)

Recommendation	Grade of Recommendation
A genetic and family history of the patient and her partner should be obtained. This may include family history of genetic disorders, birth defects, mental disorders, and breast, ovarian, uterine, and colon cancer.	1B Strong recommendation, moderate-quality evidence
Infertility	
Generally, recommendations for the length of the interpregnancy interval should not differ for women with prior infertility compared with women with normal fertility.	2C Weak recommendation, low-quality evidence
Prior Cesarean Delivery	
Women with prior cesarean deliveries, and particularly those who are considering a trial of labor after cesarean delivery, should be counseled that a shorter interpregnancy interval in this population has been associated with an increased risk of uterine rupture and risk of maternal morbidity and transfusion.	1B Strong recommendation, moderate-quality evidence

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CDC, Centers for Disease Control and Prevention; HIV, human immunodeficiency virus; STIs, sexually transmitted infections.

breastfeeding, mixed feeding, or formula feeding is optimal for her and her infant. Additionally, obstetrician–gynecologists and other health care providers can provide information and resources that might help women better understand their workplace breastfeeding rights (23). Additional guidance can be found at www.acog.org/breastfeeding.

Interpregnancy Interval

Women should be advised to avoid interpregnancy intervals shorter than 6 months and should be counseled about the risks and benefits of repeat pregnancy sooner than 18 months. Most of the data from observational studies in the United States would suggest a modest increase in risk of adverse outcomes associated with intervals of less than 18 months and more significant risk of adverse outcome with intervals of less than 6 months between birth and the start of the next pregnancy (24–40). More recent studies, however, have called into question the methodologies common to much of the literature, and the question remains open as to the causal effect of short interpregnancy intervals on some outcomes (41, 42). Interdelivery (from one delivery to the next) intervals of less than 18 months have been associated with increased risk of uterine rupture among women undergoing trials of labor after cesarean (43, 44). Interpregnancy intervals of greater than 5–10 years also may be associated with increased risk of adverse outcomes (25).

Because the interpregnancy interval is a potentially modifiable risk factor, there has been enthusiasm for providing guidance to women and their families about the benefits of intervals longer than 6 months between pregnancies. Women of lower socioeconomic status and women of color appear to be at risk of the shortest interpregnancy intervals (45–47), which highlights the interpregnancy interval as a potential opportunity to address inequities in adverse outcomes.

Interventions to Increase Optimally Spaced Pregnancies

Family planning counseling should begin during prenatal care with a conversation about the woman's interest in future childbearing (48). In the United States, 45% of pregnancies are unplanned (49), and one in three women become pregnant before the recommended 18-month interpregnancy interval (50). Contraceptive access and patient and health care provider knowledge are important enablers of adequate birth spacing (51, 52), and woman-centered family planning counseling enables each woman to select a family planning method that is acceptable to her and is commensurate with her desires for future childbearing. Starting this conversation by asking, "Would you like to become pregnant in the next year?" or, for women in the immediate postpartum period, "When would you like to become pregnant again?" allows the health care provider and the woman to center discussions of contraception on the woman's priorities. The counseling should include a discussion about birth spacing and its role in providing sufficient time to optimize health before the next pregnancy. This optimization can improve outcomes for the subsequent pregnancy as well as across the woman's lifespan (53).

Counseling should include a discussion of all contraceptive options (including implants, intrauterine devices, hormonal methods, barrier methods,

Box 1. Key Steps in Interpregnancy Care*

During Prenatal Care

Determine who will provide primary care after the immediate postpartum period
Discuss reproductive life planning and preferences for a method of contraception
Provide anticipatory guidance regarding breastfeeding and maternal health
Discuss associations between pregnancy complications and long-term maternal health, as appropriate

During the Maternity Stay†

Discuss the importance, timing, and location of follow-up for postpartum care
If desired by the patient, provide contraception, including long-acting reversible contraception or surgical sterilization
Provide anticipatory guidance regarding breastfeeding and maternal health
Ensure the patient has a postpartum medical home

At the Comprehensive Postpartum Visit‡

Review any complications of pregnancy and birth and their implications for future maternal health; discuss appropriate follow-up care
Review the reproductive life plan and provide a commensurate method of contraception
Ensure that the patient has a primary medical home for ongoing care

During Routine Health Care or Well-Woman or Pediatric Visits§

Assess whether the woman would like to become pregnant in the next year
Screen for intimate partner violence and depression or mental health disorders
Assess pregnancy history to inform decisions about screening for chronic conditions (eg, diabetes, cardiovascular disease)
For known chronic conditions, optimize disease control and maternal health
Pediatric colleagues to screen during child health visits for women's health issues such as smoking, depression, multivitamin use, and satisfaction with contraception (IMPLICIT Toolkit)‖

*Timing should take into account any changes in insurance coverage anticipated after delivery.

†See *Guidelines for Perinatal Care*, Eighth Edition, for more information.

‡See Committee Opinion 736, *Optimizing Postpartum Care,* for more information.

§See Committee Opinion 755, *Well-Woman Visit,* and www.acog.org/wellwoman for more information.

‖Implicit Toolkit Family Medicine Education Consortium. IMPLICIT interconception care toolkit: incorporating maternal risk assessment into well-child visits to improve birth outcomes. Dayton (OH): FMEC; 2016. Available at: https://health.usf.edu/publichealth/chiles/fpqc/larc/~/media/89E28EE3402E4198BD648F84339799C1.ashx. Retrieved September 12, 2018.

lactational amenorrhea, and natural family planning). The Centers for Disease Control and Prevention's (CDC) *U.S. Medical Eligibility Criteria for Contraceptive Use* and *U.S. Selected Practice Recommendations for Contraceptive Use* (54, 55) can be used to facilitate evidence-based contraception counseling to meet an individual patient's family planning and pregnancy spacing needs. Counseling should use a shared decision-making approach, which acknowledges that there are two experts in the conversation (the health care provider as an expert in clinical care and the patient as an expert on her own experiences and preferences) (48, 56) so that the woman can make an autonomous and informed decision. Health care providers also should ask what methods women have found to be effective and acceptable in the past. Family planning counseling may be perceived differently by women who historically have been marginalized and who have experienced coercive counseling and social policies (57, 58). Health care providers should be conscious of implicit biases against childbearing among marginalized women and ensure that counseling addresses the individual woman's needs and desires (57).

Every woman should have access to all contraceptive methods when needed (including immediately after giving birth) without financial or logistical barriers, and obstetrician–gynecologists and other obstetric care providers can help advocate for policies that support this (59). This includes, but is not limited

to, long-acting, reversible contraceptive methods because they may be particularly helpful in reducing unplanned pregnancy and, therefore, optimizing birth spacing (60, 61). For more information on long-acting, reversible contraceptives, see the For More Information section.

Few other interventions have proven efficacy in reducing the occurrence of short interpregnancy intervals. Other interventions that may have benefit include home visitation programs and enhanced social supports (62–64).

Depression

All women should be screened for depression in the postpartum period and then as part of well-woman care during the interpregnancy period. Such screening should be implemented with systems in place to ensure accurate diagnosis, effective treatment, and appropriate follow-up. Postpartum depression screening also may occur at the well-child visit with procedures in place to accurately convey the information to the maternal care provider. Perinatal depression and anxiety affect one in seven women, with devastating consequences for women and children (65). Screening for symptoms with a validated instrument, such as the Patient Health Questionnaire-9 or the Edinburgh Postnatal Depression Scale, is recommended by the U.S. Preventive Services Task Force (66) and by all major medical organizations that care for women and infants (65, 67, 68). The American Academy of Pediatrics recommends postpartum depression screening at the time of well-child visits at 1, 2, 4, and 6 months of age (67). Although screening alone has been demonstrated to be of benefit (65), ideally screening would be paired with available and accessible mental health interventions. A recent systematic review found that only 22% of women who screened positive for depression attended a mental health visit in the absence of an intervention to facilitate referral (69). Health care providers should be prepared to initiate treatment or refer women to a qualified caregiver, or both.

Managing Other Medical Conditions

In women with chronic medical conditions, interpregnancy care provides an opportunity to optimize health before a subsequent pregnancy. For women who will not have any future pregnancies, the period after pregnancy also affords an opportunity for secondary prevention and improvement of future health. Recommendations for counseling and goals can be found in Table 2, with recommendations for the most common conditions expanded on in the following sections.

Reducing Weight

Women should be encouraged to reach their prepregnancy weight by 6–12 months postpartum and ultimately to achieve a normal body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) of 18.5–24.9. Ideally, a woman's weight should be optimized before she attempts to become pregnant (70), although the health benefits of postponing pregnancy need to be balanced against reduced fecundity with female aging (71). Postpregnancy weight retention and gain have been associated with subsequent adverse obstetric consequences such as gestational diabetes, hypertensive disorders, stillbirth, large-for-gestational age neonates, cesarean delivery, longer-term obesity (72–78), and possibly congenital anomalies (79). Reduction of BMI between pregnancies is associated with improved perinatal outcomes (78), which makes achieving ideal body weight an important component of interpregnancy care.

Health care providers should offer specific, actionable advice regarding nutrition and physical activity, using proven behavioral techniques (70, 80). Health care providers are referred to ACOG's Obesity Toolkit for more resources (81). Several randomized controlled trials have been conducted to encourage weight loss in the postpartum period, with mixed results (82). The most effective means by which to achieve weight loss goals are not clear, but most likely include a program of diet alone or diet in combination with exercise (83, 84). There is insufficient evidence on whether breastfeeding is associated with postpartum weight change (15).

For women with a BMI greater than or equal to 40 or greater than 35 with at least one serious obesity-related morbidity, referral to a bariatric surgery program may be considered because bariatric surgery is associated with improved metabolic health (85). Studies that compared outcomes among women with pregnancies before and after undergoing bariatric surgery have found lower rates of gestational diabetes and hypertension in the postprocedure pregnancy but higher rates of small-for-gestational-age infants (86). Women should be counseled that weight loss after bariatric surgery is associated with improved fertility, and it is recommended to delay pregnancy for 12–24 months after the procedure (87). During the postoperative period, the risk of oral contraceptive failure in patients who have bariatric surgery with a malabsorptive component is increased (54). See the For More Information section for additional resources on reducing weight.

Substance Use and Use Disorders

Tobacco Cessation. Nonpregnant adult smokers should be offered smoking cessation support through behavioral interventions and U.S. Food and Drug Administration-approved pharmacotherapy (88). Tobacco use is a modifiable risk factor for a host of adverse pregnancy outcomes and longer-term health outcomes. The U.S. Preventive Services Task Force

Table 2. Specific Health Conditions

Condition	Counseling	Interpregnancy Test/Screening	Management Considerations	Goals	Medications of Concern for Pregnancy*
Gestational diabetes	Women with gestational diabetes have a sevenfold increased risk of developing type 2 diabetes.	2-hour OGTT at 4–12 weeks postpartum; screening every 1–3 years	Women with impaired fasting glucose, IGT, or diabetes should be referred for preventive or medical therapy.	Early detection of overt diabetes; diabetes prevention	
Diabetes	Poorly controlled diabetes damages the woman's eyes, heart, blood vessels, and kidneys. Poor control further increases risk of birth defects in the next pregnancy. Diabetes is a risk factor for future heart disease.	Patients should demonstrate good control of blood sugars with hemoglobin A_{1c} <7.0% (53 mmol/mol).	Weight management Testing for underlying vasculopathy: retinal examination, 24-hour urine protein testing, and electrocardiography. Thyroid screening	Hemoglobin A_{1c} <6.5% (48 mmol/mol) if a future pregnancy is desired, to reduce the risk of congenital anomalies Discuss aspirin for future pregnancies.	Medications for comorbidity ACE inhibitors Statins
Preeclampsia	Women with a history of preeclampsia have an increased risk of recurrence in subsequent pregnancies. These women also have a twofold increased risk of subsequent cardiovascular disease.	Evaluate BP for resolution of hypertension.		Maintain BP <120/80. Maintain healthy weight. Discuss aspirin for future pregnancies.	ACE inhibitors Angiotensin receptor blockers
Gestational hypertension	Women with a history of gestational hypertension have an increased risk of developing chronic hypertension. These women also have a twofold increased risk of subsequent cardiovascular disease.	Evaluate BP for resolution of hypertension.		Maintain BP <120/80. Maintain healthy weight. Discuss aspirin for future pregnancies.	ACE inhibitors Angiotensin receptor blockers

(*continued*)

Table 2. Specific Health Conditions (*continued*)

Condition	Counseling	Interpregnancy Test/Screening	Management Considerations	Goals	Medications of Concern for Pregnancy*
Chronic hypertension	Hypertensive disease is a major cause of maternal morbidity and mortality. Uncontrolled hypertension leads to end organ damage, renal disease, and cardiovascular disease such as heart attacks and strokes.	Evaluate BP for resolution of hypertension.		Maintain BP <120/80. Maintain healthy weight. Consider testing for ventricular hypertrophy, retinopathy, and renal disease for women with longstanding or uncontrolled hypertension. Discuss aspirin for future pregnancies.	ACE inhibitors Angiotensin receptor blockers
Cardiovascular disease	Cardiovascular disease is the leading cause of maternal mortality.	Optimal contraception counseling Evaluation and management by a cardiac disease specialist		To be determined with cardiac care provider	ACE inhibitors Warfarin beyond 6 weeks of gestation
Depression or mental health disorders	Screening allows for treatment and control of symptoms that may help prevent self-harm and negative family outcomes, such as impaired infant bonding, or neglect.	Use validated test to monitor.	Referral to mental health providers	Control of symptoms	Valproic acid Lithium
Overweight and obesity	Obesity is associated with increased risk of perinatal and maternal morbidity, as well as infertility. Weight loss in between pregnancy reduces that risk. Obesity increases the risk of type 2 diabetes, hypertension, certain types of cancer, arthritis, and heart disease.	Measure BMI. Preventive screening for diabetes and lipids		Reach prepregnancy weight by 6-12 months after giving birth; ultimately achieve normal BMI. Referral for bariatric surgery when appropriate Discuss aspirin for future pregnancies.	Weight loss drugs: Phentermine–topiramate Limited data on other drugs

(*continued*)

Table 2. Specific Health Conditions (*continued*)

Condition	Counseling	Interpregnancy Test/Screening	Management Considerations	Goals	Medications of Concern for Pregnancy*
HIV	HIV infection increases risk of maternal morbidity and fetal vertical transmission.	CD4 and viral load	Management by an HIV care provider	Nondetectable viral load	If future pregnancy desired, avoid antiviral medications suspected to be teratogenic.
Renal disease	Pregnancy may be associated with irreversible worsening of renal function in women with moderate to severe renal disease.	Serum creatinine Urine protein		To be determined with renal specialist Discuss aspirin for future pregnancies.	ACE inhibitors
Epilepsy	Epilepsy is associated with increased risk of malformations and seizures in offspring.	Whenever possible, monotherapy in the lowest therapeutic dose should be prescribed.	Coordination of care for optimal suppression of seizures. Maintain therapeutic levels of antiepileptic agents.	Cessation of seizure activity	Valproic acid Carbamazepine
SLE and autoimmune disease	Poorly controlled autoimmune disorders are associated with increased miscarriages and maternal morbidity. Some of these conditions are associated with cardiovascular disease.	Evaluate for renal function and end-organ disease.	Optimize disease control Evaluate for antiphospholipid antibody syndrome if there are qualifying clinical events, renal disease, and diabetes if managed with chronic steroids.		Cyclophosphamide Methotrexate Mycophenolate Leflunomide
Thyroid disease	Poorly controlled thyroid disease is associated with adverse pregnancy outcomes, such as spontaneous abortion, preterm delivery, low birth weight, preterm birth, impaired neuropsychological development of the offspring, and possibly miscarriage.	Thyrotropin (also known as thyroid-stimulating hormone) Free T4	Management by primary provider to remain euthyroid Women with symptoms of hypothyroidism should undergo thyroid screening before attempting pregnancy.	Achieve euthyroid state	Radioactive iodine

(*continued*)

Table 2. Specific Health Conditions (*continued*)

Condition	Counseling	Interpregnancy Test/Screening	Management Considerations	Goals	Medications of Concern for Pregnancy*
STI	STIs increase the risk of preterm birth and puerperal infections. Untreated STIs are associated with impairment of fertility and increased risk of HIV infection.	Screening per CDC recommendations	Counseling to engage in safer sex practice; partner screening or treatment, or both	Remain free of STI infection or reinfection	
Tobacco cessation	Tobacco use (smoked, chewed, ENDS, and vaped) is associated with adverse pregnancy outcomes such as small for gestational age and abruption. The long-term health consequences of tobacco use are well established and include increases in cardiovascular disease and cancer.	Screen using the five A's: Ask, Advise, Assess, Assist, and Arrange.	Advise cessation and provide behavioral interventions and U.S. Food and Drug Administration (FDA)-approved pharmacotherapy for cessation to adults who use tobacco.	Reduce tobacco use to none	Nicotine replacement products or other pharmaceuticals for smoking cessation are generally not recommended.
Thrombophilia	Inherited thrombophilias are associated with increased risk of venous thromboembolism and adverse pregnancy outcomes.	Consider screening in these cases: venous thromboembolism that was associated with a nonrecurrent risk factor or a first-degree relative with a high-risk thrombophilia.	Coordinate care for maintenance of thromboprophylaxis if indicated. Consider and plan for thromboprophylaxis during pregnancy.	Determined with hematologist or primary care provider	Warfarin beyond 6 weeks of gestation
Immunizations	Immunization against vaccine preventable diseases are crucial for long-term maternal and infant health.	All women should be screened for relevant vaccination opportunities per CDC guidelines.			MMR HPV Varicella Live attenuated virus

(*continued*)

Table 2. Specific Health Conditions (*continued*)

Condition	Counseling	Interpregnancy Test/Screening	Management Considerations	Goals	Medications of Concern for Pregnancy*
Psychosocial risks	Socioeconomic disadvantage, race or ethnicity, and intimate partner violence are associated with worse health outcomes.	All women should be screened for access to resources	Appropriate referrals to local and community resources should be provided		
Antiphospholipid antibody syndrome	Antiphospholipid antibody syndrome is associated with increased risk of venous thromboembolism and adverse pregnancy outcomes	Screen for anyone with a vascular thrombosis with one of the qualifying clinical scenarios: ≥3 first trimester losses, ≥1 birth at <34 weeks from preeclampsia and ≥1 loss at 10 weeks or greater.		Determine with hematologist Discuss aspirin for future pregnancies.	Warfarin beyond 6 weeks gestation

Abbreviations: ACE, angiotensin-converting-enzyme; BP, blood pressure; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CDC, Centers for Disease Control and Prevention; CD4, cluster of differentiation 4; ENDS, electronic nicotine delivery systems; HIV, human immunodeficiency virus; ID, infectious disease; IGT, impaired glucose tolerance; MMR, measles–mumps–rubella; OGTT, oral glucose tolerance test; SLE, systemic lupus erythematosus; STI, sexually transmitted infections; T4, thyroxine.

*Medications listed may or may not be appropriately prescribed during pregnancy. Health care providers should discuss the risks and benefits of the medication, review treatment goals, and discuss family planning and how long-term use might affect care during a future pregnancy before initiating a medication.

and ACOG recommend medications, behavioral interventions, or both in nonpregnant adults (89, 90). For lactating women, nicotine replacement therapy is compatible with breastfeeding because the amounts of nicotine and cotinine transferred with breast milk are generally the same or lower using replacement therapy compared with smoking (91). Specific tools are available to assist health care providers in enabling women to cease smoking after pregnancy (89, 92). Health care providers should reassess tobacco use (smoked, chewed, electronic nicotine delivery systems, vaped) at the postpartum visit (4) and continue to provide, or refer to, assistance with ongoing efforts at cessation (93).

Substance Use Disorder. In the interpregnancy period, all women should be routinely asked about their use of alcohol and drugs, including prescription opioids, marijuana, and other medications used for nonmedical reasons and referred as indicated. Substance use disorder and relapse prevention programs also should be made available (4, 48, 94). Untreated substance use disorders have implications for long-term maternal health and increase the risk of adverse pregnancy outcomes. Moreover, psychiatric disorders such as depression, anxiety, bipolar disorder, and posttraumatic stress disorder are prevalent among women with substance use disorders. Women with substance use disorder have higher rates of unintended pregnancies and lower rates of use of reliable contraception (95). Therefore, it is particularly important to ensure continuation of treatment or to identify and initiate treatment for substance use disorder during the interpregnancy period.

Women who are planning to become pregnant in the immediate future should be encouraged to discontinue recreational substance use and should be counseled that there is no safe level or type of alcohol use during pregnancy. Women who are unable to quit before or during pregnancy likely have a substance use disorder and should be referred to treatment as indicated, if this has not already been done. See the For More Information section for additional resources on substance use.

Social Determinants of Health and Racial and Ethnic Disparities

Health care providers should inquire about and document social and structural determinants of health and maximize referrals to social services to help improve patients' abilities to access health care (96). Social determinants of health (eg, stable housing, access to food and safe drinking water, utility needs, safety in the home and community, immigration

status, and employment conditions) relate closely with health outcomes, health-seeking behaviors, and health care (96, 97). Many of the resources available to women and families with specific needs are provided through state departments of health, insurers, or community health organizations, but individual health care providers and practices should engage in evaluation and referral as well. Estimates of the benefit of such programs are derived largely from observational cohort and preintervention and postintervention designs, but many demonstrate improved health outcomes (98–101).

Health care providers should be aware of prevailing disparities in health care and outcomes in order to understand the risks faced by the populations they care for, but no current evidence guides variation in care by race or ethnicity that may be needed to improve outcomes. Women of color and of low socioeconomic status are at risk of adverse pregnancy and overall poor health outcomes (102). These women may be least likely to receive prepregnancy and interpregnancy care despite their disproportionate need (7, 103). Although some interpregnancy interventions (eg, home visits, social supports) have been demonstrated to be of benefit within specific populations at risk, data on differential effects of interventions by population are scarce.

If available, health care providers should consider patient navigators, trained medical interpreters, health educators, and promotoras (lay community health care workers who work in Spanish-speaking communities [104]) to facilitate quality interpregnancy care for women of low-health literacy, with no or limited English proficiency, or other communication needs.

Intimate Partner Violence

Women of childbearing age should be screened for intimate partner violence (IPV), such as domestic violence, sexual coercion, and rape and referred for intervention services if they screen positive. Sample questions to begin the conversation and guidance on how to appropriately and safely screen for IPV are provided in ACOG Committee Opinion *Intimate Partner Violence* (105). Given the high incidence of IPV, screening for IPV should occur during all encounters (postpartum, well-woman, and at the first prenatal visit and at least once per trimester for pregnant women) (48, 106). During a lifetime, more than one in three women experience rape, physical violence, or stalking by an intimate partner (105). Intimate partner violence has a period prevalence of 17% in the first year postpartum (107). Some women experience IPV as reproductive coercion, including pregnancy pressure, pregnancy coercion, and sabotaging contraception (108).

Sexually Transmitted Infections

Women with histories of STIs before or during pregnancy should have thorough sexual and behavioral histories taken to determine risk of repeat infection or current or subsequent infection with human immunodeficiency virus (HIV) or viral hepatitis. All women should be encouraged to engage in safe sex practices; partner screening and treatment should be facilitated as appropriate. As part of interpregnancy care, women at high risk of STIs should be offered screening, including for HIV, syphilis, and hepatitis. Screening should follow guidance set forth by the CDC (109). Sexually transmitted infections have clear implications for a woman's overall health, fertility, and pregnancy outcomes. Unrecognized and untreated infections may have important sequelae. Women with history of prior STIs are at increased risk of recurrent STIs (110) and, thus, should be considered for rescreening.

Immunizations

The interpregnancy period is ideal to initiate or complete appropriate adult vaccinations that are contraindicated during pregnancy or were not completed during pregnancy but are medically indicated (111) (see Table 1 in ACOG's Committee Opinion on *Maternal Immunization*). The current recommended immunization schedule for adults 19 years or older can be found on the CDC's website. The American College of Obstetricians and Gynecologists reviews these schedules annually for endorsement. Immunizations are a proven way to prevent and, in some cases, eradicate disease. Attention to vaccines needed during the interpregnancy period can play a major role in reducing morbidity and mortality from a range of preventable diseases, including pertussis, influenza, human papillomavirus, hepatitis, and rubella for nonimmune women.

Other Components of the Well-Woman Visit

The periodic well-woman visit as a component of interpregnancy care provides the opportunity for women to receive necessary preventive services. This may include multiple well-woman visits for women who have an interpregnancy interval that lasts for more than 1 year. Guidance for the components of the well-woman examination can be found in ACOG's Committee Opinion on *Well-Woman Visit*, and at www.acog.org/wellwoman (112, 113).

► *What Is Role of Interpregnancy Care in Specific Populations?*

The provision of interpregnancy care may be particularly effective when targeted to high-risk and special populations. In addition to the aforementioned universal recommendations listed in this document, the following recommendations should be considered for specific populations. More details on each topic are provided in the For More Information section.

History of High-Risk Pregnancy

Preterm Birth

For women who delivered early, obstetrician–gynecologists and other obstetric care providers should obtain a detailed medical history of all previous pregnancies and offer women the opportunity to discuss the circumstances that led to the preterm birth. Ideally this would occur within 6–8 weeks of delivery in order to facilitate record review and accurate information gathering; a suggested plan for management of subsequent pregnancies (eg, 17α-hydroxyprogesterone, cervical cerclage, cervical length surveillance) based on current available evidence should be provided to the patient and documented in an accessible location in the medical record. Women with a history of preterm birth, whether indicated or spontaneous, are at increased risk of recurrence (114, 115) and at risk of longer-term maternal morbidity (116). A prior preterm birth is associated with an increased risk of subsequent cardiovascular disease (117). Although women with obstetric complications such as preterm birth may need greater health care services than women with normal delivery outcomes, some evidence suggests that women with obstetric complications are no more likely to access interpregnancy services (118).

Women with prior preterm births should be counseled that short interpregnancy intervals may differentially and negatively affect subsequent pregnancy outcomes and, as such, the birth spacing recommendations listed earlier are particularly important (119). Given insufficient evidence of benefit, screening and treating asymptomatic genitourinary infections in the interpregnancy period in women at high risk of preterm birth is not recommended (120, 121).

Fetal Anomalies

For women who have had pregnancies affected by congenital abnormalities or genetic disorders, health care providers should review postnatal or pathologic information with the women and offer genetic counseling, if appropriate, to estimate potential recurrence risk. Approximately 2–4% of live births are affected by congenital abnormalities. The strongest risk factors, such as age, family history, and a previously affected child, are usually nonmodifiable. In some cases, the finding of a malformation may have implications for maternal health. For example, maternal obesity and pregestational diabetes mellitus are risk factors for congenital anomalies (122, 123). In these cases, interventions to prevent a recurrence should focus on improvement in the underlying maternal medical conditions.

Modifiable risk factors for congenital birth defects also can be identified and addressed in the interpregnancy period. All women who are planning a pregnancy or capable of becoming pregnant should take 400 micrograms of folic acid daily. Supplementation should begin at least 1 month before fertilization and continue through the first 12 weeks of pregnancy. All women planning a pregnancy or capable of becoming pregnant who have had a child with a neural tube defect should take 4 mg of folic acid daily. Supplementation should begin at least 3 months before fertilization and continue through the first 12 weeks of pregnancy. A thorough review of all prescription and nonprescription medications and potential teratogens and environmental exposures should be undertaken before the next pregnancy.

The responsibility of caring for a medically fragile infant may deter women from accessing interpregnancy care. Novel strategies, such as embedding screening and referral services within pediatric follow-up clinics (124), may help women to address their own health needs.

Genetic Testing

The interpregnancy period is an ideal time for genetic counseling and carrier screening if they have not been previously completed, which allows for informed planning of the subsequent pregnancy (125, 126). Family history and carrier status are important considerations. A genetic and family history of the patient and her partner should be obtained (126–128). This may include family history of genetic disorders; birth defects; mental disorders; and breast, ovarian, uterine, and colon cancer. Further guidance on carrier screening and counseling can be found in ACOG's Committee Opinion on *Carrier Screening in the Age of Genomic Medicine* (125), ACOG's Committee Opinion on *Carrier Screening for Genetic Conditions* (126), and ACOG's Technology Assessment on *Modern Genetics in Obstetrics and Gynecology* (128).

Infertility

Underlying conditions that may contribute to subfertility (eg, polycystic ovary syndrome, infections, obesity, and thyroid dysfunction) should be evaluated and treatments optimized before a woman attempts to become pregnant. Generally, recommendations for the length of the interpregnancy interval should not differ for women with prior infertility compared with women with normal fertility. Women with histories of infertility or subfertility may need to rely on assisted reproduction to become pregnant; the timing of the next pregnancy attempt is, therefore, often more readily influenced by health care providers than it might be for other women.

Prior Cesarean Delivery

Women with prior cesarean deliveries, and particularly those who are considering a trial of labor after cesarean

delivery, should be counseled that a shorter interpregnancy interval in this population has been associated with an increased risk of uterine rupture and risk of maternal morbidity and transfusion. Evidence exists of increased risk of uterine rupture after cesarean delivery following delivery-to-delivery intervals of 18–24 months or less (43, 129). Evidence also indicates that there is increased risk of maternal morbidity and blood transfusion among women with interpregnancy intervals of less than 6 months (44, 130). Furthermore, women should be counseled that the incidence of placenta accreta spectrum increases with the number of prior cesarean deliveries (131).

For More Information

The American College of Obstetricians and Gynecologists has identified additional resources on topics related to this document that may be helpful for obgyns, other health care providers, and patients. You may view these resources at www.acog.org/More-Info/InterpregnancyCare.

These resources are for information only and are not meant to be comprehensive. Referral to these resources does not imply the American College of Obstetricians and Gynecologists' endorsement of the organization, the organization's website, or the content of the resource. The resources may change without notice.

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Society for Maternal–Fetal Medicine Grading System: Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Recommendations

Obstetric Care Consensus documents will use Society for Maternal-Fetal Medicine's grading approach: http://www.ajog.org/article/S0002-9378%2813%2900744-8/fulltext. Recommendations are classified as either strong (Grade 1) or weak (Grade 2), and quality of evidence is classified as high (Grade A), moderate (Grade B), and low (Grade C)*. Thus, the recommendations can be 1 of the following 6 possibilities: 1A, 1B, 1C, 2A, 2B, 2C.

Grade of Recommendation	Clarity of Risk and Benefit	Quality of Supporting Evidence	Implications
1A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Consistent evidence from well-performed randomized controlled trials or overwhelming evidence of some other form. Further research is unlikely to change confidence in the estimate of benefit and risk.	Strong recommendations, can apply to most patients in most circumstances without reservation. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
1B. Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.	Strong recommendation, and applies to most patients. Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
1C. Strong recommendation, low-quality evidence	Benefits appear to outweigh risk and burdens, or vice versa.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.	Strong recommendation, and applies to most patients. Some of the evidence base supporting the recommendation is, however, of low quality.
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens.	Consistent evidence from well-performed randomized controlled trials or overwhelming evidence of some other form. Further research is unlikely to change confidence in the estimate of benefit and risk.	Weak recommendation, best action may differ depending on circumstances or patients or societal values.
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burdens; some uncertainty in the estimates of benefits, risks, and burdens.	Evidence from randomized controlled trials with important limitations (inconsistent results, methodologic flaws, indirect or imprecise), or very strong evidence of some other research design. Further research (if performed) is likely to have an effect on confidence in the estimate of benefit and risk and may change the estimate.	Weak recommendation, alternative approaches likely to be better for some patients under some circumstances.
2C. Weak recommendation, low-quality evidence	Uncertainty in the estimates of benefits, risks, and burdens; benefits may be closely balanced with risks and burdens.	Evidence from observational studies, unsystematic clinical experience, or from randomized controlled trials with serious flaws. Any estimate of effect is uncertain.	Very weak recommendation, other alternatives may be equally reasonable.
Best practice	Recommendation in which either (i) there is enormous amount of indirect evidence that clearly justifies strong recommendation (direct evidence would be challenging, and inefficient use of time and resources, to bring together and carefully summarize), or (ii) recommendation to contrary would be unethical.		

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EXHIBIT AA

NBER WORKING PAPER SERIES

ESTIMATING CAUSAL EFFECTS OF FERTILITY ON LIFE COURSE OUTCOMES: EVIDENCE USING A DYADIC GENETIC INSTRUMENTAL VARIABLE APPROACH

Boyan Zheng
Qiongshi Lu
Jason Fletcher

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Estimating Causal Effects of Fertility on Life Course Outcomes: Evidence Using A Dyadic Genetic Instrumental Variable Approach

Boyan Zheng, Qiongshi Lu, and Jason Fletcher

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ABSTRACT

The causal effects of fertility are a central focus in the social sciences, but the analysis is challenged by the endogeneity of fertility choices. Earlier work has proposed several "natural experiments" from twin births or gender composition of earlier births to assess whether having more children affects adults' outcomes, though there are limitations to using rare (twins) and weak (gender composition) instrumental variables for fertility. This paper proposes a new "natural experiment" approach to assessing the causal effects of fertility by measuring the combination of couples' genetics in predicting fertility—a dyadic genetic instrumental variable, where the key idea (exclusion restriction) is that the interactions of the couple's genetics that shift the likelihood of fertility is unknown to the couples. We use a nationally representative sample of couples to examine the long-lasting effects of fertility on older adults' life outcomes, including labor market outcomes, personality traits, and subjective wellbeing. We find that fertility reduces females' extraversion and years of working and some evidence indicates that fertility reduces both males' and females' lifetime number of jobs worked.

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Introduction

The causal effects of fertility are a central focus in the social sciences, but its identification is challenged by the endogeneity of fertility behavior. Fertility is negatively selected by socioeconomic background, and decisions on childbearing are co-determined with other life choices (Balbo, Billari, and Mills 2013, Lundberg and Rose 2000). To address these issues, previous research often uses instrumental variables to overcome the endogeneity problem. The two most popular instrumental variables for fertility are multiple births (Twin IV), and the gender composition of the first and second born (Sex-Mix IV). Researchers have used the two IVs to identify the causal effect of fertility on parents' labor force participation and earnings outcomes[1] (e.g., Angrist and Evans 1998; Cools, Markussen, and Strøm 2017; Jacobsen, Pearce, and Rosenbloom 1999), and generally reported that mothers, and not fathers, labor market outcomes are negatively affected by fertility.

The existing literature has several limitations. One limitation of both the Twin IV and Sex-Mix IV is that the approaches are restricted to higher-order births and cannot estimate the effects of having one child vs. no children. For the Twin-IV, additional limitations include the relative rarity of twin births and the increasing evidence that twin births are non-random and instead follow a social gradient (Bhalotra and Clarke 2019). For the Sex-Mix IV, the influence of having two same sex children on having a third child is relatively small (i.e. a weak instrument) and the estimates may elicit the effect only on those induced to have a third child due to strong gender preferences that may not reflect the average effect of fertility (i.e. a local average treatment effect). Alternative instruments may be helpful to advance the existing knowledge concerning the causal effects of fertility.

Motivated by these limitations and recent developments in the sociogenomic study of human fertility (Mills, Barban, and Tropf 2018), we propose a novel dyadic genetic instrumental variable (DGIV) based on newly available genetic data in the Health and Retirement Study. Emerging research has shown that fertility has a large and measurable genetic component. We leverage this new information by controlling for the genetic "main" effects for each spouse and propose that the *interaction* of the measures of the genetic dispositions toward fertility (i.e., polygenic scores, or PGS) can be used as an instrument for (couple level) fertility. Intuitively, we assume that spouses select one another based on traits related to levels of fertility but not on how these levels combine (interact) to predict fertility at the couple level.

In this paper, we first review the existing IV literature and discuss the limitations of the typically used Sex-mix and Twin IVs. Next, we formally explain our proposed IV and state the assumptions that support the validity of our instruments. Finally, we apply our proposed IV to a sample of 3,282 couples in the Health and Retirement Study (HRS). We analyze the causal effects of life course fertility on older adults' labor market outcomes, including work history, income, and wealth, to compare the consistency of our results with the previous IV literature. We also investigate the causal effects of fertility on parental personality traits and subjective wellbeing to extend the study of fertility and non-labor market outcomes using a causal framework. This paper contributes to the demographic literature on fertility by providing both innovative instrumental variable methodologies and new empirical findings.

Previous Literature

Theoretical Perspectives on the Effects of Fertility on Parents

Most studies on the economic consequences of fertility on parents are driven by Becker's (1993) household specialization theory. The theory posits that household members specialize in either housework (including childbearing) or labor market work in order to maximize overall production, which is the sum of housework production, labor market production, and utility from children. Due to socialization and biological differences, females are often assumed to be more efficient in housework, whereas males have comparative advantages in labor market work. Thus, the theory predicts that higher fertility causally reduces females' labor market participation. Meanwhile, as mothers specialize in housework after the birth of children, males or fathers are expected to allocate more time in the labor market to maintain or maximize the labor market production of the family. Thus, the household specialization theory also hypothesizes a positive effect of fertility on males' labor force participation.

Social science theories also indicate that fertility affects men's and women's broader outcomes, although the direction of the effects is ambiguous. One set of outcomes that receives focus is subjective wellbeing (SWB). Life course theory suggests the influences of children on parents as multifaceted and time-dependent. On the one hand, children are one of the most important social ties to parents. At younger ages, children provide a meaning of life and joy to parents, and they also serve as a source of social control that reduces parents' unhealthy and risky behavior (Umberson and Gove 1989; Umberson, Pudrovska, and Reczek 2010). When children grow up, they become a source of social support that benefits their older parents both emotionally and materially (Seltzer and Bianchi 2013; Umberson, et al. 2010; Umberson, Crosone, and Reczek 2013). However, rearing young children also demands significant mental and material resources from parents. These demands may cause significant parenting pressure

and reduce parental wellbeing (Nomaguchi and Milkie 2020; Umberson and Gove 1989).

Finally, psychological theories indicate that childbearing also changes parents' personality traits (Jokela et al. 2006). From the perspective of social investment theory (Roberts, Wood, and Smith 2005), engaging with social institutions and social roles, such as parenthood, leads to maturity in personality traits. Thus, this theory foresees a positive relationship between fertility and more stable, "positive" personalities. However, from a life course perspective, major life events such as childbirth have complex effects on personality traits. The potential disruptive effects of childbirth on living arrangements and the burden of parenting may lead to negative changes in personality as well (Hutteman et al. 2014, Fletcher and Padron 2016; Specht et al. 2011).

Causal Evidence on the Consequences of Fertility on Parents

Because reproductive behavior is endogenous to a number of individual and institutional factors, such as socioeconomic status, childhood family structure, personality, and social policies (Balbo et al. 2013; Guzzo and Hayford 2020), it is necessary to utilize statistical methods to improve the causal confidence of the research. Some studies used experimental designs to show that maternal identity negatively affects the evaluation of women's work performances (Benard and Correll 2010; Correll, et al., 2007), but most of the studies tend to use instrumental variables (IV) to estimate causal effects of fertility on the realized labor market outcomes, particularly labor income and employment status. The use of the IV method is motivated by the canonical studies by Rosenzweig and Wolfin (1980) and Angrist and Evans (1998). The two studies proposed and popularized two IVs for fertility: Sex-mix IV and Twin-IV. Sex-mix IV uses the gender composition of the first two children as the instrumental

variable for fertility. It assumes that parents would like to achieve a balanced gender ratio, and thus the biological randomness of the same-gender of the first two children leads to an increase in the likelihood of the third child. Twin IV uses multiple second births as the instrumental variable. It assumes that the birth of twins is random, and thus the birth of twins in the second parity leads to an exogenous increase in the total number of children. Other IVs include infertility shocks (Agüero and Marks 2008; Agüero and Marks 2011) and in vitro fertilization (IVF; Lundborg, Plug, and Rasmussen 2017), though these have been used less frequently[1].

With the proposed IVs, Angrist and Evans (1998) analyzed the 1980 and 1990 US census data and found that having an additional child causally reduces females' work time, employment rate, and labor income, but no effects on men were observed. Later studies using one or both of the IVs generally replicated Angrist and Evans's (1998) findings and extended their conclusions to other contexts such as Latin America, Europe, and East Asia (Bronars and Grogger 1994; Cáceres-Delpiano 2012; Chun and Oh 2002; Gruce and Galiani 2007; Daouli, Demousis, and Giannakopoulos 2009; Jacobsen, Pearce, and Rosebloom 1999). Whereas previous studies tend to rely on cross-sectional data, Cools, Markussen, and Strøm (2017) used Sex-mix IV and Norwegian administrative data to analyze the long-term effects of fertility on labor market outcomes. They found that the negative effects of fertility on females' work time and labor income are insignificant after the 30s for females without college education. Similar to previous studies, Cools et al. (2017) observed no effects of fertility on men. The findings based on Sex-mix IV and Twin IV are rich and consistent, but the validity and utility of the IVs have been questioned by more recent literature. We will discuss these issues in the next section.

[1] Another relevant literature uses policies as instruments for fertility (e.g. Geyer et al. 2015)

Compared with the rich literature on labor market outcomes, causal studies of fertility and a broader set of (non-labor market) outcomes are rare. Existing observational studies of the United States and European countries tend to conclude that number of children is negatively related to parental SWB during early adulthood, but the association disappears or becomes positive after middle adulthood (Deaton and Stone 2012; Stanca 2012; Glass, Simon, and Andersson 2016; Margolis and Myrskylä 2011; Umberson, Pudrovska, and Reczek 2010). Although studies suggest that mothers take the more burdensome tasks in childbearing and are subject to stronger parenting stress (Musick, Meier, and Flood 2016), evidence is mixed regarding whether there are gender differences in the association between fertility and SWB. Some research found no gender differences (Glass et al. 2016; Margolis and Myrskylä 2011), others report that men's happiness is positively related to the number of children (Nelson-Coffey et al. 2019).[2]

Finally, the association between parenthood and personality traits has shown mixed evidence, with little causal analysis available. Using a Finnish sample, Jekola et al. (2007) reported that having children predicted higher emotionality, a personality trait related to negative outcomes, and higher emotional stability only among men, lending partial support to the social investment theory. However, later studies report having children to be related to a decrease or no change in emotional stability, conscientiousness, and agreeableness (Hutteman

[2] In contrast to the previous observational research, Priebe (2020) applied Twin IV and Sex-mix IV to a large sample of parents in developing countries. The author reports that although OLS results show that an additional child is negatively related to happiness, IV-based results show that an additional child significantly increases parents' happiness. Although results in developed countries and developing countries may not be comparable, contrasts between Priebe's OLS and IV results still call existing observational studies into question and suggest further analysis using causal designs is needed.

et al. 2014; Scheppingen et al. 2016; Specht et al. 2011). South American Surveys asking for fertility intention also suggest the existence of mothers who prefer an unequal child sex ratio even when they have had one boy and one girl, suggesting the existence of defier groups (Clément 2017). The limited amount of literature and lack of causal focus indicates a need for more studies.

Limitations of the Sex-mix IV and Twin IV

Despite their significant contributions, the Sex-mix IV and Twin IV approaches have some limitations in terms of methodological design. First, Twin IV and Sibling IV are by design restricted to adults with at least two children. The identified treatment effects may not be generalized to childless or one-child parents. Alternatively, infertility (Agüero and Marks 2008; Agüero and Marks 2011) and IVF instruments (Lundborg, Plug, and Rasmussen 2017) can be applied to first-order births. However, although infertility is argued to be approximately random (Agüero and Marks 2008), its exogeneity is still challenged by some more recent findings that infertility is associated with marital status, age, health insurance, and graduate-level education (Louis et al. 2013; Thoma et al. 2013). Because IVF is defined as the success of the first IVF treatment, it is applicable only to mothers who have ever received any IVF treatment and since the use of IVF is selective, concerns remain about the generalizability of the results.

In addition, when interpreted using the Local Average Treatment Effect (LATE) framework, Sex-mix IV measures the causal effects of fertility on the complier groups who wish to balance children’s sex composition by having a higher-order birth. It also assumes the absence of the defiers group who have strong sex preferences so that they want to have more

children when the sex composition is already balanced. Although these assumptions may hold in Western contexts, they may not be applicable to cultural contexts with gender preferences for births (Chun and Oh 2002). Rosenzweig and Wolpin (2000) also suggested that child sex composition may have economics of scale effects. For example, same-sex children may share their clothes to reduce expenditures, which allows more investment in education. Indeed, recent studies have provided support for the validity of sex-mix IV. For example, Huber (2010) did not find economics of scale effects using US Census data, and Clément (2017) theorized that LATE can be identified when the defier group is small or the LATE on defiers has the same sign as LATE on compliers (i.e., although IV does not work as the same on defiers, treatments still affect them). But these concerns still suggest a need for more IVs to solidify our knowledge (Black et al. 2022).

Twin IV, on the other hand, seems to clearer claim to random variation. The birth of twins was thought to be random, and its positive effects on the number of children unrelated to other family and individual characteristics, although the parents need to desire a second parity in order to be eligible for the analysis. However, recent studies have challenged the exogeneity of the Twin IV. For example, Bhalotra and Clarke (2019) found that in the US, better maternal health and higher maternal educational attainments are significant predictors of twin births. The chances of twin births can also be significantly increased by the use of fertility treatments, such as IVF.[3]

[3] Braakmann and Wildman (2015) also reported that the use of fertility treatments is associated with a 10% increase in the likelihood of twin births. Although other studies proposed that monozygotic twins can be more strictly exogenous (Farbmacher, Guber, and Vikström 2016), such information is usually unavailable in large demographic datasets.

The Present Study

As reviewed in the previous section, the existing literature concerning the causal effects of fertility has some limitations. Empirically, existing studies tend to focus on labor market outcomes, but the effects of childbearing on psychological outcomes are also useful knowledge that demands causal analysis. Although a few studies have applied causal methods to study the impacts of fertility on non-labor market outcomes (Priebe 2020), the literature is very limited compared to the study of labor market outcomes. Finally, it is worth noting that existing studies tend to rely on working-age adults, whereas few studies consider the causal effect of fertility on older adults and therefore do not examine full life course effects. Methodologically, the issues with the generalizability and validity of Sex-mix IV and Twin-IV imply the need to seek new IVs to improve the robustness of our knowledge of fertility's consequences.

To address these limitations, this paper contributes to the current literature in three respects. First, we propose a new dyadic genetic IV (DGIV). Specifically, we utilize the interaction of spousal genetic predispositions for fertility as an instrument for realized fertility. The proposed DGIV does not impose sample restrictions on parents with multiple births. We provide formal statements of identification assumptions and interpretations based on LATE in the appendix. Second, we focus on the effects of fertility on older adults, which allows us to measure the life-course effects of fertility on labor market participation. Third, we extend the use of the proposed IV to investigate the impacts of fertility on personality and mental health outcomes. These analyses will contribute to the causal knowledge of the impacts of fertility on a broader set of outcomes.

Data and Empirical Method

Sample Construction

We use data from the Health and Retirement Study (HRS). HRS is a biannual and nationally representative longitudinal survey of older adults in the United States. HRS surveyed about 20,000 respondents each wave and has so far included about 45,000 unique older adults across all waves. Beginning in 1992, HRS has documented rich data for older adults' financial conditions, labor force participation, and fertility history. Since 2006, HRS started collecting genetic data of HRS respondents and their co-residential spouses. A Psychosocial and Lifestyle Questionnaire (PLQ) was introduced in the same year, which collects information about respondents' psychological traits and non-cognitive skills. The recent advancements in HRS's data collections provide unique opportunities to use genetics to identify the effects of fertility on non-labor market outcomes. We restrict the analytical sample to HRS couples. A respondent who is identified with two or more different spouses in HRS is not included in the sample. Because polygenic scores (PGS) predicted from the European-ancestry-based genome-wide association study (GWAS) are less reliable among the non-European population (Martin et al. 2017), we further restrict the HRS couples to be both White or European Ancestry (defined by HRS's genetic data; for detail, see Ware et al. 2018). After excluding cases with missing values, we obtained an analytical sample of 6,564 White older adults or 3,282 unique couples. Using these cases, we construct our measures (see the next section) using all person-wave observations over 50 years old so that our analysis focuses on older adults. Specific sample sizes vary by the outcome. In Appendix A, we outline our procedure for sample construction.

Measures

Our DGIV is the interaction term of each spouse's genetic propensity for fertility (details

will be given in the next section). To construct our GIV, we use a PGS for the number of children ever born (NEB) to operationalize "genetic predisposition". We use the officially released NEB PGS from the HRS team (Ware et al. 2018), which is constructed based on Barban et al. (2016)[3]. The treatment variable of our study is fertility, defined as the number of biological children for the couple. We use the wife's (or female partner if not married) reported fertility as the measure of the couple's fertility whenever the data is available. If the wife's fertility information is unavailable, the husband's data are used.

We considered two sets of life course outcomes. The first set is labor market outcomes, which include work history and family finances. Work history measures include: (1) ever worked: a dummy variable indicating whether a respondent has ever worked on at least one job, (2) total years worked: a continuous measure of the total number of years that a respondent worked for, and (3) the number of jobs worked: a continuous measure of the total number of jobs that a respondent worked on. In the HRS, work history is collected in each wave and is thus a time-varying measure. We use the last available report of work history to maximize the coverage over the life course. Family finance measures include respondents' long-term income, long-term wealth, and long-term earnings. They are constructed as the mean of the available waves of household income, household wealth, and individual earning data adjusted by the 2016 consumer price index (CPI). We use the imputation values provided by Rand HRS so that the proportion of missingness is zero. Because of the negative values of household wealth, we used an inverse hyperbolic sine transformation on all three variables. The inverse hyperbolic sine has a similar property to the natural log transformation so that coefficients in the model can be interpreted as a semi-elasticity or elasticity (Bellemare and Wichman 2020). Note that

work history measures are constructed using all person-wave observations over 50, but financial outcomes are constructed using all available observations.

The second set of outcomes includes personality traits and subjective wellbeing outcomes. The personality traits are operationalized as the Big-Five personality traits, defined as five composite scales that capture dimensions of human personality in a continuum (Goldberg 1990). The five scales are openness, conscientiousness, extraversion, agreeableness, and neuroticism. We created HRS Big-Five scales using items in PLQ. The yielded scales range from 1 to 4. Following the previous literature about childlessness and older adults' subjective wellbeing (Umberson et al. 2010; Nomaguchi and Milkie 2020), we consider three measures of subjective wellbeing, including depression, life satisfaction, and loneliness. For depression, we used the CESD scale provided by Rand HRS, which ranges from 0 to 8. For life satisfaction, we used the 7-point scale of Diener's measure of life satisfaction (Diener et al. 1985), which ranges from 1 to 7. The scale is available in PLQ since 2008. The loneliness variable is constructed using the 3-item adapted UCLA-R loneliness scale (Hughes et al. 2004) and ranges from 0 to 6. The scale is available since 2006. Except for the depression scale, all the scales are constructed based on the official manual (Smith, Ryan, and Sonnega 2019). When more than half of the items for PLQ-based scales are missing, the respective scale will be set to missing. All of the original measures are time-varying, and we take the mean of the measures across waves to create time-invariant outcome variables. Similar to work history outcomes, only person-wave observations over 50 years old are used.

We include spouses' years of birth and gender as demographic controls. In addition, we recognize that the current version of PGS may be subject to three sources of confounding:

population stratification, pleiotropy, and parental genetics effects (Young et al. 2019). Population stratification refers to the differential frequencies of alleles in ancestry groups, making PGS capture non-genetic effects. We minimize population stratification by controlling for the spouses' first principal components (PC; for detail, see Price et al. 2006) and 100 cross-spousal interaction terms of the spouses' PCs. Pleiotropy generally implies that the same genetic invariant may affect multiple life outcomes, which could invalidate the exclusion restriction of NEB PGS as instruments. We account for this problem by controlling for spouses' education (EA) PGS as covariates in the model and note that we also control for NEB-PGS for each spouse as the main effects. The principal components and EA PGS data are also drawn from the HRS team's public release (Ware et al. 2018). Finally, parental or sibling genetics are necessarily related to individuals' genetics and may directly affect individuals' life outcomes. Thus, PGS may also capture the indirect genetic effects from parents and siblings. As reviewed earlier, Mills et al. (2016) showed that the NEB PGS we use captures parental effects. When we take PGS as a measure of the causal effects of individuals' own genetics, such indirect genetic effects are confounding effects. In the next section, we will explicate how our IV method can account for this source of confounding.

Analytical Method: The Genetic IV

We use 2SLS to identify the causal effects of fertility on older adults' life course outcomes. The first stage is specified as:

$$F_j = b_0 + b_1 G_{0j} + b_2 G_{1j} + b_3 G_{0j} \times G_{1j} + \boldsymbol{X_{ij}\gamma} + \epsilon_{ij} \qquad (1)$$

Where j denotes a couple, $0j$ denotes the husband or male spouse, $1j$ denotes the wife or female spouse, F_j denotes fertility or the number of children born to the couple, and G

denotes genetic disposition toward fertility, which is operationalized as NEB PGS in this paper. In addition, $\boldsymbol{X_{ij}}$ denotes covariates, $\boldsymbol{\gamma}$ is a vector of coefficients for the covariates, and ϵ_{ij} denotes the error term. Covariates include the spouses' birth year, gender, principal components, and EA PGS. In addition, we include interaction terms of all principal components (100 interaction terms in total) and spousal interaction of EA PGS for additional controls. Finally, the spousal interaction of NEB PGS, $G_{0j} \times G_{1j}$, is the excluded instrument.

The second stage is specified as:

$$Y_{ij} = b_0 + b_1 G_{0j} + b_2 G_{1j} + b_3 \hat{F}_j + \boldsymbol{X_{ij}}\boldsymbol{\delta} + \eta_{ij} \quad (2)$$

Where Y_{ij} refers to the outcome of interest, $\hat{F}_j$ refers to the predicted value of fertility by Eq. (1), $\boldsymbol{X_{ij}}$ denotes the same set of covariates as in Eq. (1), $\boldsymbol{\delta}$ is a vector of coefficients for covariates, and η_{ij} denotes the error term.

Mirroring the conventional IV method (Angrist, Imbens, and Rubin, 1996), we make (A1) relevance assumption, (A2) monotonicity assumption, (A3) exclusion restriction, and (A4) exchangeability assumptions. The assumptions are also presented in the counterfactual framework in Appendix B. The relevance assumption suggests that spouses' genetic propensity has a multiplicative or interaction effect on realized fertility. Despite the fact that the relevance assumption is empirically testable, we also argue that this assumption has theoretical foundations. Although genetics is often regarded as an individual characteristic, fertility behavior is essentially a couple-level dyadic outcome that relies on the characteristics of both spouses. In this sense, genetics for fertility is a "couple-level" characteristic, and a spouse's genetic propensity for higher fertility is likely to have multiplier effects in increasing the number of children ever born.

The exclusion restriction requires that multiplicative effects of spouses' genetic propensity for fertility on life outcomes are only transmitted via realized fertility. Our rationale is that the spousal interaction term of NEB PGS is associated with an outcome variable either due to its association with the respective main terms (G_{0j}, G_{1j}) or through pleiotropy. Controlling for the main effect of NEB PGS will effectively rule out the former pathway. For the latter pathway, we can understand the pleiotropy problem as the association between NEB PGS and other PGS variables due to shared underlying genetic variants between PGS variables. If NEB is associated with another PGS variable that also impacts fertility through certain behavioral mechanisms, the exclusion restriction would be violated. We account for this problem by controlling for EA PGS, because EA PGS predicts educational attainments, income, cognitive ability, and other social status outcomes that significantly select fertility behavior. We argue that by controlling for EA PGS, including the spousal interaction of EA PGS, we can reasonably assume the exclusion restriction. Nevertheless, we acknowledge a more direct and ideal control for pleiotropy would be the PGS for the respective phenotype, which may capture and block the effects of the shared genetic variants causing pleiotropy biases. Yet such PGS has limited availability. For example, the HRS has no PGS for labor market outcomes such as the number of jobs. To examine the potential influences of the uncaptured pleiotropy, we add robustness analysis by controlling for the neuroticism, extraversion, depression, and life-satisfaction PGS in the analysis of respective phenotypes, as these PGS have been officially provided (Ware et al. 2016). We expect that if EA PGS is a good control or pleiotropy has minimal influences, adding these controls would not change our estimates.

(A3) Exchangeability Assumption: conditional on covariates, the causal effects of the

spousal interaction of genetic propensity on life outcomes can be identified. Key to our assumptions is that we do not assume that the main effects of genetic propensities on life outcomes are identifiable. We acknowledge that, unless particular assumptions of the causal structure are made, the identifiability of main effects is usually the pre-condition for the identifiability of the interaction effect (Vanderweele 2009). That the main effects of PGS variables are confounded (Young et al. 2019, Mills et al. 2016) does challenge the validity of our Assumption A3. In order to justify our Assumption (A3), we assume the independence of confounding structure between spouses. Specifically, we made the following sub-assumptions: Sub-Assumption (1) the spouses' genetic measures do not share any confounders; Sub-Assumption (2) the confounding effect of one spouse's genetic measure (for example, parental effects) is not moderated by the genetic propensity of the other spouse's genetic measure. Regarding Sub-Assumption (1), we believe that the genetic unrelatedness of spouses ensures that the spouses do not share the source of confounding for their genetic measures. For example, genetically unrelated individuals are unlikely to share the same source of parental effects in their PGS measures. Regarding Sub-Assumption (2), we think there are few substantive mechanisms that can explain such cross-spousal interaction effects. In Appendix C, we provide an informal proof regarding how the two sub-assumptions support the validity of Assumption (A3).

(A4) Monotonicity Assumption: this assumption indicates that given a higher level of multiplicative interaction of the couple's NEB PGS, all couples are expected to either have more children (compliers) or have the same number of children (always-takers or never-takers), and no couples would have the lower expected number of children (i.e., no defiers). This

assumption also specifies our compliers or our local average treatment effects (LATE), as the compliers to our IV are those who can be affected positively by stronger genetic dispositions toward fertility. The compliers to our IV thus are distinctive from the compliers to classical sex-mix IV, which refers to parents who prefer an equal sex ratio of their children. We also assume the absence of defiers whose tendency to have children is negatively affected by stronger genetic propensity.

Given the specified assumptions, we proceed to the summary statistics, the first stage results, the falsification test, and the 2SLS results in the next section. In the summary statistics, we will compare the distribution of key variables and covariates between spouses. In the first stage results, we show OLS estimates of the effects of spousal interaction of NEB PGS on fertility and the respective F-statistics for the interaction term. In the falsification test, we try to obtain the OLS, 2SLS, and Intention-to-Treatment (ITT) estimates of the effect of fertility on educational attainments. Finally, we show the OLS and 2SLS estimates of the causal effect of fertility on our selected outcome variables.

Results

Summary Statistics

[TABLE 1 ABOUT HERE]

Summary statistics by gender are presented in Table 1. The statistical significance of gender differences is also presented for most variables. Although almost all respondents have worked at least one job, the male respondents have a much higher number of years worked. The labor income for the male respondents is higher as well, corresponding to the well-documented gender pay gap. Although our analytical sample is composed of couples, family

income and wealth still slightly differ by gender. This is because HRS co-residential couples tend to report slightly different household incomes and wealth. Regarding gender differences in the non-labor market outcomes, we can observe a mixture in terms of the direction of gender differences. For personality traits, the female respondents are rated higher in extraversion, openness, and agreeableness but also higher in neuroticism, a trait related to negative health and social consequences. This pattern corresponds to the existing literature (Weisberg, Young, and Hirsh 2011). The female respondents also exhibit a higher level of loneliness and depression, which is also consistent with the population pattern recorded in the psychology literature (Luhmann and Hawkley 2016).[4]

First Stage Results: The Relevance Assumption

[TABLE 2 ABOUT HERE]

Relevance is the pre-condition for the use of the IV method and is the only assumption that can be empirically tested in a sufficient way. Table 2 presents the first stage results that assessed the relevance assumption. Model 3 is used as the final first stage model in the subsequent 2SLS regressions. In Model 1, we can see that the spousal genetic interaction term has a significantly positive coefficient on the spouses' number of children. This result supports our hypothesis of the multiplicative effect of spousal genetics. Controlling for EA PGS and PCs, including their interactions (i.e., interactions between spouses' EA PGS, and 100 cross-

[4] In Table D1, Appendix D, we compared our analytical sample with all White/European Ancestry HRS respondents with genetic data (N = 10,290). This larger White genetic subsample can be regarded as the pool from which our analytical sample is drawn. Note that the subjects in the White genetic subsample are not necessarily couples. The comparison shows that our analytical sample is very similar to the overall White genetic subsample, although our analytical sample is slightly advantaged in household income, household wealth, and subjective wellbeing (life satisfaction). Respondents in our analysis are living with their spouses in at least one wave, but the White genetic sample includes living-alone respondents. Co-residence is expected to lead to advantages in household finances and mental health.

spousal interaction terms of PCs), has minimal impacts on the genetic interaction effect, which we interpret as suggestive evidence that the inclusion of additional genetic measures would not affect our results and indirect evidence against large pleiotropic effects. This pattern indicates that the spousal interaction effect of NEB PGS is robust. At the bottom of the table, we also report F-statistics for the spousal genetic interaction term. Model 3 shows that F-statistics (15.87) (Stock and Yogo 2005). In the subsequent analyses, the sample sizes may vary by outcome variable, and F-statistics vary as well. We note that for all the 2SLS results reported in the subsequent sections, F-statistics is consistently larger than 10.

Falsification Test

[TABLE 3 ABOUT HERE]

Table 3 presents the results from the falsification test, which estimates the "effect" of the number of children born on educational attainment. Since most (but not all) fertility occurs after schooling (see Rosenbaum 2020 and others), we ask whether the genetic IV can "correct" for any estimated effect of completed fertility on schooling, which is likely to reflect reverse causality and confounding effects. Indeed, since education tends to delay and reduce fertility behavior (Guzzo and Hayford 2020), it is not surprising that OLS yields a negative coefficient (Row 1, Table 3). Consistent with our expectation, 2SLS results imply that fertility has no causal effects on education. We acknowledge that despite statistical insignificance, the coefficients of 2SLS are positive and large in magnitude. To account for the limitation, we also implement ITT analysis, which is an OLS regression of the educational outcomes directly on the proposed IV or spousal genetic interactions. We can see that the ITT coefficient sizes are very small and close to zero (< 0.1), so their statistical insignificance cannot be simply

explained by large standard errors. These results lend support to the validity of our proposed IV.

Main Results

[TABLE 4 ABOUT HERE]

Table 4 presents the estimated effects of completed fertility on life course labor market outcomes. For work history outcomes, OLS results indicate that fertility is associated with all of the outcomes for females, but 2SLS results show that fertility only reduces older females' total years worked ($p < 0.05$). The 2SLS estimates are also substantially larger than OLS in absolute magnitudes, indicating that an additional child reduces women's length of working by five years. The differences in 2SLS and OLS estimates correspond to previous IV-based studies (e.g., Angrist and Evans 1997). On the other hand, males' total years worked is unaffected, as was observed by previous studies (Angrist and Evans 1997; Cools 2017). A more novel finding regarding the 2SLS estimates is that an additional child similarly reduced the number of jobs worked for males by about 0.5 ($p < 0.1$). Different from previous studies, this result suggests that males' labor force participation is not free from the effect of fertility. Given that males' years of working were not influenced, a reduced number of jobs may imply that males are less likely to change their jobs when they have children perhaps because they desire stable jobs. However, we acknowledge that these findings are suggestive and not conclusive due to the lack of precision in the estimates.

Meanwhile, although OLS results show that an additional child decreases long-term household income and wealth by 3% and 20% and decreases females' labor income by 12.4%, the 2SLS results do not support the conclusions. 2SLS results provide no evidence regarding

the causal effects of fertility on older adults' long-term income. Nonetheless, we note HRS records older adults' income at later ages when childbearing is finished. The conclusion of null effects of fertility may simply imply that within each gender, the differences in income at older ages are not influenced by the total number of children. This result does not indicate that working-age females' income at younger ages is not affected by fertility. In addition, we recognize that the 2SLS coefficients are negative and larger in terms of magnitudes than OLS results. It is likely that null findings result from larger standard errors (2SLS standard errors are ten times larger than OLS). Larger sample sizes would be necessary to make clearer conclusions concerning these outcomes.

[TABLE 5 ABOUT HERE]

Table 5 presents OLS and 2SLS results for non-labor market outcomes. For personality traits, OLS results suggest that fertility is positively related to agreeableness for both males and females. However, 2SLS results show that an additional child significantly reduces females' extraversion by 0.194 ($p < 0.05$). Marginally significant evidence suggests that the birth of an additional child reduces, instead of increasing, females' agreeableness ($p < 0.1$). For males, no effects of fertility on personality are observed by 2SLS regression. This pattern may be explained by the fact that the increased number of children primarily restrains mothers' capability and frequency of social interactions in early and middle adulthood, which leads to differences in personality traits in the later life. Furthermore, 2SLS results did not show any significant effects of fertility on depression, life satisfaction, or loneliness on either males or females. These results show the need for much larger samples when using IV methods on these outcomes.

Finally, we examine the potential bias due to pleiotropy. As noted earlier, we do so by adding spousal PGS variables for neuroticism, extraversion, depression, and life satisfaction, and the spousal interaction of the PGS variables to the respective 2SLS model of each outcome. The results, shown in Table E1 in Appendix E, suggest that adding these more direct controls for pleiotropy leads to minor changes to the 2SLS estimates. It implies that our results are robust to the potential violation of exclusion restriction due to pleiotropy.

Conclusion and Discussion

In this paper, we made methodological and empirical contributions to the literature on the causal consequences of fertility on older adults. Methodologically, we propose a novel genetic instrumental variable that utilizes the recent advancements of genotyping technology and large-scale genetic survey data. The proposed IV is the interaction of the spousal genetic propensity for higher fertility (Dyadic Genetic Instrumental Variable, DGIV). The validity of the proposed DGIV relies on two key assumptions: (1) spouses do not share any unobserved confounders for the measured genetic dispositions or PGS measures, and (2) the effect of one spouse's genetic propensity for fertility on realized fertility does not interact with any unobserved confounders to the measures of the genetic propensity of the other spouse. Essentially, these two assumptions imply the independence of the confounding structure of the PGS measurements for spouses. We believe that the fact that spouses are unrelated genetically is consistent with the validity of these two assumptions as well as the validity of our proposed DGIV. We argue that our proposed DGIV overcomes the difficulty that the measurements of genetic propensities tend to be confounded by family and environmental factors and can serve as a new tool for analyzing human fertility behavior.

Using a sample of 3,282 couples from HRS, we apply the proposed GIV to analyze the impacts of fertility on labor market outcomes and non-labor market outcomes of personality traits and subjective wellbeing. Since we utilized an older adult sample whose career path is finished, our estimates for labor market outcomes provide a summary measure of the life-course labor force participation, a novel perspective that is rare in the previous reach due to the limitation of data. Similar to previous works using census data and Twin and Sibling IV (Angrist and Evans 1998; Jacobsen et al. 1999), we find that an additional child leads to reduced lifetime work length for females by five years. Utilizing the advantage that HRS is a survey of older adults, we also analyzed how the number of jobs throughout the life course is affected by fertility. We find suggestive evidence that males' work for 0.5 fewer jobs if they have one more child. For males, this effect may be explained by fewer job changes or desire for stable work schedules after significant family change. This finding also to some degree challenges the previous finding that males are unaffected by fertility behavior. We also believe that the consistency of our findings on labor force participation with the previous IV literature provides empirical support for the validity of our DGIV.

Regarding personality traits, our results show that fertility causally decreases older females' extraversion. This may be the result of the fact that mothers have reduced social interactions due to childcare workloads and less labor force experience. Suggestive evidence also shows that females have reduced agreeableness if they have more children. This may be related to the increased life conflicts, such as work-life conflicts, that women face after childbearing (Nomaguchi and Milkie 2020). We also analyzed links between completed fertility and mental health in older age but the results were too imprecise to be conclusive.

This study has two more general implications. First, we believe that our paper adds more evidence that fertility has unequal impacts for males and females, particularly in underexamined non-labor market outcomes. We suggest that more causality-driven studies would be necessary to enrich our knowledge in subjective wellbeing outcomes, a topic that is still understudied compared to labor market outcomes. Second, this study demonstrates a wider utility of the use of genetics in social science research. Previous sociogenomic research tends to focus on a relatively narrower range of topics, including gene-by-environment interaction, nature versus nurture, or heritability and intergenerational mobility (Freese and Shostak 2009; Conley 2016). This study shows that genes can be used as a statistical tool that benefits a much wider range of social science inquiries. While many studies have used genetic measures as instrumental variables, previous work has uniformly focused on individual level genetic instruments, which have clear concerns over being invalid (i.e. not excludable from the second stage regression) (Conley and Fletcher 2017). We extend the use of genetic instruments to a more defensible scenario by constructing couple-level instruments (DGIV) to predict couple-level endogenous outcomes. Future methodological and empirical literature could continue to explore the potential of genes as a tool that is beyond current uses.

Nevertheless, we acknowledge that this study has several limitations. First, the biological or molecular mechanisms behind the significant spousal genetic interaction effects on realized fertility are unclear. A mechanism-based explanation for this interaction effect would be essential for consolidating the validity of our proposed DGIV. Second, a sample size of 3,282 coupes limited our ability to estimate precise results in several cases. Empirically, the previous IV studies tend to rely on census (e.g. Angrist and Evans 1998; Jacobsen et al. 1999) or register

data (e.g. Cools et al. 2017). The sample sizes of these more powerful IV studies are at the level of hundreds of thousands of respondents. The empirical power of our analysis is unavoidably limited by the more modest sample sizes compared to the older studies. The empirical application of our approach using large samples would be important for future research. Finally, our study restricts the analysis to European ancestry respondents due to the current lack of useful polygenic scores for other population groups. However, we do expect that this inequality in the availability of genetic data and the production of genetic knowledge will be reduced in the future so that work will not be forced to limit analysis to respondents of European ancestry.

Note

1. Although a large literature has examined the effects of early (i.e. teenage) fertility on longer term outcomes (Furstenberg 2013; Sweeny and Raley 2014, Kane et al. 2013, Fletcher and Wolfe 2009, Fletcher 2012; Fletcher and Polos 2017 reviews this literature), our paper focuses on total fertility and adults.
2. Fletcher and Kim (2018) applied the twin-IV to an American adolescent sample and found that sibship sizes causally affect adolescents' personality traits, but similar methods have not been applied to the study of parents.
3. Later analyses reveal that the NEB PGS is confounded by childhood family environments, but the magnitude of confounding is limited and the coefficient of the NGB PGS remains large after family fixed effects ruled out family environmental confounders (Mills, Barban, and Tropf 2016).

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Table 1. Summary statistics (mean and standard deviation) of the analytical sample.

Variable	Female	Male	T-Tests of Differences
Labor Market Outcome			
Ever worked	0.96 (0.19)	0.996 (0.07)	***
Total years of working	22.74(11.71)	35.39 (9.47)	***
Number of jobs	1.74 (1.08)	2.12 (1.21)	***
Long-term household income	10.89 (12.83)	11.13 (12.83)	Insig.
Long-term net household wealth	70.23 (117.82)	71.60 (123.06)	Insig.
Long-term labor income	1.90 (2.91)	3.45 (5.58)	***
Non-Labor Market Outcome			
Neuroticism	2.10 (0.56)	1.95 (0.53)	***
Extraversion	3.23 (0.52)	3.13 (0.51)	***
Openness	2.94 (0.51)	2.94 (0.50)	Insig.
Agreeableness	3.65 (0.36)	3.37 (0.45)	***
Conscientiousness	3.40 (0.37)	3.27 (0.40)	***
Depression	1.21 (1.34)	0.91 (1.10)	***
Life Satisfaction	5.04 (1.29)	4.99 (1.22)	†
Loneliness	1.31 (1.37)	1.14 (1.31)	***
Falsification Test			
Years of schooling	13.34 (2.27)	13.53 (2.69)	Insig.
Treatment and Instruments			
Fertility (Number of children)	2.59 (1.49)	2.59 (1.49)	--
NEB PGS	0.04 (1.01)	0.002 (1.08)	--
Covariates			
Year of Birth	1944 (10.92)	1940 (10.89)	***
EA PGS	0.001 (0.99)	0.03 (0.99)	--

Data source: The Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. "Insig." stands for insigificnat. Standard deviations are presented in parentheses. Population refers to all HRS respondents with non-missing values for any of the variables. To save some digits, long-term household income, long-term household wealth, and long-term labor income are reported in thousands. Year of birth is rounded to integers. PGS measures have been standardized. Fertility variable is constructed to be the same for males and females. Equal variance is assumed for T-tests. T-tests are not implemented on EA PGS, NEB PGS, and fertility, because they are constructed to have no group differences in means. Summary statistics of PCs are not reported.

Table 2. Regression of Couples' Fertility on Proposed IV and Control Variables.

	Model 1	Model 2	Model 3
	Outcome: Number of Children Ever Born		
Husband's NEB PGS	0.322***	0.326***	0.316***
	(0.025)	(0.025)	(0.025)
Wife's NEB PGS	0.428***	0.429***	0.434***
	(0.027)	(0.027)	(0.028)
Husband's NEB PGS × Wife's NEB PGS	0.103***	0.104***	0.102***
	(0.025)	(0.025)	(0.026)
Husband's Age	-0.011*	-0.011*	-0.011*
	(0.005)	(0.005)	(0.005)
Wife's Age	0.039***	0.039***	0.039***
	(0.005)	(0.005)	(0.005)
Husband's Education PGS		0.039	0.022
		(0.024)	(0.024)
Wife's Education PGS		-0.002	-0.008
		(0.024)	(0.024)
Husband's Education PGS × Wife's Education PGS		0.018	0.006
		(0.022)	(0.023)
Couple's PCs, Main Effects	Controlled	Controlled	Controlled
Couple's PCs, Interaction Effects			Controlled
F-statistics for the proposed GIV (Husband's PGS × Wife's PGS)	16.55	16.86	15.87
R-Squared	0.20	0.20	0.23
N	6,564	6,564	6,564

Data source: Health and Retirement Study, 2004–2016.

Note: † p < 0.1, * p < 0.05, ** p < 0.01, *** p < 0.001. Cluster standard errors at the spousal level are presented in paretheses.

Table 3. OLS, 2SLS, and ITT Estimation of the Effects of Fertility on Educational Attainments

Outcome Variable	Spouses' Mean Years of Schooling	Husband's Years of schooling	Wife's Years of schooling
Ordinary Least Square (OLS)	-0.111***	-0.074*	-0.147***
	(0.028)	(0.037)	(0.029)
Two-State Least Square (2SLS)	0.218	0.367	0.125
	(0.314)	(0.437)	(0.324)
Intention to Treatment (ITT)	0.026	0.040	0.015
	(0.031)	(0.042)	(0.032)
Control Variables	Yes	Yes	Yes

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. In ITT model, the coefficients reflect the direct regression of years of schooling on the spousal genetic interaction term. Cluster standard errors at the spousal level are presented in parentheses.

Table 4. Selected coefficients of OLS and 2SLS regressions of selected labor market outcomes on realized fertility.

Gender	Ever Worked	Total years of working	Number of Jobs	Long-term Household Income	Long-term Net Household Wealth	Long-term Labor Income
			OLS			
Male	-0.001	0.042	-0.015†	-0.030***	-0.215***	0.044
	(0.001)	(0.140)	(0.008)	(0.008)	(0.044)	(0.050)
Female	-0.006**	-1.648***	0.006	-0.029**	-0.210***	-0.124*
	(0.002)	(0.196)	(0.02)	(0.009)	(0.045)	(0.054)
			2SLS			
Male	-0.003	-0.758	-0.504†	-0.054	-0.568	0.217
	(0.010)	(1.663)	(0.295)	(0.100)	(0.522)	(0.594)
Female	-0.043	-4.826*	-0.391	-0.009	-0.504	-0.009
	(0.027)	(2.309)	(0.250)	(0.101)	(0.53)	(0.643)

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Cluster standard errors at the spousal level are presented in parentheses. Control variables are adjusted in all models. Long-term income, wealth, and labor income are rescaled by hyperbolic sine function, and the respective coefficients can be interpreted as semi-elasticity. Detailed results are available in Table D2.1 to D2.4 in Appendix D.

Table 5. Selected coefficients of OLS and 2SLS regressions of selected non-labor market outcomes on realized fertility.

Gender	Neuroticism	Extraversion	Openness	Agreeable-ness	Conscientio-usness	Depression	Life Satisfaction	Loneliness
				OLS				
Male	-0.002	0.010	-0.011	0.015*	-0.004	0.027†	0.013	0.009
	(0.007)	(0.007)	(0.007)	(0.006)	(0.006)	(0.015)	(0.017)	(0.018)
Female	-0.010	-0.005	-0.015*	0.013**	-0.006	0.039*	-0.013	0.034†
	(0.008)	(0.007)	(0.007)	(0.005)	(0.005)	(0.018)	(0.018)	(0.019)
				2SLS				
Male	0.033	-0.087	0.075	-0.045	-0.013	0.152	0.216	0.046
	(0.081)	(0.081)	(0.076)	(0.071)	(0.062)	(0.174)	(0.19)	(0.201)
Female	-0.078	-0.194*	-0.022	-0.105†	-0.052	-0.221	0.091	0.184
	(0.088)	(0.091)	(0.079)	(0.063)	(0.059)	(0.209)	(0.208)	(0.217)

Data source: Health and Retirement Study, 2004–2016.

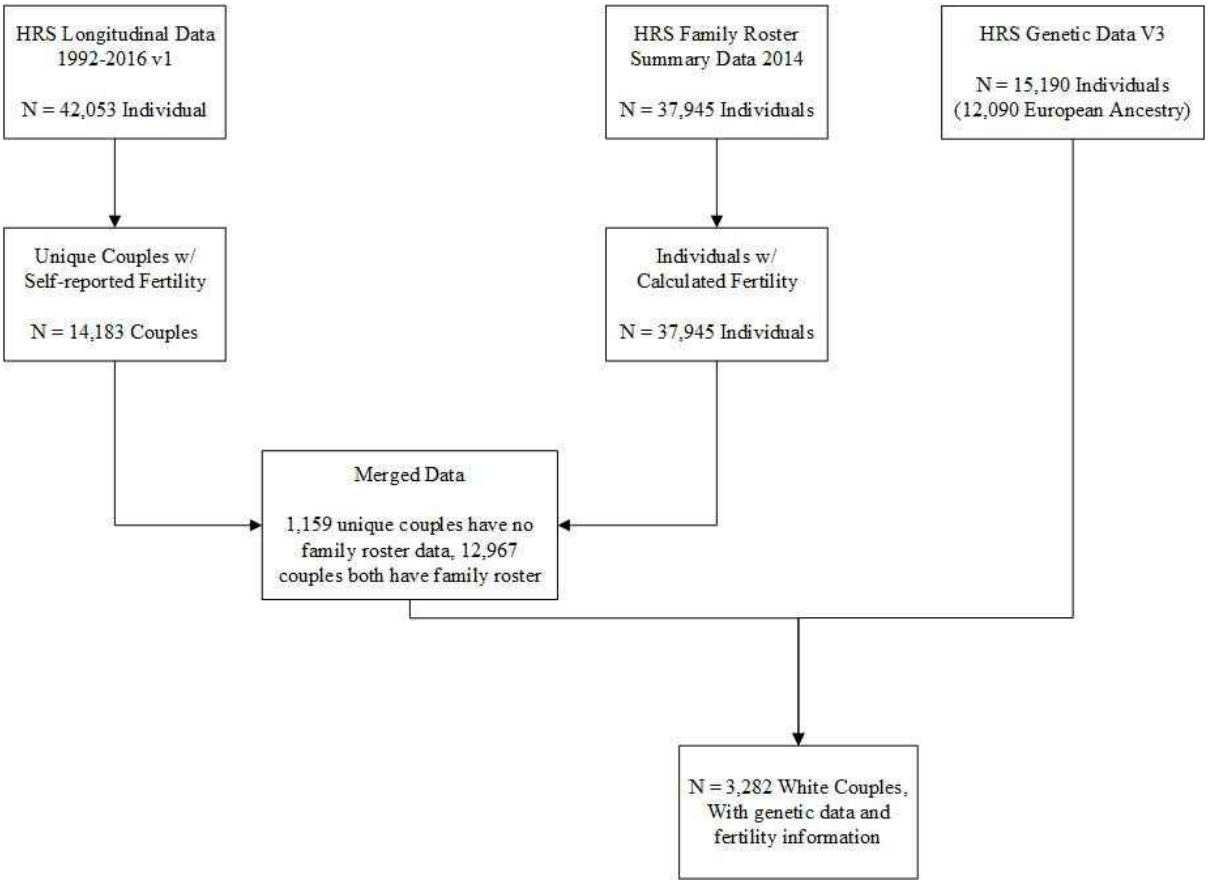
Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Cluster standard errors at the spousal level are presented in parentheses. Control variables are adjusted in all models. Neuroticism, Extraversion, Openness, Agreeableness, and Conscientiousness are measured by Big-5 personality scale and ranges from 1 to 4. Depression is measured by the short CESD scale provided and ranges from 0 to 8. Life-satisfaction is measured by Diener's measure of life satisfaction and ranges from 1 to 7. Loneliness is measured by the 3-item adapted UCLA-R loneliness scale and ranges from 0 to 6. Cognitive ability is measured by the Rand HRS sum scores that range from 0 to 35. Detailed results are available in Table D3.1 to D3.4 in Appendix D.

Supplementary Materials for

Estimating Causal Effects of Fertility Outcomes: Evidence Using A Dyadic Genetic Instrumental Variable Approach

Appendix A: Sample Construction

Figure A1. Construction of Fertility IV Data using RAND HRS Data Files



We construct our analytical sample using two HRS datasets: (1) Rand HRS Longitudinal Data 1992-2006 v1 (2) Rand HRS Family Roster Data 2014.

Rand HRS Longitudinal Data is used to identify unique couples and gather basic demographic information. By unique couple, we refer to the females and males who identify no more than one spouse in Rand HRS longitudinal data file 1992-2016 data file. Using this standard, we identified a sample of 14,183 unique couples.

Although Rand HRS Longitudinal Data provides a fertility variable, “Number of Children Ever Born”, we are concerned that this self-report variable has limited accuracy. We reach the Rand HRS

Family Roster Data 1992-2014 to obtain fertility data calculated from the family roster. Rand HRS Family Roster Data has two files: a summary file, where each observation represents a HRS respondent regardless of whether they have kids, and a kid-roster file, where each observation represents a child of the HRS respondent.

The summary data provides a calculated variable of "respondent's own kid" in the summary file. Rand used "kid" to refer to the children of HRS respondents. Rand HRS constructed this variable using the kid-roster data. According to Rand HRS document, this variable summarizes the number of children in the family roster file whose relationship with HRS respondent can be confidently considered as biological child:

> "Respondent's own kid (RwOWNKIDKN) is a count of Respondent's own kids … the variable is the sum up of reported kids who have good linkage".

The summary data provides data for N = 37,945 cases. We merged the cleaned family roster data with the unique couple data. Among all the unique couples, N = 1,159 unique couples have no family roster data. Using the merged dataset, we create a realized fertility variable based on the following rules:

1. When the female (wife) has "respondent's own kid" information, the female's report is used as the self-reported couple fertility
2. When the female's report information is missing, the male's report is used as the self-reported couple fertility
3. When neither of the spouses has non-missing respondent's own kid variable, the realized fertility variable is set to missing.
4. If both spouses self-report to give birth to zero children (e.g. both spouses have non-

missing "number of children ever born" variables that have values of zero) and have missing respondent's own kid variable, then the Rand-calculated couple fertility variable is imputed with zero.

Finally, we merged the unique couple data with the HRS Genetic Data V3, which includes N = 15,190 cases. Among them, 12,090 are identified as European Ancestry by the HRS team. The distribution of fertility of the Rand-calculated couple fertility among the 3,289 white couples with genetic data are given in Table A. After omitting 8 couples that have no fertility information, the final analytical sample includes 3,282 unique couples. The fertility information for the analytical sample is presented in Table A1.

Table A1. Summary of the Distribution of Fertility Information in the Analytical Sample

Reported Couple Fertility (# of children)	Frequency (# of couples)	Percent (%)
0	216	6.58
1	378	11.52
2	1,173	35.74
3	813	24.77
4	406	12.37
5	168	5.12
6	76	2.32
7	27	0.82
8	15	0.46
9	6	0.18
10	3	0.09
19	1	0.03
Total Number of Couples	3,282	100

Data source: The Health and Retirement Study, 2004–2016.
Note: Mean = 2.59. SD = 1.49.

Appendix B. Genetic IV Identification Assumptions.

In this Section, we present our IV Assumptions via counterfactual notations.

$$E\left[F_j\left(G_{0j}, G_{1j}\right) - F_j\left(G'_{0j}, G_{1j}\right)\right] \neq E\left[F_j\left(G_{0j}, G'_{1j}\right) - F_j\left(G'_{0j}, G'_{1j}\right)\right] \qquad \text{(B1)}$$

Where G'_{0j} and G'_{1j} denotes counterfactual values of G_{0j} and G_{1j} so that $G_{0j} \neq G'_{0j}$ and $G_{1j} \neq G'_{1j}$, and $F_j(\cdot)$ stands for the potential outcomes of fertility given certain values of genetic dispositions.

Formula (B1) explicates Assumption (A1), which specified a causal interaction effect of the spouses' genetic dispositions on fertility (Vanderweele 2009). This implies that the causal effect of one spouse' genetic dispositions is contingent on the other's genetic dispositions. Thus, Assumption (A1) serves as our relevance assumption, which states that the couple's genetic dispositions have a multiplicative effect on their realized fertility.

$$Y_{ij}\left(G_{0j}, G_{1j}, F_j\right) - Y_{ij}(G'_{0j}, G_{1j}, F_j) = Y_{ij}\left(G_{0j}, G'_{1j}, F_j\right) - Y_{ij}(G'_{0j}, G'_{1j}, F_j) \qquad \text{(B2)}$$

Where $Y_{ij}(\cdot)$ stands for the potential outcomes of life outcomes given certain values of spousal genetic dispositions.

Formula (B2) explicates our Assumption (A2). Assumption (A2), or the exclusion restriction, states that any interaction effects of the spouses' genetics on life outcomes are transmitted via realized fertility.

$$\begin{aligned} E\{Y_{Ij}\left(G_{0j}, G_{1j}\right) - Y_{Ij}\left(G'_{0j}, G_{1j}\right) - \left[Y_{Ij}\left(G_{0j}, G'_{1j}\right) - Y_{Ij}\left(G'_{0j}, G'_{1j}\right)\right] \big| \boldsymbol{X_{ij}}\} \\ = E\left(Y_{Ij} \middle| G_{0j}, G_{1j}, \boldsymbol{X_{ij}}\right) - E\left(Y_{Ij} \middle| G'_{0j}, G_{1j}, \boldsymbol{X_{ij}}\right) \\ - \left[E\left(Y_{Ij} \middle| G_{0j}, G'_{1j}, \boldsymbol{X_{ij}}\right) - E\left(Y_{Ij} \middle| G'_{0j}, G'_{1j}, \boldsymbol{X_{ij}}\right)\right] \end{aligned} \qquad \text{(B3)}$$

Formula (B3) explicates Assumption (A3), or exchangeability assumption. Assumption (A3) states that conditional on all control variables, the causal effects of the spousal interaction

of genetic dispositions on life outcomes can be identified.

In our parametric model, Assumption (A) implies that the spousal interaction of NEB PGS, $G_{0j} \times G_{1j}$, does not share the same cause with the outcome variable, holding constant all covariates. In other words, we argue that even if $E(G_{0j}\varepsilon_{0j}|\boldsymbol{X_{ij}}) \neq 0$ and $E(G_{1j}\varepsilon_{1j}|\boldsymbol{X_{ij}}) \neq 0$, controlling for the "contaminated" main effects will keep the spousal interaction term free from each spouses' family-level confounders. In addition, let u_{0j} and u_{1j} stand for the unobserved confounders for the husband's and wife's genetics effects, the sub-assumptions can be parametrically presented as (1) $E\left(G_{0j}^{NEB}\mathrm{u}_{1j}\right) = 0$ and $E\left(G_{1j}^{NEB}\mathrm{u}_{0j}\right) = 0$; (2) the interaction terms $G_{0j}^{NEB}\mathrm{u}_{1j}$ and $G_{1j}^{NEB}\mathrm{u}_{0j}$, or any other higher-order interactions that involve any of these two terms, have zero coefficients on the outcome variables.

$$F_j\left(G_{0j}, G_{1j}\right) - F_j\left(G'_{0j}, G_{1j}\right) \geq F_j\left(G_{0j}, G'_{1j}\right) - F_j\left(G'_{0j}, G'_{1j}\right) \text{ if } G_{1j} > G'_{1j} \quad \text{(A4)}$$

Where $F_j(\cdot)$ stands for the potential outcomes of the number of children born to the couple given certain values of spousal genetic dispositions.

Assumption (A4), or monotonicity assumption, states that there is no couple who acts against the interaction between genetic dispositions. In other words, the interaction effect is either positive (compliers) or zero (always-takers or never-takers). There are no defiers who display a negative interaction effect.

Note that for the purpose of simplicity, we present counterfactual notations to our proposed IV by fixing the change in the male's genetic disposition and use the reference level of the female' s genetic dispositions as the moderator. We note that our assumptions also apply to the case when the female's genetic dispositions are presented as the moderator in counterfactual notations.

Appendix C. The Assumption of Independence of Confounding Structure

In this Section, we would prove that our stated assumptions support the identification of causal interaction effects without assuming absence of unobserved confounders. We will use general notations such as X_1, X_2, instead of notations specific to this paper (G_{0j}, G_{1j}), to facilitate reading and show that our assumptions are applicable to general setting not limited to genetics. We use X_1, X_2 to refer to the treatment variables whose causal interaction effects are of analytical interests. We use U_1 and U_2 to denote two unobserved variables that may cause X_1, X_2, and Y, the outcome of interests, at the same time, and therefore U_1 and U_2 are confounders to the causal effects of X_1, X_2 on Y. We also use $\boldsymbol{C}$ to denote a set of unobserved confounders that may cause X_1, X_2, and Y.

Given the specifications above, an estimand for the causal interaction effects can be specified as (Vanderweele 2009)

$$E\{Y(x_1, x_2) - Y(x_1', x_2) - [Y(x_1, x_2') - Y(x_1', x_2')]|\boldsymbol{C}, U_1, U_2\} \quad (1)$$

Where $Y(\cdot)$ denotes the potential outcomes given certain values of X_1 and X_2, and the lower case x_1, x_2, x_1', and x_2' denotes a particular value assigned to X_1 and X_2. $Y(x_1, x_2)$ is an abbreviation of $Y(X_1 = x_1, X_2 = x_2)$.

The first part of Formula (1), $Y(x_1, x_2) - Y(x_1', x_2)$, denotes the effect of change in X_1 from x_1' to x_1 on Y, given certain levels of $X_2 = x_2$, $\boldsymbol{C}$, U_1 and U_2. $Y(x_1, x_2') - Y(x_1', x_2')$ denotes the effect of the same magnitude of change in X_1 on Y, when the level of X_2 has been changed to a different value, x_2', and $\boldsymbol{C}$, U_1 and U_2 are hold constant. Therefore, this estimand describes the causal interaction effect where X_2 causally moderates the effect of X_1 on Y. Note that with a simple rearrange of these counterfactual terms, X_1

can be presented as the moderator as well. We just arbitrarily choose to present X_2 as the moderator.

$$E(Y|x_1, x_2, \boldsymbol{C}, U_1, U_2) - E(Y|x_1', x_2, \boldsymbol{C}, U_1, U_2) - [E(Y|x_1, x_2', \boldsymbol{C}, U_1, U_2) - E(Y|x_1', x_2', \boldsymbol{C}, U_1, U_2)] \quad (2)$$

The formula (Estimator (2)) above presents an unbiased estimator of the causal interaction effect. The estimator is unbiased because $E(Y|X_1, X_2, \boldsymbol{C}, U_1, \boldsymbol{U_2}) = E[\, Y(x_1, x_2)|\boldsymbol{C}, U_1, \boldsymbol{U_2}]$ by backdoor criterion. However, because U_1 and U_2 are in fact unobserved, only the following estimator can be estimated via observed data,

$$E(Y|x_1, x_2, \boldsymbol{C}) - E(Y|x_1', x_2, \boldsymbol{C}) - [E(Y|x_1, x_2', \boldsymbol{C}) - E(Y|x_1', x_2', \boldsymbol{C})] \quad (3)$$

Because confounders U_1 and U_2 are not properly controlled, the estimator above (Estimator (3)) cannot be generally used to identify the causal interaction effects specified by Formula (1). Nonetheless, we can make two assumptions to make Estimator (3) an unbiased estimator:

Sub-Assumption (1): $X_i \perp U_j|\boldsymbol{C}$, where $(i, j) \in \{(1,2), (2,1)\}$

Sub-Assumption (1) states that conditional on observed covariates, the X_1 is independent from U_2 and X_2 is independent from U_1. In other words, X_1 and X_2 (in the case of this paper, the spouses' genetic measures) do not have any shared confounder. The conditional independence assumption implies that U_2 does not confound the causal effects of X_1 on Y, and, similarly, U_1 does not confound the causal effects of X_2 on Y; take X_1 as an example, this sub-assumption means that $E(Y|x_1, x_2, \boldsymbol{C}, U_1, U_2) - E(Y|x_1', x_2, \boldsymbol{C}, U_1, U_2) = E(Y|x_1, x_2, \boldsymbol{C}, U_1) - E(Y|x_1', x_2, \boldsymbol{C}, U_1)$.

Next, Let $\delta_{bias|x_j,U_i} = E\big(Y\big|x_i, x_j, \boldsymbol{C}, U_i\big) - E\big(Y\big|x_i', x_j, \boldsymbol{C}, U_i\big) - \big[E\big(Y\big|x_i, x_j, \boldsymbol{C}\big) - E\big(Y\big|x_i', x_j, \boldsymbol{C}\big)\big]$, where $(i, j) \in \{(1,2), (2,1)\}$. This effect refers to the bias in the estimation of the effect of X_i changing from x_i' to x_i on Y due to U_i, given that $X_j = x_j$. Similarly, we can define, $\delta_{bias|x_j',U_i} = E\big(Y\big|x_i, x_j', \boldsymbol{C}, U_j\big) - E\big(Y\big|x_i', x_j', \boldsymbol{C}, U_i\big) - \big[E\big(Y\big|x_i, x_j', \boldsymbol{C}\big) - E\big(Y\big|x_i', x_j', \boldsymbol{C}\big)\big]$, which refers to the he bias in the estimation of the effect of X_i changing from x_i' to x_i on Y due to U_i, given that $X_j = x_j'$. Then, the second Sub-Assumption is,

Sub-Assumption (2): $\delta_{bias|x_j,U_i} = \delta_{bias|x_j',U_i}$ for all $x_j, x_j' \in X_j$

Sub-Assumption (A2) essentially states that the bias caused by U_1 is constant across levels of X_2, and the magnitude of bias caused by U_2 is constant across levels of X_1. In order words, neither X_1 nor X_2 has an interaction effect with the confounders to the other.

Based on the two assumptions, it can be shown that Estimator (3) can unbiasedly identify the causal interaction effects. To simply the proof, let $\delta_{true|x_2}$ and $\delta_{true|x_2'}$ denotes the true causal effects of X_1 on Y at different levels of X_2. Then, by Assumption (A1)

$$\delta_{true|x_2} = E\{Y(x_1, x_2) - Y(x_1', x_2)|\boldsymbol{C}, U_1, U_2\} = E(Y|x_1, x_2, \boldsymbol{C}, U_1) - E(Y|x_1', x_2, \boldsymbol{C}, U_1)$$

$$\delta_{true|x_2'} = E\{Y(x_1, x_2') - Y(x_1', x_2')|\boldsymbol{C}, U_1, U_2\} = E(Y|x_1, x_2', \boldsymbol{C}, U_1) - E(Y|x_1', x_2', \boldsymbol{C}, U_1)$$

Furthermore,

$E(Y|x_1, x_2, \boldsymbol{C}) - E(Y|x_1', x_2, \boldsymbol{C}) - [E(Y|x_1, x_2', \boldsymbol{C}) - E(Y|x_1', x_2', \boldsymbol{C})]$

$= \delta_{true|x_2} - \delta_{bias|x_2} - (\delta_{true|x_2'} - \delta_{bias|x_2'})$

$= \delta_{true|x_2} - \delta_{bias|x_2} - \delta_{true|x_2'} + \delta_{bias|x_2'}$

$= \delta_{true|x_2} - \delta_{bias|x_2} - \delta_{true|x_2'} + \delta_{bias|x_2}$, by Assumption (A2)

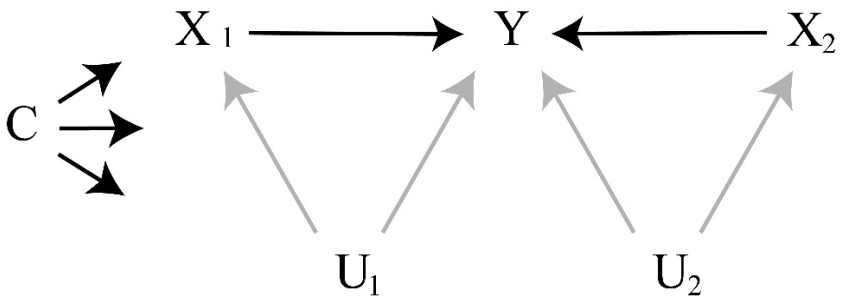
$= \delta_{true|x_2} - \delta_{true|x_2'}$

$= E\{Y(x_1, x_2) - Y(x_1', x_2)|\boldsymbol{C}, U_1, U_2\} - E\{Y(x_1, x_2') - Y(x_1', x_2')|\boldsymbol{C}, U_1, U_2\}$, which is

equivalent to the causal estimand specified by Formula (1).

Therefore, it has been proved that without controlling for unobserved confounders and without identifying causal effects of X_1 or X_2, the causal interaction effect of X_1 or X_2 can still be identified when assumptions (A1) and (A2) hold.

Figure C1. A Directed Acyclic Graph (DAG) of the Assumed Causal Structure.



The directed acyclic graph (DAG) in Figure 1 presents reflects the causal structure given Assumption (A2). The absence of arrows from U_2 to X_1 and U_1 to X_2 reflects Assumption (A2). Sub-Assumption (A2) cannot be reflected in a DAG.

When the causal structure can be properly estimated by linear models, Assumption (A2) can be understood as such: there are neither interaction effects between U_2 and X_1 on Y nor interaction effects between U_1 and X_2 on Y.

Finally, we would like to evaluate Assumption (A1) and (A2) in the scenario of our study. In the scenario of this paper, X_1 and X_2 refers to the couples NEB PGS (G_{0j}, G_{1j}). U_1 and U_2 are confounders to PGS variables, which can be parental genetics or, when there are any siblings, sibling genetics. Suppose that the unobserved confounders are parental genetics, which almost exist for every respondent, Assumption (A1) implies that the wife's parental genetics does not confound the husband's NEB PGS, and vice versa. We think that this assumption is very reasonable. Unless the spouses are close relatives, the genetic effects

for the spouses would be independent from each other. Assumption (A2) implies that the wife's parental genetics do not have any interaction effects with the husband's genetic dispositions, and vice versa. We also think that this is a reasonable assumption. It is hard to come up with substantive mechanisms that could explain such intergenerational cross-spousal interaction between genetic dispositions.

Appendix D. Extended Results Supplementary to the Results Section

Table D1. Summary statistics (mean and standard deviation) of the analytical sample.

Variable	Female		Male	
	Analytical Sample	HRS White/ European Ancestry Genetic Subsample	Analytical Sample	HRS White/ European Ancestry Genetic Subsample
Labor Market Outcome				
Ever worked	0.96 (0.19)	0.95 (0.21)	0.996 (0.07)	0.99 (0.10)
Total years of working	22.74 (11.71)	23.56 (12.65)	35.39 (9.47)	34.54 (10.74)
Number of jobs	1.74 (1.08)	1.73 (1.12)	2.12 (1.21)	2.11 (1.24)
Long-term household income	10.89 (12.83)	8.45 (10.33)	11.13 (12.83)	10.10 (11.42)
Long-term net household wealth	70.23 (117.82)	54.6 (99.46)	71.60 (123.06)	65.84 (120.06)
Long-term labor income	1.90 (2.91)	1.69 (2.68)	3.45 (5.58)	3.20 (5.16)
Non-Labor Market Outcome				
Neuroticism	2.10 (0.56)	2.08 (0.57)	1.95 (0.53)	1.96 (0.55)
Extraversion	3.23 (0.52)	3.21 (0.52)	3.13 (0.51)	3.12 (0.53)
Openness	2.94 (0.51)	2.91 (0.52)	2.94 (0.50)	2.94 (0.51)
Agreeableness	3.65 (0.36)	3.63 (0.38)	3.37 (0.45)	3.37 (0.47)
Conscientiousness	3.40 (0.37)	3.37 (0.39)	3.27 (0.40)	3.27 (0.41)
Depression	1.21 (1.34)	1.42 (1.45)	0.91 (1.10)	1.07 (1.28)
Life Satisfaction	5.04 (1.29)	4.85 (1.34)	4.99 (1.22)	4.86 (1.28)
Loneliness	1.31 (1.37)	1.52 (1.47)	1.14 (1.31)	1.31 (1.42)
Falsification Test				
Years of schooling	13.34 (2.27)	13.12 (2.36)	13.53 (2.69)	13.45 (3.41)
Treatment and Instruments				

Fertility (Number of children)	2.59 (1.49)	2.72 (1.54)	2.59 (1.49)	2.82 (1.59)
Covariates				
Year of Birth	1944 (10.92)	1940.99 (16.60)	1940 (10.89)	1940.55 (15.21)
N	3,282	6,894	3,282	5,196

Data source: The Health and Retirement Study, 2004–2016.

Note: † p < 0.1, * p < 0.05, ** p < 0.01, *** p < 0.001. “Insig.” stands for insigificnat. Standard deviations are presented in parentheses. Population refers to all HRS respondents with non-missing values for any of the variables. To save some digits, long-term household income, long-term household wealth, and long-term labor income are reported in ten thousands. Year of birth is rounded to integers. PGS measures have been standardized. Fertility variable is constructed to be the same for males and females. Equal variance is assumed for T-tests. T-tests are not implemented on EA PGS, NEB PGS, and fertility, because they are constructed to have no group differences in means. Summary statistics of PCs are not reported.

Table D2.1 Coefficients of OLS regressions of selected labor market outcomes on realized fertility, males only

Gender	Ever Worked	Total years of working	Number of Jobs	Long-term Household Income	Long-term Net Household Wealth	Long-term Labor Income
Number of Children	-0.001	0.042	-0.015†	-0.030***	-0.215***	0.044
	(0.001)	(0.140)	(0.008)	(0.008)	(0.044)	(0.050)
Male's NEB PGS	0.001	0.496**	-0.007	0.000	-0.027	0.043
	(0.001)	(0.18)	(0.01)	(0.011)	(0.056)	(0.065)
Females' NEB PGS	0.000	-0.027	-0.002	-0.017	0.043	0.005
	(0.0002)	(0.216)	(0.013)	(0.013)	(0.068)	(0.078)
Male's Birthyear	0.000	0.496***	0.001	-0.009***	0.029*	-0.107***
	(0.0002)	(0.038)	(0.002)	(0.002)	(0.012)	(0.013)
Female's Birthyear	0.001	-0.075*	0.003	-0.009***	0.044***	-0.078***
	(0.001)	(0.038)	(0.002)	(0.002)	(0.012)	(0.013)
Male's EA PGS	0.002*	0.71***	-0.005	0.131***	0.35***	0.278***
	(0.001)	(0.198)	(0.012)	(0.012)	(0.062)	(0.071)
Females' EA PGS	0.000	0.141	-0.006	0.091***	0.176**	0.038
	(0.001)	(0.196)	(0.011)	(0.012)	(0.061)	(0.070)
Male's EA PGS	0.000	-0.099	0.011	0.003	-0.003	0.157*
X Female's EA PGS	(0.001)	(0.189)	(0.011)	(0.011)	(0.059)	(0.068)
N	3270	3270	3270	3282	3282	3282

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Control variables are adjusted in all models. Long-term income, wealth, and labor income are rescaled by hyperbolic sine function, and the respective coefficients can be interpreted as semi-elasticity.

Table D2.2 Coefficients of 2SLS regressions of selected labor market outcomes on realized fertility, males only

Gender	Ever Worked	Total years of working	Number of Jobs	Long-term Household Income	Long-term Net Household Wealth	Long-term Labor Income
Number of Children	-0.003	-0.758	-0.504†	-0.054	-0.568	0.217
	(0.010)	(1.663)	(0.295)	(0.100)	(0.522)	(0.594)
Male's NEB PGS	0.001	0.760	0.188†	0.008	0.088	-0.014
	(0.003)	(0.576)	(0.102)	(0.034)	(0.179)	(0.203)
Females' NEB PGS	0.001	0.326	0.228†	-0.007	0.199	-0.071
	(0.005)	(0.762)	(0.135)	(0.046)	(0.24)	(0.273)
Male's Birthyear	0.000	0.488***	-0.016*	-0.009***	0.025†	-0.105***
	(0.0002)	(0.041)	(0.007)	(0.002)	(0.013)	(0.015)
Female's Birthyear	0.000	-0.043	0.019	-0.008	0.058*	-0.085**
	(0.0004)	(0.075)	(0.013)	(0.005)	(0.024)	(0.027)
Male's EA PGS	0.002*	0.728***	0.048	0.131***	0.357***	0.275***
	(0.001)	(0.199)	(0.035)	(0.012)	(0.062)	(0.071)
Females' EA PGS	0.000	0.136	-0.006	0.091***	0.174**	0.039
	(0.001)	(0.193)	(0.034)	(0.012)	(0.061)	(0.069)
Male's EA PGS	0.000	-0.041	-0.024	0.003	-0.002	0.157*
X Female's EA PGS	(0.001)	(0.186)	(0.033)	(0.011)	(0.058)	(0.066)
N	3270	3270	3270	3270	3282	3282

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Control variables are adjusted in all models. Long-term income, wealth, and labor income are rescaled by hyperbolic sine function, and the respective coefficients can be interpreted as semi-elasticity. Coefficients for principal components are omitted.

Table D2.3 Coefficients of OLS regressions of selected labor market outcomes on realized fertility, females only

Gender	Ever Worked	Total years of working	Number of Jobs	Long-term Household Income	Long-term Net Household Wealth	Long-term Labor Income
Number of Children	-0.006**	-1.648***	0.006	-0.029**	-0.210***	-0.124*
	(0.002)	(0.196)	(0.02)	(0.009)	(0.045)	(0.054)
Male's NEB PGS	-0.005†	-0.243	-0.004	0.003	-0.017	-0.020
	(0.003)	(0.251)	(0.026)	(0.011)	(0.057)	(0.07)
Females' NEB PGS	-0.001	-0.048	0.015	-0.020	0.033	0.066
	(0.003)	(0.303)	(0.031)	(0.013)	(0.069)	(0.084)
Male's Birthyear	-0.001	-0.089†	-0.005	-0.011***	0.019	-0.033*
	(0.001)	(0.053)	(0.005)	(0.002)	(0.012)	(0.014)
Female's Birthyear	0.000	0.034	0.036***	-0.008***	0.055***	-0.152***
	(0.001)	(0.055)	(0.006)	(0.002)	(0.012)	(0.015)
Male's EA PGS	0.002	-0.370	0.035	0.126***	0.358***	-0.051
	(0.003)	(0.276)	(0.028)	(0.012)	(0.063)	(0.077)
Females' EA PGS	0.009**	1.276***	-0.008	0.094***	0.184**	0.376***
	(0.003)	(0.273)	(0.028)	(0.012)	(0.062)	(0.076)
Male's EA PGS	-0.003	-0.108	-0.037	0.003	-0.009	-0.020
X Female's EA PGS	(0.003)	(0.264)	(0.027)	(0.011)	(0.06)	(0.073)
N	3231	3231	3231	3282	3282	3282

Data source: Health and Retirement Study, 2004–2016.

Note: † p < 0.1, * p < 0.05, ** p < 0.01, *** p < 0.001. Control variables are adjusted in all models. Long-term income, wealth, and labor income are rescaled by hyperbolic sine function, and the respective coefficients can be interpreted as semi-elasticity. Coefficients for principal components are omitted.

Table D2.4 Coefficients of 2SLS regressions of selected labor market outcomes on realized fertility, females only

Gender	Ever Worked	Total years of working	Number of Jobs	Long-term Household Income	Long-term Net Household Wealth	Long-term Labor Income
Number of Children	-0.043	-4.826*	-0.391	-0.009	-0.504	-0.009
	(0.027)	(2.309)	(0.250)	(0.101)	(0.53)	(0.643)
Male's NEB PGS	0.007	0.794	0.141	-0.004	0.079	-0.058
	(0.009)	(0.793)	(0.086)	(0.035)	(0.181)	(0.22)
Females' NEB PGS	0.016	1.388	0.189	-0.029	0.163	0.015
	(0.013)	(1.084)	(0.117)	(0.046)	(0.243)	(0.295)
Male's Birthyear	-0.002*	-0.125*	-0.004	-0.011***	0.015	-0.032*
	(0.001)	(0.06)	(0.007)	(0.002)	(0.013)	(0.016)
Female's Birthyear	0.001	0.162	-0.013	-0.009†	0.067**	-0.157***
	(0.001)	(0.108)	(0.012)	(0.005)	(0.024)	(0.029)
Male's EA PGS	0.003	-0.297	-0.033	0.126***	0.364***	-0.054
	(0.003)	(0.287)	(0.031)	(0.012)	(0.063)	(0.076)
Females' EA PGS	0.008**	1.266***	0.055†	0.094***	0.182**	0.376***
	(0.003)	(0.279)	(0.03)	(0.012)	(0.061)	(0.075)
Male's EA PGS	-0.003	-0.090	-0.037	0.003	-0.008	-0.021
X Female's EA PGS	(0.003)	(0.27)	(0.029)	(0.011)	(0.059)	(0.072)
N	3231	3231	3231	3282	3282	3282

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Control variables are adjusted in all models. Long-term income, wealth, and labor income are rescaled by hyperbolic sine function, and the respective coefficients can be interpreted as semi-elasticity. Coefficients for principal components are omitted.

Table D3.1 Coefficients of OLS regressions of selected non-labor market outcomes on realized fertility, males only

Gender	Neuroticism	Extraversion	Openness	Agreeable-ness	Conscientio-usness	Depression	Life Satisfaction	Loneliness
Number of Children	-0.002	0.010	-0.011	0.015*	-0.004	0.027†	0.013	0.009
	(0.007)	(0.007)	(0.007)	(0.006)	(0.006)	(0.015)	(0.017)	(0.018)
Male's NEB PGS	-0.007	0.011	0.001	0.014†	-0.003	-0.011	0.041†	-0.052*
	(0.009)	(0.009)	(0.009)	(0.008)	(0.007)	(0.019)	(0.022)	(0.023)
Females' NEB PGS	0.013	-0.019†	-0.005	-0.007	-0.004	0.014	0.006	0.012
	(0.011)	(0.011)	(0.01)	(0.01)	(0.009)	(0.022)	(0.026)	(0.028)
Male's Birthyear	-0.001	-0.005*	-0.007***	-0.007***	-0.003	0.004	-0.011*	0.006
	(0.002)	(0.002)	(0.002)	(0.002)	(0.002)	(0.004)	(0.005)	(0.005)
Female's Birthyear	-0.003	0.001	-0.001	0.006**	0.002	-0.009*	0.015**	-0.017***
	(0.002)	(0.002)	(0.002)	(0.002)	(0.002)	(0.004)	(0.005)	(0.005)
Male's EA PGS	-0.023*	-0.014	0.043***	-0.019*	0.009	-0.099***	0.067**	-0.019
	(0.01)	(0.01)	(0.009)	(0.009)	(0.008)	(0.021)	(0.024)	(0.025)
Females' EA PGS	-0.017†	0.005	0.024**	0.006	0.014†	-0.090***	0.05*	-0.018
	(0.01)	(0.01)	(0.009)	(0.009)	(0.008)	(0.02)	(0.023)	(0.025)
Male's EA PGS	0.006	-0.010	-0.008	-0.002	0.006	0.052**	-0.023	0.024
X Female's EA PGS	(0.01)	(0.01)	(0.009)	(0.008)	(0.007)	(0.02)	(0.022)	(0.024)
N	3126	3127	3122	3129	3129	3269	3128	3117

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Control variables are adjusted in all models. Coefficients for principal components are omitted.

Table D3.2 Coefficients of 2SLS regressions of selected non-labor market outcomes on realized fertility, males only

Gender	Neuroticism	Extraversion	Openness	Agreeable-ness	Conscientio-usness	Depression	Life Satisfaction	Loneliness
Number of Children	0.033	-0.087	0.075	-0.045	-0.013	0.152	0.216	0.046
	(0.081)	(0.081)	(0.076)	(0.071)	(0.062)	(0.174)	(0.19)	(0.201)
Male's NEB PGS	-0.019	0.044	-0.028	0.034	0.000	-0.053	-0.029	-0.064
	(0.029)	(0.029)	(0.028)	(0.026)	(0.022)	(0.06)	(0.069)	(0.073)
Females' NEB PGS	-0.003	0.025	-0.044	0.020	0.000	-0.042	-0.085	-0.005
	(0.038)	(0.038)	(0.036)	(0.033)	(0.029)	(0.08)	(0.089)	(0.094)
Male's Birthyear	-0.001	-0.006**	-0.006**	-0.008***	-0.004*	0.005	-0.009†	0.006
	(0.002)	(0.002)	(0.002)	(0.002)	(0.002)	(0.004)	(0.005)	(0.005)
Female's Birthyear	-0.004	0.005	-0.004	0.008**	0.002	-0.014†	0.007	-0.019*
	(0.004)	(0.004)	(0.004)	(0.003)	(0.003)	(0.008)	(0.009)	(0.009)
Male's EA PGS	-0.024*	-0.012	0.041***	-0.017†	0.009	-0.102***	0.063**	-0.020
	(0.01)	(0.01)	(0.01)	(0.009)	(0.008)	(0.021)	(0.024)	(0.026)
Females' EA PGS	-0.017†	0.005	0.024**	0.006	0.014†	-0.089***	0.05*	-0.018
	(0.01)	(0.01)	(0.009)	(0.009)	(0.008)	(0.02)	(0.023)	(0.025)
Male's EA PGS X Female's EA PGS	0.006	-0.010	-0.008	-0.002	0.006	0.051**	-0.023	0.024
	(0.01)	(0.01)	(0.009)	(0.008)	(0.007)	(0.019)	(0.023)	(0.024)
N	3126	3127	3122	3129	3129	3269	3128	3117

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Control variables are adjusted in all models. Coefficients for principal components are omitted.

Table D3.3 Coefficients of OLS regressions of selected non-labor market outcomes on realized fertility, females only

Gender	Neuroticism	Extraversion	Openness	Agreeable-ness	Conscientio-usness	Depression	Life Satisfaction	Loneliness
Number of Children	-0.010	-0.005	-0.015*	0.013**	-0.006	0.039*	-0.013	0.034†
	(0.008)	(0.007)	(0.007)	(0.005)	(0.005)	(0.018)	(0.018)	(0.019)
Male's NEB PGS	0.006	0.011	0.009	0.002	0.001	-0.019	0.059*	-0.026
	(0.01)	(0.009)	(0.009)	(0.006)	(0.007)	(0.023)	(0.023)	(0.024)
Females' NEB PGS	0.003	0.007	0.004	-0.011	-0.003	-0.037	-0.007	-0.009
	(0.012)	(0.011)	(0.011)	(0.008)	(0.008)	(0.028)	(0.027)	(0.029)
Male's Birthyear	0.001	0.000	-0.002	-0.001	-0.001	-0.001	-0.006	0.001
	(0.002)	(0.002)	(0.002)	(0.001)	(0.001)	(0.005)	(0.005)	(0.005)
Female's Birthyear	-0.006**	0.000	-0.002	0.000	0.000	-0.005	0.011*	-0.011*
	(0.002)	(0.002)	(0.002)	(0.001)	(0.001)	(0.005)	(0.005)	(0.005)
Male's EA PGS	-0.022*	0.003	0.022*	-0.011	0.001	-0.114***	0.063*	-0.072**
	(0.011)	(0.01)	(0.01)	(0.007)	(0.007)	(0.025)	(0.025)	(0.027)
Females' EA PGS	-0.027*	0.007	0.033**	-0.015*	0.007	-0.133***	0.079**	-0.058*
	(0.011)	(0.01)	(0.01)	(0.007)	(0.007)	(0.025)	(0.025)	(0.027)
Male's EA PGS	0.002	0.017†	0.016†	0.010	0.006	0.009	-0.025	-0.029
X Female's EA PGS	(0.01)	(0.01)	(0.009)	(0.007)	(0.007)	(0.024)	(0.024)	(0.026)
N	3093	3092	3088	3093	3092	3230	3095	3096

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Control variables are adjusted in all models. Coefficients for principal components are omitted.

Table D3.4 Coefficients of 2SLS regressions of selected non-labor market outcomes on realized fertility, females only

Gender	Neuroticism	Extraversion	Openness	Agreeable-ness	Conscientio-usness	Depression	Life Satisfaction	Loneliness
Number of Children	-0.078	-0.194*	-0.022	-0.105†	-0.052	-0.221	0.091	0.184
	(0.088)	(0.091)	(0.079)	(0.063)	(0.059)	(0.209)	(0.208)	(0.217)
Male's NEB PGS	0.029	0.075*	0.012	0.041†	0.017	0.066	0.024	-0.077
	(0.031)	(0.032)	(0.028)	(0.022)	(0.021)	(0.072)	(0.074)	(0.076)
Females' NEB PGS	0.035	0.096*	0.008	0.044	0.019	0.080	-0.055	-0.079
	(0.042)	(0.044)	(0.038)	(0.03)	(0.028)	(0.098)	(0.101)	(0.105)
Male's Birthyear	0.000	-0.002	-0.002	-0.003	-0.002	-0.004	-0.005	0.003
	(0.002)	(0.002)	(0.002)	(0.002)	(0.002)	(0.005)	(0.005)	(0.006)
Female's Birthyear	-0.003	0.008*	-0.002	0.006*	0.002	0.005	0.007	-0.017
	(0.004)	(0.004)	(0.004)	(0.003)	(0.003)	(0.01)	(0.01)	(0.011)
Male's EA PGS	-0.021†	0.007	0.023*	-0.009	0.001	-0.108***	0.061*	-0.075**
	(0.011)	(0.011)	(0.01)	(0.008)	(0.007)	(0.026)	(0.025)	(0.027)
Females' EA PGS	-0.027*	0.007	0.03***	-0.015†	0.007	-0.134***	0.079***	-0.058*
	(0.011)	(0.011)	(0.009)	(0.008)	(0.007)	(0.025)	(0.024)	(0.026)
Male's EA PGS X Female's EA PGS	0.002	0.017	0.016†	0.010	0.006	0.010	-0.025	-0.030
	(0.010)	(0.011)	(0.009)	(0.007)	(0.007)	(0.024)	(0.024)	(0.025)
N	3093	3092	3088	3093	3092	3230	3095	3096

Data source: Health and Retirement Study, 2004–2016.

Note: † p < 0.1, * p < 0.05, ** p < 0.01, *** p < 0.001. Control variables are adjusted in all models. Coefficients for principal components are omitted.

Appendix E: Robustness Analysis Results Concerning Potential Pleiotropy Bias

Table E1. Selected coefficients of 2SLS regressions of selected non-labor market outcomes on realized fertility, with or without additional adjustments.

Gender	Neuroticism	Extraversion	Depression	Life Satisfaction
		No Additional Adjustments		
Male	0.033	-0.087	0.152	0.216
	(0.081)	(0.081)	(0.174)	(0.19)
Female	-0.078	-0.194*	-0.221	0.091
	(0.088)	(0.091)	(0.209)	(0.208)
		With Additional Adjustments		
Male	0.034	-0.085	0.136	0.231
	(0.081)	(0.082)	(0.174)	(0.192)
Female	-0.084	-0.192*	-0.239	0.091
	(0.088)	(0.090)	(0.209)	(0.208)

Data source: Health and Retirement Study, 2004–2016.

Note: † $p < 0.1$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Cluster standard errors at the spousal level are presented in parentheses. Control variables are adjusted in all models. Neuroticism and Extraversion are measured by Big-5 personality scale and range from 1 to 4. Depression is measured by the short CESD scale provided and ranges from 0 to 8. Life-satisfaction is measured by Diener's measure of life satisfaction and ranges from 1 to 7. "No Additional Adjustments" refer to the results reported in the main text (Table 5). "With Additional Adjustments" denotes the 2SLS results when the spousal PGS variables for the respective outcome and their interaction term have been controlled (e.g., spousal PGS variables for neuroticism and the interaction between the spousal neuroticism PGS variables).

EXHIBIT BB

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The Effects of Teenage Childbearing on Adult Soft Skills Development

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Abstract

Research examining impacts of teenage childbearing on economic and social outcomes has focused on completed schooling and labor force outcomes. In this paper, we examine outcomes that have remained largely unexplored, soft-skills and personality. We use Add Health data to construct relevant controls for teenage mothers and explore a set of measures that proxy for what is usually deemed in economics as “non-cognitive” or “soft-skill” traits. We find that teenage childbearing increases impulsivity, a trait that has been found to have negative effects on a large set of outcomes and has a negative effect on other personality traits perceived as positive, such as openness to experiences. Our results remain consistent through a set of robustness checks, and we interpret our findings to suggest that adolescence may be a sensitive period for the development of soft skills and that childbearing may interrupt this process.

Keywords

Soft Skills; Teenage Childbearing; Personality; Non-Cognitive Skills

JEL Codes

J13; J24

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I. Introduction

In this study, we explore teenage childbearing and its effects on non-cognitive or soft-skills later in life. Our focus is on adolescence because of the timing of the development of soft skills such as personality, risk preferences and planning abilities (Johnson, Blum, & Giedd, 2009), and disrupted development during adolescence may have important repercussions on socioeconomic life trajectories. The previous literature on the causal effects of teenage childbearing on later life outcomes has focused on educational and earnings indicators, however other developmental and psychological outcomes that are plausibly affected as a result of a pregnancy during adolescence have not been studied.

There is a consensus across several literatures that non-cognitive skills represent an important source of unobserved heterogeneity in economic behavior, and have a direct effect on the returns to schooling and other forms of human capital (Heckman, Stixrud, and Urzua 2006). At the same time, developments in neuroscience and related fields show that these skills are shaped largely during *sensitive periods* over the life cycle when brain structures and processes are developed.[2]

We follow Fletcher and Wolfe (2009) and Ashcraft et al. (2013) in estimating both OLS and instrumental variables models that employ different comparison groups and make different assumptions to investigate a range of estimates that likely bound the "true" causal impacts. Additionally, we complement our analyses with a set of alternate specifications to investigate the robustness of our results.

We find that teenage childbearing has a negative effect on some measures of personality in adulthood. In particular, women who had a child as teenagers had lower openness to experience (one of the Big Five personality traits) and greater impulsivity than women who did not have a child as a teenager. Our estimates should be interpreted as the effects of teenage childbearing, compared to women who have a child later in life, on personality and soft skills measured around age 30. Since by age 30, most women have had a child, the effects we are estimating suggest that childbearing during adolescence may interrupt a sensitive period of development for non-cognitive skills and traits—that is, we are implicitly estimating interaction effects of childbearing and developmental period rather than the effects of childbearing on soft skill development[3].

II. Overview of the Existing Literature

For the most part, past literature has studied the effects of teenage childbearing on human capital measures, such as educational attainment and wages. Other, related, outcomes that have been studied are marital status, hours of work, and being the recipient of welfare assistance (Fletcher and Wolfe 2009), short term health behavioral outcomes (Fletcher and

[2]In particular, the cerebral neocortex —an area of the brain governing perception, behavior, and cognition — undergoes two waves of development: First during pre-natal and early childhood periods, and a second one during late childhood and adolescence (Pletikos et al. 2013). In this sense, adolescence can be considered a sensitive period of human development where personality traits and other non-cognitive abilities and soft skills are shaped, and which can be affected by life events such as teenage childbearing.

[3]An alternative interpretation is that having a miscarriage as a teenage may affect non-cognitive skill development. We know of no evidence of the magnitude of these potential effects and view them as an unlikely explanation of our findings.

Wolfe 2012), and depression later in life and the socio-economic outcomes of children of teenage mothers (Jutte et al. 2010).[4]

There are both biological and environmental reasons why teenage childbearing might have an impact on non-cognitive abilities or soft skills later in life. First, adolescence is a period of active brain development. In particular, there is evidence that a series of neurodevelopmental processes during adolescence occur in brain regions associated with motivation and impulsivity, due to maturational changes in frontal cortical and subcortical monoaminergic systems (Chambers, Taylor, and Potenza 2003). These areas of the brain coordinate higher-order cognitive processes needed for goal-directed behavior, planning, response-inhibition, working memory and attention and hence have effects on many aspects of behavior and habits. It is plausible that some life events—such as childbirth— might interrupt the processes that are developing and shaping the brain's "connectivity".

Second, there is evidence that important soft skills are developed and learned in high school. The formation of social structures and peer behavior in high school have also been found to have far-reaching and lasting effects (Mora and Oreopoulos 2011). By the same token, there is evidence of the importance of the "high school experience." Heckman (2012) finds that even after accounting for pre-existing cognitive ability, GED recipients perform much worse in the labor market than high school graduates. It is likely that the experience of high school itself—beyond its completion—is altered for girls who become mothers as teenagers. There is also ample evidence on the non-pecuniary benefits of attending school in general, and high school in particular, where important social networks are formed (Rosenbaum et al. 1990, Oreopoulos and Salvanes 2011).

These previous strands of literature suggest that childbearing could differentially impact the development of soft skills based on the timing of the birth—whether during adolescence or as an adult. In this paper, we use the nationally representative Add Health data to compare the adult non-cognitive outcomes and traits of women who became pregnant in high school but miscarried with women who became pregnant and gave birth. Since the non-cognitive traits are measured during adulthood (approximately age 30), nearly all the women in our sample have had a child. Thus, we interpret our results as an interactive effect between childbearing and developmental period (adult vs adolescent) that may indicate that adolescence is a sensitive period for the development of non-cognitive traits and personality.

III. Estimation

As summarized by Fletcher and Wolfe (2009) (and earlier by Ribar (1994)) the academic literature on the subject can be divided in three large sets: Initially, studies used an OLS regression approach with a set of controls to estimate the effects of teenage childbearing on educational attainment (Moore and Waite (1997); Mott and Marsiglio (1985)). This line of research considered fertility as exogenous to educational attainment, and found large and negative associations. A second set of studies focused on the timing of births to account for

[4]While nearly all research in this area is focused estimating the effects of teenage motherhood, some research has begun to examine teenage fatherhood (Fletcher 2012). A separate literature has explored peers as an important determinant of teenage pregnancy (Yakusheva and Fletcher 2015, Fletcher and Yakusheva in press).

the endogeneity of fertility found a smaller, but still negative effect, on schooling outcomes. Subsequent studies used an instrumental variables approach to use teenagers who were pregnant as teens but miscarried to teens who gave birth (Hotz et al. 2005). This study found no negative effect from giving birth as a teen on schooling and even a positive effect. The most recent literature has placed considerable effort in defining the appropriate counterfactual group. Reduced to its simplest idea, the research on the effects from teenage pregnancy on educational outcomes posits the following thought experiment: *what would have been the life trajectories of women who had a teenage childbirth been had they not experienced a teenage childbirth* (or had teenage childbirth been assigned completely at random). In the absence of lab experiments where true randomization could be produced, defining the comparison (counterfactual) group is crucial for estimation.

Ashcraft and Lang (2013) showed evidence of the susceptibility of the Hotz et al. results to bias due to not establishing an accurate comparison group. They showed that using miscarriage as an instrument is biased towards a 'benign view' because while *"the assignment of miscarriage might be random conditional on key risk factors, the event of miscarriage is frequently censored by a woman having an abortion."* In a separate study, Fletcher and Wolfe (2009) also provide evidence that girls who miscarry come from more disadvantaged backgrounds. In this sense, the IV estimator using miscarriage underestimates the effects of teenage childbearing and results in a biased (downward) interpretation. On the other hand, the OLS estimates of effects from teenage childbearing are biased upward. Intuitively, this is because women who miscarry could be either 'abortion types' or 'non-abortion types' and therefore belong to a more favored population than women who gave birth (strictly 'non-abortion' types). Women who have abortions were found to be of more privileged backgrounds in both Fletcher and Wolfe (2009) and Ashcraft, Fernandez-Val, and Lang (2013). Further discussion on the direction of the bias in these estimates can be found in Ashcraft and Lang (2013).

In this article we use three specifications: 1) OLS estimates with a set of controls as in the initial literature (estimate will be biased upward); 2) IV estimates using miscarriage as an instrument for the timing of the birth (estimate will be biased downward); and 3) our preferred specification, which drops teenage abortions from the sample and uses the group of girls who experience a miscarriage as the control group of those who experience a teenage birth[5]. The estimates from this last specification are 'bounded' by specification 1 and 2.

The primary relationship of interest is:

$$\text{Outcome} = \beta_0 + \beta_1 Teen\,Birth + \beta_2 X + \varepsilon$$

In this basic OLS specification, the control group is women who had a teen pregnancy that resulted in either miscarriage or abortion. Girls who choose an abortion are, on average,

[5]Ashcraft, Ferdandez-Val, and Lang (2013) develop a consistent estimator assuming that miscarriage is random conditional on some controls. We proceed in this spirit and use the same type of control variables (age at conception and smoking status during pregnancy) in our preferred specification.

from more advantaged backgrounds than girls who miscarry (for a detailed discussion see (Ashcraft, Fernández-Val, and Lang 2013, Fletcher and Wolfe 2009); hence, using this control group overestimates the true cost of teenage childbirth.

Hotz et al. (2005) proposed using the nature of miscarriages as a "natural experiment", and used miscarriages as an instrument for live birth status for women who became pregnant as teenagers. The set of equations estimated are:

$$\text{Outcome} = \beta_0 + \beta_1 \textit{Teen Birth} + \beta_2 X + \varepsilon$$
$$\text{Teen Birth} = \delta_0 + \delta_1 \textit{Miscarriage} + \beta_2 X + \nu$$

This strategy may still result in biased estimates as the group of women who miscarry may not be random.

Our third—and preferred strategy—uses an ordinary least square (OLS) approach as in the first strategy, but excludes abortions from the estimation. Therefore the control group is composed of only women whose teenage pregnancy ended in a miscarriage. To be clear, the sample in these analyses is of women who had a teenage pregnancy and ended either in childbirth or miscarriage (not in abortion).

IV. Data

The dataset used in this paper is the National Longitudinal Study of Adolescent Health (Add Health). This is a nationally representative survey of 20,745 students in 132 high schools. As in Fletcher and Wolfe (2009), we limit our analysis to the first pregnancies of women who were pregnant as adolescents (pregnancies that ended before age 18 years and 9 months). Outcomes are measured at wave IV of the dataset (when the respondents are for the most part in their late twenties to their mid-thirties). Reported miscarriages and still-births are coded into one category as "miscarriages".

There are 41 survey items in the personality module of Wave IV of the Add Health data. With the exception of the Big Five personality scale, we present results from these variables and "factors" which we constructed to proxy for specific traits or soft skills. We describe each of the variables in detail in Appendix A.

V. Results—The Effects of Teenage Childbearing on Adult Outcomes

Table 1 shows basic summary statistics for the sample (it includes all women who reported having a teenage pregnancy which could have concluded in miscarriage, abortion or childbirth). As other studies on teenage pregnancy and childbirth conducted with these data have noted, an advantage of the Add Health data is that respondents use computer-assisted personal interview technology (CAPI). Hence respondents do not have to verbally answer sensitive questions, and the potential for misreporting is lower than with other available data (Fletcher and Wolfe 2009). In our sample, 24% of first pregnancies end in abortion and 17% end in miscarriage.

Table 2 reports the summary statistics (of all women who experienced a teen pregnancy) by pregnancy outcome. As in previous studies, it emerges that even in these simple descriptive statistics, women who end pregnancies in abortion had more privileged family characteristics (higher maternal education and higher family income). Women who had an abortion also scored higher on the Peabody Picture Vocabulary Test and were also in better overall health. We also note that the table suggests slight socio-demographic advantages for females who report a miscarriage compared to women who report a live birth. These small differences may suggest that our results that compare the two groups may be biased towards finding worse outcomes for women who report a live birth compared with those who report a miscarriage.

Personality—International Personality Item Pool five-factor mode

In Table 3 we show the results of the three estimation approaches described in our empirical strategy to investigate the effects of teenage childbirth on the Big Five personality variables. The first column compares the personality component between women who experienced a teenage childbirth and individuals who did not have a completed pregnancy (abortion or miscarriage), and controls for factors that have been identified in the literature as risk factors for miscarriage(Hotz, McElroy, and Sanders 2005, Garcıa-Enguıdanos et al. 2002, Fletcher and Wolfe 2009).

The personality measures are standardized in the results, so the results are in standard deviation units and show relatively large but imprecisely measured effects. The results suggest that women who experienced a teenage childbirth score (statistically significantly) lower on the personality items of extraversion (-.18 of a SD), agreeableness (−.117), and openness (−.249). The items of neuroticism and conscientiousness were higher among women who experienced a teenage childbirth, but these estimates are very modest and not statistically significant.

Column 2 shows results for the instrumental variable specification where we follow Hotz et al. (2005) and use miscarriage as an instrument for live births. These results, which are biased toward finding favorable outcomes of childbearing, suggest that there is no statistically significant relationship between teenage childbearing and any of the personality measures (with the exception of neuroticism which is −.320 of SD).

Column 3 presents results from our preferred specification. As discussed above, this specification will have estimates that are expected to be ‘bounded’ by those in columns 1 and 2. Although the direction of the estimates remains for the most part unchanged—none of the measures of personality are statistically significant. Many of the coefficients are quite small, but the results for openness to experience are suggestive—the first column estimate is nearly a 0.25 standard deviation reduction and the preferred third column is still close to 0.18, though with larger standard errors (p-value <0.11).

Impulsivity

Table 4 shows the results for our factor measure of impulsivity and its components. As discussed above, we formed a series of factor variables using the available data from the

personality module of the Add Health data via factor analysis. We present the results for the factor and its components separately[6].

The specification in column 1 compares women who had childbirth as teenagers and women for whom their teenage pregnancy ended in miscarriage or abortion. The constructed factor for impulsivity is statistically significant and positive (.096). However, "*I go with my gut feeling"* a measure used previously as a proxy for impulsivity (Fletcher, Deb, Sindelar 2009) is only statistically significant in columns 2 and 3. As expected, the results from column 3 lie within those of columns 1 and 2. As an additional test on the potential for selection into miscarriage vs. teen birth, we estimate the "I go with my gut feeling" measure at Wave I and find no effect in our preferred specification (coefficient: 0.012 standard error: 0.114; full results available upon request).

Column 3 shows that women whose teenage pregnancy resulted in a childbirth had scores . 263 higher than women for whom their teenage pregnancy ended in a miscarriage. The measure of "*I live my life without much thought for the future*" in the last row is also higher across all specifications for women who had a teenage childbirth but only statistically significant when comparing women whose teenage pregnancy resulted in childbirth compared to women whose teenage pregnancy ended in miscarriage.

Locus of Control

Table 5 shows the results for the factor measure of 'locus of control' and its components. The results indicate that across all measures, the specification that compares teenage childbirth with no birth (bias to overestimate the effects of teenage childbirth) shows a negative effect of teenage childbirth. The measures are on a one to five likert scale, and the magnitudes are relatively modest. With the exception of the variable "there are many things that interfere with what I want to do" (−.127), none of the estimates are statistically significant at conventional levels. For the other two specifications, the direction of the effects is positive and small although none of the estimates are statistically significant.

Depression, Optimism, Pessimism

Table 6 presents the results for the measures of depression, optimism and pessimism. The second and third specifications indicate that women who had a teenage childbirth were less likely to have ever received a diagnosis of depression, though this effect could be reflecting different receipt of regular care. The next row shows results of the depression scale (minimum value of zero and maximum of 15). Women who had a teenage childbirth scored higher (.355), but the direction and magnitude of the estimate changed in the other specifications.

Rows 3–5 present the results for the factor measure of 'optimism' and its components. The first specification, which compares teenage childbirth with no childbirth (either abortion or miscarriage) indicate a small but positive effect on the optimism factor measure and one of its individual components ("*overall I expect good things to happen to me*"). The variable "*I*

[6]Results in Bond and Lang (2014) suggest that results using variables measured using Likert scales can be difficult to interpret. We present results for both the overall factor scores for these combined variables as well as the variables separately.

am always optimistic about my future" is found to be negative for women who had a teenage childbirth in this specification. None of the measures are statistically significant in our third (preferred) specification.

VI. Robustness Checks and Extensions

We explore four sets of robustness checks to investigate the potential effects of teenage childbearing on later life outcomes across soft skills, personality and depression.

First, using our third specification we investigate whether there are any differences in outcomes by "hormonal age", which we measure by the time since menarche. The rationale for this set of analyses is that variation on the onset of puberty may result in differential levels of certain hormones (such as gonadal steroid hormones) which may in turn make some women be more or less susceptible to life events or result in differential effects from childbearing during adolescence on our outcomes of interest (Hirsch and Brizendine 2007, Dahl 2004, Sisk and Zehr 2005).

Second, we investigate whether there are differential effects if the teenage mother's mother was also a teenage mom herself. While there is not an overall consensus on whether children of teenage parents are more likely to be teenage parents themselves, there is still a perception that this is the case. Indeed, there is some evidence of intergenerational correlations of fertility decisions (Furstenberg Jr, Levine, and Brooks-Gunn 1990, Kahn and Anderson 1992). We investigate an interaction effect of "live birth" (treatment) and being the child of a teenage mother.

In addition, we replicate our empirical strategy using quantile regressions to investigate whether there are differential effects along the distribution of the outcomes of interest and finally, we rerun our analyses on a subsample of women who did not have other children by wave 4 besides their teenage pregnancy.

Results from Robustness Checks

To explore the robustness of our results we examined whether age since menarche or whether having a teenage mother played a role influencing the outcomes we study. Here, our focus is on whether there are other factors that 'split the sample' and can give us a better understanding of the robustness of the magnitude and direction of our results. We re-estimated all of our regressions for our third specification (OLS with those who had a teenage childbirth and those who experienced a miscarriage). Results are shown in Appendix C and include controls for "hormonal age" (and its interaction with the treatment), and having a teen mom (and its interaction with the treatment) for all outcomes.

In Table C-1 we can see the results for the big-five personality measures. While time since menarche is not significant, our results on openness are robust for those who had a teen mom (−.365 of a standard deviation). Thus our results suggest a larger negative influence for those women who had a child while teenager and their mothers were teenage mothers themselves.

Table C-2 shows the results for impulsivity. Here, our results are robust to the specifications including “hormonal age”. The factor of impulsivity (.177), “gut feeling” (.240) and “live my life without much thought about the future” (.191) indicate that for those women whose menarche was below the median age the effects from having a child as a teenager on impulsivity are larger.

In separate checks we ran all three specifications using quantile regressions to investigate whether the effects on our outcomes of interest were concentrated on specific points of the distribution (median, 75^{th}, 90^{th}). We find that the results for openness (from the Big Five) and impulsivity are similar. In addition, we re-ran our estimation using the sub-sample of women who did not have children by wave 4 after having reported a teenage pregnancy. Despite larger standard errors (because this is smaller sample), the results of impulsivity (factor) and gut feeling remain statistically significant and positive indicating that women who had a child as teenagers have a higher impulsivity and are more likely to report taking decisions by “gut feeling”.

VII. Conclusions

This paper builds on the literature on the long term effects of teenage childbearing and explores a set of outcomes that has remained largely unexplored: “soft skills”, personality and depression. While we are constrained by the available measures in the Add Health, our results suggest that there are causal effects of teenage childbearing on some personality and soft-skill outcomes. As better and more varied measures become available this should be further explored.

In line with the latest methodological research on teenage childbearing, we pay careful attention to the potential for bias in our estimates and complement our analyses with an extensive set of specifications and robustness checks. In particular, we highlight the importance of constructing the relevant control groups for the estimation and interpretation of the causal effects of teenage childbearing.

The story that emerges is that teenage childbearing increases impulsivity (the factor variables as well as its components) and decreases the measure of openness. In addition, adult women who were teenage mothers were marginally less likely to report ever having a diagnosis of depression. The remaining measures were not consistently found to be statistically significant, in line with previous research reporting small later life effects from teenage childbirth, and with the limited literature on longitudinal stability of personality traits.

An inherent disadvantage in self-reported survey data is that questions are asked during periods of “cold cognition”, that is via hypothetical questions during circumstances of low stress. This issue may be particularly important for measurement error in the available ‘non-cognitive’ variables.

What we present here are the components of the factors that resulted in significant loadings. Our goal is not to propose these as validated measures but rather to investigate if in these

'crude proxies' we could explore the effects of teenage childbearing on a series of soft skills and personality outcomes.

It is difficult to put the magnitude of our results in context as it has not been previously explored in the literature, but as more and better data becomes available exploring these issues should be explored further. In particular—as our results point out—while not all aspects of personality and soft skills may be affected, impulsivity, a trait with far reaching effects on many aspects of economic and social activity is affected by teenage pregnancy (Fletcher 2013).

Current political discourse centers on outcomes of educational attainment and earnings. It has been estimated that the public cost of teenage pregnancy is of about $9 billion, and that public programs of sex education and teenage pregnancy campaigns could save $356 million (Thomas 2012). Understanding the effects of teenage childbearing on non-cognitive outcomes and soft skills later in life would help in having a more complete political and economic debate on how to allocate policy resources.

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Appendix A. Variables

Personality

Although there is strong evidence that personality has effects on an individual's socio-economic trajectory, there is little evidence on the extent to which personality traits are developed, changed or remain stable over the life cycle (Almlund et al. 2011). Our goal is to explore whether the 'treatment' of becoming a teenage mother results in observable differences in personality later in life.

The Add Health survey fielded a 20-item short-form version of the 50-item International Personality Item Pool-Five-Factor Model known as the Mini-IPIP. Previous studies have validated this instrument's consistency (Donnellan et al. 2006). The Mini-IPIP scale has four items per Big Five trait: Extraversion, neuroticism, agreeableness, conscientiousness, and openness. Responses to each item were coded in a five point likert scale ranging from 1

(strongly agree) to 5 (strongly disagree); with a neutral point 3 (neither agree nor disagree). As discussed in (Almlund et al. 2011) the "Big Five" posits a hierarchical organization of personality traits. In this context, the five components of the Big Five are at the highest level and summarize a larger set of more specific personality facets. In appendix A, we present a table with brief descriptions of the components of the Big Five.

Impulsivity

Modern literature in the field of psychology defines impulsivity as "*a predisposition toward rapid, unplanned reactions to internal or external stimuli without regard to the negative consequences of these reactions to the impulsive individual or to others*" ((Moeller et al. 2001) (Grant and Potenza 2011)). Studies on addiction, delinquency and crime have investigated the association of impulsivity and these behaviors as well as its effects on the treatment outcomes for addiction and other conditions (Krishnan-Sarin et al. 2007, Nagin and Pogarsky 2003, Mitchell 1999). In general, high levels of impulsivity are associated with preferences for immediate gratification, risky activities, novel sensations, and easier routes to self-gratification, as well as an inability to persist at a task and shorter reaction time*s* (Mitchell 1999).

Although some measures of impulsivity are widely used (such as the Barratt's Impulsivity Scale (BIS)), we are constrained by the survey questions available in the Add Health survey. For our measure of self-control we follow Nagin and Pogarsky (2003) and Fletcher et al., (2003) ((Fletcher, Deb, and Sindelar 2009, Nagin and Pogarsky 2003)) and use the survey question "*When making decisions, you usually go with your gut feeling without thinking too much about the consequences of each alternative*." This question has been used previously as a proxy for impulsivity, and is in line with Barratt's measure of *Motor impulsivity*. The answers include five categories from "strongly agree" through "strongly disagree" (the neutral response is the omitted category). In addition, we use two other survey questions: "I like to take risks" and "I live my life without much thought for the future", and a factor variable of the three measures available in the survey.

There is ample evidence on the association of impulsivity and addictive behaviors, delinquency and treatment outcomes. In addition, laboratory task investigations have indicated that individuals with high impulsivity tend to perform poorly on fine perceptual-motor performance tasks (Barratt et al., 1981). This indicates that this individual trait may have large effects on an individual's returns to education and ultimately on his ability to perform in the labor market and as a parent.

Locus of Control

Locus of control has been increasingly studied in the economics literature as part of the wave of studies that for the last decade have focused on the economic returns to non-cognitive or 'soft' skills (Heckman, Stixrud, and Urzua 2006, Coleman and DeLeire 2003). Measures of locus of control have also been explored in the public health context, and evidence indicates that a stronger internal locus of control is associated with better outcomes

and adherence to treatment, as well as other positive behavioral outcomes (AbuSabha and Achterberg 1997, Currie 2009).

Locus of control measures the extent to which individuals believe they have control over their lives and outcomes. There is a substantial discussion in the literature on the development of locus of control and personality during childhood (Bradley and Corwyn 2002, Cobb-Clark and Schurer 2011). However, whether events later in life have or not an effect on an individual's locus of control has been somewhat less studied.

Cobb-Clarke and Schurer (2011) find that at least in a four year period, the measure they use is stable within individuals. Relevant to our study, they investigate whether negative/positive life events resulted in a change to an individual's baseline locus of control. However none of their 'life event' measures included a teenage childbirth.

We use the following available variables independently, and present also results of the factor: "*There is little I can do to change the important things in my life*"; "*Other people determine most of what I can and cannot do"; "There are many things that interfere with what I want to do*"; "*I have little control over the things that happen to me*"; "*There is really no way I can solve the problems I have.*"

Optimism

The literature on *dispositional optimism* defines optimism as "generalized positive expectations about future events"(Puri and Robinson 2007). Different measures and instruments of optimism have consistently found that optimism has large and far reaching effect over a wide set of outcomes. For instance, optimism is positively associated with coping habits and behavior (Carver, Scheier, and Segerstrom 2010), as well as faster recovery from surgery (Kiecolt-Glaser et al. 1998). In the economics realm, optimism has also been found to be related to many work and life choices. In particular, optimistic people are found to work harder, expect to retire later, invest more in individual stocks, and save more (Puri and Robinson 2007) (Laajaj 2013).

The question whether life events may change an individual's optimism has not yet been answered conclusively. Although some evidence indicates that adverse health circumstances (such as the risk of death from coronary disease) decreases the level of an individual's optimism (Giltay et al. 2006, Mols et al. 2010). However, whether teenage childbearing in particular has an effect on an individual's optimism and how persistent this effect is has not been studied before.

We use two separate measures and also present results of the factor of the two: "*I'm always optimistic about my future"* and "*Overall, I expect more good things to happen to me than bad.*" In addition, we explore a separate variable as a proxy for *pessimism*: "*I rarely count on good things happening to me."*

Depression

We explore two separate measures for depression. One is a measured using the Center for Epidemiological Studies Depression Scale (CES-D 10), a widely used instrument in depression research, and for which a short form is available in the Add Health. This measure is designed to capture current levels of depressive symptoms.

A separate measure is the answer to the question: *"Has a doctor, nurse or other health care provider ever told you that you have or had: depression?"*

Control Variables

As discussed in Fletcher and Wolfe (2009) and Ashcraft, Fernandez-Val and Lang (2013), including variables that are correlated with both the outcomes of interest and the birth outcomes could worsen results or change the sign of the bias in our estimating equations; So we follow Fletcher and Wolfe (2009) and Aschcraft, Fernandez-Val and Lang (2013), and only control for factors that have been cited in the literature as being risk factors for miscarriage such as whether pregnancy occurred before age 15 and whether teenage smoke, drank alcohol, or used drugs during pregnancy. We include race (Black, Hispanic and reference group, White), age at wave four, maternal education and a dummy for parent in the household.

Appendix B

The Big Five Personality Traits	
Openness	There is some evidence that it can be considered a 'primarily cognitive' trait (DeYoung, Peterson, and Higgins 2005). Generally, is defined as a tendency to be open to new intellectual and aesthetic experiences.
Conscientiousness	Tendency to be organized, responsible and hard-working. This trait has been linked to longevity and better health (Penley and Tomaka 2002).
Extraversion	It has been linked to higher returns of education, and leadership roles (Heineck and Anger 2010). It is broadly defined as a tendency for sociability and positive affect.
Agreeableness	Tendency to act in an unselfish and cooperative manner.
Neuroticism	In economics it has been found to be associated with risk aversion (Borghans et al. 2009). A broad definition is that neuroticism is a chronic level of emotional instability and/or proneness to psychological distress (Almlund et al. 2011).

This table is adapted from (Almlund et al. 2011).

Appendix C. Robustness checks

Table C-1

Robustness Results

VARIABLES	Hormonal Age Extraversion	Teen Mom Extraversion	Hormonal Age Neuroticism	Teen Mom Neuroticism	Hormonal Age Agreeableness	Teen Mom Agreeableness
Live Birth	−0.055	−0.106	−0.115	−0.171	−0.031	−0.105
	(0.116)	(0.156)	(0.117)	(0.151)	(0.099)	(0.109)
Age (at wave 4)	−0.061**	−0.060**	0.038	0.041*	−0.009	−0.016
	(0.025)	(0.025)	(0.025)	(0.024)	(0.020)	(0.021)

VARIABLES	Hormonal Age Extraversion	Teen Mom Extraversion	Hormonal Age Neuroticism	Teen Mom Neuroticism	Hormonal Age Agreeableness	Teen Mom Agreeableness
Conception before 15	−0.236	−0.240	0.177	0.145	−0.276***	−0.291***
	(0.167)	(0.161)	(0.158)	(0.161)	(0.100)	(0.101)
Black	−0.118	−0.114	0.077	0.069	−0.049	−0.058
	(0.114)	(0.115)	(0.095)	(0.095)	(0.093)	(0.095)
Hispanic	0.097	0.102	−0.189*	−0.206**	−0.107	−0.110
	(0.113)	(0.113)	(0.103)	(0.103)	(0.106)	(0.105)
Smoke during pregnancy	0.015	0.015	0.112	0.105	−0.110	−0.099
	(0.114)	(0.113)	(0.101)	(0.100)	(0.100)	(0.096)
Married	−0.001	−0.018	−0.181**	−0.173**	0.208**	0.196**
	(0.091)	(0.093)	(0.088)	(0.087)	(0.080)	(0.079)
Maternal Education	0.053**	0.051**	−0.040**	−0.039**	0.068***	0.058***
	(0.020)	(0.021)	(0.019)	(0.019)	(0.022)	(0.021)
Parent in Household (dummy)	−0.003	0.022	0.106	0.092	−0.005	0.015
	(0.075)	(0.078)	(0.081)	(0.079)	(0.072)	(0.075)
Hormone Median	−0.277		0.397		−0.127	
	(0.455)		(0.391)		(0.342)	
Hormone × Live Birth (interaction)	0.371		−0.226		0.153	
	(0.487)		(0.420)		(0.369)	
Teen Mom		−0.415*		0.101		−0.481***
		(0.215)		(0.195)		(0.171)
(Missing) Teen mom		−0.093		0.030		−0.073
		(0.127)		(0.114)		(0.105)
Teen Mom × Live Birth (interaction)		0.365*		0.008		0.443**
		(0.214)		(0.208)		(0.194)
Constant	1.188	1.278*	−0.086	−0.153	−0.516	−0.085
	(0.758)	(0.752)	(0.742)	(0.711)	(0.624)	(0.630)
	690	696	691	697	691	697
Observations	0.029	0.034	0.037	0.035	0.044	0.049

VARIABLES	Hormonal Age Conscientiousness	Teen Mom Conscientiousness	Hormonal Age Openness	Teen Mom Openness
Live Birth	0.069	−0.053	−0.260**	−0.365***
	(0.106)	(0.118)	(0.124)	(0.131)
Age (at wave 4)	0.061**	0.070***	−0.026	−0.036*
	(0.026)	(0.024)	(0.020)	(0.019)
Conception before 15	−0.090	−0.147	−0.107	−0.114
	(0.149)	(0.155)	(0.139)	(0.139)
Black	0.067	0.051	0.103	0.101
	(0.108)	(0.107)	(0.107)	(0.108)
Hispanic	0.178	0.169	0.145	0.145
	(0.116)	(0.115)	(0.130)	(0.128)
Smoke during pregnancy	−0.181*	−0.172*	−0.094	−0.098
	(0.098)	(0.103)	(0.093)	(0.089)
Married	0.026	0.026	0.115	0.106
	(0.088)	(0.089)	(0.087)	(0.085)
Maternal Education	0.049**	0.047**	0.037**	0.028*
	(0.019)	(0.018)	(0.016)	(0.017)
Parent in Household (dummy)	−0.031	0.031	−0.103	−0.100
	(0.093)	(0.090)	(0.079)	(0.077)
Hormone Median	0.274		−0.494	
	(0.261)		(0.484)	
Hormone × Live Birth (interaction)	−0.279		0.505	
	(0.326)		(0.510)	

VARIABLES	Hormonal Age Conscientiousness	Teen Mom Conscientiousness	Hormonal Age Openness	Teen Mom Openness
Teen Mom		−0.241		−0.717***
		(0.181)		(0.254)
(Missing) Teen mom		−0.178		−0.001
		(0.119)		(0.113)
Teen Mom × Live Birth (interaction)		0.381*		0.677**
		(0.202)		(0.270)
Constant	−2.354***	−2.481***	0.172	0.687
	(0.811)	(0.731)	(0.587)	(0.565)
Observations	691	697	687	693
R-squared	0.032	0.041	0.032	0.044

Robust standard errors in parentheses
*** p<0.01,
** p<0.05,
* p<0.10

Table –C2

Robustness Results

VARIABLES	Hormonal Age Impulsiveness (Factor)	Teen Mom Impulsiveness (Factor)	Hormonal Age When making decisions I go with my gut feeling	Teen Mom When making decisions I go with my gut feeling	Hormonal Age I like to take risks	Teen Mom I like to take risks	Hormonal Age I live my life without much thought for the future	Teen Mom I live my life without much thought for the future
Live Birth	0.177**	0.129	0.240**	0.228	0.080	0.050	0.191*	0.089
	(0.078)	(0.093)	(0.119)	(0.144)	(0.106)	(0.116)	(0.098)	(0.114)
Age (at wave 4)	0.012	0.015	−0.021	−0.015	0.048*	0.052**	0.020	0.020
	(0.017)	(0.018)	(0.026)	(0.028)	(0.025)	(0.025)	(0.020)	(0.020)
Conception before 15	0.033	0.057	0.053	0.083	0.118	0.144	−0.044	−0.027
	(0.100)	(0.102)	(0.150)	(0.153)	(0.129)	(0.135)	(0.122)	(0.119)
Black	0.138**	0.137**	0.106	0.114	0.098	0.089	0.208***	0.203***
	(0.066)	(0.066)	(0.096)	(0.097)	(0.101)	(0.101)	(0.073)	(0.074)
Hispanic	−0.046	−0.053	−0.058	−0.058	−0.114	−0.125	0.008	−0.007
	(0.080)	(0.079)	(0.124)	(0.124)	(0.141)	(0.142)	(0.087)	(0.085)
Smoke during pregnancy	−0.068	−0.062	−0.090	−0.074	−0.012	0.002	−0.090	−0.097
	(0.070)	(0.070)	(0.101)	(0.103)	(0.109)	(0.108)	(0.081)	(0.083)
Married	0.101	0.111	0.112	0.126	0.101	0.091	0.095	0.114
	(0.068)	(0.067)	(0.107)	(0.107)	(0.095)	(0.096)	(0.076)	(0.074)
Maternal Education	0.036**	0.039***	0.040*	0.045**	0.002	0.004	0.058***	0.061***
	(0.015)	(0.015)	(0.021)	(0.021)	(0.020)	(0.020)	(0.017)	(0.017)
Parent in Household (dummy)	0.084	0.095*	0.138	0.162*	0.116	0.145	0.008	−0.009
	(0.054)	(0.055)	(0.087)	(0.085)	(0.087)	(0.088)	(0.054)	(0.061)
Hormone Median	−0.190		−0.389		−0.091		−0.072	
	(0.410)		(0.475)		(0.497)		(0.360)	
Hormone × Live Birth (interaction)	0.159		0.310		0.194		−0.006	
	(0.435)		(0.505)		(0.542)		(0.387)	
Teen Mom		−0.137		−0.115		−0.118		−0.181
		(0.204)		(0.249)		(0.262)		(0.212)
(Missing) Teen mom		−0.040		−0.103		−0.104		0.070
		(0.086)		(0.142)		(0.124)		(0.089)
Teen Mom × Live Birth (interaction)		0.230		0.157		0.206		0.337
		(0.210)		(0.259)		(0.272)		(0.217)
Constant	−1.010*	−1.118**	3.162***	2.925***	1.524*	1.425*	2.437***	2.449***
	(0.543)	(0.560)	(0.766)	(0.814)	(0.837)	(0.812)	(0.631)	(0.670)
Observations	690	696	691	697	691	697	690	696
R-squared	0.052	0.057	0.032	0.031	0.020	0.023	0.063	0.072

Robust standard errors in parentheses

*** p<0.01,
** p<0.05,
* p<0.10

Table –C3

Robustness Results

VARIABLES	Hormonal Age Optimism (Factor)	Teen Mother Optimism (Factor)	Hormonal Age Optimistic About the Future	Teen Mother Optimistic About the Future	Hormonal Age Overall Expect Good Things	Teen Mother Overall Expect Good Things
Live Birth	−0.048	−0.048	0.251	0.238	−0.044	−0.094
	(0.077)	(0.091)	(0.280)	(0.346)	(0.098)	(0.115)
Age (at wave 4)	0.008	0.010	0.021	0.013	0.015	0.019
	(0.014)	(0.014)	(0.057)	(0.055)	(0.021)	(0.021)
Conception before 15	0.010	−0.019	−0.024	−0.024	−0.023	−0.052
	(0.091)	(0.092)	(0.459)	(0.452)	(0.136)	(0.134)
Black	−0.191***	−0.188***	0.787***	0.763***	−0.208**	−0.198**
	(0.056)	(0.058)	(0.238)	(0.245)	(0.083)	(0.084)
Hispanic	−0.206***	−0.205***	0.880***	0.878***	−0.174*	−0.166*
	(0.069)	(0.068)	(0.236)	(0.245)	(0.101)	(0.099)
Smoke during pregnancy	0.153***	0.155**	−0.611**	−0.590**	0.221**	0.224**
	(0.058)	(0.060)	(0.265)	(0.274)	(0.095)	(0.093)
Married	−0.048	−0.050	0.540**	0.552**	−0.027	−0.028
	(0.060)	(0.061)	(0.230)	(0.229)	(0.085)	(0.086)
Maternal Education	−0.017	−0.018	0.191***	0.184***	−0.027*	−0.028*
	(0.012)	(0.012)	(0.049)	(0.048)	(0.015)	(0.015)
Parent in Household (dummy)	−0.049	−0.035	−0.051	−0.023	0.002	0.025
	(0.043)	(0.047)	(0.195)	(0.210)	(0.070)	(0.073)
Hormone Median	−0.071		−0.204		0.011	
	(0.246)		(0.621)		(0.319)	
Hormone × Live Birth (interaction)	0.143		−0.331		0.053	
	(0.263)		(0.736)		(0.354)	
Teen Mom		−0.082		−0.054		−0.229
		(0.156)		(0.419)		(0.174)
(Missing) Teen mom		−0.058		0.014		−0.104
		(0.068)		(0.298)		(0.091)
Teen Mom × Live Birth (interaction)		0.044		0.075		0.205
		(0.153)		(0.459)		(0.169)
Constant	0.209	0.193	10.644***	10.881***	2.139***	2.085***
	(0.420)	(0.406)	(1.760)	(1.722)	(0.645)	(0.642)
Observations	688	694	691	697	690	696
R-squared	0.052	0.053	0.077	0.069	0.035	0.038

Robust standard errors in parentheses
*** p<0.01,
** p<0.05,
* p<0.10

Table –C4

Robustness Results

VARIABLES	Hormonal Age Pessimism	Teen Mom Pessimism
Live Birth	0.104 (0.113)	0.138 (0.142)
Age (at wave 4)	0.021 (0.023)	0.021 (0.022)
Conception before 15	−0.048 (0.181)	−0.102 (0.182)
Black	0.156 (0.098)	0.156 (0.098)
Hispanic	0.186* (0.111)	0.195* (0.115)
Smoke during pregnancy	−0.127 (0.100)	−0.111 (0.103)
Married Parents	0.286*** (0.093)	0.287*** (0.092)
Maternal Education	0.083*** (0.017)	0.078*** (0.018)
Parent in Household (dummy)	−0.153* (0.085)	−0.118 (0.088)
Hormone Median	−0.242 (0.360)	
Hormone × Live Birth (interaction)	0.157 (0.403)	
Teen Mom		−0.092 (0.224)
(Missing) Teen mom		−0.097 (0.135)
Teen Mom × Live Birth (interaction)		−0.015 (0.258)
Constant	1.578** (0.723)	1.636** (0.711)
Observations	691	697
R-squared	0.061	0.058

*** p<0.01,
** p<0.05,
* p<0.10

Table –C5

Robustness Results

VARIABLES	Hormonal Age Locus of Control (factor)	Teen Mom Locus of Control (factor)	Hormonal Age Little I can do to change important things	Teen Mom Little I can do to change important things
Live Birth	0.093 (0.104)	−0.051 (0.102)	0.043 (0.084)	−0.020 (0.099)
Age (at wave 4)	0.026 (0.020)	0.028 (0.020)	0.015 (0.022)	0.019 (0.022)

VARIABLES	Hormonal Age Locus of Control (factor)	Teen Mom Locus of Control (factor)	Hormonal Age Little I can do to change important things	Teen Mom Little I can do to change important things
Conception before 15	−0.100 (0.169)	−0.079 (0.164)	−0.013 (0.183)	−0.009 (0.178)
Black	0.138 (0.092)	0.139 (0.092)	0.083 (0.099)	0.087 (0.098)
Hispanic	0.009 (0.098)	0.005 (0.098)	0.081 (0.085)	0.084 (0.084)
Smoke during pregnancy	−0.221*** (0.081)	−0.229*** (0.083)	−0.128 (0.085)	−0.131 (0.090)
Married	0.216*** (0.075)	0.219*** (0.075)	0.201*** (0.068)	0.208*** (0.068)
Maternal Education	0.076*** (0.017)	0.075*** (0.017)	0.061*** (0.017)	0.062*** (0.017)
Parent in Household (dummy)	0.019 (0.075)	0.031 (0.073)	0.012 (0.058)	0.037 (0.063)
Hormone Median	0.254 (0.292)		0.018 (0.328)	
Hormone × Live Birth (interaction)	−0.316 (0.316)		−0.150 (0.353)	
Teen Mom		−0.395** (0.185)		−0.197 (0.169)
(Missing) Teen mom		−0.091 (0.100)		−0.094 (0.124)
Teen Mom × Live Birth (interaction)		0.453** (0.195)		0.219 (0.189)
Constant	−1.992*** (0.675)	−1.923*** (0.661)	2.574*** (0.723)	2.479*** (0.712)
Observations	690	696	690	696
R-squared	0.068	0.077	0.041	0.045

VARIABLES	Hormonal Age Other people determine most of what I do	Teen Mom Other people determine most of what I do	Hormonal Age Many things interfere with what I want to do	Teen Mom Many things interfere with what I want to do
Live Birth	−0.012 (0.092)	−0.124 (0.095)	0.072 (0.119)	0.019 (0.115)
Age (at wave 4)	0.009 (0.019)	0.011 (0.019)	−0.004 (0.025)	−0.008 (0.024)
Conception before 15	−0.078 (0.135)	−0.078 (0.129)	−0.101 (0.164)	−0.051 (0.157)
Black	0.161** (0.076)	0.160** (0.074)	0.029 (0.107)	0.030 (0.106)
Hispanic	0.008 (0.087)	0.003 (0.086)	0.091 (0.115)	0.081 (0.117)
Smoke during pregnancy	−0.216*** (0.078)	−0.221*** (0.081)	−0.316*** (0.093)	−0.336*** (0.090)
Married	0.059 (0.066)	0.056 (0.066)	0.197** (0.093)	0.221** (0.093)
Maternal Education	0.054*** (0.014)	0.052*** (0.015)	0.054** (0.021)	0.058*** (0.022)
Parent in Household (dummy)	0.086 (0.061)	0.103 (0.065)	−0.005 (0.077)	−0.056 (0.084)

VARIABLES	Hormonal Age Other people determine most of what I do	Teen Mom Other people determine most of what I do	Hormonal Age Many things interfere with what I want to do	Teen Mom Many things interfere with what I want to do
Hormone Median	0.071		0.039	
	(0.200)		(0.297)	
Hormone × Live Birth (interaction)	−0.040		−0.159	
	(0.226)		(0.358)	
Teen Mom		−0.391**		0.022
		(0.166)		(0.218)
(Missing) Teen mom		−0.089		0.173
		(0.097)		(0.117)
Teen Mom × Live Birth (interaction)		0.423**		0.108
		(0.184)		(0.243)
Constant	3.094***	3.180***	2.528***	2.580***
	(0.550)	(0.565)	(0.762)	(0.747)
Observations	691	697	691	697
R-squared	0.053	0.064	0.033	0.038

VARIABLES	Hormonal Age I have little control over what happens to me	Teen Mom I have little control over what happens to me	Hormonal Age There is no way I can solve the problems I have	Teen Mom There is no way I can solve the problems I have
Live Birth	0.077	−0.043	0.108	0.012
	(0.105)	(0.105)	(0.074)	(0.079)
Age (at wave 4)	0.026	0.028	0.023	0.024*
	(0.019)	(0.019)	(0.014)	(0.015)
Conception before 15	−0.109	−0.088	−0.045	−0.033
	(0.142)	(0.139)	(0.105)	(0.102)
Black	0.085	0.088	0.071	0.070
	(0.074)	(0.076)	(0.062)	(0.061)
Hispanic	−0.006	−0.008	−0.059	−0.063
	(0.089)	(0.091)	(0.068)	(0.068)
Smoke during pregnancy	−0.191**	−0.192**	−0.019	−0.023
	(0.095)	(0.094)	(0.058)	(0.058)
Married	0.118	0.119	0.167***	0.164***
	(0.076)	(0.077)	(0.058)	(0.059)
Maternal Education	0.051***	0.050***	0.039***	0.037***
	(0.016)	(0.016)	(0.014)	(0.014)
Parent in Household (dummy)	−0.023	−0.015	−0.004	0.006
	(0.083)	(0.082)	(0.049)	(0.048)
Hormone Median	0.211		0.335*	
	(0.286)		(0.178)	
Hormone × Live Birth (interaction)	−0.276		−0.324	
	(0.303)		(0.198)	
Teen Mom		−0.316		−0.254*
		(0.208)		(0.133)
(Missing) Teen mom		−0.062		−0.089
		(0.086)		(0.066)
Teen Mom × Live Birth (interaction)		0.359*		0.273**
		(0.206)		(0.129)
Constant	2.346***	2.408***	2.710***	2.801***
	(0.629)	(0.604)	(0.472)	(0.475)
Observations	691	697	691	697
R-squared	0.038	0.043	0.045	0.048

Robust standard errors in parentheses
*** p<0.01,
** p<0.05,
* p<0.10

Table 1

Summary Statistics: National Longitudinal Study of Adolescent Health Sample of females who were pregnant by age 18

Full Sample (Weighted)					
Variable	**Obs**	**Mean**	**Std Dev**	**Min**	**Max**
Birth Outcomes					
Live Birth	889	0.59	0.49	0.00	1
Miscarriage	889	0.17	0.37	0.00	1
Abortion	889	0.24	0.43	0.00	1
Outcomes					
Extraversion	886	0.07	0.99	−3.00	2.20
Neuroticism	887	0.35	0.97	−2.36	3.40
Agreeableness	887	0.17	0.93	−3.44	1.97
Conscientiousness	887	0.05	0.95	−3.57	1.98
Openness	883	−0.26	0.95	−3.04	2.27
Impulsivity (factor)	886	0.06	0.65	−2.10	1.46
Go with my Gut Feeling	887	3.43	1.02	1.00	5
Like to take Risks	887	3.14	0.97	1.00	5
Live Life without Future Thought	886	4.01	0.72	1.00	5
Locus of Control (factor)	886	−0.10	0.83	−3.27	1.55
Little Control to Change Important Things	886	3.93	0.78	1.00	5
Other People Determine what I can Do	887	4.11	0.78	1.00	5
Many Things Interfere with what I Want to Do	887	3.21	1.02	1.00	5
I Have Little Control Over Things that Happen to me	887	3.83	0.82	1.00	5
There is Really no Way I can Solve my Problems	887	4.05	0.62	1.00	5
Optimism (factor)	883	0.10	0.58	−0.95	1.67
Optimistic About the Future	887	14.42	2.42	6.00	20.00
Overall I Expect more Good Things than Bad	886	2.14	0.81	1.00	5
Pessimism	887	3.50	0.96	1.00	5
Depression Diagnosis	889	0.34	0.47	0.00	1
Depression Scale	889	3.46	2.82	0.00	15
Individual Characteristics					

Full Sample (Weighted)					
Variable	**Obs**	**Mean**	**Std Dev**	**Min**	**Max**
Age (at wave 4)	889	28.45	1.66	25.17	33.33
White	889	0.56	0.50	0.00	1
Black	889	0.26	0.44	0.00	1
Hispanic	889	0.15	0.36	0.00	1
PPVT Test Score	889	96.86	12.81	58.00	131
General Health	889	2.36	0.96	1	5
Number of Births by wave 4	862	2.08	1.23	0.00	7
Family Characteristics					
Mother's Education	889	12.63	1.86	0.00	17
Family Income (In thousands of dollars)	889	37.55	25.58	0.00	426
Parents Married (=1)	889	0.62	0.45	0.00	1
Mother Work	889	0.69	0.42	0.00	1
Parent Missing Data	889	0.36	0.48	0.00	1
Age of Parent	889	40.29	6.78	18.00	80
Pregnancy Variables					
Conception Before age 15	889	0.07	0.26	0.00	1
Smoke During Pregnancy	874	0.27	0.44	0.00	1

Sample of Females who were pregnant by age 18. Statistics weighted using wave IV weights.

Miscarriages includes stillbirths

Table 2

Summary Statistics: National Longitudinal Study of Adolescent Health By pregnancy outcome

(Weighted)	Live Births		Abortions		Miscarriages	
Variable	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Outcomes						
Extraversion	−0.002	1.048	0.343	0.819	−0.050	0.925
Neuroticism	0.373	0.938	0.230	1.053	0.427	0.959
Agreeableness	0.090	0.924	0.448	0.769	0.081	1.057
Conscientiousness	0.086	0.920	−0.047	0.977	0.064	1.018
Openness	−0.354	0.887	−0.002	0.946	−0.318	1.107
Impulsivity (factor)	0.099	0.615	0.092	0.614	−0.117	0.800
Go with my Gut Feeling	3.484	1.016	3.469	0.936	3.176	1.108
Like to take Risks	3.186	0.965	3.099	0.953	3.046	0.993
Live Life without Future Thought	4.028	0.680	4.091	0.670	3.846	0.868
Locus of Control (factor)	−0.143	0.788	0.090	0.854	−0.193	0.895
Little Control to Change Important Things	3.929	0.768	4.049	0.708	3.791	0.867
Other People Determine what I can Do	4.064	0.783	4.191	0.812	4.133	0.724
Many Things Interfere with what I Want to Do	3.159	1.029	3.392	0.975	3.150	1.023
I Have Little Control Over Things that Happen to me	3.776	0.826	3.954	0.780	3.826	0.821
There is Really no Way I can Solve my Problems	4.035	0.574	4.186	0.638	3.923	0.698
Optimism (factor)	0.080	0.577	0.097	0.567	0.163	0.624
Optimistic About the Future	14.386	2.382	14.911	2.334	13.857	2.549
Overall I Expect more Good Things than Bad	2.132	0.805	2.096	0.796	2.238	0.866
Pessimism	3.446	0.938	3.739	0.856	3.323	1.104
Depression Diagnosis	0.340	0.474	0.244	0.429	0.464	0.499
Depression Scale	3.555	2.845	2.873	2.670	3.936	2.821
Individual Characteristics						
Age	28.549	1.674	28.379	1.697	28.230	1.508
White	0.515	0.500	0.601	0.490	0.682	0.466
Black	0.301	0.459	0.228	0.419	0.160	0.367
Hispanic	0.166	0.372	0.106	0.307	0.150	0.357

(Weighted)	Live Births		Abortions		Miscarriages	
Variable	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
PPVT Test Score	95.268	12.500	101.099	12.255	96.482	13.277
General Health	2.356	0.978	2.415	0.946	2.313	0.903
Family Characteristics						
Mother's Education	12.392	1.666	13.126	2.125	12.797	1.943
Family Income (In thousands of dollars)	35.179	23.402	43.597	27.099	37.356	29.086
Parent Married (=1)	0.595	0.449	0.641	0.460	0.681	0.424
Mother Work	0.672	0.416	0.792	0.378	0.604	0.449
Age of Parent	40.246	7.196	40.362	5.074	40.359	7.381
Pregnancy Variables						
Conception Before age 15	0.053	0.224	0.126	0.332	0.068	0.253
Smoke During Pregnancy	0.206	0.405	0.330	0.470	0.382	0.486

Sample of Females who were pregnant by age 18. Statistics weighted using wave IV weights.

Miscarriages includes still births

Table 3

Effects of Teenage Childbearing on Adult Outcomes

	OLS		OLS
	Birth/No birth	**Miscarriage as an IV**	**Birth or Miscarriage (No abortions)**
Personality Item Pool-Five-Factor Model			
Extraversion	−0.180**	0.173	−0.018
	(0.074)	(0.174)	(0.117)
Observations	929	929	696
R-squared	0.036	0.01	0.027
Neuroticism	0.097	−0.320*	−0.164
	(0.080)	(0.174)	(0.119)
Observations	930	930	697
R-squared	0.03	−0.006	0.033
Agreeableness	−0.117*	0.096	0.006
	(0.070)	(0.150)	(0.100)
Observations	930	930	697
R-squared	0.038	0.027	0.039
Conscientiousness	0.041	−0.034	0.038
	(0.072)	(0.163)	(0.099)
Observations	930	930	697
R-squared	0.026	0.025	0.030
Openness	−0.249***	−0.080	−0.182
	(0.076)	(0.207)	(0.110)
Observations	926	926	693
R-squared	0.050	0.043	0.025

Controls: Age, indicator for conception <15 years old, smoke during pregnancy. Each cell is a separate regression

*** p=1%,

** p=5%,

* p=10%

Table 4

Effects of Teenage Childbearing on Adult Outcomes

	OLS		OLS
	Birth/No birth	**Miscarriage as an IV**	**Birth or Miscarriage (No abortions)**
Impulsiveness	0.096** (0.047)	0.204 (0.130)	0.189** (0.086)
Observations	929	929	696
R-squared	0.029	0.023	0.051
Factor Components			
When making a decision, I go with my 'gut feeling' and don't think much about the consequences of each alternative	0.122 (0.077)	0.390** (0.194)	0.263** (0.126)
Observations	930	930	697
R-squared	0.016	0.002	0.029
I like to take risks	0.126** (0.063)	−0.047 (0.153)	0.099 (0.101)
Observations	930	930	697
R-squared	0.013	0.006	0.019
I live my life without much thought for the future	0.051 (0.058)	0.206 (0.153)	0.188* (0.099)
Observations	929	929	696
R-squared	0.048	0.039	0.063

Controls: Age, indicator for conception <15 years old, smoke during pregnancy. Each cell is a separate regression;

*** p=1%,

** p=5%,

* p=10%

Table 5

Effects of Teenage Childbearing on Adult Outcomes

	OLS		OLS
	Birth/No birth	**Miscarriage as an IV**	**Birth or Miscarriage (No abortions)**
Locus of control	−0.079 (0.063)	0.183 (0.141)	0.064 (0.085)
Observations	929	929	696
R-squared	0.055	0.035	0.067
Factor Components			
There is little I can do to change the important things in my life	−0.037 (0.056)	0.134 (0.143)	0.031 (0.081)
Observations	929	929	696
R-squared	0.035	0.026	0.041
Other people determine most of what I can and cannot do	−0.062 (0.059)	−0.041 (0.119)	−0.017 (0.077)
Observations	930	930	697
R-squared	0.042	0.041	0.054
There are many things that interfere with what I want to do	−0.127* (0.070)	0.153 (0.169)	0.065 (0.108)
Observations	930	930	697
R-squared	0.038	0.023	0.034
I have little control over the things that happen to me	−0.053 (0.061)	0.147 (0.139)	0.049 (0.087)
Observations	930	930	697
R-squared	0.033	0.020	0.037
There is really no way I can solve the problems I have	−0.033 (0.047)	0.193* (0.110)	0.078 (0.064)
Observations	930	930	697
R-squared	0.025	−0.002	0.040

Controls: Age, indicator for conception <15 years old, smoke during pregnancy. Each cell is a separate regression;

*** p=1%,

** p=5%,

* p=10%

Table 6

Effects of Teenage Childbearing on Adult Outcomes

	OLS		OLS
	Birth/No birth	**Miscarriage as an IV**	**Birth of Miscarriage (No abortions)**
Depression Diagnosis	0.003 (0.031)	−0.203*** (0.074)	−0.097** (0.049)
Observations	932	932	699
R-squared	0.046	0.003	0.067
Depression Scale	0.355* (0.208)	−0.812 (0.523)	−0.215 (0.347)
Observations	932	932	699
R-squared	0.021	−0.010	0.025
Optimism	0.012 (0.043)	−0.103 (0.119)	−0.042 (0.075)
Observations	926	926	694
R-squared	0.053	0.045	0.051
Factor Components			
I'm always optimistic about my future	−0.327* (0.181)	0.745* (0.426)	0.260 (0.269)
Observations	930	930	697
R-squared	0.061	0.021	0.069
Overall, I expect more good things to happen to me than bad	0.023 (0.059)	−0.099 (0.146)	−0.048 (0.095)
Observations	929	929	696
R-squared	0.042	0.037	0.035
Pessimism			
I rarely count on good things happening to me	−0.118 (0.084)	0.268 (0.181)	0.123 (0.115)
Observations	930	930	697
R-squared	0.051	0.018	0.056

Controls: Age, indicator for conception <15 years old, smoke during pregnancy. Each cell is a separate regression;

*** p=1%,

** p=5%,

* p=10%

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POLITICS

Republican lawmakers reject special session Evers called to end 1849 abortion law

Ben Baker Milwaukee Journal Sentinel

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MADISON – Republican lawmakers who control the state Legislature on Wednesday rejected a special legislative session called by Gov. Tony Evers to overturn an 1849 law that would outlaw abortion in the state except when necessary to save the life of the mother.

Evers first called Wednesday's session earlier this month in response to a leaked Supreme Court draft opinion indicating a majority of justices are poised to strike down Roe v. Wade, leaving abortion access laws up to the states.

Wisconsin's 1849 law is currently on the books but has been unenforceable since 1973, following the Supreme Court's landmark decision to guarantee abortion as a right.

That could change this summer should Roe fall, creating a scenario in which seeking professional help to terminate a pregnancy could essentially become illegal statewide overnight.

"The protections that people in this state have relied upon for nearly 50 years are in peril, and without swift action, so many people — our neighbors, parents, families and friends — could soon be unable to access the health care they need and deserve," Evers wrote in his order calling for a legislative session on the issue.

The 1849 statute would most directly target doctors who perform abortions, as the law punishes "any person, other than the mother, who intentionally destroys the life of an unborn child" with a Class H felony, which may result in up to a six-year prison sentence.

The law does not explicitly punish pregnant women for performing self-induced abortions.

Supporters of abortion access also expressed concerns that existing statutes would leave doctors in a bind, alleging the current language of state abortion laws leaves much to be

interpreted regarding what constitutes an act that "intentionally destroys the life of an unborn child."

In addition to calling on the Legislature to reverse the 1849 ban, Attorney General Josh Kaul issued a statement implying the state's current abortion legislation may prove difficult to logistically manage and enforce given shifts in medical practices in the nearly two centuries since the law was first enacted.

"There will also likely be widespread uncertainty about the state law as people try to decipher whether, and if so how, an archaic and long-dormant 19th-century law would apply to 21st-century medicine," Kaul said.

More: Bracing for Roe's fall, Planned Parenthood of Wisconsin's sets June 25 as last day for abortions

Evers' decision to convene the Legislature was met with stiff opposition by conservatives as GOP leadership almost immediately outlined plans to open the session and instantly gavel out, shutting down any debate, and effectively dooming efforts to reverse the state's 19th-century abortion law.

"Wisconsin law has not changed and our pro-life position has not changed," Senate Majority Leader Devin LeMahieu, R-Oostburg, said in a statement. "We will gavel out of another blatantly political special session call from this partisan governor."

More: Assembly Speaker Robin Vos backs exception for rape and incest if Wisconsin's abortion ban goes into effect

Wisconsin state law requires the Legislature to meet if the governor takes executive action and call for a special session. It is up to the discretion of lawmakers, however, to determine how long a session lasts and what topics are or are not discussed.

The push to abruptly end Evers' mandated meeting is just the latest example of similar efforts launched by Republicans who also gaveled out sessions called by the governor to expand BadgerCare Plus and reform policing.

The rapid end to the legislative session angered Democrats who gathered to push for an overhaul of state abortion policy and urge their colleagues to reconsider upholding the existing 173-year-old law.

"We are at a crossroads in Wisconsin," said Assembly Minority Leader Greta Neubauer, D-Racine. "Our Republican colleagues have the opportunity to join us, Governor Evers and the people of Wisconsin in protecting choice. They can join us and act on the will of the people, or they can continue to sit on their hands."

More: Ron Johnson predicts Wisconsin's near-total ban on abortions wouldn't last long if Roe v. Wade is overturned

Conservatives lambasted Evers' move to hold a special session Wednesday with Sen. Chris Kapenga in a statement calling the governor's actions "nothing more than a calculated campaign move and the exact reason why the Legislature isn't in session during campaign season."

"He's not fooling anyone with this disingenuous political stunt," Kapenga added.

Lawmakers were met with chants upon entering their respective chambers as abortion rights activists held protests on Capitol grounds and demonstrated while both houses of the Legislature convened.

The Senate and Assembly meetings lasted approximately 15 and 25 seconds, respectively, and Republican-led closures of each session were met with shouts of disapproval from attending Democrats.

Evers rebuked GOP legislators' decision to gavel out, and issued a statement citing a Marquette University poll that found 70% of Wisconsinites believe abortion should be legal in all or most instances to defend his stance.

"Time and time again, the people of Wisconsin have asked Republicans legislators to do what they are elected to do — to take action on pressing our state, to do the right thing, and to help the people we are elected to serve," Evers said. "Today, they once again failed to muster the courage to perform that simple duty."

Today's session comes as tensions surrounding abortion access reach a boiling point. Last month, the Madison office of the anti-abortion group Wisconsin Family Action was targeted by arsonists who threatened to engage in further attacks, according to a statement from the group.

In the wake of rising potential for violence, Republican gubernatorial candidate Tim Michels urged Evers to brace the state for similar actions and prepare for "impending acts of mass civil disobedience" in the event that Roe is reversed in the coming weeks.

"He should immediately convene Wisconsin Emergency Management leadership, raise the Emergency Operations Center status level from the current threat level five and put the Wisconsin National Guard on notice for possible deployment," Michels said in a statement.