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Preface

The Fall edition features an article by Christina Cirucci MD and Michael Valley MD. In a recent *American Journal of Obstetrics and Gynecology*, 900 professors submitted a Special Report calling for reinstating federal protection for abortion. In this article the authors provide an alternative consensus statement. Induced abortion is not a constitutional right. The authors also value patient autonomy, but autonomy does not allow for causing harm to another human being, in this case, the human fetus. They share concern about maternal mortality in the United States, but evidence shows that induced abortion increases, not decreases, maternal mortality. They share the AJOG authors' concern for the effect of induced abortion on minority populations and mourn the fact that the abortion rate in non-Hispanic black patients is three times that of non-Hispanic white patients and twice that of Hispanic patients. Many obstetricians/gynecologists, like the authors, do not support abortion, and most obstetricians/gynecologists do not perform abortions. Induced abortion is not necessary to provide evidence-based care. We all have seen tragic situations and misinformation and want to work toward addressing these issues. The authors support the highest level of clinical practice, bodily autonomy, reproductive freedom, and evidence-based care for both our patients—the pregnant woman and the human being in utero—whom they have dedicated their lives to serving.

The second article, by James Studnicki et al., seeks to compare mental health morbidity after an induced abortion or natural loss. Continuously eligible Medicaid beneficiaries age 16 in 1999 were assigned to two cohorts based upon the first pregnancy outcome: abortion (n = 1,331) or natural loss (n = 605). Outcomes were mental health outpatient visits, inpatient hospital admissions and hospital days of stay per patient per year. Average exposure periods before and after the first pregnancy outcome for each cohort were used to adjust the mental health service rates. Prior to the first pregnancy outcome, all three utilization rates were significantly higher for the natural loss cohort compared to the abortion cohort. For the abortion cohort, the per-patient per-year increase from the pre- to post-pregnancy periods was significant for all three rates: 2.04 times visits ($p < 0.0001$), 3.04 times for inpatient admissions ($p = 0.0003$), and 3.01 times for hospital days of stay ($p = 0.0112$). None of the pre-to-post rate increases were significant for the natural loss cohort. The authors conclude that higher pre-pregnancy use rates for women who experience a natural pregnancy loss indicate that increased mental health services use following abortion cannot be solely attributed to pre-existing mental illness. Only the abortion cohort, but not

the natural loss cohort, experienced significant increases in mental health services use following the first pregnancy outcome.

In the third article, professors Meliha Sermin Paksoy and Zeynep Taner examine the compatibility of mandatory vaccinations with human rights, a very current issue with the COVID-19 pandemic and the Vavricka ruling by the European Court of Human Rights. The Vavricka ruling has faced criticism for not conducting examinations related to disease and vaccines based on direct scientific evidence. In this paper, an assessment will be made based on direct scientific evidence about tetanus and its vaccine. The prevailing reason for mandatory tetanus vaccination is to protect the health of the vaccinated individual. Competent adults have the right to refuse treatment. This rule also applies to preventive medical interventions, including tetanus vaccination. As a rule, parents are entitled to give consent for medical interventions on their children. If an immediate and serious threat permanently endangers the minor's life, medical intervention can be carried out against the parents' will. The limitation of parental autonomy is more disputed when the minor's life is not immediately threatened. With respect to tetanus vaccination as a preventive medical intervention, it does not eliminate an immediate and serious risk of harm. As a result, interference with the parent's discretion on tetanus vaccination as a preventive medical intervention should be evaluated for its compatibility with the current legal approach to medical interventions on minors and patient rights.

The fourth article, by David C. Reardon, examines the results from the Turnaway Study, by Advancing New Standards in Reproductive Health (ANSRH), which have widely been represented as definitive proof that women denied access to abortion will suffer severe injury to their health and economic wellbeing. Yet a careful examination reveals that the study is based on a non-random, non-representative sample of women that grossly under-represents the experiences of the majority of women undergoing abortions. In addition, a reanalysis of its reported results reveals that the effect size of the outcomes observed have been grossly overstated, leading to conclusions that are not supported by the results. There also appears to be selective reporting and misrepresentation of results previously published. In addition, inconsistencies in ANSRH's published record strongly suggest that the credit history reports of the Turnaway Study participants were obtained without their informed consent.

The fifth article is AAPLOG's Practice Guideline on Counseling the Abortion Vulnerable Patient. Induced abortion is defined as a procedure done to end a pregnancy in such a manner as to avoid a live birth, i.e. intentional feticide. Many physicians will encounter patients considering intentional feticide (induced abortion) for various reasons. Such interactions present an opportunity not only to create a lasting bond with the patient, but also to open doors for her

to explore possibilities she may not have considered, and thereby enable her to make a life-affirming decision. Given the importance of offering accurate information about induced abortion and continuation of pregnancy, this Guideline provides guidance and resources for the pro-life physician encountering an abortion-vulnerable patient.

This edition concludes volume 39 of *Issues in Law & Medicine*, the second year that *Issues* is being published solely as an open access, electronic journal, available free of charge at *IssuesinLawandMedicine.com*. Thank you for your continued interest in *Issues in Law and Medicine*.

Barry A. Bostrom, J.D.
Editor-In-Chief

Articles

A Statement on Abortion by 170 Obstetricians/ Gynecologists after the Reversal of Roe v Wade

Christina Cirucci MD* and Michael Valley MD**

ABSTRACT: In a recent American Journal of Obstetrics and Gynecology, 900 professors submitted a Special Report calling for reinstating federal protection for abortion. Here, we provide an alternative consensus statement. Induced abortion is not a constitutional right. We, too, value patient autonomy, but autonomy does not allow for causing harm to another human being, in this case, the human fetus. We share concern about maternal mortality in the United States, but evidence shows that induced abortion increases, not decreases, maternal mortality. We share the authors' concern for the effect of induced abortion on minority populations and mourn the fact that the abortion rate in non-Hispanic black patients is three times that of non-Hispanic white patients and twice that of Hispanic patients. Many obstetricians/gynecologists, like ourselves, do not support abortion, and most obstetricians/gynecologists do not perform abortions. Induced abortion is not necessary to provide evidence-based care. We also have seen tragic situations and misinformation and want to work toward addressing these issues. We support the highest level of clinical practice, bodily autonomy, reproductive freedom, and evidence-based care for both our patients—the

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pregnant woman and the human being in utero—whom we have dedicated our lives to serving.

Key Words: **abortion restrictions, abortion rights, induced abortion**

Introduction

Here, 170 obstetricians/gynecologists* (OB/GYNs) share the following consensus response to the published Special Report, A Statement on Abortion by 900 Professors of Obstetrics and Gynecology** after the Reversal of *Roe v Wade*" (hereafter called the Statement).[1] We too support the highest level of clinical practice, bodily autonomy, reproductive freedom, and evidence-based care for both our patients—the pregnant woman and the human being in utero—whom we have dedicated our lives to serving. Strikingly absent in the Statement is any acknowledgment of the human fetus who is killed in an abortion.

In the Statement, the authors call for reinstating "federal protection for abortion," contending that in the *Dobbs* decision, the Supreme Court retracted the "constitutionally protected right to abortion." They state that the decision has harmed the lives and health of patients and the ability to train upcoming physicians in "this medically necessary evidence-based care." They argue that they expect future harm, including adverse effects on maternal mortality. They refer to the *Dobbs* decision as a "disastrous decision for public health." We find much misinformation in the Statement and offer the following clarifications.

Induced Abortion: A Constitutional Right?

The authors refer to induced abortion as a constitutionally protected right that was removed by *Dobbs*. In the majority opinion for *Dobbs*, the justices stated, "The critical question is whether the Constitution, properly understood, confers a right to obtain an abortion."[2] The decision explains that the *Roe* "right to abortion" was fabricated by the *Roe* court. In *Dobbs*, the Supreme Court returned to the people and their elected representatives the ability to consider both the rights of the preborn human and pregnant patient. The Justices further state, "Like the infamous decision in *Plessy* v. *Ferguson*, *Roe* was also egregiously wrong and on a collision course with the Constitution from the day it was decided. *Casey* perpetuated its errors."[2] The authors of the Statement

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* See Appendix for list of 170 obstetricians/gynecologists supporting this Sspecial Report.

** Although the article claims these are all OB/GYN professors, not all are physicians, nor are all in the field of OB/GYN..

may not like the decision, but abortion was never a constitutional right. Many pro-abortion jurists agreed that *Roe* was bad jurisprudence.[3,4]

Patient Autonomy

The authors refer to abortion as a "federally protected right to bodily autonomy for women." Autonomy is one of the basic principles of medical ethics according to the most widely used account of medical ethics, along with beneficence, non-maleficence, and justice. Autonomy is never absolute. Although patients have autonomy in medical decisions, this does not mean they can have any procedure they want. A patient does not have the autonomy to have a healthy arm amputated. In an induced abortion, the aborted human in the uterus is denied any autonomy.

Abortion is not only about autonomy but also about non-maleficence. In the case of pregnancy, we, as physicians, have two patients. Abortion sometimes harms the woman; abortion always ends the life of our second patient.[5,6]

We do not minimize the difficult situations that women face when encountering unplanned or complicated pregnancies. Ending a life is never the solution to a complicated social problem. Would the authors support killing an unwanted newborn, a one-year-old, or a six-year-old in difficult circumstances? Do the authors see the fetus as their patient only when the fetus is stipulated as a wanted pregnancy? We all care for pregnant women facing tragic, difficult, and complex situations. Induced abortion does not solve any of these problems and often compounds them. None of us would allow or help a mother to kill her born children because of poverty, rape, disability, unwantedness, or a life-limiting condition. As physicians, we live by "first do no harm."

Maternal Mortality

We share the concern of the authors about the high maternal mortality rate in the United States, but the evidence does not support the assertion that unrestricted induced abortion decreases maternal mortality. The high maternal mortality rates were documented before the *Dobbs* decision when unrestricted abortion was widely available.[7] Furthermore, multiple studies have shown that abortion restrictions in other countries do not result in increased maternal mortality.[8] In fact, there is evidence that maternal mortality increases after legalization of abortion.[9] Countries with very restrictive abortion policies have much lower maternal mortality ratios (MMRs), which is the number of maternal deaths per 100,000 live births, than the United States. The MMR in the United States is 21, compared to Poland (which prohibits abortion except to preserve the life of the mother), which has an MMR of 2, and Malta (which restricts abortion completely), which has an MMR of 3.[10,11]

The widely quoted study by Raymond et al. concluded that abortion is fourteen times safer than childbirth.[12] In this study, the abortion-related mor-

tality (legal abortion-related deaths divided by number of legal abortions) was compared to mortality related to live birth (the number of pregnancy-related deaths among women who delivered live neonates divided by the number of live births). In order to calculate mortality related to abortion, however, we must have accurate information on both the number of deaths from abortion and the number of abortions. We have neither. There are no federally mandated abortion reporting requirements, so these numbers are only estimates. The states of California, Maryland, New Hampshire, and New Jersey do not require reporting of abortions, and only 28 states require reporting of abortion complications.[13] Additionally, abortion by drugs ordered online will not be included in statistics.

Furthermore, in the Raymond study, the authors seem to have considered deaths only from immediate physical causes. Multiple studies have shown a relationship between abortion and mental health; suicide has been demonstrated to be more common after abortion than live birth.[6,14] Deaths from mental health causes, however, are rarely reported as abortion-related deaths.[15,16] Multiple other studies using high-quality linkage data show far more deaths after induced abortion than after childbirth.[15,17-22]

Effect on Minorities

The authors of the Statement believe that abortion restrictions disproportionately affect low-income patients and people of color, providing no references for their claims. Data show that induced abortion disproportionately kills black fetuses in the uterus. The latest Centers for Disease Control and Prevention surveillance report shows that 38.4% of abortions are in non-Hispanic black women, even though the population percentage is only 13.6%.[23-24] The induced abortion rate in non-Hispanic black women (21.2 per 1000 women) is more than three times that of non-Hispanic white women (6.3 per 1000) and almost twice that of Hispanic women (10.9 per 1000).[23] Induced abortion does not benefit women of color or their babies. It reduces their population. Induced abortion is the leading cause of death among black people; sixteen million black fetuses have been eliminated by abortion since *Roe v Wade*.[25]

Support for Abortion

The authors contend that there is widespread support in the medical community for induced abortion. We and many other physicians do not support abortion. We have known many patients who seek us out because they want a doctor who does not support elective abortion. Multiple studies have shown that the large majority of practicing OB/GYNs do not perform abortions, and a significant percentage do not refer for abortion.[26-30] These same physicians frequently perform the same surgical procedure that is used for induced abortion in different circumstances, such as a fetal demise or incomplete miscarriage.

"While much of the Western academic community has lamented the fall of *Roe*, this lament is unrepresentative of the views of most people in the West. It is even less representative of the majority of people around the world, who broadly oppose abortion on demand even in the first trimester."[3]

Evidence-Based Care

The authors indicate that abortion is necessary to provide evidence-based care and that if fewer residency programs provide abortion training, there will be no one to take care of women with a second-trimester obstetric complication that requires delivery of the fetus. This allegation is false. We do not perform abortions,[***] yet we can and do evacuate the uterus when a pregnant woman's life is at risk, such as from a septic abortion or severe preeclampsia in the second trimester. Dismemberment abortion is not required to provide evidence-based care. As noted, the large majority of OB/GYNS do not perform abortions. Are the authors alleging that these doctors do not and cannot provide quality care? If performing induced abortions is necessary for evidence-based patient care, why do so few obstetricians perform abortions?

Tragic Situations and Misinformation

The authors provide examples of patients they have cared for who were treated with doubt and suspicion when presenting for miscarriage, women pregnant with children with disabilities who need resources, and delayed care for women with ectopic pregnancies. No abortion restriction in any state precludes care for these patients. We should be correcting the misinformation that may prevent women from getting evidence-based care for a miscarriage or ectopic pregnancy. Every state law protecting unborn life allows separating the mother and the unborn fetus if necessary to protect the mother's life. Every state law allows treatment for ectopic pregnancy and treatment for miscarriage. We have never confused the treatment of miscarriage or ectopic pregnancy with induced abortion and are working to correct the promulgation of this misinformation and dispel its myths.

Legal induced abortion may also result in tragic situations such as death from overwhelming sepsis and massive hemorrhage.[8,31] Additionally, there have been ruptured ectopic pregnancies following attempted induced abortion, including some resulting in death, because the patient did not have an ultrasound.[31]

[***] We define abortion as the intentional killing of the unborn. We acknowledge that there are situations in which a pregnancy must be ended prematurely to save the life of the mother with the foreseeable death of the child. Some may define this as an abortion. Semantics aside, these life- saving interventions are a tiny proportion of abortions and do not in any way require legalization for elective abortion.

It is impossible to provide gestational age-specific informed consent prior to abortion without an ultrasound to document gestational age and rule out ectopic pregnancy. Best evidence-based care includes an ultrasound prior to an abortion to determine gestational age and pregnancy location and abortion providers providing continuity of care for their patients who experience abortion complications. The large majority of abortion complications are managed by someone other than the abortion provider.[31]

Furthermore, multiple studies have shown higher risks with mifepristone abortion than with surgical abortion, so mifepristone abortion should not be the primary means of pregnancy termination.[32-34] However, at this time, over half of induced abortions are mifepristone abortions.[35] This percentage does not reflect those who purchase abortion drugs online without any interaction with a health care provider.

Are We Going Backward?

The authors claim we are going backward and refer, without any references, to wards of patients with septic abortion and state that the United States is among only three other countries that have restricted access to abortion. They did not state that our country is among only eight nations (the others are Australia, Canada, China, Guinea-Bissau, Mexico, South Korea, and Vietnam) that allow abortion on demand at any gestational age. Additionally, the United States is one of only 15 United Nations countries that allow abortion on demand after 15 weeks.[10] The abortion law in the United States is much more permissive than the vast majority of the rest of the world. The recent promotion of medically unsupervised "self-managed" abortions by mail is a step backward to the time when women initiated and managed their abortions on their own.[36]

Call To Action

We, too, have a call to action. We ask the 900 professors to work with us to promote evidence-based care and best practices for women. We do not agree on the ethics of induced abortion, but we can agree to work together on aspects of maternal and child healthcare. We invite the authors to collaborate and work with us in the following ways:

- Dispel the misinformation that treatment of miscarriage and ectopic pregnancy is induced abortion.
- Clarify that pre-viable fetal delivery or abortion to protect the life of the mother is allowed by every state abortion law. Failure to provide a necessary intervention harms women.
- Work to minimize mifepristone abortion over surgical abortion because of the increased risks associated with mifepristone abortion.

- Promote ultrasound prior to abortion to determine gestational age and pregnancy location; all women considering an abortion deserve the best evidence-based care.
- Discourage buying of abortion drugs online. "Self-managed abortion" exposes women to increased risks. Buying abortion drugs online or without a provider visit is not evidence-based care for women.
- Promote accurate data collection of all abortion procedures and complications. Inaccurate and incomplete data limits our ability to improve women's healthcare.

We stand by both our patients, doing what is best for women and their preborn children.

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Appendix

First Name	Last Name	Degree	Credentials	Institution (if chose to list)	City	State
Samir	Abadeer	MD	FACOG, dip ABOG	Abadeer OBGYN	Wausau	WI
Jonathan	Abbott	MD	FACOG, dip ABOG	Jennie Stuart OB/GYN	Hopkinsville	KY
Sharai	Amaya	MD	FACOG, dip ABOG	Cornerstone Clinic For Women	Little Rock	AR
Jennifer	Anderson	MD	dip ABOG	Cornerstone Clinic For Women	Little Rock	AR
Michele L.	Ashton	MD	FACOG, dip ABOG		St. Joseph	MI
Kathi Ann	Aultman	MD	FACOG, dip ABOG		Orange Park	FL
Susan	Bane	MD, PhD	dip ABOG		Wilson	NC
John	Bard	MD	FACOG	Corewell Health	St. Joseph	MI
Gustav K	Barkett	DO	FACOOG		Muskegon	MI
Jeffrey	Barrows	DO, MA (Ethics)	FACOOG		Bellafontaine	OH
Philip A	Basala	DO	FACOG, dip ABOG, FPMRS		Keyser	WV
Angela	Beale Martin	MD	dip ABOG		Cincinnati	OH
Scott	Beard	MD	FACOG, dip ABOG, FPMRS	Associate clinical professor UNM; Associate clinical professor Burrell Medical College	Lovington	NM
Stephen	Blaha	MD	FACOG dip ABOG	Medical Director, Natural Family Planning	Charlotte	NC
Kevin D	Blair	MD	FACOG, dip ABOG	Director of Women's Care, Christus Santa Rosa Hospital;Chairman of OB-GYN, and Womens & Childrens Dept	New Braunfels	TX
Jeffrey M.	Blake	MD	FACOG, dip ABOG, FPMRS		Pendleton	IN
Gayle	Borkowski	MD	dip ABOG	North Central Indiana Medical Clinic	Milford	IN
Steven	Braatz	MD	dip ABOG		Janesville	CA
Kevin	Breniman	MD	FACOG, dip ABOG	Cornerstone Clinic For Women	Little Rock	AR
John T	Bruchalski	MD	FACOG, dip ABOG	Tepeyac OBGYN, Divine Mercy Care	Fairfax	VA
Thomas	Burns	MD	dip ABOG		Alexandria	VA
Byron C	Calhoun	MD, MBA	FACOG, dip ABOG,FACS, FASAM	Professor and Vice Chair, Dept of OBGYN,West Virginia University- Charleston	Charleston	WV

Appendix *(Continued)*

First Name	Last Name	Degree	Credentials	Institution (if chose to list)	City	State
Mark S.	Campbell	MD	dip ABOG		Douglas	WY
Josette	Chamberlain	MD	Former ACOG/ABOG		Columbia City	IN
Kay	Chandler	MD	FACOG, dip ABOG	Cornerstone Clinic For Women	Little Rock	AR
Alex J.	Childs	MD	dip ABOG		Birmingham	AL
Sandy	Christiansen	MD	FACOG, dip ABOG	Care Net National Medical Director	Lansdowne	VA
Christina	Cirucci	MD	FACOG, dip ABOG		Sewickley	PA
Joe	Cloud	MD	FACOG, dip ABOG		Morrilton	AR
Geoffrey C	Cly	MD			Fort Wayne	IN
Katrina	Conrad	MD	FACOG, dip ABOG		Morehead City	NC
Brian J.	Crisp	MD	FACOG, dip ABOG	OB/GYN Residency Faculty, Marian Regional edical Center	Santa Maria	CA
Damon	Cudihy	MD	dip ABOG	Acadiana OB/GYN	Lafayette	LA
Howard	Curlin	MD		Associate Professor OBGYN, Vanderbilt University Medical Center	Nashville	TN
Lorna	Cvetkovich	MD	FACOG, dip ABOG	Tepeyac Ob-Gyn	Fairfax	VA
J. Michael	Davidson	MD	FACOG, dip ABOG	McLeod Gyn Specialists	Florence	SC
Robert W	Davis	MD	dip ABOG	Emeritus, Saint Luke's The Women's Clinic, Boise	Boise	ID
Myles	Dotto	MD	FACOG, DABOG		Southport	NC
Joy	Draper	MD, JD	FACOG, dip ABOG, FAAFP		Greenwood	SC
Kevin	Dumpe	MD	dip ABOG	Director of OB/GYN Training, Heritage Valley Health System	Beaver	PA
Amy J	Fisher	DO	FACOG, dip ABOG		St. Paul	MN
James Michael	Fite	MD	ACOG, ABOG		Fort Worth	TX
Steven	Foley	MD	FACOG, dip ABOG	Carmel Indiana OBGYN	Carmel	IN
Christina	Francis	MD	dip ABOG	OBGYN Hospitalist	Fort Wayne	IN

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First Name	Last Name	Degree	Credentials	Institution (if chose to list)	City	State
Wayne	Friedman	MD	dip ABOG	Magnolia Women's Center	Bainbridge	GA
Thomas J	Furey	MD	FACOG, dip ABOG	Staff member at Hinsdale Hospital & LaGrange Hospital	Indian Head Park	IL
Amanda	Gacetta	DO	FACOG, dip ABOG	Teaching Faculty Member at the Medical College of Wisconsin	Wisconsin Rapids	WI
Donald	Gaddy	MD	FACOG, dip ABOG	Gaddy OBGYN	Gulfport	MS
Yadira	Garcia	MD	dip ABOG		Towson	MD
Pamela G	Gaudry	MD		The Georgia Center for Menopausal Medicine and Direct Primary Care, LLC	Savannah	GA
Patricia	Giebink	MD	FACOG		Chamberlain	SD
Jamie Lynne	Gladden	MD				
Michael	Glover	DO	FACOOG, dip AOBOG		Cleburne	TX
Tess M.	Gordon	MD, MBA	dip ABOG		Clare	MI
Thomas L	Gray	MD	FACOG	Medical Director LifeChoices Pregnancy Help Medical Center	Memphis	TN
J Paul	Gray	MD	FACOG, dip ABOG, FPMRS	Womans Clinic PA	Jackson	TN
Stephanie	Grosvenor	DO	FACOOG	Society of Procreative Surgeons	Fort Wayne	IN
James F	Guenther	DO	FACOG dip ABOG		Columbus	OH
Lanette McKown	Guthmann	MD			Littleton	CO
Laura	Guttierrez	MD	FACOG, dip ABOG		El Paso	TX
Edward C.	Hall	MD	dip ABOG	Clinical Faculty University of KY	Edgewood	KY
Kevin W	Hamburger	MD	FACOG, dip ABOG	Siouxland Women's Health Care, PC	Sioux City	IA
Stephen	Hammond, Sr	MD	FACOG, dip ABOG		Jackson	TN
James A.	Hanser	MD	FACOG, dip ABOG		Fairfield	CA
Anthony	Harbin	MD	dip ABOG		Dalton	GA
Kim	Hardey	MD			Lafayette	LA

Appendix *(Continued)*

First Name	Last Name	Degree	Credentials	Institution (if chose to list)	City	State
Amy	Harrell	MD	dip ABOG		Bryan	TX
Mary Jo	Heinrichs	MD	dip ABOG		Phoenix	AZ
Christine	Hemphill Jones	MD	dip ABOG		Camden	SC
Timothy	Hepworth	MD	FACOG, dip ABOG		Cedar Springs	MI
Sheila	Hill	MD	FACOG, dip ABOG		Houston	TX
Christopher	Homeyer	MD	FACOG, dip ABOG		Evans	GA
Teresa A.	Hubka	DO MS	FACOOG,FACOG, dip AOBOG	Medical Director, Comprehensive Wellness Care, LLC		
Ana Maria Garcia	Iguaran	MD, MS	FACOG, dip ABOG	Thrive OB/GYN	Miramar	FL
Angela	Jackson-Lopez	MD	FACOG	Physicians & Surgeons for Women Inc	Springfield	OH
Patricia Smith	Jay	MD			Dedham	MA
Sudheer	Jayaprabhu	MD, MBA	dip ABOG		Texarkana	TX
Karl H	Johansson	MD	FACOG			
Jillian Martell	Johnston	MD	FACOG	FEMM telehealth		
Lawrence R	Jones	MD			Cullman	AL
L. Carl	Jurgens	MS, MD	dip ABOG			
Maureen	Kennedy	MD			Arden	NC
Hanna	Klaus	MD	FACOG, dip ABOG		Philadelphia	PA
Jeri	Klobutcher	MD	AAPLOG		Ashland	OH
Erica	Kreller	MD	dip ABOG	Morning Star OB/GYN	Gilbert	AZ
Donna	LaFontaine	MD	dip ABOG		Cumberland	RI
Margaret	Lambert	MD	FACOG, dip ABOG		Neptune	NJ
Katherine S	Lammers	MD	FACOG		Rochester	NY
Paul	LaRose	MD	dip ABOG		Pensacola	FL
Robert C.	Lawler	MD	FACOG, dip ABOG		Lemont	IL

Appendix *(Continued)*

First Name	Last Name	Degree	Credentials	Institution (if chose to list)	City	State
Christy	Lee	MD	FACOG, dip ABOG	Associate Professor	Greenville	SC
Clint	Leonard	MD	FACOG, dip ABOG	Morning Star OB/GYN	Gilbert	AZ
Anthony	Levatino	MD, JD	dip ABOG	Affiliate Professor of Clinical Medicine. OB/GYN Burrell College of Osteopathic Medicine	Las Cruces	NM
Danny L	Lickness	MD	FACOG, dip ABOG	Medical Director, Lifeline Pregnancy Center	Grover Beach	CA
Karen F	Liebert	MD	FACOG, dip ABOG	Medical Director of Community Pregnancy Clinics in Sarasota.	Bradenton	FL
James	Lindemulder	DO	FACOOG (distinguished)		Goshen	IN
James	Linn	MD	dip ABOG	Associate Clinical Professor OB/GYN Medical College of Wisconsin	Milwaukee	WI
Charles	Lively	MD	dip ABOG, NBPAS		Odessa	TX
Anne Marie	Manning	MD	dip ABOG	UPMC Divine Mercy Women's Health	Carlisle	PA
Greg	Marchand	MD	FACOG, dip ABOG, FACS, FICS	Marchand Institute for Minimally Invasive Surgery	Mesa	AZ
Pat	Marmion	MD, MPH	dip ACPM		Georgetown	TX
Leonard	Marotta	MD, MS	dip ABOG		Dunedin	FL
David P.	Martinez	MD	FACOG, dip ABOG		Lakewood	CO
James P	McBride	MD	FACOG		Rochester Hills	MI
Tamberly Ford	McCarus	MD	FACOG, dip ABOG	Advent Health Physician and Volunteer Medical Director of Choices Women's Clinid Orlando FL	Orlando	FL
Shani K.	Meck	MD	FACOG, dip ABOG	East Lakeland OG/GYN	Flowood	MS
Gary	Meyer	DO	FACOOG		Glenwood Springs	CO
Julie	Mickelson	MD	dip ABOG		Minneapolis, MN	MN
Gregory A.	Miller	MD	dip ABOG		Littleton	CO

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First Name	Last Name	Degree	Credentials	Institution (if chose to list)	City	State
John	Moraca	MD	FACOG, dip ABOG		Sewickley	PA
Eric	Mudafort	MD			Terra Ceia	FL
Alan J	Murnane	MD	FACOG dip ABOG	Managing Partner, Westar OB/ Gyn; Attending Physician, Mt Carmel St Ann's Hospital	Westerville	OH
Elizabeth	Nelson	MD	FACOG, dip ABOG		Orlando	FL
Michael	Nelson	DO	FACOOG, dip AOBOG		Cheyenne	WY
Bennie	Nobles	MD			New Orleans	LA
Jaime	Obst	DO	FACOG, dip ABOG		Fort Worth	TX
Jerry	Orbitsch	MD	dip ABOG		Bismarck	ND
Jazmin D.	Parcon	MD	FACOG		Las Vegas	NV
Michael S	Parker	MD, KM	dip ABOG	Obstetric Hospitalist	Galena	OH
Mahate	Parker	MD, MPH	dip ABOG	COFMC, Ada, OK	Ada	OK
Brent	Parnell	MD	FACOG, dip ABOG, FPMRS		Birmingham	AL
Marianne	Peck	MD	FACOG, dip ABOG		The Woodlands	TX
Elina	Pfaffenback	MD	FACOG, dip ABOG	Women's Health Specialists	Appleton	WI
John G.	Pierce, Jr	MD	FACOG, dip ABOG	Women's Health Services of Central Virginia	Lynchburg	VA
Robert G.	Porto	MD	FACOG, FACS, dip ABOG		Fort Lauderdale	FL
Lance E.	Radbill	DO	dip ABOG		Birmingham	AL
Kathleen M.	Raviele	MD	FACOG		Atlanta	GA
Christi L.	Redmon	MD				IN
Braden	Richmond	MD	FACOG, dip ABOG	Special Care for Women	Anniston	AL
Steven	Roth	MD	dip ABOG		Cleveland	GA
Peter	Rothschild	MD	FACOG, dip ABOG	LifeSpring Pregnancy Center	Charlottesville	VA
Susan	Rutherford	MD	FACOG, dip ABOG	MFM	Redmond	WA
Thomas B	Ryan	MD	dip ABOG		New Orleans	LA

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First Name	Last Name	Degree	Credentials	Institution (if chose to list)	City	State
Allan	Sawyer	MD, MS, MATS	dip ABOG		Peoria	AZ
Anna Lisa	Schmitz	MD	FACOG, dip ABOG			IL
Fred (Rocky)	Seale	MD	dip ABOG		New Braunfels	TX
Matthew	Sellers	MD	FACOG, dip ABOG	Cornerstone Clinic for Women	Little Rock	AR
Kenneth G.	Singleton	MD	dip ABOG, ABAARM	Cornerstone Clinic for Women	Little Rock	AR
Tonia L.	Skakalski	DO	dip ABOG		New Castle	PA
Ingrid	Skop	MD	FACOG, dip ABOG		San Antonio	TX
Melissa Halvorson	Smith	MD	FACOG, dip ABOG		Lansing	MI
Marie	Sohner	MD	dip ABOG	Tomball Women's Healthcare	Tomball	TX
Mary Ann	Sorra	MD	FACOG, FACS	Ascension St Agnes Hospital	Baltimore	MD
Thomas	Sparks	MD	dip ABOG		Baton Rouge	LA
Jonathan	Stafford	MD	FACOG, dip ABOG		Wichita	KS
Jillian	Stalling	MD	dip ABOG	Medical/Surgical NaProTechnology; Ferrtility & Midwifery Care Center	Fort Wayne	IN
Catherine	Stark	MD	dip ABOG	Medical Director, Crossroads Care Center, Auburn Hills, MI; Adjunct Assistant Professor, Dept of Family Medicine and Community Health, Oakland University-William Beaumont School of Medicine, Rochester, MI Emeritus Attending Staff, Beaumont Hospital Troy, MI	Auburn Hills	MI
Mark F	Stegman	MD	dip ABOG		Johnston	IA
John Charles	Stitt	MD	FACOG, dip ABOG		Hopkinsville	KY
Christopher	Stroud	MD	CFCMC	Fertility and Midwifery Care Center, LLC; Holy Family Birth Center, LLC	Fort Wayne	IN
Barbara	Susang-Talamo	MD	dip ABOG		Export	PA
Lourell	Sutliff	MD	FACOG, dip ABOG		Tyler	TX

Appendix *(Continued)*

First Name	Last Name	Degree	Credentials	Institution (if chose to list)	City	State
Shawn	Swan	MD	FACOG, dip ABOG	Ascension Anderson OB/GYN Hospitalist	Anderson	IN
Eric	Swisher	MD	FACOG, dip ABOG		Roanoke	VA
J. Leonard	Tadvick	MD	dip ABOG		Abilene	TX
Mayra Jimenez	Thompson	MD	FACOG, dip ABOG		Dallas	TX
Audrey	Tool	MD	FACOG		Fort Collins	CO
Michael	Valley	MD	dip ABOG, FPMRS		Minneapolis	MN
Karla	Van Keulen	MD	dip ABOG	Medical Arts Ltd	Moline	IL
Marilyn	Vanover	MD	FACOG		San Antonio	TX
Melinda J	Velez	DO	FACOOG, dip AOBOG		Dallas	TX
Steven	Verbeek	MD	dip ABOG	Avera Health	Pipestone	MN
John	Voltz	MD	ABOG		Lafayette	LA
Stephen C.	Walker	MD	dip ABOG		Orange	CA
Michael	Watkins	MD	ABOG, OBHG		Spartanburg	SC
Elizabeth	Wehlage	MD	FACOG		Indianapolis	IN
Catherine	Wheeler	MD	FACOG dip ABOG		Teller County	CO
Nancy Goodwine	Wozniak	MD	dip ABOG		Fishers	IN
Ronald	Young	MD	FACOG, dip ABOG		Tupelo	MS
Jared	Zotz	MD	FACOG		Bloomington	IL

First Pregnancy Abortion or Natural Pregnancy Loss: A Cohort Study of Mental Health Services Utilization

James Studnicki,* Tessa Longbons Cox,* John W. Fisher,* Christina A. Cirucci,* David C. Reardon,** Ingrid Skop,* Christopher Craver,* Maka Tsulukidze,*** Zbigniew Ras****

ABSTRACT: *Introduction:* While both induced abortion and natural pregnancy loss have been associated with subsequent mental health problems, population-based studies directly comparing these two pregnancy outcomes are rare. We sought to compare mental health morbidity after an induced abortion or natural loss.

Methods: Continuously eligible Medicaid beneficiaries age 16 in 1999 were assigned to two cohorts based upon the first pregnancy outcome: abortion (n = 1,331) or natural loss (n = 605). Outcomes were mental health outpatient visits, inpatient hospital admissions and hospital days of stay per patient per year. Average exposure periods before and after the first pregnancy outcome for each cohort were used to adjust the mental health service rates.

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Results: **Prior to the first pregnancy outcome, all three utilization rates were significantly higher for the natural loss cohort compared to the abortion cohort. For the abortion cohort, the per-patient per-year increase from the pre- to post-pregnancy periods was significant for all three rates: 2.04 times for outpatient visits ($p < 0.0001$), 3.04 times for inpatient admissions ($p = 0.0003$), and 3.01 times for hospital days of stay ($p = 0.0112$). None of the pre-to-post rate increases were significant for the natural loss cohort.**

Conclusion: **Higher pre-pregnancy use rates for women who experience a natural pregnancy loss indicate that increased mental health services use following abortion cannot be solely attributed to pre-existing mental illness. Only the abortion cohort, but not the natural loss cohort, experienced significant increases in mental health services use following the first pregnancy outcome.**

Keywords: **abortion, miscarriage, mental health**

Introduction

Intentional pregnancy loss by means of induced abortion has been consistently linked to an increased risk of subsequent mental health morbidity.[1] While literature reviews from a previous decade concluded that there was inadequate evidence that abortion was the direct and sole cause of mental illnesses,[2,3] subsequent studies and more recent reviews have demonstrated that induced abortion is at least a contributing cause to the triggering or worsening of mental health issues, including symptoms of depression, suicide and suicidal ideation, bipolar disorder, anorexia, substance abuse and others.[1,4–12]

Similarly, other studies have revealed a link between natural pregnancy loss (e.g., miscarriage) and mental health morbidity. A recent Portuguese study indicated that a substantial proportion of women showed persistent symptoms of mental health morbidity (grief, anxiety, depression, PTSD) for three or more years after an early pregnancy loss.[13] Similarly, a recent study of US veterans with a history of miscarriage or stillbirth indicated that they were more likely to have a diagnosis of anxiety, depression, PTSD, have experienced sexual trauma (harassment or rape), and received healthcare services during their pregnancy than did women without a history of pregnancy loss.[14]

Investigators combining both induced abortion and natural loss as forms of pregnancy loss have found increasing risks of post-pregnancy mental

health issues with either type of pregnancy loss[12,15,16] but studies directly comparing these two pregnancy outcomes are rare. A Norwegian single hospital study surveyed women 10 days, six months, two years and five years after pregnancy termination by either abortion (n=80) or miscarriage (n=40) using questionnaires to determine perceived quality of life, depression, anxiety and their feelings about terminating the pregnancy.[17] Women with abortions had greater feelings of guilt and shame than women with miscarriages at two and five years after the termination. The 120 participants were 47% of the 255 who were asked to participate. Of the participants, 91% completed the study. The authors noted that limitations in their study were a lack of control for both former psychiatric health status and knowledge of prior and subsequent pregnancy outcomes. Especially problematic are studies based on non-random samples of women solicited at abortion clinics. These non-replicable studies are characterized by extremely low participation rates, high attrition rates, selective reporting and a systematic exclusion of the women at greatest risk of psychological sequelae.[18]

A critical methodological concern in this domain is the determination of the mental health status of the women in the periods prior to their exposure to a pregnancy loss. Previous research has claimed that post-abortion rates of first-time psychiatric contact and first non-fatal suicide attempts are not significantly different than pre-abortion rates.[19,20] These findings are taken to suggest that women who have an abortion may be mentally or emotionally troubled before the abortion, and that problems subsequent to the abortion are not the result of the abortion itself. This dilemma suggests that the pre- and post-pregnancy outcome periods must be long enough to allow for the detection of psychological problems and disorders which may gradually evolve over a reproductive history extending over multiple pregnancy outcomes. In a previous longitudinal cohort study, we followed Medicaid-eligible women who were or turned 16 in 1999 for 17 years, recording each subsequent pregnancy outcome and grouping them into cohorts based on the first pregnancy (live birth, abortion, or miscarriage).[21] Since prior research had indicated that women with repeat abortions are at an increased risk for adverse psychological outcomes and death from all causes, we determined that further post hoc testing of these cohorts would enable us to address the long-term mental health consequences of having an abortion as the terminus of the first pregnancy.[22,23] Further, the characteristics of the dataset and research design would enable the study to utilize objective paid claims events avoiding the problems inherent in survey research; utilize a range of outpatient and inpatient treatment events that provide a comprehensive, composite view of mental health morbidity rather than a narrowly defined single adverse event; provide precise measurement of the duration of the exposure to mental health problems before and af-

ter the first pregnancy outcome; and provide an analysis of the mental health consequences of vastly different reproductive lifetime experiences which are associated with abortion, miscarriage, or birth as the first pregnancy outcome. In a recent analysis comparing the birth cohort with the abortion cohort, we found that having a first-pregnancy abortion was associated with a significantly greater risk of experiencing a mental health treatment event following the first pregnancy outcome.[24] In this present analysis, we take a similar approach to measure differences in mental health treatment utilization between the abortion and natural pregnancy loss cohorts.

Methods

Data were obtained from the Medicaid Analytic eXtract (MAX) files licensed through the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse (CCW), which contain patient-level data for healthcare services provided to Medicaid enrollees. As described in a previous study, the total analytic dataset comprises Medicaid-enrolled women 13 years of age and older with a minimum of one pregnancy from the 17 states that used state funds to cover induced abortions beyond those eligible for coverage by federal Medicaid.[21] To ensure that no pregnancies would be missed due to gaps in reporting, for this specific study, our study population was drawn from the seven states which consistently submitted full Medicaid claims data for the entire 17-year study period (1999-2015): Connecticut, New Jersey, New Mexico, New York, Oregon, Vermont, and West Virginia. Similarly, to ensure that no pregnancies were missed as a result of eligibility gaps, each woman included in the study population was eligible for Medicaid for at least one month in all years of the study period. Cohorts were developed from all women who were or turned 16 years old in 1999 based upon their first pregnancy outcome. In a similarly defined population of women 15 years old in 1999, less than 0.47% had a pregnancy, providing high confidence that women were assigned to study cohorts based on their first pregnancy outcomes. This analysis focused on the two cohorts experiencing either a first-pregnancy abortion or natural loss.

All unique pregnancy outcomes were identified for each Medicaid enrollee using International Classification of Diseases, Ninth Revision (ICD9) and Tenth Revision (ICD10) codes: natural pregnancy loss (a category that includes miscarriage, stillbirth, ectopic pregnancy, and other pregnancies not ending in induced abortion or live birth) (ICD9 V27.1, V27.4, V27.7, 630, 631, 633, 634 and ICD10 O00, O01, O02, O03) and induced abortion (ICD9 635.xx, ICD10 O04, CPT4: 59840, 59841, 59850, 59851, 59852, 59855, 59856, 59857, and HCPCS: S0199, S2260, S2265, S2266, S2267, X7724, X7726, S0190, S0191). Multiple diagnostic or treatment codes occurring within 30 days of an induced abortion or natural loss were collapsed into a single outcome using the first date associated with that series of Medicaid claims. When twins or higher-order pregnancies

resulted in a combination of live birth and natural pregnancy loss, they were excluded from the analysis. Current Procedural Terminology, Fourth Edition (CPT4) and Healthcare Common Procedure Coding System (HCPCS) codes were also used to confirm pregnancy outcomes.

We used a comprehensive list of 3-digit ICD9 (ICD9 290-319) and ICD10 (ICD10 F01-F48, F50-F98) codes to identify outpatient visits and inpatient hospitalizations resulting from a range of mental, behavioral, psychiatric or psychological problems, diseases, and disorders.

The analytic strategy was composed of five phases:

1) Each eligible enrollee was assigned to one of two cohorts based upon her first pregnancy outcome: abortion or natural loss.
2) Using each woman's age at her first pregnancy outcome, we determined the average length of the periods of exposure both before (pre) and after (post) the first outcome for each cohort.
3) We identified all mental health-related events that occurred before and after the first pregnancy outcome for both cohorts. The outcome variables are three event categories: a) outpatient visits; b) inpatient hospital admissions; and c) inpatient hospital days of stay.
4) Cohort-specific rates (per patient, per year) were calculated for each of the three outcome variables.
5) All cohort rate information was calculated using individual, event level utilization indicator counts for each woman in each of the pre and post time periods. For comparisons of the abortion and natural loss cohorts within each time period for each utilization indicator rate, we used a two-sample t-test for independent samples. For comparisons within each of the cohorts of the mean difference between the pre and post period rates we used a paired sample t-test for dependent analyses.

Summary analytic tables were created using (SAS/STAT) software, version (10) of the SAS system for (Unix), copyright (2019) SAS Institute, Inc. The study has been exempted from Institutional Review Board (IRB) review pursuant to the U.S. Department of Health and Human Services Policy for Protection of Human Research Subjects at C.F.R. 46.101(b). See IRB ID: 7269, www.sterlingirb.com.

Results

As shown in Table 1, 475 (35.7%) of the women in the abortion cohort experienced 14,066 outpatient mental health visits, and 42 (3.1%) experienced 77 mental health inpatient admissions and 707 days of hospital stay in the period before the first pregnancy outcome (which was 77.10 months or 6.43 years in duration on average). In the period after the first pregnancy outcome, which was 126.90 months or 10.57 years on average, 785 (59.0%) abortion cohort women experienced 46,103 outpatient visits and 105 (7.9%) experienced 334 inpatient admissions and 3,425 days of hospital stay.

Of 605 women in the natural loss cohort, 303 (50.1%) experienced 14,221 outpatient mental health visits and 39 (6.4%) experienced 142 inpatient admissions and 1,475 days of hospital stay in the 86.08 months or 7.17 years average exposure before the first pregnancy outcome. In the period following the first pregnancy outcome, with an average exposure duration of 117.92 months or 9.83 years, 399 (65.9%) women from the natural loss cohort experienced 19,775 mental health outpatient visits and 48 (7.9%) experienced 107 hospital inpatient admissions and 869 days of hospital stay.

In the period before the first pregnancy outcome, all three of the mental health services utilization rates were statistically significantly higher for the natural loss cohort than for the abortion cohort. The natural loss cohort mean outpatient visit/patient/year rate was 3.1693; the mean abortion cohort rate was 1.5934; $t = 4.55$, $p < 0.0001$. Inpatient admissions/patient/year rates were: natural loss M = 0.0216; abortion M = 0.0076; $t = 3.57$, $p = 0.0004$. Inpatient days of hospital stay/patient/year were: natural loss M = 0.2002; abortion M = 0.0724; $t = 2.68$, $p = 0.0074$. The natural loss cohort rate difference is 1.99 times the abortion cohort for outpatient visits, 2.84 times for inpatient admissions and 2.76 times for days of stay.

In the period after the first pregnancy outcome, the natural loss and abortion cohorts have nearly identical rates for all three mental health utilization indicators. The natural loss cohort rate outpatient visits/patient/year is still slightly higher than the abortion cohort (natural loss M = 3.5942, abortion M = 3.2559) and the inpatient admissions rate (natural loss M = 0.0227, abortion M = 0.0231) and hospital days rate (natural loss M = 0.2079, abortion M = 0.2176) are now marginally lower for the natural loss cohort. However, none of the post-pregnancy between group outcome rate differences are significantly different (Table 2).

The differences in mental health utilization before and after the first pregnancy outcome were all statistically significant for the abortion cohort. For the rate of outpatient visits/patient/year, the abortion cohort mean difference (MD), or the post-period mean minus the pre-period mean, is 1.6624, $t = 5.16$, $p < .0001$, and represents a doubling of the rate (2.04 times). The inpatient hospital admissions/patient/year rate MD is 0.0154, $t = 3.16$, $p = 0.0003$, and represents a 3.04 times pre to post increase. The inpatient hospital days/patient/year rate MD is 0.1452, $t = 2.54$, $p = 0.0112$, and represents a 3.01 times pre to post increase. For the natural loss cohort, none of the pre to post rate increases are significant. The post rate represents 1.13 times the pre rate for outpatient visits; and 1.05 and 1.04 times the pre rates for inpatient admissions and days of stay, respectively, per patient per year (Table 3, Figures 1, 2, 3).

Table 1. Data Summary, by Cohort, Pre and Post First Pregnancy Outcome

	Abortion (n=1331)		Natural Loss (n=605)	
Variable	**Pre**	**Post**	**Pre**	**Post**
Outpatients	475	785	303	399
Inpatients	42	105	39	48
Months/years exposure	77.10/6.43	126.90/10.57	86.08/7.17	117.92/9.83
Age first outcome				
No pre use	21.4 yrs		21.8	
Pre use	23.1 yrs		23.7	
Outpatient visits	14066	46103	14221	19755
Inpatient admissions	77	334	142	107
Inpatient days	707	3425	1475	869
OP visit rates*	1.5934	3.2559	3.1693	3.5942
IP admission rates	0.0076	0.0231	0.0216	0.0227
IP days rates	0.0724	0.2176	0.2002	0.2079

*event per patient per year

Discussion

Although there is an extensive literature which independently links both natural losses and induced abortion to an elevated risk of mental health disorders, very little attention has been given to directly comparing the mental health consequences of natural losses and induced abortions. The present study reveals that rates of subsequent utilization of mental health services significantly increase after a first pregnancy ending in abortion compared to a first pregnancy ending in a natural loss. In the periods before and after the first pregnancy outcome, women with first pregnancy abortions doubled their rate of mental health outpatient visits and tripled their rate of inpatient hospital psychiatric admissions and days of hospital stay. By contrast, women with first pregnancy natural losses had no statistically significant increase in either outpatient or inpatient mental health services utilization from the pre to the post periods.

Table 2. Between Cohorts Independent Sample T-Tests

	OP Visit Rate Pre					
	N	**Mean**	**Std**	**SE**	**T value**	**Pr>(t)**
Abortion	1331	1.5934	6.0354	0.0570	4.55	<.0001
Natural Loss	605	3.1693	8.9027	0.0350		
			OP Visit Rate Post			
Abortion	1331	3.2559	11.5400	0.3164	0.62	0.5342 (NS)
Natural Loss	605	3.5942	10.0590	0.4090		
			IP Admission Rate Pre			
Abortion	1331	0.0076	0.0580	0.0016	3.57	0.0004
Natural Loss	605	0.0216	0.1135	0.0046		
			IP Admission Rate Post			
Abortion	1331	0.0231	0.1603	0.0044	0.1545	0.962 (NS)
Natural Loss	605	0.0227	0.1185	0.0048		
			IP Days Rate Pre			
Abortion	1331	0.0724	0.6703	0.0184	2.68	0.0074
Natural Loss	605	0.2002	1.4267	0.0800		
			IP Days Rate Post			
Abortion	1331	0.2176	2.0641	0.0266	0.1	0.919 (NS)
Natural Loss	605	0.2079	1.6336	0.0664		

Abortion is associated with complicated grief, substance use disorders, affective disorders, eating disorders and self-destructive behaviors.[1,9,10,25,26] While both natural losses and unwanted abortions may trigger a grief process, social and interpersonal issues may make it more difficult to complete the grief process after an unwanted abortion.[1,27,28] Any resulting complicated, disenfranchised, or impacted grief may contribute to affective and behavioral disorders, especially when there are pre-existing issues.[1,28] There is substantial evidence that the negative psychological effects associated with abortion are greatest among those women who feel pressured to have abortions contrary to their own personal values and preferences.[8,29-31] The fact that a first abortion

Table 3. Within Cohorts, Pre to Post, Paired (Dependent) Samples T-Tests

	Mean difference	Std	SE	T value	Pr>(t)
Abortion (n=1331)					
OP Visits	1.6624	11.76	0.3225	5.16	<0.0001
IP Admissions	0.0154	0.1557	0.0043	3.16	0.0003
IP Days	0.1452	2.0847	0.0571	2.54	0.0112
Natural Loss (n=605)					
OP Visits	0.4249	10.7017	0.4351	0.98	0.3291 (NS)
IP Admissions	0.0011	0.1065	0.0043	0.26	0.7925 (NS)
IP Days	0.0077	1.1571	0.0470	0.16	0.8693 (NS)

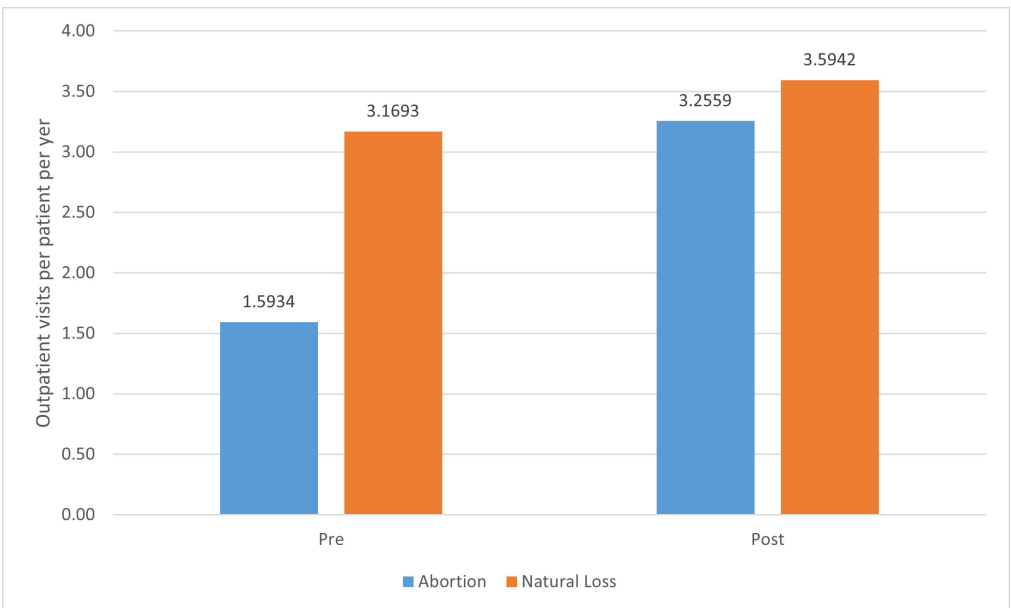

Figure 1. Outpatient visits per patient per year—event level means

increases the risk of multiple abortions,[32,33] each of which may increase the risk of mental health issues, may be greater than the similar risks associated with multiple natural losses. This elevated risk of multiple abortions when a first pregnancy ends in abortion,[33] may predispose women to a cascade of mental health problems.

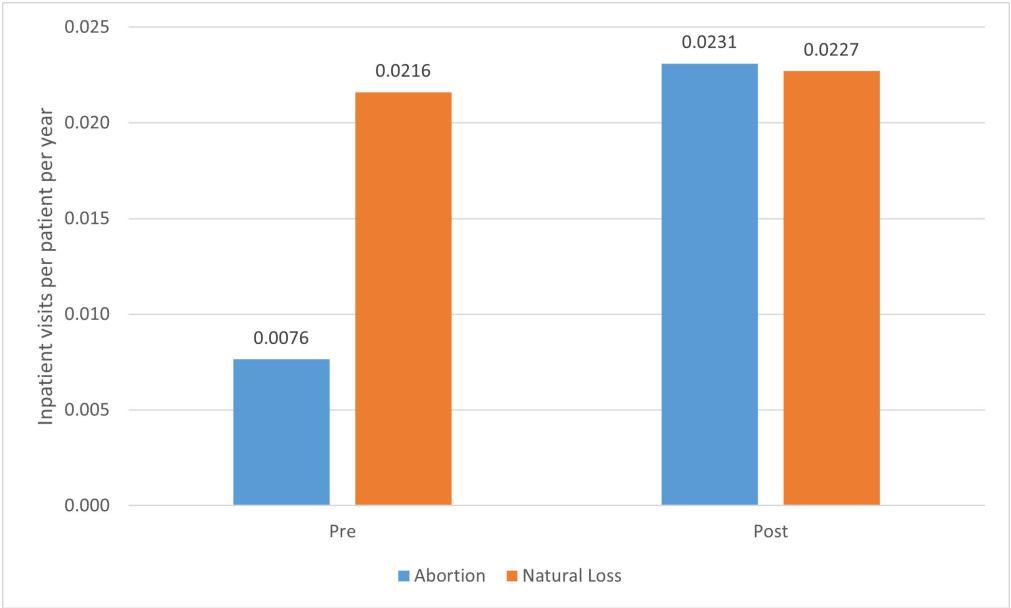

Figure 2. Inpatient visits per patient per year—event level mean

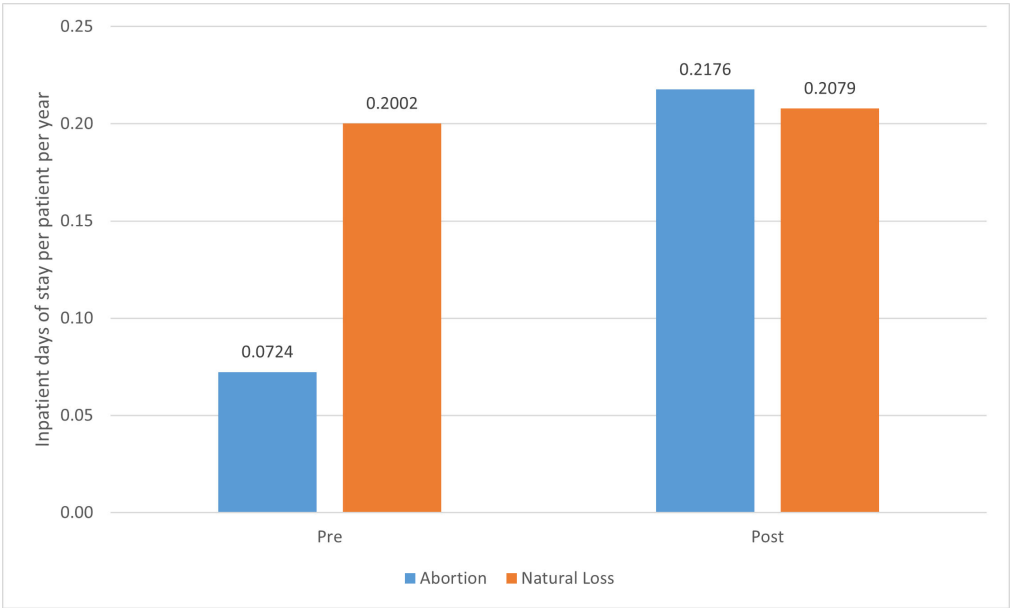

Figure 3. Inpatient days of stay per patient per year—event level means

Contributing to this relatively flat rate of pre- to post-first pregnancy mental health utilization for women with first pregnancy natural losses is their significantly higher pre-pregnancy mental health morbidity compared to women with first pregnancy abortions. Prior to the first pregnancy, women who will have natural pregnancy losses had twice the outpatient use and two and one-half times the inpatient admissions and days of stay than women who subsequently had first pregnancy abortions. While there is some overlap in treatment protocols for complications of induced abortion and spontaneous miscarriage, our findings underscore the disparate impact of these two pregnancy outcomes on patients' mental health both before and after the first pregnancy outcome. Healthcare providers should be aware of the diverse needs of Medicaid recipients experiencing abortion versus natural pregnancy loss and be prepared to offer appropriate mental healthcare. Patients presenting with symptoms of pregnancy loss should be screened for the type of loss.

Advanced maternal age and chromosomal abnormalities (aneuploidy) have been long associated with an increased risk of miscarriage.[34,35] Most of the available research, however, has looked at the question of whether a miscarriage is a causal factor predisposing a woman to some psychiatric disorder in the post-pregnancy period. Recent research assessed whether psychiatric disorders in the prior period were associated with an increased risk of miscarriage.[36] Using all the registered pregnancies in Norway between 2010-2016, the researchers determined that a wide range of psychiatric disorders in the pre-pregnancy period were associated with an increased risk of miscarriage: bipolar disorders, personality disorders, anxiety, depression, somatoform disorders and eating disorders. The findings of our research are consistent with these results. Our findings are also consistent with analyses from the National Longitudinal Study of Adolescent to Adult Health which revealed that induced abortion is an independent risk factor for mental health disorders even after controlling for over 20 confounding variables, including prior mental health.[8,9]

Our study has limitations. The study population is composed of Medicaid-eligible women and, as a result, these findings are not generalizable to a population of different sociodemographic composition. Services received outside the Medicaid program, regardless of Medicaid eligibility, will not appear in this data. While the use of a comprehensive aggregated index of mental health problems across a 17-year observation period is a strength of our study design, it does not allow conclusions regarding a first pregnancy natural loss or abortion and any specific mental health illness, disorder, or problem. Similarly, the cohort as the unit of analysis may mask any number of associations that could be specific to some subpopulation of the cohort; e.g., post-pregnancy outcome utilization for women with and without histories of specific mental illness. Our study focused on the quantity of mental health events but did not

evaluate the severity of events nor the specific diagnoses. These could be areas of future research. Our study utilized three coding systems applied to the Medicaid claims paid: the International Classification of Diseases (ICD) ninth and tenth revisions; the Current Procedural Terminology, Fourth Edition (CPT4); the Healthcare Common Procedure Coding System (HCPCS). There are limitations with the use of coding systems applied to research rather than administrative purposes: diagnoses not relevant to payment tend to be underreported; there is often variability in coding practices across hospitals and geographic regions; coding may be inaccurate due to upcoding, reflecting the "code creep" resulting from approaches to maximize payment; and the simple inability of any coding system to capture the clinical detail that may be available in the notes of the total medical record.[37]

Conclusion

Our study has important clinical significance. In the period following the outcome of a first pregnancy, abortion is associated with significantly greater increases in utilization rates for both outpatient and inpatient mental health services than is a natural pregnancy loss. The relatively low rates of mental health services utilization prior to a first-pregnancy abortion indicate that this increase cannot be solely attributed to pre-existing mental illness. Health care providers should be aware of and attentive to the increase in mental health utilization that may occur after induced abortion. Clinicians typically understand that a woman who has undergone a miscarriage will experience grief and a sense of loss, but may easily overlook the issues that women face following abortion. Women with first pregnancy abortions, on average, have more than three times as many subsequent abortions during the reproductive period than women with first pregnancy natural losses.[21] Therefore, the influence of multiple or repeat abortions contributes to this difference and also supports the conclusion that induced abortion is an independent risk factor for mental health disorders. Increased attentiveness to this risk by health care providers may enable patients to have earlier access to mental health services and increased access to available resources. High levels of mental health morbidity prior to the first pregnancy outcome for women who subsequently miscarry suggests that mental health problems may be a risk factor for unwanted pregnancy loss.

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Institutional Review Board: The study has been exempted from Institutional Review Board (IRB) review pursuant to the U.S. Department of Health and Human Services Policy for Protection of Human Research Subjects at C.F.R. 46.101(b). See IRB ID: 7269, www.sterlingirb.com.

Data Availability: Restrictions apply to the availability of these data. Data was obtained from Centers for Medicare and Medicaid Services subject to a signed data use agreement (DUA). Due to the data use policy of the Centers for Medicaid and Medicare Services, supporting data is not available from the authors.

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Challenging Vavřička: Questioning Compatibility of the Mandatory Tetanus Vaccination with ECHR

Meliha Sermin Paksoy* and Zeynep Taner**

ABSTRACT: The compatibility of mandatory vaccinations with human rights has become a very current issue with the COVID-19 pandemic and the Vavřička ruling by the European Court of Human Rights. This ruling has faced criticism for not conducting examinations related to disease and vaccines based on direct scientific evidence. In this analysis, an assessment will be made based on direct scientific evidence about tetanus and its vaccine.

The prevailing reason for mandatory tetanus vaccination is to protect the health of the vaccinated individual. Competent adults have the right to refuse treatment. This rule also applies to preventive medical interventions, including tetanus vaccination. As a rule, parents are entitled to give consent for medical interventions on their children. If an immediate and serious threat permanently endangers the minor's life, medical intervention can be carried out against the parents' will. The limitation of parental autonomy is more disputed when the minor's life is not immediately threatened. With respect to tetanus vaccination as a preventive medical in-

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tervention, it does not eliminate an immediate and serious risk of harm. As a result, interference with the parent's discretion on tetanus vaccination as a preventive medical intervention should be evaluated for its compatibility with the current legal approach to medical interventions on minors and patient rights.

***Keywords*: best interest, mandatory vaccination, preventive medical intervention, right to reject a medical intervention, vaccine refusal, tetanus**

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I. Introduction

Mandatory vaccinations have long been a topic of debate in relation to the fundamental rights and freedoms enshrined in countries' constitutions and the European Convention on Human Rights (ECHR).[1] This debate has been reignited by the COVID-19 pandemic and the European Court of Human Rights (the Court) Vavřička and Others v. The Czech Republic decision (App. No 47621/13 and five others). In this 2021 decision, the Court questioned the compatibility of the Czech Republic's mandatory vaccination legislation regarding nine childhood diseases comprising diphtheria, tetanus, whooping cough (pertussis), Haemophilus influenzae type b infections, poliomyelitis, hepatitis B, measles, mumps, rubella with the European Convention on Human Rights.

[1] *Boffa v Others v San Marino* Application No 26536/95, Admissibility, 15 January 1998; *Solomakhin v Ukraine* Application No 24429/03, Admissibility, 15 March 2012; *Jacobson v Massachusetts* (1905) 197 US 11; *Zucht v King*, (1920) 225 SW 267; Flanigan, 'A Defense of Compulsory Vaccination', (2014) 26(1) HEC Forum 5; Chemerinsky and Goodwin, 'Compulsory Vaccination Laws Are Constitutional', (2016) 110(3) Northwestern University Law Review 589; Zoltan, 'Jacobson Revisited: Mandatory Polio Vaccination as an Unconstitutional Condition', (2005) 13(3) George Mason Law Review 735.

The Court noted that mandatory vaccination laws aimed at preventing potential outbreaks and protecting the best interest of children and individuals who cannot get vaccinated.[2] The Court considered the Czech Republic's requirement for children to be vaccinated against diphtheria, tetanus, whooping cough (pertussis), Haemophilus influenzae type b infections, poliomyelitis, hepatitis B, measles, mumps, rubella to attend nursery schools, and the imposition of fines up to nearly 400 EUR on parents who refused to vaccinate their children, to be a necessary and proportionate intervention in a democratic society. It was also pointed out in the decision that Czech authorities did not exceed their margin of appreciation.[3]

The Court did not conduct a disease and vaccine-specific examination, instead assessing all nine diseases and vaccines targeting them collectively, whereas for example, applicant Mr. Vavřička refused consent for his children to receive only the poliomyelitis, hepatitis B, and tetanus vaccines. Mr. Vavřička contended that the regulations in question violated his inherent rights and freedoms, specifically his right to reject medical interventions (as outlined in Articles 5 and 6 of the Convention on Human Rights and Biomedicine). He objected to what he characterized as reckless experimentation with human well-being, underscored the actual and potential adverse effects of vaccines, and asserted that there was no threat to public health in his case, pointing out that the last instance of poliomyelitis dated back to 1960, hepatitis B primarily affected high-risk groups, and tetanus was not communicable among humans.[4]Diphtheria, tetanus, whooping cough (pertussis), Haemophilus influenzae type b infections, poliomyelitis, hepatitis B, measles, mumps, rubella and their vaccines have different characteristics that could affect the assessment. Indeed, the dissenting opinion by Judge Wojtyczek also indicated that a separate assessment should be made for each disease.[5]

Tetanus differs from the other diseases considered in the decision as it is not transmitted from person to person and has no potential to cause outbreaks, requiring a separate evaluation. The Court justifies mandatory vaccination on

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[2] *Vavřička and Others v The Czech Republic* Application No 47621/13, Admissibility, 8 April 2021.

[3] ibid 285, 290.

[4] *Vavřička*, supra n 2 at 24.

[5] ibid 9-10, Judge Wojtyczek; Some other articles have also criticized the decision on the same grounds. See Ważyńska-Finck, 'Anti-Vaxxers Before The Strasbourg Court: Vavřička And Others v The Czech Republic', *Strasbourg Observers*, 2 June 2021, available at: strasbourgobservers.com/2021/06/02/anti-vaxxers-before-the-strasbourg-court-vavricka-and-others-v-the-czech-republic/ [last accessed 26 October 2023]; Savulescu, Giubilini and Danchin, 'Global Ethical Considerations Regarding Mandatory Vaccination in Children', (2021) 231 The Journal of Pediatrics, available at: www.jpeds.com/article/S0022-3476(21)00028-7/fulltext [last accessed 26 October 2023].

the grounds of social solidarity and best interest of the child.[6] In the case of tetanus, social solidarity justification is mostly invalid.[7] Also in the literature, most arguments for compulsory vaccination are based on the need to protect society from infectious diseases.[8] Therefore, compatibility of mandatory tetanus vaccination with the ECHR deserves closer scrutiny.

One criticism of the Vavřička decision is that there was no direct reference to scientific evidence for each disease and vaccine.[9] Referring to the prominent health authorities, the Court accepted that childhood vaccinations in general are one of the most important cost-effective public health measures.[10] The incidence and risks of each disease, content of the relevant vaccines, incidence of complications, and side effects for each rejected vaccine haven't been questioned or explained.

In this study, the authors question the validity of the European Court of Human Rights' decision regarding the mandatory tetanus vaccine by making an analysis based on scientific data. Part II provides scientific information on tetanus disease and its vaccination. Part III analyzes the right to refuse preventive medical intervention and its relationship to vaccination refusal in competent adults. The right of mature minors to refuse medical intervention and tetanus vaccination is discussed in Part IV. Part V evaluates the limits of parental rejection of medical interventions in minors. In the same part, the question is asked whether compulsory tetanus vaccination for minors is compatible with the European Convention on Human Rights.

The issue of the mandatory vaccines' compliance with the European Convention on Human Rights is comprehensive and intricate. It is possible to evaluate this matter from various perspectives. In this article, however, the authors focus on the question of whether an interference with the individual's right to reject tetanus vaccination and the parents' right not to consent to the tetanus vaccination are compatible with ECHR. From this analysis, it is possible to draw conclusions regarding vaccines for other non-communicable diseases. However, the incidence, risks, treatment options, and costs associated with

[6] Ibid 288, 306; Nugraha, Regules and Vrancken, 'Vavřička and Others v The Czech Republic', (2022) 116(3) American Journal of International Law 579; Nilsson, 'Is Compulsory Childhood Vaccination Compatible with the Right to Respect for Private Life? A Comment on Vavřičkaa and Others v the Czech Republic', (2021) 28 European Journal of Health Law 323. 330.

[7] Nilsson, supra n 6 at 334; Archard, Brierley and Cave, 'Compulsory Childhood Vaccination: Human Rights, Solidarity, and Best Interests', (2021) 29(4) Medical Law Review 716. , available at: academic.oup.com/medlaw/article/29/4/716/6324237 [last accessed 26 October 2023].

[8] Giubilini, 'An Argument for Compulsory Vaccination: The Taxation Analogy', (2020) 37(3) Journal of Applied Philosophy, available at: doi.org/10.1111/japp.12400 [last accessed 26 October 2023].

[9] *Vavřička*, supra n 2 at 9, Judge Wojtyczek; Archard, Brierley and Cave, supra n 7 at 721.

[10] *Vavřička*, supra n 2 at 277.

each non-communicable disease may lead to a different analysis. The authors believe that when assessing the constitutionality of vaccines, each disease and vaccine necessitate a separate analysis.

II. Information on Tetanus

A. Brief Facts on Tetanus

The bacteria *Clostridium tetani* produces a toxin that causes tetanus. The disease is marked by muscle spasms and dysfunctions of the autonomic nervous system.[11] Muscle spasms can last for minutes to weeks and begin in the face before spreading to the rest of the body. After infection, weakness begins with a feeling of numbness at the wound site.[12] Initial findings may be trismus and locking in the jaw. Then, because of the involvement of all facial muscles, the sarcastic smile "risus sardonicus" appears. Other early signs are sweating and irritability (even small external stimuli can initiate contractions). The contractions are in the form of flexion of the arms and extension of the legs. As a result of constant muscle spasms in the back muscles, the "opustotonus" position occurs. Contractions are very painful. The most common cause of death is asphyxia (suffocation), which is caused by the involvement and contraction of the respiratory muscles. Despite this severe clinical picture, the patient is fully conscious.[13]

Clostridium tetani spores are ubiquitous in the environment, especially in soil, cinder, human or animal feces, skin surfaces and rusting objects such as nails, injectors, fence, etc. Due to their extreme capacitance to heat and most detergents, spores can endure for long years.[14] Most tetanus cases result from dirty puncture wounds or contaminated burns, but poor natal hygiene especially involving the umbilical cord can result in neonatal tetanus.Tetanus is not contagious. It does not cause epidemics; it causes deaths one by one.[15] If

[11] Yen and Thwaites, 'Tetanus', (2019) 393(10181) Lancet 1657, available at: www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)33131-3/fulltext#%20 [last accessed 26 October 2023].

[12] Bae and Bourget, 'Tetanus', (2019) StatPearls Publishing, available at: www.ncbi.nlm.nih.gov/books/NBK459217/ [last accessed 26 October 2023].

[13] World Health Organization, '*Tetanus*', (2023), available at: www.who.int/health-topics/tetanus#tab=tab_1 [last accessed 26 October 2023]; Rhinesmith and Fu, 'Tetanus Disease, Treatment, Management', (2018) 39(8) Pediatrics in Review 430, available at: doi.org/10.1542/pir.2017-0238 [last accessed 26 October 2023].

[14] Dhir, Dewan and Gupta, 'Maternal and Neonatal Tetanus Elimination: Where are We Now?', (2021) 12 Research and Reports in Tropical Medicine 247, available at: doi.org/10.2147/RRTM.S201989 [last accessed 26 October 2023].

[15] Centers for Disease Control and Prevention, '*Tetanus- Causes and How It Spreads*', (2022), available at: www.cdc.gov/tetanus/about/causes-transmission.html [last accessed 26 October 2023]; Koc, 'Neonatal Tetanoz',(2000)STED, available at: www.ttb.org.tr/sted/sted0400/04004.html#:~:text=NT'den%20her%20y%C4%B1l%20yakla%C5%9F%C4%B1k,50%20ile%2090%20aras%C4%B1nda%20de%C4%9Fi%C5%9Fmektedir [last accessed 26 October 2023].

tetanus vaccine is not administered, tetanus disease, which occurs because of especially dirty injuries, can result in death. In disseminated tetanus disease, 10-30% of patients may die despite the intensive care treatments applied.[17]

B. Risk Groups and Risk Factors

The disease can affect anyone, but newborn infants and pregnant individuals who have not been adequately vaccinated with tetanus-toxoid-containing immunization are particularly susceptible.[16]

Adolescents and adult males undergoing circumcision are at increased risk of tetanus in many countries due to declining immunity and limited access to supplemental doses.[17] Injecting drug addicts are also classified in high-risk group.[18]

Conflicts and natural disasters can raise the prevalence of tetanus even in countries with an effective public health system by uprooting populations, disrupting vaccination campaigns, and increasing injuries that are prone to the disease. For example,106 cases of tetanus, among adults, were reported in the month following the 2004 tsunami in Indonesia.[19]

In 2016, more than 40 million people were forced to flee their homes due to armed conflicts, which created new difficulties for many international immunization campaigns, including the tetanus vaccination.[20]

C. Incidence

Before vaccination programs, the incidence of deaths caused by tetanus in USA was between 2.5/ 100.000 and 0.5/100.000.[21] Annually 500-600 cases were reported nationwide in USA before the start of the vaccination program in 1940.[22] It is reported that 140 people died of tetanus in 1951, one year before the

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[16] Due to the limitations on surveillance system in low-income and middle-income countries, it is challenging to determine the full burden of tetanus, Yen, supra n 11; In 2015, approximately 34.000 newborns perished of neonatal tetanus, a 96% decrease from 1988, when an estimated 787 000 newborns died of tetanus during their first month of life, Dhir, supra n 16 at 247; World Health Organization, supra n 15.

[17] World Health Organization, supra n 15.

[18] Cherubin, 'Epidemiology of Tetanus in Narcotic Addicts', (1970) 70 NY State Journal of Medicine 267.

[19] Jeremijenko, McLaws and Kosasih, 'A Tsunami Related Tetanus Epidemic in Aceh, Indonesia', (2007) 19(1) Asia Pacific Journal of Public Health 40.

[20] UNHCR, *'Global trends: forced displacement in 2016'*, (2017), available at: www.unhcr.org/5943e8a34.pdf [last accessed 26 October 2023].

[21] Blain and Tiwari, *'Chapter 16: Tetanus'*, (CDC, 2020) , available at: www.cdc.gov/vaccines/pubs/surv-manual/chpt16-tetanus.html and, available at: www.cdc.gov/vaccines/pubs/surv-manual/images/chapt16-figure01.gif [last accessed 26 October 2023].

[22] World Health Organization, *'Global Health Observatory Data Repository'* (2023), available at: apps.who.int/gho/data/view.main.1540_46?lang=en [last accessed 26 October 2023].

start of vaccination in the Czech Republic.[23] In relation to the population of the Czech Republic at that time, this corresponds to an incidence of 1.5/100,000.[24] This data suggests that deaths related to tetanus were infrequent even prior to the introduction of vaccination programs.[25]

The incidence of this disease was reduced because of vaccination. WHO reported that, in 2018, 25000 newborns died from neonatal tetanus, an 88% decrease from the condition in 2000.[26] Since 1947, the number of reported tetanus cases has decreased by over 95%, and the number of tetanus-related deaths has decreased by over 99% in the US. These decreases were partially brought about by the introduction of tetanus immunization in the 1940s as well as use of antitoxin in the treatment of high-risk wounds.. Adults who have not had all the advised tetanus immunizations sometime get tetanus today.. This includes individuals who have never had a tetanus shot and adults who have not had their 10-year booster shot.[27]

In a study conducted in 2020 on global diseases, it was estimated that more than 73,000 cases of tetanus occurred in 2019. Out of the 34,700 fatalities from tetanus that year, the majority were concentrated in South Asia and Sub-Saharan Africa.[28] Occasional cases of tetanus are reported in high-income countries, most frequently among older persons (60 years) and drug injectors.[29] The estimated global death toll from tetanus has significantly decreased over the last three decades. It is estimated that tetanus killed hundreds of

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[23] EUC, *'Tetanus – People Forget about Prevention of the Disease'*, (2020), available at: euc.cz/clanky-a-novinky/clanky/tetanus-people-forget-about-prevention-of-the-disease/ [last accessed 26 October 2023].

[24] Population Pyramid, *'Population Pyramids of the World from 1950 to 2100'*, (2022), available at: www.populationpyramid.net/czech-republic/1951/ [last accessed 26 October 2023].

[25] Leading causes of death in Czech Republic, in year 2000, were ischaemic heart disease (328/100.000), stroke (166/100.000), trachea, bronchus and lung cancer (56/100.000), colon and rectum cancers (44/100.000), chronic obstructive pulmonary disease (27/100.000), lower respiratory infections (26/100.000), breast cancer (20/100.000), falls (19/100.000), cirrhosis of the liver (17/100.000), self-harm (16/100.000), available at: https://www.who.int/data/gho/data/themes/mortality-and-global-health-estimates/ghe-leading-causes-of-death[last accessed 10 May 2024].

[26] Shimizu, *'Tetanus'*, (2017), available at: www.who.int/health-topics/tetanus#tab=tab_1 [last accessed 26 October 2023].

[27] Centers for Disease Control and Prevention, *'Tetanus- Surveillance'*, (2023), available at: www.cdc.gov/tetanus/surveillance.html [last accessed 26 October 2023].

[28] CDC Global Tetanus Vaccination, https://www.cdc.gov/global-tetanus-vaccination/why/index.html#:~:text=A%202020%20study%20of%20global,are%20increasing%20among%20adult%20men [last accessed 21 May 2024].

[29] Beeching and Crowcroft, 'Tetanus in Injecting Drug Users', (2005) 330(7485) BMJ 208; Filia et al., 'Tetanus in Italy 2001–2010: A Continuing Threat in Older Adults', (2014) 32 Vaccine 639.

thousands of people annually in the 1990s. By the 2010s, however, that number has dropped to about 50,000 deaths per year.[30]

D. Treatment

Tetanus management can be done by preventing toxin absorption, controlling muscle spasms, and providing intensive care. Wounds must be thoroughly cleaned and debrided. The only available treatments for tetanus specifically are antibiotics and antitoxin.[31]

Tetanus is treated according to the severity of the disease. The treatment objectives for all patients should include, prompt wound excision, supportive treatment, antibiotic treatment, early administration of human tetanus immunoglobulin (HTIG) intramuscularly or intravenously, neuromuscular blockade, regulating various manifestations and dealing with complications.[32] In accordance with the tetanus , the patient must be vaccinated for immunization.[30]

Sedation and mechanical ventilation are frequently used during intensive care unit (ICU) hospitalizations for patients with severe tetanus, which increases the risk of mortality and long-term sequelae.[33] Complications that may develop due to tetanus are uncontrolled and involuntary spasm in the vocal cords (vocal cords), bone fractures, hospital infections, pulmonary embolism, aspiration pneumonia due to foreign materials in the respiratory tract, and respiratory distress that is likely to result in death.[34]

E. Immunization as a Preventive Measure

The infected individual does not become immune. The only way to be immunized is to get vaccinated.[35] A dose of tetanus toxoid (TT) vaccine provides minimal if any, long-term immunity. In approximately 90% of individuals, a second dose confers protection within 2-4 weeks, but immunity is transient in many cases. The protective levels of immunity are induced generally by a primary series of three doses and immunity typically persists for at least five years. After the third primary dose, each additional booster dose given after at least a one-year interval increases tetanus antitoxin levels and further pro-

[30] Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2019 (GBD 2019) Results. Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2021.

[31] Yen, supra n 13; In cases that are not hospitalized, the mortality is 100%. On which see TC Saglik Bakanligi Asi Portali, '*Tetanos Hastaligi*', available at: asi.saglik.gov.tr/liste/48-tetanoz-hastal%C4%B1%C4%9F%C4%B1.html [last accessed 26 October 2023].

[32] Bae, supra n 12.

[33] ibid.

[34] ibid.

[35] Rhinesmith, supra n 13.

longs the duration of immunity. Immunity may persist for approximately ten years after the fourth dose and for at least twenty years after the fifth dose.[36]

According to the WHO, children should receive the initial series of tetanus vaccinations. Due to the need for protection against multiple diseases, multi-antigen immunization formulations are usually used.[37] Before turning 7 years old, children must complete the 5-dose DTaP (diphtheria, tetanus, acellular pertussis) immunization series.[38] After the 4- to 7-year-old booster-obtained immunity, Tdap (tetanus, diphtheria, and pertussis) boosters are recommended every ten years (same as DTaP, but with decreased dosages of antigens). A Tdap booster administered ten years after the initial series of vaccines is generally well-tolerated and highly effective.[39] As contrast WHO does not find the adult booster doses for tetanus necessary for individuals who have completed their childhood vaccination series.[40]

F. Vaccine Content

Many people refrain from getting vaccinated or having their children vaccinated due to doubts and concerns about the content of the vaccine. Therefore, information about the content of the tetanus vaccine will be provided in this section. The content of the vaccine may change depending on the manufacturer and combination with other vaccines. The most commonly used tetanus (T) vaccines for children, which is a pentavalent vaccine contain antigens against four other diseases, usually diphtheria (D or d depending on dose), pertussis (P or aP or ap), polio (IPV), and hepatitits B (HepB) or *Haemophilus influenza* type B (Hib). [41] There are now seven different types of pediatric DTaP vaccinations licensed and in use around the world.[42] Tetanus vaccine can be administered

[36] World Health Organization, Immunological Basis for Immunization Series Module 3: Tetanus Update 2018, (2018), available at: apps.who.int/iris/bitstream/handle/10665/275340/9789241513616-eng.pdf?sequence=1&isAllowed=y [last accessed 26 October 2023].

[37] Acres, 'Statement on Tetanus Toxoid', (1987) 137(8) Canadian Medical Association Journal 734.

[38] Liang et al., 'Prevention of Pertussis, Tetanus, and Diphtheria with Vaccines in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP)', (2018) 67(2) MMWR Recommendations and Reports Journal 1.

[39] Halperin, 'Randomized Controlled Trial of the Safety and Immunogenicity of Revaccination With Tetanus-Diphtheria-Acellular Pertussis Vaccine (Tdap) in Adults 10 Years After a Previous Dose', (2019) 8(2) Journal of the Pediatric Infectious Diseases Society 105; Rabadi and Brady, *Tetanus Toxoid* (2022), available at: www.ncbi.nlm.nih.gov/books/NBK557415/ [last accessed 26 October 2023].

[40] Slifka et al., 'Incidence of Tetanus and Diphtheria in Relation to Adult Vaccination Schedules', (2021) 72(2) Clinical Infectious Diseases 285, available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC7840100/ [last accessed 26 October 2023].

[41] [38] WHO, supra n 44.

[42] In 2013, UNICEF, which provides immunizations to a significant part of the world's children, purchased 100% of the DTP-containing vaccines as pentavalent vaccines. See UNICEF,

as monovalent vaccine or as part of a combination vaccine. For families who refuse the tetanus vaccine, it is also possible for diphtheria and pertussis vaccines to be administered separately. In fact, in the Vavřička case, despite Mr. Vavřička refusing the tetanus vaccine, his children have received diphtheria and pertussis vaccines.[43]

In the context of Islam and Judaism, consuming products derived from pigs, such as gelatin, can be a source of concern because these religions prohibit the consumption of pork products. A material called gelatin is made from the collagen of animals like chickens, cattle, pigs, and fish. Tendons, ligaments, bones, and cartilage all contain collagen. Porcine collagen is the source of porcine gelatin. All types of gelatin used in pharmaceutical products are produced in accordance with stringent safety and hygiene standards. Numerous capsules and several vaccinations, among many other medications, contain gelatin. To keep the vaccine stable and safe while being stored, porcine gelatine is utilized in some vaccines. Tetanus vaccines don't contain porcine gelatin.[44]

Aluminum is another material targeted by vaccine opponents due to unsubstantiated claims that it causes certain illnesses. There is no preservative and only a small amount of aluminum in each dose of the DTaP vaccine. DTaP-HepB-IPV (Pediarix), DTaP-IPV/Hib (Pentacel), DTaP-IPV-Hib-HepB (Vaxelis), DTaP-IPV (Kinrix), and DTaP-IPV (Quadracel) all contain neomycin and polymyxin B as antibiotics, also DTaP-IPV-Hib-HepB (Vaxelis) contains

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'Diphtheria Tetanus and Pertussis DTP Vaccine' (2016), available at: www.unicef.org/supply/documents/diphtheria-tetanus-and-pertussis-vaccine-dtp-price-data [last accessed 21 August 2023]; DTaP (Infanrix, Daptacel) or Tdap (Boostrix and Adacel) vaccines. Tdap (Boostrix) is approved for persons age 10 years or older; Tdap (Adacel) is approved for persons age 10 through 64 years. DTaP vaccine is used in five combination vaccinations. For the first three doses of the DTaP series in children aged 6 weeks to 6 years, DTaP-HepB-IPV (Pediarix) has a license. For the first four doses of the component vaccinations in children between the ages of 6 weeks and 4 years, DTaP-IPV/Hib (Pentacel) is licensed. Only the fifth DTaP dose and the fourth IPV dose are permitted for use with DTaP-IPV (Kinrix) in children between the ages of 4 and 6 years. Only the fifth dose of DTaP and the fourth or fifth dose of IPV in children between the ages of 4 and 6 are authorized for use with DTaP-IPV (Quadracel). It is legal to administer DTaP-IPV-Hib-HepB (Vaxelis) to kids from 6 weeks old to 4 years old. See Centers for Disease Control and Prevention, *'DTaP (Diphtheria, Tetanus, Pertussis) VIS'*, (2021), available at: www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html [last accessed 26 October 2023]; In Turkey, a pentavalent vaccine pentaxim (DTaP-IPV-Hib) (Sanofi Pasteur SA) has been used since 2020. See Elektronik Kamu Alımları Platformu (EKAP), 'Karma Aşı', (2023) Tender Number 2020/32427, available at: ekap.kik.gov.tr/EKAP/Ortak/IhaleArama/index.html [last accessed 26 October 2023].

[43] *Vavřička*, supra n 2 at 24.

[44] UK Health Security Agency and NHS, *'Vaccines and Porcine Gelatine'* (2015), available at: assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1107767/UKHSA-12462-vaccines-porcine-gelatine-English.pdf [last accessed 26 October 2023].

Streptomycin as an antibiotic. Yeast protein is a component of the DTaP-HepB-IPV (Pediarix) and DTaP-IPV-Hib-HepB (Vaxelis) vaccines. Some vaccines, including the diphtheria toxoid vaccine, are packaged with latex rubber.[45]

G. Vaccine Side Effects

It is not easy to find official statistics on side effects, although countries should have statistics on serious vaccine side effects. Statistical data for serious side effects were not specified by WHO and CDC.[46] In the Vavřička case, the Czech Republic reported that serious side effects with lifelong health consequences are very rare, no more than six such incidents per year for 100,000 vaccinated infants.[47] This data applied to side effects from childhood vaccines against nine diseases including pertussis, polio, tetanus, diphtheria, hepatitis B, *Haemophilus influenzae* type b (Hib), measles, rubella and mumps.

Injection site responses from the DTaP vaccine could include discomfort, redness, or swelling. Local reactions were found in 20-40% of infants after each of the first 3 doses.After the fourth and/or fifth dosages, local reactions tend to occur more frequently. Moreover, mild systemic responses including fatigue, anxiety, and fever are possible. A temperature of 101˚F or greater was reported in 3-5% of DTaP recipients.These responses are self-contained and can be controlled with acetaminophen or ibuprofen for symptom relief.[48]

Although they have been reported after the administration of DTaP, moderate to severe systemic reactions (such as high fever, febrile seizures, persistent crying, and hypotonic-hyporesponsive episodes) are less common than among kids who received whole-cell DTP. In general, fewer than 1 in 10,000 doses result in moderate or severe systemic responses, though rates change depending on the symptom and the vaccine.[49]

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[45] The same components for poliovirus, diphtheria, tetanus, and pertussis indicated in Infanrix® above, as well as 10 ng of hepatitis B virus surface antigen, are present in each 0.5-mL dosage of Pediarix® (GlaxoSmithKline) (HBsAg). Aluminum salts as adjuvant (not more than 0.85 mg aluminum by assay) and 4.5 mg of sodium chloride are both present in each 0.5-mL dosage. Moreover, each dose contains ≤100 µg of polysorbate 80 and ≤100 µg of residual formaldehyde (Tween 80). Neomycin sulfate and polymyxin B are used in the poliovirus vaccine's production. The final vaccine may contain those components at ≤0.05 ng of neomycin and ≤0.01 ng of polymyxin B per dose. The HBsAg antigen is produced using processes that yield a product with ≤5% yeast protein. To see the ingredients of other vaccines, it is possible to visit the following webpage: www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/about-vaccine.html [last accessed 26 October 2023].

[46] Centers for Disease Control and Prevention, '*Tdap (Tetanus, Diphtheria, Pertussis) VIS*', (2021), available at: www.cdc.gov/vaccines/hcp/vis/vis-statements/tdap.html [last accessed 26 October 2023]; WHO Tetanus, available at https://www.who.int/health-topics/tetanus#tab=tab_3[last accessed 26 October 2023].

[47] *Vavřička*, supra n 2 at 207.

[48] Centers for Disease Control and Prevention, supra n 44.

[49] ibid.

In 2017 WHO reported that severe generalized side effects as brachial neuritis and other severe widespread adverse effects are relatively uncommon. It has been documented that peripheral neuropathy, in particular brachial plexus neuritis, can develop hours to weeks following vaccination. According to passive surveillance conducted in the USA, 0.69 incidences of brachial neuritis occurring 0–60 days after vaccination were reported for every 10 million doses. Rare reports of Guillain-Barré syndrome (GBS) after immunization (with tetanus toxoid) have been made, although findings from population-level studies do not corroborate this. Tetanus toxoid-containing vaccines (TTCV) are rarely associated with anaphylaxis.. According to recent passive monitoring data, there are 1.6 anaphylactic episodes for every million Td doses delivered.[50] Seldom recorded, but possible are exaggerated local (Arthus-type) reactions after receiving a diphtheria or tetanus toxoid vaccine.[51]

III. Clash of Right to Refuse Treatment and Tetanus Vaccination Mandate for Competent Adults

According to Article 5 of the Convention on Human Rights and Biomedicine to which many countries are a party "*an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it*".[52] In many cases, the Court has ruled that imposing medical treatment, even where refusal to receive certain treatment could result in death, without the consent of a mentally competent adult patient would interfere with his or her right to physical integrity.[53] Accordingly, in many jurisdictions, a competent adult has the right to refuse treatment, even if this intervention constitutes an absolutely necessary intervention for the individual's survival.[54] The right to refuse medical intervention is internationally accepted as a fundamental principle of liberty.[55] Within this framework, a competent adult may

[50] World Health Organization, '*Tetanus Vaccines: WHO Position Paper – February 2017*' 92(6) (2017) at 53, available at: apps.who.int/iris/bitstream/handle/10665/254583/WER9206-53-76.pdf?sequence=1&isAllowed=y [last accessed 26 October 2023].

[51] Centers for Disease Control and Prevention, supra n 44.

[52] Convention on Human Rights and Biomedicine 1999, CETS 164, available at: www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=164 [last accessed 26 October 2023].

[53] See *Pretty v UK* Application No 2346/02, Admissibility, 29 April 2002 at paras 63-65; *Glass v UK* Application No 61827/00, Admissibility ,9 March 2004 at paras 82-83; *Jehovah's Witnesses of Moscow v Russia* Application No 302/02, Admissibility, 10 June 2010 at para 135; *Haas v Switzerland* Application No 31322/07, Admissibility, 20 January 2011.

[54] *Malette v Shulman* 72 OR 417 (CA 1990); Douglas, Forsberg and Pugh, 'Compulsory Medical Intervention Versus External Constraint in Pandemic Control', (2021) 47(12) Journal of Medical Ethics; *Montgomery v Lanarkshire* Health Board [2004] UKSC 11 [87].

[55] Stern, 'Parents Patriae and Parental Rights: When Should the State Override Parental Medical Decisions', (2019) 33(1) Journal of Law and Health 82; *Cruzan v Director* 497 US 261 (1990).

make "medically unreasonable" decisions regarding their own health.[56] The purpose of the medical intervention, whether it is preventive, diagnostic, therapeutic, or low risk will not change this rule. Preventive medical interventions such as routine blood tests, check-ups, smear tests, and mammograms can prevent significant health problems from occurring or enable early diagnosis with a significantly higher chance of successful treatment. However, if only the well-being of a mature and competent individual is at stake, as a rule, it is not possible to compel this person to undergo these preventive medical interventions.

On the other hand, patients' right to refuse treatment can also be restricted.[57] However, for the imposition of a mandatory medical intervention, there must be a particularly strong justification.[58] In the Jehovah's Witnesses of Moscow and Others v. Russia case, the Court stated:

> *that free choice and self-determination were themselves fundamental constituents of life and that, absent any indication of the need to protect third parties – for example, mandatory vaccination during an epidemic, the State must abstain from interfering with the individual freedom of choice in the sphere of health care, for such interference can only lessen and not enhance the value of life.*[59]

In this context, a competent adult should also be able to refuse to receive a tetanus vaccine.[60] The tetanus vaccine has a protective effect against tetanus as explained above. Even though adult booster doses are mandatory in few countries like Czech Republic,[61] it is important to reemphasize that after com-

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[56] Malette, supra n 52.

[57] Rillo, 'Constitutional Law: The Limits of a Patient's Right to Refuse Medical Treatment', (1994) 46 Florida Law Review 347; Wicks, 'The Right to Refuse Medical Treatment under the European Convention on Human Rights', (2001) 9 Medical Law Review 19.

[58] *Vavřička*, supra n 2 at 8; *YF v Turkey* Application No 24209/94, Admissibility, 22 July 2003 at paras 33- 37; *Solomakhin v Ukraine*, supra n 1 at 33-36; Richins, 'Jacobson Revisited: An Argument for Strict Judicial Scrutiny of Compulsory Vaccination', (2011) 32(4) Journal of Legal Medicine 409.438.

[59] *Jehovah's Witnesses of Moscow*, supra n 51 at 136.

[60] Richins, supra n 56 at 436.

[61] In Czech Republic, tetanus "booster" doses are listed among the regular vaccination programs in the relevant ministerial Decree, while these regular vaccines are compulsory under the Act on the Protection of Public Health. See *Vavřička*, supra n 2 at 205-77; Rozalio, supra n 10; ECDC, '*Czech Republic: Recommended Vaccinations*', (2023), available at: vaccine-schedule.ecdc.europa.eu/Scheduler/ByCountry?SelectedCountryId=201&IncludeChildAgeGroup=true&IncludeChildAgeGroup=false&IncludeAdultAgeGroup=true&IncludeAdultAgeGroup=false [last accessed 26 October 2023]; It is also important to point that there are few mandatory vaccines for adults even though some sicknesses on vaccination schemes require booster doses for a continuous immunity. This is also the case for tetanus. See McNeill, 'Mandatory Vaccination for Healthcare Professionals: Preparation for Future Pandemics', (2022) Master's Thesis, Durham University 106 , available at: etheses.dur.ac.uk/14742/ [last accessed 26 October 2023].

pletion of a childhood vaccination series, WHO does not recommend adult booster doses for tetanus any more, necessity of the booster dose is disputed[62] In addition, as explained in part II, tetanus vaccine can be applied when this bacterium is encountered. An adult person may refuse application of tetanus vaccination in both cases.

Since tetanus is not transmitted from human to human, there is no risk of epidemic. Protection of the other members of the society cannot be a valid justification for imposition of a tetanus vaccine mandate. Maybe the cost of treatment can be considered a burden for the public. As pointed above, treatment of tetanus will likely require treatment in intensive care units, which is very expensive in many countries.[63] However, if the incidence of the disease

[62] World Health Organization, '*Immunization, Vaccines and Biologicals*', (2017), available at: www.who.int/teams/immunization-vaccines-and-biologicals/diseases/tetanus [last accessed 26 October 2023]; In one scientific research analysis of 11 billion person-years of incidence data exhibited decrease associated with performing adult booster vaccinations against tetanus or diphtheria. See Slifka, supra n 39.

[63] Intensive care is one of the most expensive categories of hospital-based care worldwide due to the high number of specialized personnel and sophisticated medical equipment required. In the United States (US), intensive care unit (ICU) costs are estimated to account for 13 to 39% of total hospital costs. See Halpern and Pastores, 'Critical care medicine beds, use, occupancy and Costs in the United States: a methodological review', (2015) 43(11) Critical Care Medicine, available at: journals.lww.com/ccmjournal/abstract/2015/11000/critical_care_medicine_beds,_use,_occupancy,_and.23.aspx [last accessed 26 October 2023]; Coopersmith et al., 'A Comparison of critical care research funding and the Financial Burden of Critical Illness in the United States', (2012) 40(4) Critical Care Medicine 1072, available at: journals.lww.com/ccmjournal/abstract/2012/04000/a_comparison_of_critical_care_research_funding_and.4.aspx [last accessed 26 October 2023]; The documented daily ICU costs in high-income countries range from $1,464 to $4,518 (adjusted to 2019 prices). See Tan et al., 'Direct cost analysis of intensive care unit stay in four European countries: Applying a Standardized Costing Methodology', (2012) 15(1) Value Health 81, available at: www.valueinhealthjournal.com/article/S1098-3015(11)03509-1/fulltext?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301511035091%3Fshowall%3Dtrue [last accessed 26 October 2023]; Although critical care is less expensive in LMICs (due in part to reduced labor costs), cost information is limited. See Turner et al., 'Achieving affordable critical care in Low-Income and Middle-Income Countries', (2019) 4 BMJ Global Health, available at: gh.bmj.com/content/4/3/e001675 [last accessed 26 October 2023]; The daily ICU costs reported in Thailand, Malaysia, China, and India range from $292 to $1,421 (2019 prices adjusted). See Aung et al., 'Determining the Cost and Length of Stay at Intensive Care Units and the Factors Influencing Them in a Teaching Hospital in Malaysia', (2020) 21 Value in Health Regional Issues 149, available at: www.valuehealthregionalissues.com/article/S2212-1099(19)30615-6/fulltext [last accessed 26 October 2023]; Peter et al., 'Cost of Intensive Care in India', (2016) 32 International Journal of Technology Assessment in Health Care 241, available at: www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/abs/cost-of-intensive-care-in-india/9FDABCCC59E5AD6332C6C8D85C891D9B?utm_campaign=shareaholic&utm_medium=copy_link&utm_source=bookmark [last accessed 26 October 2023]; These costs are equivalent to between 2.2 and 4.0 times the nation's 2018 health care expenditures per capita. See The World Bank, '*Current health expenditure per capita (current US$) - China,*

does not impair the functioning of the health system, the cost and length of treatment or necessity of treatment in ICU should not constitute a reason for a mandatory intervention. Moreover, in the cases of Vavřička v. Czech Republic, Solomakhin v. Ukraine, and Boffa and Others v. San Marino, the expense of treating unvaccinated individuals was not cited as a justifiable rationale for imposing mandatory vaccination requirements. On the other hand, unvaccinated persons may argue that they are paying high premiums for their social health insurance and cover the cost of a possible tetanus treatment in advance. It's worth mentioning that for preventive medical measures primarily concerned with an individual's well-being, most countries typically do not enforce mandates.[64] Many life-saving preventive medical interventions can be named and most of them have no or very rare side effects.[65] For example, cervical cancer is the fourth most common cancer among women, and routine HPV and pap-smear tests are highly recommended. Regular tests increase the chance of recovery and reduce the cost and the duration of the treatment of cervical cancer due to early diagnosis. However, mostly, these preventive tests are not ruled to be mandatory considering the cost of cancer treatment.[66]

IV. Mature Minors' Right to Reject Tetanus Vaccination

According to Article 6 of the Convention on Human Rights and Biomedicine:

Malaysia, Thailand, India, Vietnam', (2023), available at: data.worldbank.org/indicator/SH.XPD.CHEX.PC.CD?end=2018&locations=CN-MY-TH-IN-VN&start=2017 [last accessed 26 October 2023]; In a study conducted in Vietnam in 2022, the direct medical cost of tetanus, patients in an intensive care unit is calculated and for patients that did not require mechanical ventilation, the median total ICU cost per patient was found between US$64.40 and US$675. The costs were higher for patients that required mechanical ventilation, with the median total ICU cost per patient for the different diseases varying between US$2,590 and US$4,250. The main cost drivers varied according to disease and associated severity. See Hung et al., 'Direct Medical Costs of Tetanus, Dengue, and Sepsis Patients in an Intensive Care Unit in Vietnam', (2022) 10 Frontiers in Public Health, available at: doi.org/10.3389/fpubh.2022.893200 [last accessed 26 October 2023].

[64] Stubbs, 'Health Matters - Cervical Screening: It's Your Choice', *UKHSA*, 30 August 2017, available at: ukhsa.blog.gov.uk/2017/08/30/health-matters-cervical-screening-its-your-choice/ [last accessed 26 October 2023].

[65] Like routine screening blood tests, check-ups, doctor visits, blood pressure tests.

[66] Public Health England, *'Cervical Screening: Program Overview'* (2015), available at: www.gov.uk/guidance/cervical-screening-programme-overview#:~:text=It%20is%20an%20individual's%20choice,want%20to%20receive%20screening%20invitations [last accessed 26 October 2023]; Uruguay enacted mandatory breast cancer screening for working women aged 40-59 in 2006. This rule is challenged. See Rosengurtt, 'Uruguay's mandatory breast cancer screening is Challenged' *The BMJ Opinion*, 26 October 2017, available at: blogs.bmj.com/bmj/2017/10/26/ana-rosengurtt-uruguays-mandatory-breast-cancer-screening-is-challenged/ [last accessed 26 October 2023].

> *Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.*
>
> *The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.*

If a minor is able to make an informed judgment about medical treatment, some countries grant that mature/competent/Gillick competent minor the right to consent to all or some medical procedures.[67] If a state allows mature minors to consent to medical interventions, then these mature minors should also have a right to refuse the medical interventions like competent adults. However, in some countries, it is possible to subject the decision of a mature minor to judicial review if the refusal poses a serious risk to the health of the minor.[68]

A minor accepted as mature to consent to medical interventions in his or her home country should have the same freedom as adults to be not vaccinated as a preventive medical intervention. This freedom can only be interfered

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[67] § 95 Czech Republic Civil Code, No 89/2012: "*A minor without full legal capacity may, in usual matters, also give his consent to an intervention on his body himself, if this is adequate to the intellectual and volitional maturity of minors of his age, and if it is an intervention not resulting in any permanent or serious consequences.*"; § 36 New Zealand Care of Children Act 2004, No 90: "*A consent, or refusal to consent, to any of the following, if given by a child of or over the age of 16 years, has effect as if the child were of full age: (a) any donation of blood by the child: (b) any medical, surgical, or dental treatment or procedure (including a blood transfusion, which, in this section, has the meaning given to it by section 37(1)) to be carried out on the child for the child's benefit by a person professionally qualified to carry it out.*" ; §8 UK Family Law Reform Act 1969: "*(1)The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian. (2) In this section "surgical, medical or dental treatment" includes any procedure undertaken for the purposes of diagnosis, and this section applies to any procedure (including, in particular, the administration of an anaesthetic) which is ancillary to any treatment as it applies to that treatment. (3) Nothing in this section shall be construed as making ineffective any consent which would have been effective if this section had not been enacted.*"; §173 Austria ABGB: "(1) *Consent to medical treatment can only be given by the child who is capable of understanding and judgement; in case of doubt, the existence of this capacity for understanding and judgement is presumed in the case of minors of age. If the child lacks the necessary capacity to understand and judge, the consent of the person entrusted with care and education shall be required.*"; § 129 (2-3) South Africa Children's Act 39, 2005, available at: www.justice.gov.za/legislation/acts/2005-038%20childrensact.pdf [last accessed 27 July 2023].

[68] *Re R (A Minor)* [1991] EWCA Civ J0724-4; *Re W (A Minor)* [1993] EWHC 64 (Fam); *Re X (A Child)* [2021] EWHC 65 (Fam); Critical of these precedents, Birch, 'Mature Minors and the Refusal of Medical Treatment: A Misuse of Gillick' (2017) Durham University 104, available at: etheses.dur.ac.uk/12354/ [last accessed 26 October 2023].

with if there is an additional justifiable reason, such as the protection of public health. In the case of the tetanus vaccine, there is no such additional justification as explained in the previous part. His children were 13 and 14 years old when Mr. Vavřička was fined for not vaccinating his children against tetanus, poliomyelitis, and hepatitis B.[69] It is also conceivable that children aged 13 and 14, who have not received any tetanus vaccine before,[70] could decide for themselves about the tetanus vaccination after being informed.[71] As a matter of fact, the legal regulation in the Czech Republic gives minors the right to make their own decisions about medical intervention, according to the maturity of children at certain ages and the severity of the medical intervention.[72] However, the legislation requiring vaccinations in the Czech Republic, it is stated that the consent of the legal representative is required for those under the age of 15.[73] From this point of view, the decision is also questionable in terms of the fact that the parents are fined by the state at an age when the children are mature enough to make their own decisions about vaccination. The child applicants of *Vavřička* case contended that denying them entry to nursery school due to their parents' refusal was arbitrary. They also invoked their right to personal autonomy in making health-related decisions.[74]

V. When to Intervene if Parents Object to Children's Tetanus Vaccination?

The Vavřička decision and the discussion on tetanus vaccination mainly concern the age range in which the child is incapable of judgment in such a way as to make his own decision about whether to have the tetanus vaccine. As a rule, the parents, as the legal representatives of the minor, consent to medical interventions on the minor who is incapable of judgment (Article 6 II of the Convention on Human Rights and Biomedicine). In this case, the decision authority is given to the parents, thinking that the best interests of the child will be best determined by the parents. It should be emphasized that the decision authority is vested in parents, not in physicians. Citing this convention too, the Court in Glass v. The United Kingdom case ruled that the administration of a high dose of diamorphine to a disabled child against the opposition of his legal representative violated Article 8 of the Convention. In M.A.K. and R.K. v. The

[69] *Vavřička*, supra n 2 at 23.

[70] *Vavřička*, supra n 2 at 24, 302

[71] Doležal, 'Informed Consent of Minors with A Special Focus on The Czech Legal Regulation', (2021) 11(1) The Lawyer Quarterly 126.130; Weithorn and Campbell, 'The Competency of Children and Adolescents to Make Informed Treatment Decisions', (1982) 53(6) Child Development 1589.

[72] §31 Czech Republic Civil Code, No 89/2012; Doležal, supra n 71 at 134-137.

[73] *Vavřička*, supra n 2 at 11.

[74] *Vavřička*, supra n 2 at 172-173.

United Kingdom, it was found that taking blood samples and photographing of the nine-year-old child without the consent of his legal representative was contrary to Article 8 of the Convention.

On the other hand, parents' right to consent to medical interventions on minors can be restricted. At this point, a distinction needs to be made based on the nature of medical interventions. An intervention may be aimed at treating the child's existing health problem or preventing a potential health risk the child may encounter in the future. Vaccination is the most important example of the latter type of medical intervention. Additionally, some medical interventions performed on minors with parental consent are neither therapeutic nor preventive in nature. This group, which can be referred to as non-indicated medical interventions, includes circumcision of male minors and cosmetic medical procedures.

In the case of medical interventions on minors, the decision-making authority of parents is debated mostly when it comes to therapeutic medical interventions. However, the assessments regarding the discretion of parents in therapeutic medical interventions also shed light on preventive medical treatments. Therefore, the examination will begin with assessments concerning the discretion of parents in therapeutic medical interventions.

A. The Limits of Parental Discretion in Therapeutic Interventions

As mentioned above, medical interventions on minors will as a rule require parental consent. However, parents' discretion in this matter is not unlimited. The best interest and harm-based principles have been established to determine under which conditions parental authority over medical interventions on minors can be overruled.[75] 'Best interest' refers to making decisions based on what is in the best interest of the child's overall well-being, considering their physical and emotional health. According to this criterion, if the proposed medical intervention serves the best interests of the child, the judge can intervene in the parents' refusal to receive the treatment.[76] However, the best interest of the child does not provide a clear standard. In most cases, physicians are medically more knowledgeable than the child's legal representatives, who are mostly parents, in assessing whether a medical intervention is in the child's best interest. Then, medical best-interest determination might always be based on the physicians' judgment. This is not in line with the ratio legis of legal

[75] MacDougall, 'Intervention Principles in Pediatric Health Care: The Difference Between Physicians and The State', (2019) 40(4) Theoretical Medicine and Bioethics 279, available at: doi.org/10.1007/s11017-019-09497-6 [last accessed 26 October 2023]; Other different standards are suggested for decision making in such cases. See DeMarco, Powell and Stewart, 'Best Interest of the Child: Surrogate Decision Making and the Economics of Externalities', (2011) 8 Bioethical Inquiry 289, available at: doi.org/10.1007/s11673-011-9315-1 [last accessed 26 October 2023].

[76] NHS, *'Children and young people: Consent to Treatment'*, (2022), available at: www.nhs.uk/conditions/consent-to-treatment/children/ [last accessed 26 October 2023].

regulations that grant parents the decision-making authority over medical interventions on minors. Hence, it is suggested that the best interest evaluation should be subjected to restrictive interpretation.[77] Furthermore, it is stated that this criterion does not offer physicians a clear guideline on when to initiate legal proceedings to override the refusal of the legal representative. Therefore, it is emphasized that the 'significant risk of serious preventable harm' principle should be considered as an alternative.[78] "Harm-based" principles focus on preventing or minimizing potential harm or risks to the child. Within the framework of this principle, if there is a high probability of significant harm to the child's health when medical intervention is not applied, and the recommended medical intervention can mitigate this danger without substantial risks on its own, the legal representative's decision to withhold medical intervention can be overridden in favor of the intervention.[79] It is interesting to note that childhood vaccinations are used as an example when discussing when a "significant risk of serious harm" can be addressed.[80] According to this example, many physicians may advise parents to have their child vaccinated during childhood, but they do not resort to legal measures against parents who refuse vaccination for their child. This is because in countries where vaccination is widespread, the likelihood of contracting vaccine-preventable diseases and thus suffering serious harm is low. As a result, utilizing such criteria and legal regulations, efforts are made to determine the limits of parental discretion. Some case samples are established to limit parental discretion.

In emergency cases where minors' life is at high risk, physicians can proceed with necessary medical intervention without parental consent or legal authorization.[81] This is in accordance with Article 8 of the Convention on Human Rights and Biomedicine.[82]

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[77] Stern, supra n 65 at 88; Buchanan and Brock, *Deciding for Others: The Ethics of Surrogate Decision Making* (1989) at 145.

[78] Kopelman, 'The Best-Interests Standard as Threshold, Ideal, and Standard of Reasonableness', (1997) 22 Journal of Medicine and Philosophy 271.275; Buchanan, supra n 87, Ekundayo, 'Legal Basis for the Court's Intervention over Medical Treatment of Children', (2022) 121 Journal of Law Policy and Globalization 39.49.

[79] Diekema, 'Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention', (2004) 25 Theoretical Medicine and Bioethics 243.

[80] UW Medicine Department of Bioethics and Humanities, available at https://depts.washington.edu/bhdept/ethics-medicine/bioethics-topics/detail/72 [last accessed 23 October 2023]

[81] Guadarrama-Orozco et al., 'Informed Consent and Parental Refusal for Medical Treatment in Childhood. The Threshold of Medical and Social Tolerance: Part II', (2015) 72(4) Boletín Médico del Hospital Infantil de México 184, available at: www.elsevier.es/en-revista-boletin-medico-del-hospital-infantil-201-articulo-informed-consent-parental-refusal-for-X244434091543972X [last accessed 26 October 2023].

[82] Emergency situation "When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned."

In many legal systems, if the recommended medical intervention is a life-saving measure for the child, but the parents refuse to consent for reasons other than the medical intervention's higher risks, the court or a similar authority may intervene and authorize the necessary treatment.[83]

In cases where medical intervention is necessary to prevent significant health problems for the child, and the risks associated with the medical intervention are low while the chances of successful treatment are high, courts often intervene when parents refuse the treatment. The court's intervention aims to ensure that the child receives the necessary medical care for their well-being and health.[84]

If the likelihood of success of a medical intervention is low or the treatment process is risky, prolonged, or painful, there is a tendency not to interfere with parental discretion. In such cases, more respect is given to the parents' preferences.[85]

B. Limits of Parents' Decisive Authority in Preventive Medical Interventions

Compared to therapeutic medical interventions, preventive medical intervention is performed with the aim of protecting the minor from a health problem that may occur in the future. In preventive medical interventions, consent for this treatment will also be given by the parents as a rule, for the minors who are incapable of judgment.

In the case of preventive medical interventions, healthcare practitioners or state authorities may deem a medical intervention necessary, but parents may refrain from giving consent. In such situations, whether the parental discretion can be overridden should be determined considering factors such as the seriousness and incidence of the health risk being addressed, the effectiveness of the preventive medical intervention, and the risks associated with the intervention itself, and the reasons behind the parents' refusal of the treatment.

Among preventive medical interventions, vaccines are considered the most effective in terms of cost and impact. The risk of a child contracting tetanus depends on the family's lifestyle and can vary from one country to another. Neonatal tetanus is very unlikely with hospital births and circumcisions and is also much less likely to occur in non-hospital settings when mothers have received at least two doses of tetanus vaccine before and during pregnancy.

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[83] *Willmann* 493 N E 2d 1380 (OH 986); *Matter of D* R 20 P 3d 166 (OK 2001); *Custody of a Minor* 379 N E 2d at 1056 (Mass 1978); Townsend, 'Judicial Limitations on Parental Autonomy in the Medical Treatment of Minors', (1980) 59(4) Nebraska Law Review 1093.1094.

[84] Guadarrama-Orozco, supra n 89; Stern, supra n 65 at 88; *Custody of a Minor*, supra n 93; Ekundayo supra n 88 at 49; *Sampson* 37 AD 2d 668 (NY 1971).

[85] Guadarrama-Orozco, supra n 89; *Newmark v Williams* 588 A 2d 1108 (DE 1990); *Re Greene* 448 PA at 348 292 A 2d at 392 (PA 1972).

Additionally, if there is no drug use in the child's vicinity, the likelihood of the child encountering this disease significantly decreases. According to the data mentioned above, the incidence of tetanus was not high even without any vaccination programs. Additionally, as described earlier, when an unvaccinated person contracts tetanus, early diagnosis allows for effective treatment. Therefore, the refusal of the tetanus vaccine does not expose the child to an immediate risk of harm.

The pentavalent vaccine when administered in recommended doses and at specific intervals, as explained above, provides effective protection against tetanus disease.[86] On the other hand, as mentioned earlier, the likelihood of the vaccine causing serious harm to the child is told to be low. However, considering the low incidence of tetanus itself, the states should make more specific and transparent declarations on the incidence of the serious side effects. This information is crucial for parents who want to give informed consent to this medical intervention.

The content of the tetanus vaccine is provided in the section above. According to manufacturers, despite possible variations in content, tetanus vaccine types do not contain porcine gelatin, which shouldn't be consumed in accordance with Jewish and Islamic beliefs. Even though the level of aluminum is also very low in vaccine contents, parents' concerns about vaccines may arise due to the use of aluminum as an adjuvant in vaccines. The use of aluminum as an adjuvant in vaccines raises doubts in some parents about potential negative effects on human health. On the other hand, some parents may refuse the vaccine due to their lack of trust in vaccine manufacturers and their country's health authorities.

As a result, parents' doubts about the safety or effectiveness of vaccines, concerns about the ingredients in vaccines, and/or religious beliefs may lead them to decide against vaccinating their children. These concerns of parents may not be justified according to medical science.[87] However, in this case, it should be considered whether parental discretion can be overridden regarding the risk mitigated by the tetanus vaccine. There can be several other preventive medical interventions for a child's health besides the tetanus vaccine. Regular blood tests and developmental check-ups by a pediatrician may be more effective health measures to prevent many potential health issues for the child compared to the tetanus vaccine. Parents influence their children's psychological and physiological health through the many decisions they make every day. Choices such as their dietary preferences, not encouraging their children to engage in sports, not restricting screen time, allowing biking or scooter riding

[86] *Troxel v Granville* 530 US 57 (2000) [65].

[87] Rhinesmith and Fu, 'Tetanus Disease, Treatment, Management', (2018) Pediatrics in Review 430, 430–432; Slifka, supra n 39, 285-292.

without helmets, neglecting basic safety measures at home, and not knowing first aid can negatively impact a child's health and may be deemed inappropriate by experts. However, it is not feasible to intervene in every decision that is perceived as incorrect as parents are raising their children. On the contrary, intervention in parental rights should be possible in exceptional cases.[88] The relatively low risk of encountering tetanus, the possibility of early diagnosis and treatment, and the principle of intervention in parental rights in exceptional cases make mandatory preventive tetanus vaccination for young children not a proportionate measure.[89] On the other hand, parents have the right to make informed decisions. There is no transparency about the incidence of tetanus in unvaccinated persons and frequency of the serious side effects of tetanus vaccine. Countries should ideally already have this information and make it available to parents so they can make informed decisions.

In the Acmanne and Others v Belgium case, the European Court of Human Rights ruled that the regulation subjecting children to routine tuberculosis testing and chest X-rays is lawful, as it is in the best interest of the child and society.[90] However, it is important to point out that mandatory vaccination is a much more serious intervention in the body than a test since vaccination injects a substance in the the body.[91] Additionally, unlike tuberculosis, tetanus does not spread from person to person. Therefore, mandatory tetanus vaccination as a preventive measure requires a different analysis than the one in Acmanne case.

Conclusion

A competent adult may refuse treatment, even if the result is death. This is a general rule accepted by the European Court of Human Rights in many of its decisions. Therefore, adults and mature minors who are authorized to decide on such medical interventions should have the right to refuse tetanus vaccination. At this point, sanctioning an adult for not getting vaccinated against tetanus will not be in line with the Oviedo Convention and ECHR.

A more controversial legal situation arises when mandatory tetanus vaccine is intended for minors who are incapable of judgment. In the case of therapeutic medical interventions, parents' right to refuse a suggested medical treatment is set within the framework of the 'best interests of the child' or 'significant risk of serious harm' criteria. However, the intervention to be made according to these criteria should be exceptional and should not transfer the

[88] *Strand Lobben and others v Norway* Application No 37283/13, Admissibility, 10 September 2019 at para 211; *Vavřička*, supra n 2 at 13.

[89] Vaccinating each child is not justified by its being in their best interests alone. On which see Archard, Brierley and Cave, supra n 7 at 7.

[90] *Acmanne and Others v Belgium* Application No 10435/83, 10 December 1984.

[91] Douglas, Forsberg and Pugh, supra n 52.

discretion of the parents regarding the proposed medical intervention to the physicians. The likelihood that a child will have tetanus will vary depending on the environment, country, and family attitudes. If the child lives in hygienic conditions, the probability of getting infected with tetanus is not high. Despite its high mortality rate, tetanus is treatable especially when it is diagnosed in a timely manner and when intensive care services including mechanical ventilation is available. There are many other preventive medical interventions for minors, such as routine blood tests and pediatrician check-ups, and some of them may be even more effective than the tetanus vaccine. On the other hand, countries are not transparent with the specific incidence of the serious side effects of the vaccines. In our opinion, due to the rarity of tetanus, its non-contagious nature, and parents' rights to choose what they believe is best for their children, even if it goes against medical advice, it is not in accordance with the European Convention on Human Rights (ECHR) to interfere with parents' discretion regarding preventive tetanus vaccination.

Turnaway Study Report Unethically Violated Participants' Privacy and Misleads Public with a Non-Representative Sample, Selective Reporting, and Overstated Conclusions

David C. Reardon*

ABSTRACT: Results from the Turnaway Study, conducted by Advancing New Standards in Reproductive Health (ANSRH), have widely been represented as definitive proof that women denied access to abortion will suffer severe injury to their health and economic wellbeing. Yet a careful examination reveals that the study is based on a non-random, non-representative sample of women that grossly underrepresents the experiences of the majority of women undergoing abortions. In addition, a reanalysis of its reported results reveal that the effect size of the outcomes observed have been grossly overstated, leading to conclusions that are not supported by the results. There also appears to be selective reporting and misrepresentation of results previously published. In addition, inconsistencies in ANSRH's published record strongly suggest that the credit history reports of the Turnaway Study participants were obtained without their informed consent.

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Advancing New Standards in Reproductive Health's (ANSIRH) Turnaway Study, led by Diana Greene Foster, has resulted in more than fifty peer reviewed studies (Foster 2020). With a well-funded public relations department, many of those studies have captured national headlines (Reardon 2018b) and have been widely cited in legislative hearings and court cases relevant to abortion laws (Shutt 2024; Douglis 2022; Lenharo 2021). One of the most recent Turnaway Study reports was published in the *American Economic Journal: Economic Policy* and concludes, per the abstract, that "women who were denied an abortion experience a large increase in financial distress that remains for years" (Miller, Wherry, and Foster 2023).

In this critique, I argue that this conclusion relies on unreliable data, is overstated, and was based on human data collected without the informed consent of the persons being studied. To provide context to this critique, it is notable that ANSIRH provides abortion advocacy and training (Goodman, Wolfe, and Group 2012). It was founded by Tracey Weitz (ANSIRH, n.d.) who also directs the Susan Thompson Buffett Foundation's population control efforts (Callahan 2014). Warren Buffett is known to have a "Malthusian dread" of population growth (Philanthropy Roundtable 2023; Weise 2015), a concern which is shared by other foundations which also support ANSIRH (Martin 2016; Harlow 2009; Ludwig 2020) and that are also investors in the testing, manufacture and distribution of the abortion drug, mifepristone, also known as RU-486 (Novielli 2019; Levintova 2023).

In short, ANSIRH's staff and their donors do not approach abortion research from a neutral perspective. Indeed, it is possible, even likely, that their individual and organizational desires to increase abortion access and abortion rates in targeted "underserved" communities have contributed to the inconsistencies, misrepresentations, overstatements, and lapses in scientific rigor which are discussed below.

It is also notable that ANSIRH along with other abortion advocates have called for the retraction of studies that have reported negative effects associated with abortion which they have described as being "unreliable" (Littell et al. 2024). They have insisted that any research touching on public policy regarding abortion that "cannot be relied upon" should be retracted, noting: "We must maintain uncompromising standards of quality and integrity at every stage in the production and dissemination of scientific research.... Allowing inaccurate information to remain in the scientific record can have lasting and deleterious effects on law, public policy, clinical practice, and public health" (Littell et al. 2024). Surely, the same standards for quality and integrity should also apply to studies published by abortion advocates.

This critique of the Turnaway Study in general, and their credit history analysis in particular, is formulated around the same standards ANSIRH has used to call for the retraction of other papers. In light of the observations,

criticisms, and unanswered questions detailed below, it will be clear that those same standards require the correction of overstated conclusions published regarding the Turnaway Study, notices of concern regarding results that are being withheld, and in at least some cases the retraction of published papers that are based on unethically obtained data.

The Turnaway Study Sample is Not Representative.

In short, the Turnaway Study is based on a non-random, non-representative convenience sample (Reardon 2018b; Coleman 2022). The sampling flaws are so serious that none of the results from any of the studies can be relied upon for drawing substantive conclusions about the general population. Such a convenience sample may be useful for forming hypotheses. But it should not be presented as evidence that ANSIRH's hypotheses have been confirmed to be true, which is how it is regularly presented (Foster 2020).

The Invitation Process was Not Random and Required Exclusion of Women at Higher Risk of Negative Reactions.

The Turnaway Study utilized a convenience sample drawn disproportionately from 30 different abortion clinics. The invitation process was not random. Clinic staff were instructed to exclude women who were seeking abortions for therapeutic reasons, such as fetal anomalies (Foster 2020). This single exclusion criteria makes the sample unrepresentative of all women seeking abortions and was most likely implemented precisely to exclude a subset of women known to have more negative reactions to their abortions (Reardon 2018a).

In addition, clinic staff were free to exercise their own judgment on when to invite patients to participate (Reardon 2018b), with some staff inviting less than 20% of eligible patients while others invited 70% to 100% (Dobkin et al. 2014). The lack of a random invitation process, alone, prevents any results from being applied to the general population of women who have had, or have sought, abortions.

Sample Quality was Further Reduced by a Low Participation Rate and Self-censure.

Of 3,045 women invited to participate, only 1,132 (37.2%) agreed to participate. Normally, such a low participation rate would often result in automatic rejection of studies by many journals. For example, the journal *Obstetrics & Gynecology* requires a minimum response rate of 60% or higher ("Instructions for Authors" 2019).

But this low participation rate was even further damaged by a 15.5% drop-out among those who had agreed to be interviewed during the seven to eight days prior to their first interview. This dropped the actual participation rate

(completion of at least one interview) to 31%. Over the course of the five years that additional interviews were attempted, approximately half of the remanent dropped out (Reardon 2018b).

In any context, a mere 31% participation rate introduces an overwhelming imputation that the results are tainted by self-selection bias. This is even more true when the subject matter is one's recent abortion, where it is well established that abortion patients who anticipate the most post-abortion distress are least likely to agree to post-abortion interviews (Söderberg et al. 1998; Adler 1976; Reardon 2018a). This effectively results in self-censure, the omission of data representing an important subgroup of the target population. This self-censure is especially significant when the outcomes of interest are related to the emotional and psychological responses associated with abortion.

In an effort to deflect criticism of the fact that only 31% of women invited to participate in the Turnaway Study did so, ANSRIH has asserted that these low rates of participation are similar to those of other post-abortion survey studies initiated at other abortion clinics (Foster 2020). But comparisons to other poor studies do not convert a poor study into a good study.

Similarly, ANSRIH has asserted that their study compares well (A. Biggs et al. 2022) to the attrition rate reported in the Nurse's Health studies (Bao et al. 2016). But while a 5% attrition rate every six months is not unprecedented, the original Nurse's Health Study had a 71.2% participation rate (Bao et al. 2016), not a mere 31%. Plus, the participants in the Nurse's Health Study were not incentivized with $50 gift cards at each interview. So ANSIRH's attempt to claim that the Turnaway Study participation rates are in any way similar to the Nurse's Health Study lacks any merit.

In fact, the Turnaway Study's low participation rate does not even fare well in comparison to other ANSRIH abortion clinic sponsored studies. In another ANSRIH study collecting data only from pre-abortion interviews, 72% of women invited to participate did so (M. A. Biggs et al. 2020) well over twice the Turnaway Study participation rate. Notably, this higher rate of participation for a pre-abortion interview was most likely due to the fact that the women who anticipated post-abortion stress were not being asked to participate in a post-abortion interview.

The Sample Disproportionately Excludes Women Who Experienced Pressure to Abort.

Women who feel pressured to abort contrary to their own values and preferences are significantly more likely to attribute negative emotional and psychological reactions to their abortions (Rue et al. 2004; Reardon and Longbons 2023; Reardon, Rafferty, and Longbons 2023; Reardon 2024b).

One retrospective study of patients at health care facilities found that 64% of women with a history of abortion reported being pressured to choose

abortion by others (Rue et al. 2004). Another study of a national population of women 41-45 years of age, part of the Unwanted Abortion Studies, found that 61% of those with a history of abortion reported high levels of pressure to abort and that pressure to abort was strongly correlated to undergoing an abortion contrary to the woman's own moral beliefs or maternal desires, more negative than positive emotions, and a decline in overall mental health (Reardon and Longbons 2023). Pressure to abort was also associated with feeling greater stress in completing a post-abortion survey (Reardon and Longbons 2023).

In sharp contrast to the above studies, only 1.2% of the aborting women in the Turnaway Study reported feeling pressure from others (M. A. Biggs, Gould, and Foster 2013). This suggests that the Turnaway Study's sample severely underrepresents the majority of abortion patients who do report external pressures to choose abortion.

Further confirmation of the non-representative nature of ANSIRH's sample is found in the Unwanted Abortions Studies' retest of one of the Turnaway Study's key variables, "decision rightness." Using a 101-point scale for measuring decision rightness, instead of the yes or no measure employed in the Turnaway Study, the Unwanted Abortions Studies' analyses revealed that the Turnaway Study's results regarding decision rightness most closely align with only the 33% of women who describe their abortions as freely desired and consistent with their own values and preferences (Reardon, Rafferty, and Longbons 2023). All the other groups, who reported pressure to abort contrary to their own preferences, reported less "decision rightness" and higher rates of negative effects. Notably, the value of 33% describing the women who freely chose their abortions is nearly identical to the 31% of the invited women who participated in the Turnaway Study. This suggests that self-censure limited the Turnaway Study population principally to women who freely chose abortions in a manner consistent with their own values and preferences.

Conversely, the Unwanted Abortion Studies had a 91% completion rate, and the percentage of women reporting a history of abortion (22.6%) matched the Guttmacher Institute's estimate for lifetime incidence rates (Jones and Jerman 2017). This suggests that the survey methodology employed in the Unwanted Abortion Studies, which was designed to lower fears of judgment before asking women to reveal their abortion histories (Reardon 2024b), was more likely to be acceptable to a more representative sample of the national population of women who have had abortions.

ANSIRH's Own Attrition Analyses Confirms that there is Turnaway Study Sample Bias.

As previously mentioned, approximately 50% of Turnaway Study respondents dropped out over the course of the five-year biannual interviews.

Notably, the dropout rate was higher among women who reported less relief and happiness at the baseline interview which occurred one week after recruitment at the abortion clinic (Rocca et al. 2015). This is consistent with the expectation that women who have more negative feelings and more stress, when responding to questions about their abortions, are the most likely to opt out.

In yet another Turnaway Study report examining suicidal ideation and thirteen covariates, ANSIRH reported that three of the thirteen covariates were not associated with attrition (M. A. Biggs et al. 2018), suggesting that the other ten covariates and suicidal ideation itself *were* significantly associated with attrition (Reardon 2024a). ANSIRH has not explained why the associations between attrition and these other variables have not been reported and has refused requests for data that would allow for any reanalysis (Reardon and Foster 2024).

Turnaway Study Incentives May Have the Biased Sample Toward Lower Income Women.

ANSIRH reports that the Turnaway Study participation rates were even lower prior to the introduction of $50 gift cards provided to women each time they participated in an interview, a practice which tripled participation rates (Dobkin et al. 2014). This incentive may have disproportionately induced participation among lower income women for whom $50 was a significant reward. In contrast, the Unwanted Abortions Studies were conducted at a cost of less than $4 per completed interview paid to the electronic survey distributor, with only a portion of that amount provided as an incentive to participants (Reardon and Longbons 2023; Reardon 2024b).

Reticent Participants May Have Given False Information.

In ANSIRH's credit history analyses, it is also worth noting that the authors reported that 18.1% of the women agreeing to participate could not be matched to Experian credit reports based on the names, birth year, and addresses provided, and that the failure to match was higher for women who withdrew from the study prior to their first interview, one week after going to the abortion clinic (Miller, Wherry, and Foster 2023, 407). The authors dismiss the significance of the missing data by proposing the theory that these women were simply too young or too poor to have credit records. Yet, given the very high dropout and non-participation rates overall, it may be more likely that many of these women who agreed to participate actually provided false contact information in order to appear compliant or in the hope of obtaining a gift card.

The Turnaway Study Inappropriately Mixed Groups That Obfuscates Findings.

Conceptually, the Turnaway Study is portrayed as an examination of the effects associated with having an abortion or not having an abortion. Specifically, the 1,132 women who initially consented to participate were divided into groups: 304 women who aborted in the first trimester (the Early Abortion Group), 536 women who aborted within two weeks of the gestational limits (the Near Limit Group), and 262 women who were denied abortions because their pregnancies were beyond gestational limits (the Turnaway Group) (Miller, Wherry, and Foster 2023). The dropout rate prior to the first interview one week later was significantly different between groups: 10%, 16% and 21% for the Early Abortion Group, Near Limit Group, and Turnaway Group, respectively (M. A. Biggs et al. 2017). Another 14 women in the Turnaway Group dropped out after the one-week interview, so the outcome of their pregnancies is unknown (Miller, Wherry, and Foster 2023).

Reproductive Histories Were Not Adequately Segregated.

Instead of limiting ANSIRH's credit history study to women with known pregnancy outcomes, the authors inexplicably chose to mix women who (a) had delayed abortions at a different clinic and (b) women who carried to term and (c) women who had natural losses into a single Turnaway Group (Miller, Wherry, and Foster 2023). ANSIRH has acknowledged that at least 50 women in the Turnaway group with known pregnancy outcomes either had late term abortions elsewhere or natural losses, though they have withheld information about how many had which kind of loss.

This admixture of women who carried to term and women who had abortions is both unnecessary and inappropriate. It makes it impossible to separate the effects associated with abortion from the effects associated with carrying a pregnancy to term, which is the entire point of the investigation.

In addition, the Turnaway Group is further adulterated by including women with prior and subsequent abortions in it. ANSRIH has elsewhere revealed that 40% of the Turnaway group had prior histories of abortion (Rocca et al. 2013). In addition, given the high rate of rapid repeat abortions reported elsewhere (Studnicki et al. 2020; Reardon and Craver 2021), it is likely that at least some women had one or more abortions during the five-year period following the index pregnancy.

As a result, ANSIRH's Turnaway Study analyses are actually comparing two groups of women who are known to have had abortions (Early Abortion Group and Near Limit Group) to an admixture of women *with and without* a history of induced abortions (the Turnaway Group). This inappropriate

admixture makes it impossible to separate any effects associated with having an abortion and not having an abortion.

It is well established that women with a history of abortion have higher rates of mental health issues (Studnicki et al. 2023; Reardon 2015; 2018a; Sullins 2016) and remain on public assistance longer (Studnicki et al. 2021; Strahan 1995) than low-income women who carry to term. These issues may make it more difficult for these women to maintain relationships and/or advance their economic well-being. Therefore, if the women in the Turnaway Group who obtained delayed abortions elsewhere had disproportionately more economic differences than women who carried to term, ANSIRH's blending of these two distinct groups (Miller, Wherry, and Foster 2023) into a single group could lead to a misattribution of negative effects associated with abortion to the group of women who did not have abortions.

Obviously, a better study design would have been to simply publish results that either excluded or segregated into a separate subgroup the women in the Turnaway group who had prior or subsequent abortions. Indeed, this option is so obvious that it is impossible for ANSIRH researchers to have missed it. If women who carried to term who had no history of abortion suffered significant economic disadvantages compared to women who had abortions, that finding would have more clearly strengthened their hypothesis that abortion benefits women's economic wellbeing.

But instead, they chose to report results based on an inappropriate admixture of women with and without a history of abortion. This raises the suspicion that they were seeking results which could be portrayed as demonstrating economic harm to the women who carried to term even though an actual analysis of that subgroup, which was withheld from publication, did not support that assertion.

Gestational Ages and Reasons for Abortion Refusal are Inappropriately Mixed.

In ANSIRH's credit history study, the authors conclude that "Our study indicates that laws that impose gestational limits for abortion result in worse financial and economic outcomes for the women who are denied an abortion" (Miller, Wherry, and Foster 2023). This conclusion is not supported by their data and thereby violates STROBE guidelines (Cuschieri 2019).

In fact, the authors' elsewhere reveal that "many in the Turnaway group are denied abortions at a gestational age lower than what is legally allowed" (Miller, Wherry, and Foster 2023, 405). Indeed, examination of their provided "histogram of gestational age at time of abortion receipt or denial" (Figure 1) reveals that 10% of the Turnaway Group were turned away at or before 12 weeks gestation, 22% were turned away at or before 18 weeks of gestation, and

55% were turned away prior to or during the 24th week of gestation. This data suggests that over 50% of patients were turned away for *medical reasons*, not legal reasons.

During the time the Turnaway Study participants were recruited, *Roe v Wade* prohibited any restrictions prior to 24-weeks of gestation that were not strictly directed to protecting women's health. At the same time, most abortion providers have the right and duty to refuse to do abortions that are contraindicated by important medical reasons, such as concurrent raging infections, coercion, intoxication, or the abortion provider's inability to treat complications associated with later term abortions (Baker 1999; Baker and Beresford 2009).

Clearly, ANSIRH could have analyzed their data using only the subset of women who were turned away due to legal restrictions on late term abortions. But they chose not to. That decision eviscerates the value of any of their published findings being applicable to effects associated with laws regulating gestational age limits.

Summary Statements Regarding Turnaway Study Findings are Misleading.

ANSIRH's decision to blend those who aborted elsewhere with those who carried to term under the same label, the Turnaway Group, has hidden significant differences between these two distinctly different groups. For example, in their credit history analysis (Miller, Wherry, and Foster 2023, 403) the authors mislead readers on page 403 when they state: "This body of work [the Turnaway Study published papers] finds that women who were turned away by the abortion clinics experienced worse mental health in the short run (Biggs et al. 2017)." This statement falsely suggests that all women turned away by abortion clinics, on average, experienced adverse mental health effects, at least in the short term. But in fact, a closer reading of the cited reference reveals that there were no differences beyond one week and the differences observed at one week were chiefly limited to a continued presence in anxiety among only the 50 *women still seeking abortions* (OR=2.29; 95% CI 1.39 to 3.18) (M. A. Biggs et al. 2017). At the same point in time, the women in the Turnaway Group who ultimately carried to term actually had *much lower anxiety* scores (OR= 0.57; 95% CI 0.01 to 1.13) compared to all the aborting groups (M. A. Biggs et al. 2017). Arguably, this finding could have been interpreted as a sign of improved mental health among women who are "denied an abortion," provided they do not continue to seek one. Yet this finding is never highlighted.

In another Turnaway Study report ANSIRH revealed that 16% of the women who had abortions reported at least three symptoms of PTSD, of whom 19% attributed their symptoms to their abortions (M. A. Biggs et al. 2016). This finding was largely ignored by ANSIRH, however, based on their claim that

the observed PTSD symptoms were more often attributed to other experiences. But that argument does not diminish the underlying fact that many women reported that their abortions *were* a contributing factor in PTSD symptoms, as is also reported in other studies (Rousset et al. 2011; Rue et al. 2004; Van Rooyenm and Smith 2004) and that abortion, if experienced as a subsequent stressor, may contribute to and aggravate preexisting PTSD symptoms (Kube, Elssner, and Herzog 2023).

In yet another study ANSIRH revealed that the majority of aborting women in the Turnaway Study reported negative feelings: sadness (64%), guilt (53%), regret (41%), and anger (31%), but in every case these negative emotions were lower among the Turnaway group who carried to term (Rocca et al. 2013).

In yet another study, ANSIRH revealed that there were higher rates of suicidal ideation among the women who had abortions compared to those who carried to term (M. A. Biggs et al. 2018). But the significance of this finding was concealed through an unjustifiably complex multivariate regression which inflated the confidence intervals in such a manner so as to allow the authors to assert that there were no statistically significant differences, at least in their "adjusted" results (Reardon 2024a).

Typically, ANSRIH has hidden the fact that negative reactions are common behind the single data point claim that "the most common reaction to abortion is relief," which was reported by 81% of the aborting women included in the Turnaway Study (Rocca et al. 2013). But they fail to mention that their measure of relief encompasses a wide range of meanings. It includes relief that a dreaded medical procedure is over. Relief that one's partner will stop pressuring for an abortion. Relief that one's parents won't learn of the pregnancy. Relief that one won't need to find a bigger house. Relief that one can simply focus on something else in the future.

In short, nearly all women will experience some form of relief when an abortion is over. This is precisely because abortion is almost always both a stress releaser and a stress creator (Speckhard and Rue 1992). It typically exchanges the release of immediate stresses for a set of new stressors. This is why most women who report positive emotions also report concurrent negative emotions (Reardon et al. 2023; Reardon 2018a). In addition, when women are provided with a wide range of emotions associated with abortion, relief is not even in the top five. In a self-reported grading of the most prominent feelings experienced by abortion, guilt, grief, depression, and anxiety are rated more highly than relief (Reardon 2024b).

In summary, readers of the Turnaway Study credit history study were misled by the statement that the Turnaway Study had already proven that "women who were turned away by the abortion clinics experienced worse mental health in the short run." This is a distortion of what the body of

Turnaway Study papers has actually revealed. Negative emotions were only prominent among the 50 women in the Turnaway group who continued to seek and found abortions elsewhere. Indeed, ANSIRH's own data shows that the majority of the women in the Turnaway group actually experienced abortion denial as a welcomed reprieve, as will be discussed in the next section.

The Classification of "Women Who Are Denied Abortions" is Misleading.

While not revealed in the credit history analysis, the Turnaway Study's principal investigator has elsewhere admitted that the women in the Turnaway group who carried to term were overwhelmingly happy and relieved not to have had abortions, even as soon as just one week after being turned away (Foster 2020, 121,204). Foster also admits her surprise at being unable to prove there are any mental health harms associated with being denied an abortion, writing:

> "I expected that raising a child one wasn't planning to have might be associated with depression or anxiety. But this is not what I found over the long run. *Carrying an unwanted pregnancy to term was not associated with mental health harm.* Women are resilient to the experience of giving birth following an unwanted pregnancy, at least in terms of their mental health."

(Foster 2020, 109) (emphasis added) Considering the aforementioned research, revealing that nearly 70% of abortions are sought contrary to women's own preferences (Reardon, Rafferty, and Longbons 2023), it seems likely that the immediate reduction in anxiety experienced by at least some of those who were turned away was because they had been *spared unwanted abortions.*
Even ANSIRH's own research reveals that less than 42% of women seeking abortions characterize their pregnancies as "unwanted" (M. A. Biggs et al. 2020). For the others, the pregnancy is untimely or even described as "wanted". In addition, analyses of the National Longitudinal Study of Adolescent to Adult Health found that 20% of women admitting a history of abortion reported that the aborted pregnancy was wanted (Sullins 2019).

Many women who fear being forced into unwanted abortions will conceal their pregnancies until they anticipate it will be "too late" for the abortion to be performed (Burke and Reardon 2007). In such cases, women whose concealed pregnancies are finally revealed or discovered may go to the abortion clinic for a late term abortion only at the behest of a pressuring partner or parent. In these cases, the women may be hoping the abortion provider will agree it is too late to do the abortion. If this scenario applied to any of the Turnaway Group women who gave birth, this would help to explain the high levels of happiness and relief they reported after being spared unwanted abortions (Foster 2020).

The Study Design is Flawed and Does Not Test the Uunderlying Hypothesis.

Notably the conceptual design of ANSIRH's credit history study (Miller, Wherry, and Foster 2023) is also fundamentally flawed. The underlying hypothesis is that women compelled to raise unwanted children who might otherwise have been aborted suffer economic hardships. But the authors do not investigate, or at least report, on the participant's initial and transitional assessment of their pregnancies' wantedness.

As previously discussed, only a fraction of women seeking an abortion consider their pregnancies to be unwanted (M. A. Biggs et al. 2020; Reardon 2018a; Sullins 2019; Rue et al. 2004). Many feel compelled to submit to unwanted abortions due to external pressures (Burke and Reardon 2007; Reardon and Longbons 2023). Moreover, initially unwanted, unplanned, or untimely pregnancies often quickly transform into *welcomed pregnancies*. This last point is verified by ANSIRH's own finding that six months after going to the abortion clinic, 88% of the women "denied" an abortion were happy they had not had one, and by the end of the five-year study, only 4% still said they wished they could have had an abortion (Foster 2020, 204). Indeed, a significant percentage of those who carried to term (estimated to be around 50% or more) reported they were glad they didn't have an abortion at their first interview, one week after being recruited at the abortion clinic (Rocca et al. 2013).

From this perspective, the Turnaway Group who gave birth should really be framed as women who were "spared unwanted abortions" rather than as women who were "denied abortions." Better yet, the authors could and should have segregated their results between the women who are glad they did not have abortions and those who continued to believe abortion would have been their better option.

In short, ANSIRH's credit history study truly tells us nothing about how credit data varied among the 4% in the Turnaway group who *actually felt that they had been denied abortions* that may have made their lives better.

The Study Lacked an Appropriate Control Group.

Comparing the credit history of the Turnaway Group to women who had abortions is inappropriate if the goal is to investigate economic markers associated with delivering a child that was at risk of abortion.

Clearly, family size impacts financial obligations. The authors observed only a few differences between the credit reports of the Near Limit and Turnaway groups. These mostly had to do with increased debt, which is most likely explained by the fact that the Turnaway group, on average, had more expenses related to having one more child.

Therefore, a better designed investigation would have compared the Turnaway birth group to a psychosocial and economically matched control group of women who carried planned pregnancies to term and never considered abortion. That comparison would at least have helped to isolate effects associated with unplanned pregnancies that are either carried to term or aborted. In contrast, the Turnaway Study design offers no such insights.

Most of the Credit History Results Were Not Statistically Significant, and Gross Exaggerations Were Applied to the Few That Were.

Despite the claims of the abstract and summary conclusions, a careful reading of the Turnaway Study credit history analyses reveals that most of the metrics investigated did not significantly vary between the study groups (Miller, Wherry, and Foster 2023, 412). Specifically, as seen in Table 2 of the report, ten outcome measures were combined into three summary index scores: debt delinquency, access to credit, and consumer borrowing levels.

For two of the three indexes ("credit access" and "borrowing") the authors admit that they found no statistically significant differences. Small, but statistically significant, differences were observed in the delinquency index, however, leading the authors to relabel the "delinquency outcomes" index as the "financial distress" index.

The Authors' Definition of Their Financial Distress Index is Misleading and Double Penalized the Same Debts to Inflate Statistical Differences.

Digging into the details, the authors' delinquency outcomes / financial distress index was defined as including (1) any elevation in the amount of debt paid to a collection agency, (2) any debt 30 days or more past due, (3) the number of court appearances identified in public records reported to Experian, and (4) the percentage of the group with credit scores below 600 (the threshold for having subprime credit) (Miller, Wherry, and Foster 2023, 410). The key question this "financial distress" index raises is this: how much confidence can we have in the authors' assertion that this combination of four equally weighted metrics are a meaningful measure of financial distress?

As argued below, it is my view that this index, both in its development and naming, was nothing more than a post facto construction that is, in fact, a poor measure of financial distress. The first variable in this index, reports of payments made to collection agencies, is truly a sign of debt. But it may also be a sign of improved financial health if it indicates the payor finally has funds to pay a previously unpaid bill. So, on its own, it is not properly recharacterized as "financial distress." It is a metric of debt.

The second variable, bills 30 days overdue is also a sign of debt. But it can also reflect disputed payments, forgetfulness, obstinacy, acceptance of debt to be paid overtime, or gaming of the system. But whatever the circumstances, wouldn't it be more accurate to characterize this debt as simply overdue debt rather than "financial distress?"

The authors' choices for what should be included in this index really become suspicious when we examine the third variable in their financial distress index: the number of court records associated with each woman. Regarding this variable, the authors admit that Experian doesn't report any specifics regarding the court cases. But despite the huge cloud of ignorance surrounding this metric, the authors choose to include it as an *equally weighted measure* of "delinquency" and "financial distress" because, they argue, some of these cases would include "bankruptcies, tax liens, or evictions" (Miller, Wherry, and Foster 2023, 410). Yet, some of these cases might also include civil suits to collect child support, reimbursements for medical expenses related to childbirth, or any number of other issues.

Moreover, to the degree the authors are right and some of these cases really are related to financial debts, by including these case counts into a contrived index that *already includes debt collections* and *past due bills* the authors created an index number that penalizes delinquent payors twice, once for the collected debt and a second time for its related court case.

Similarly, the fourth index variable, a subprime credit score, is also known to be closely correlated to a history of unpaid debts. So, once again, inclusion of this variable as an equal weight factor in in a four-factor constructed index is repetitive and inflationary. Subprime credit scores are not independent of indebtedness. Therefore, its inclusion only serves to double penalize women who have a downgraded credit score due to their delinquent debts.

In short, while it may have been reasonable to include the first two elements of debt delinquency (renamed as "financial distress") into an outstanding debt index, the combination of the four index variables used was duplicative and unwarranted. More importantly, is there any precedent for using these four variables as a measure of financial distress? No. This is simply a label the authors prefer to use because "financial distress" sounds more ominous than "elevated debt" much less "increased child related expenses."

Differences in the Delinquency Index are Exaggerated.

Given their disappointment in failing to find any differences in credit access and borrowing indices, the authors are left with only the finding of a small increase in debt of "about one-tenth of a standard deviation among the Turnaway group in the postperiod" (Miller, Wherry, and Foster 2023, 417). Yet this small difference is quickly transmuted into the proclamation that they had found "a *jump* in markers of financial distress in the Turnaway group"

(emphasis added) (Miller, Wherry, and Foster 2023, 415) and their repeated exaggeration of having found "*strong evidence* that being denied an abortion had *large effects* on markers of *financial distress*" (emphasis added, pages 420, 429 and in the abstract). These claims are both unwarranted and misleading, for many reasons.

First, as discussed above, the Turnaway Study sample is non-random, non-representative and tainted by the admixture of women with a history of abortion in both the Near Limits Group and Turnaway Group. Such a convenience sample cannot provide "strong evidence" regarding any generalizable conclusions. Secondly, statistical associations, especially weak ones, are not proof of a direct causal connection. Any differences found cannot be elevated to "strong evidence" simply because differences are statistically significant at a 95% confidence interval. Even in better studies, such differences should only be characterized as "may increase the likelihood of" the observed outcome. Thirdly, the few data points grouped together as "financial distress" are at best markers of debt, not comprehensive measures of "financial distress." Fourthly, and most importantly, the authors failed to provide an objective measure of effect size that would justify their characterization of the observed differences as being "large effects."

Specifically, the normal convention for describing the degree of effects is to report the Cohen's d statistic (the difference between the group means divided by the pooled standard deviation of the two groups). Conventionally, a Cohen's d value of 0.8 or larger is described as a "large effect" and a value below 0.2 is a "very small effect" (Sullivan and Feinn 2012; Sawilowsky 2009). While the authors of this credit history report chose not to report the Cohen's d values, we can calculate this measure of effect size using the mean and standard deviations reported in Table 2 and the group sizes from Table 1: Near Limit (n=333) and Turnaway (n=150).

Table 1. Cohen's d measure of effect size for the four components of the "financial distress index"

	Cohen's d	Conventional description
Collections	0.11	Very small effect
Amount past due	0.07	Very small effect
Public records	0.10	Very small effect
Subprime credit score	0.04	Very small effect

As seen in these calculations, all of the effect sizes should have been classified as "very small."

The lack of significant differences is also visible in the effect size graphs shown in Figure 3 of the Turnaway Study report. It reveals that the lowest

upper limit of the 95% confidence intervals prior to the index pregnancy overlap the lower 95% confidence limit at every time following the index pregnancy. This overlap signifies that the differences *are not statistically significant*, at least at the 95% confidence level.

In summary, while the authors may have had enough statistical power to identify differences in these variables that are statistically associated with "abortion denial," describing these differences as "strong evidence" of a "very large" effect was grossly misleading.

The Authors' Assessment of Financial Distress is Contradicted by the Turnaway Group's Own Self Report.

A critical reading of the reported results reveals additional exaggerations and misrepresentations. Specifically, the authors report that the past due debt of the Turnaway group rose by an average of $1,750 (Miller, Wherry, and Foster 2023, 417). But this should clearly be interpreted in light of the fact that most of these women had more hospital expenses related to childbearing and another child to clothe and feed. Indeed, if the total household debt were divided by the number of household members, the total per person debt might be lower, at least in many cases.

Most importantly, there was no difference between the two groups in regard to women feeling they did not have enough money "most of the time."(Miller, Wherry, and Foster 2023, 427) In other words, according to the Turnaway Group's own self-assessment, they were not experiencing higher rates of "financial distress," at least as measured by the metric of feeling a lack of enough money. In addition, as discussed above, the vast majority of the women in the Turnaway Group who gave birth reported they were glad their welcomed child was not aborted (Miller, Wherry, and Foster 2023, 121,204). Given that context, wouldn't the increased debt these women faced be more accurately described as simply evidence of an increase in household expenses following the birth of a welcomed child rather than a terrifying increase in "financial distress"?

Finally, the argument that the authors have mischaracterized these increased expenses as "financial distress" is underscored by their own admission that the Turnaway group did not experience an increase in past due collections (Miller, Wherry, and Foster 2023, 418). The new mothers were in fact taking on more debt, but they were also mostly getting by and, on average, their finances were gradually improving.

In short, while the authors admit that most of the differences in the outcome variables they investigated were not statistically significant, they repeatedly and willfully describe the evidence of increased household expenses (most likely due to the addition of a welcomed child into the household) as "*strong evidence* that being denied an abortion had *large effects* on markers of

financial distress" (emphasis added, page 420, 429 and in the abstract), despite their own evidence that the women who carried to term did not perceive themselves as more financially distressed.

"The Economic Consequences of Being Denied an Abortion" is a Misleading Title.

The assertion that ANSIRH's credit history report measures the "economic consequences" associated with having or not having an abortion is overly broad and strictly untrue. In fact, the study measures only statistical associations related to a few credit record variables. Association is not causation, and nothing in the study remotely establishes that any of the observed differences are wholly, or even partially, direct consequences of being "denied an abortion."

Nor are all economic associations investigated. For example, most children grow into productive tax paying adults. But those economic consequences are not included. Also, some new parents accelerate their efforts to gain educational and career advancements in order to better provide for their children. But the lifetime effects of these economic consequences are not investigated, either.

Instead, what the authors actually investigated are only a few credit score metrics which they then imbue with exaggerated importance. An accurate title for the paper would have been: "A Few Credit Score Metrics Associated with a Non-Representative, Convenience Sample of Women Turned Away from Abortion Clinics." But this title would not have lent itself to exaggeration.

The Interpretation of Results Does Not Follow STROBE Guidelines.

As previously noted, the authors also failed to comply with the STROBE guidance regarding interpretation of the results: "Give a *cautious* overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence" (emphasis added). Most of the limitations on the data described above are never mentioned. Nor can the interpretation of the results be characterized as "cautious." Instead, the authors are overreaching in their claim that they have produced "*strong evidence* that being denied an abortion had *large effects* on markers of *financial distress*" (Miller, Wherry, and Foster 2023, 420) (emphasis added). This is subsequently expanded into: "We find evidence that being denied an abortion has *large* and *persistent negative effects* on a woman's *financial well-being*" (Miller, Wherry, and Foster 2023, 429) (emphasis added).

In fact, only well-informed and critical readers will recognize that (a) the sample of women interviewed is non-representative, (b) most of the variables for which the authors expected differences were not significantly different,

(c) for the few variables for which there were observed differences, the effect size was very small, declined rapidly, and was limited to measures of debt (which most likely was due to increased expenses related to having a new and welcomed child in their households), (d) the authors' definition of "financial distress" (subsequently mutated into "financial well-being") is overly broad and deliberately chosen to exaggerate the readers' impression of the small and minor differences actually observed, and (e) the claimed discovery of financial distress was contradicted by the birthing groups' own self reports which revealed no increased perception of insufficient monies.

In addition, the authors discuss abortion laws at least 22 times, leading to their conclusion that "Our study indicates that laws that impose gestational limits for abortion result in worse financial and economic outcomes for the women who are denied an abortion" (Miller, Wherry, and Foster 2023, 431). But as noted above, their own data reveals that 10% of the Turnaway Group were turned away prior to 12 weeks gestation and over 22% were turned away prior to 18 weeks of gestation and 55% prior to 24 weeks gestation, which was the earliest limit allowed by *Roe v Wade* for laws to restrict access to abortion. So, it would appear that nearly half of the women were turned away for medical reasons imposed by their abortion providers, not state restrictions. Moreover, the authors fail to identify which of these women went on to get abortions elsewhere. While the authors could have used the subset of only those women who were turned away after 24 weeks to test their hypothesis that laws restricting abortion were associated with differences in credit history data, they did not provide such analyses. Therefore, the author's attempt to assert that their findings demonstrate economic harm to women who are "denied an abortion" due to state laws is overreaching and inappropriate.

Unethical Collection of Human Data Without Consent of the Subjects.

For all the reasons discussed above, findings from the Turnaway Study papers, and the credit history analysis in particular, are unreliable and overstated. They can truly tell us nothing that is applicable to the general population of women who have had or are considering abortions. For these reasons alone, publishers should issue expressions of concern and require ANSIRH to revise the papers to more fully disclose the limitations of their dataset and to narrow their discussion of findings to more cautiously interpret their results in a manner that more accurately reflects the limits of their data, alternative explanations, and the body of research revealing conflicting results.

In regard to the Turnaway Study credit history analyses, however, in my view an expression of concern would be inadequate. Unless the authors can thoroughly document that all Turnaway Study participants, including those

who dropped out prior to the first interview, consented to having their personal identifying information used to retrieve their credit histories and court records, the paper should clearly be retracted due to the authors' unethical collection of data without their subjects' full informed consent (Barbour et al. 2009)

I have requested such documentation from the authors (Reardon and Foster 2024), but have received no additional response. My reasons for believing that the subjects did not give consent are strong, and likely irrefutable. Specifically, the Turnaway Study's solicitation of volunteers among women seeking abortions occurred between January 2008 and December 2010, with interviews conducted by telephone one week after seeking an abortion and every six months thereafter for up to five years, meaning the last interviews were conducted in 2015 (Foster 2020). Yet, in Foster's book, *The Turnaway Study* (Foster 2020, 178), she states that the idea to link identifying data of the study participants with Experian credit reports was first brought to her attention in 2018 by economist Sarah Miller, "an economist I had never met before."

Therefore, it is clear that the consent forms signed by the participants did not include consent to access their credit reports or the court records accessed by Experian, either at the time of their enrollment between 2008 and 2010. Nor could the consent forms have disclosed the fact that accessing their credit scores might cause some negative impact on their credit scores.

It is also clear that this 2018 plan to draw information from Experian's Credit Report Archives could not have been submitted to, much less approved by, the Committee for Human Research at the University of California, San Francisco at the time the study was first conceived and approved. It is possible that a subsequent request to use the research subjects' personally identifying information to access their credit histories without obtaining further consent from the women was submitted to and approved by the Committee on Human Research. But this is not a published claim by the authors, and is has certainly not been documented, despite requests for such documentation (Reardon and Foster 2024). Moreover, it seems highly unlikely that an institutional review board would approve collection of credit history data using the personally identifying information provided over ten years earlier without participants being offered an opportunity to approve or disapprove such data collection.

The authors have also refused to provide a copy of the informed consent form signed by participants, which would indicate the range of information participants agreed to disclose (Reardon and Foster 2024). Normally, consent to participate in interviews is limited to only the answers participants offer at the time the questions are asked. In other words, consent is conditional and can be withdrawn at any time.

It would be uncommon to ask participants in a survey to also agree to grant the researchers with a blanket waiver to use their names, addresses and birth dates to collect additional data from third party sources, such as credit

records, criminal records, medical records, or other public records. One would certainly expect that requesting such a grant to link interview data to other databases would result in a larger number of eligible participants refusing to agree to be interviewed. If this was the case, perhaps this would help to further explain the Turnaway Study's very low participation rate. But if such expansive liberties were granted by the signed consent forms, surely ANSIRH would share proof of this. Instead, in the only publicly accessible copy of the "Turnaway Study Operating Procedures Manual," deposited with the American Medical Association (Gould, Barar, and Foster 2016), both the consent forms and survey questions have been redacted, without explanation or justification.

In addition, it is notable that of the 1,132 women who told abortion clinic personnel that they agreed to be contacted by ANSIRH to answer questions about their experience, 176 (15.5%) changed their minds and refused to complete even the first interview, and approximately 50% dropped out, or were lost to follow up prior to the 2015 (Reardon 2018b), three years before the credit history study was conceived. Yet despite these women's explicit or implicit withdrawal from continued participation in the study, credit history reports were pulled for all 1,132 women who signed the undisclosed consent form at the time of their enrollment, even if they never actually participated in even a single interview.

The Authors' Claims Regarding Data Privacy are Unlikely, Unrealistic, and Self-Contradictory.

In the "Additional Materials, Replication Package" provided by the authors (Miller, Wherry, and Foster, n.d.; 2023), the ReadMe.pdf file contains a data availability statement which declares that "The consent form signed by the Turnaway study participants also states that the data will only be used within the Turnaway research team and cannot be posted publicly." This statement is either untrue or violated at whim.

As described above, the consent form itself has been withheld from public scrutiny. So, its contents and provisions cannot be verified. Moreover, Sara Miller was not part of the Turnaway research team at the time any of the data was collected. Yet at least some of that data was shared with Miller in violation of the asserted policy.

In addition, the suggestion that participants did not want to have non-identifying data shared with other researchers is not reasonable. While surely participants would deserve and want a guarantee that *identifying information* would not be shared, it is not reasonable that they would insist on withholding all other non-identifying data. Indeed, most participants in scientific research want their data to be used as widely as possible to generate the most results possible. Most would also likely agree that results based on the data they

provide should be subject to re-analysis and verification by other researchers. In other words, most people are pro-science. They want their privacy protected, but they also want the data they provide to have maximized value. Therefore, there is no reasonable justification for ANSIRH to have insisted on participants signing a consent form placing an unlimited embargo on all non-identifying data.

If in fact the consent form signed by participants explicitly stated that every data point collected would be restricted solely to use by ANSIRH, that restriction in itself may have introduced additional self-selection bias. Those women who recognized that their agreement to participate gave sole proprietorship of their data to an abortion advocacy group may have been more likely to refuse to participate.

Most importantly, restrictions on data sharing (if in fact it was in the consent form at all) were clearly conceived and written up, not by the study participants, but by ANSIRH. Putting such restrictions into the consent form would only serve ANSIRH's proprietary interests (not those of the participants). In short, if any data sharing restrictions truly exist in ANSIRH's undisclosed consent form, they exist solely to give ANSIRH an excuse to deny critics access to the very same data that may expose weaknesses or inconsistencies in the interpretations of ANSIRH's results.

Finally, it is important to note that in the heavily redacted copy of the "Turnaway Study Operating Procedures Manual" (Gould, Barar, and Foster 2016, 72), there is a provision which states: "Permission to utilize Turnaway Study data and publish analyses can only be granted by the Study's PI, Dr. Diana Foster. Interested researchers must submit a proposal to Dr. Foster prior to starting any analysis projects." This provision for data sharing is clearly what Foster would rely upon when she provided the study participants' personal identifying information to Miller and Experian. But it also contradicts the claim that the non-identifying information cannot be shared with other researchers.

Based on this evidence from the operations manual, the data sharing statement "The consent form signed by the Turnaway study participants also states that the data will only be used within the Turnaway research team and cannot be posted publicly," is clearly inaccurate. It should read: "Dr. Foster reserves the right to refuse to share any and all data with anyone who fails to convince her that they share her goals and objectives."

In short, either (1) the consent form included provisions that forbad sharing data with Miller and Experian, or (2) the authors have lied to journal editors and readers about what was really in their undisclosed consent forms. There is no third alternative.

The Turnaway Study is Unreliable Because it is Unverifiable and Nonreplicable.

Good science relies upon findings being verifiable and replicable. This is why data sharing of non-identifiable data is not only a common practice it is the preferred practice, under the FAIR principles guiding reuse of scholarly data (Wilkinson et al. 2016), the American Psychological Association's ethical principles (American Psychological Association 2010), and the American Economic Association's (AEA) own data sharing requirements.[1] ANSIRH's evasion of data sharing requirements is a violation of these standards and has rendered their Turnaway Study finding unverifiable and nonreplicable.

The AEA adheres to the Data and Code Availability Standard[2] which allows withholding of personally identifying data, but otherwise requires posting of a replication package that "allows for replication by researchers unconnected to the original parties." It also requires "Raw data used in the research (primary data collected by the author and secondary data not otherwise available) is made publicly accessible." In addition, "survey instruments or experiment instructions as well as details on subject selection are included."

In other words, ANSIRH should have provided all the data it used so their own findings can be verified and further investigated, plus all survey instruments fully documenting all questions that were asked and in what order. The latter is necessary to allow investigation regarding how the ordering of questions may affect results and to allow replication of the study using a different study population. But as previously mentioned, the only publicly posted copy of the "Turnaway Study Operating Procedures Manual" (Gould, Barar, and Foster 2016), is heavily redacted. All survey interviews, originally contained in appendices K, S and T, were among the materials redacted. Therefore, these redactions make it impossible to replicate the study design.

Also, it is clear from the data sharing statement in the same procedures manual that Foster could have used her authority to share data with researchers who are not connected with an abortion advocacy group (Gould, Barar, and Foster 2016, 72). But she chooses not to. Therefore, the data availability statement the authors provided to AES (Miller, Wherry, and Foster, n.d.) hides the fact that Foster has the authority to make the data generally available but has chosen to withhold it, using the undisclosed consent form as an excuse to prevent reanalyzes by researchers who may not share ANSIRH's political objectives.

1 The American Economic Associations's data code policy is found here: https://www.aeaweb.org/journals/data/data-code-policy

2 The American Economic Association endorses the DCAS, the Data and Code Availability Standard v1.0 posted here: https://datacodestandard.org/

In the AES data availability statement, the authors also assert that "The data use agreement with Experian precludes posting these data publicly" (Miller, Wherry, and Foster 2023). But that claim, too, is suspect. While certainly Experian would require withholding of personally identifying information, it is unlikely Experian, if asked, would have opposed the posting of recoded data covering 10 credit card metrics for a mere 483 women for study replication purposes. This data would have no additional economic value to Experian, would pose no threats to consumer privacy, would help to advance science, and would help to demonstrate the potential value of buying Experian data to other social scientists. This presumption that ANSIRH's researchers are misreading Experian's data license would be dispelled if they provided documentation that they made efforts to obtain Experian's permission to include data in the replication package which were refused. Otherwise, it seems more likely that the authors did not seek any clarification, much less permission from Experian. Instead, it seems most likely they decided that the user license could be turned into an excuse for withholding data, which is obviously their preference.

In short, instead of offering a real replication package, as required by the publisher, the authors offered only thinly veiled excuses for withholding the data they do not want to expose to any further examination. This makes it impossible to check how the results would have been different if weaknesses in the original study were investigated in a more careful analysis. For example, skeptics cannot investigate how the debt metrics among the Turnaway group varied between those who had abortions and those who carried to term. Nor can a reanalysis be done to examined if the effects varied among women who had prior or subsequent abortions. Nor can a reanalysis be done limiting the groups to those women who sought abortions only after 24 weeks of gestation, which would be the only way to test how state laws on gestational limits might have affected the credit history metrics.

This study is also nonreplicable because of the divisive politics surrounding the abortion issue. Clearly, the abortion clinics that cooperated with ANSIRH did so only because they were confident the researchers shared their pro-abortion biases. This makes it impossible for researchers who take a more critical view of abortion to gather similar information from women at the time they are seeking or have recently undergone an abortion.

That barrier to data collection makes ANSIRH's withholding of data even more significant. If only a narrow set of biased, ideologically aligned researchers have access to obtaining a data through the cooperation of abortion providers, it is even more important for that data to be accessible for review, verification and interpretation of results by researchers who may have different insights and biases.

Anonymous Funding Sources and Related Conflicts of Interest.

The authors state "This study was supported by research and institutional grants from the Wallace Alexander Gerbode Foundation, the David and Lucile Packard Foundation, The William and Flora Hewlett Foundation, and an anonymous foundation" (Miller, Wherry, and Foster 2023, 1). Since when are authors allowed to conceal funding behind "an anonymous foundation"? The whole point of requiring disclosure of funding is to help readers identify the potential influences and goals of funding partners.

As previously noted, Warren Buffett's Susan Thompson Buffett Foundation is a major ANSIRH supporter, is deeply engaged in population control efforts, and is well known for its desire to maintain a low public profile (Ludwig 2020; Philanthropy Roundtable 2023; Harlow 2009; Martin 2016; Callahan 2014; Weise 2015). Perhaps it is the anonymous foundation. In any event, all three of the named funding sources are also deeply involved in supporting population control via abortion (Martin 2016; Brathwaite and Uchida 2023; Influence Watch 2024; Levintova 2023). This includes investments in Danco, the manufacturer of the abortion pill, mifepristone, at least by the Packard Foundation (Novielli 2019; Bernstein 2000; Levintova 2023) and perhaps others funding this study.

In other words, the funders of this study may have a vested interest in promoting the claim that abortion benefits women's economic well-being, even if the evidence collected does not actually support that view. Conversely, in the face of disappointing results, ANSIRH researchers who received funds based on the expectation that their findings will help to prove economic harm from being denied abortions may felt obligated to exaggerate their findings in a manner designed to reflect those expected results.

In any event, the funding sources for this study have direct and indirect financial interests in abortion and the abortion pill manufacturer and distributor. These interests are not adequately disclosed. And crediting support to an unnamed foundation is simply an evasion of the ethical obligation to accurately report funding sources.

The *American Economic Journal: Economic Policy* Declines Publication of Criticism.

It is worth noting that a summary of the above issues was conveyed to the editor of the *American Economic Journal: Economic Policy* (AESEP). The editor declined to investigate the issue of lack of informed consent but invited me to write a commentary critiquing the paper for the journal's consideration. The result was this paper, excluding this subsection, which was submitted in April of 2024 and languished there until July of 2024, at which point I received a

rejection of the commentary on the basis that it "does not represent a significant enough contribution" to the literature.

The editor also wrote: "Lastly, both the referee and I agree that it is unfortunate that the researchers did not explicitly ask for consent to link their Experian credit data. The economics profession can do better in terms of informed consent and this is a subject of active discussion within the American Economic Association."

To my knowledge, the journal has not published any notice of concern about this "unfortunate" business. Nor, to my knowledge, has the editor requested verification of the ANSIRH authors' claims regarding the Turnaway Study consent form and data sharing policies. At the very least, at the time of this submission to Issues in Law and Medicine, the journal has failed to post a notice alongside the ANSIRH provided replication package notifying readers of any the concerns raised in my query to the editor.

Summary Statement

The Turnaway Study's principal investigator, Foster, has called for the retraction of abortion related studies that may have unreliable results (Littell et al. 2024). By that same standard, *every* Turnaway Study publication should be retracted.

Considering the limitations discussed above, the Turnaway Study is clearly unreliable. It uses a nonrandom, nonrepresentative convenience sample that suffers from a high degree of self-censure and clearly underrepresents the majority of women who feel pressured to abort contrary to their own values and preferences.

In addition, the three subpopulations used in the Turnaway Study analyses are inappropriately mixed. This results in analyses that obscure rather than clarify differences between those who had abortions and those who carried to term. In at least some cases, these obfuscations have been summarized in a manner that implied negative effects were observed among all the women who were "denied abortions" when in fact the negative outcomes were only applicable to the women whose abortions were only delayed because of the first abortion clinics own rules. While this convenience sample may have been useful for testing survey instruments, or developing hypotheses that can be tested with better samples in the future, it is not suited for drawing *any* general conclusions. Despite these limitations, which are never adequately disclosed, ANSIRH repeatedly selectively reports, misrepresents, and exaggerates the significance of their findings.

At the very least, publishers of the various Turnaway Study analyses should require the authors to publish corrigendums fully disclosing all the limitations discussed above and to provide more cautious interpretations and discussions of their results per STROBE guidelines (Cuschieri 2019). A better

solution, given the inability of this weak data set to justify the conclusions ANSIRH has proclaimed as verified scientific truths (ANSIRH 2019; Foster 2020), is to retract these papers. Afterall, ANSIRH staff have themselves called for a retraction of abortion research that may be unreliable, arguing "Allowing inaccurate information to remain in the scientific record can have lasting and deleterious effects on law, public policy, clinical practice, and public health" (Littell et al. 2024).

Specifically in regard to the credit history paper, unless the authors provide the publisher and public with evidence that the signed informed consent forms included a waiver to allow identifying information to be used to obtain credit report data, the AESEP credit history paper (Miller, Wherry, and Foster,. 2023) should also be retracted per COPE guidelines due to its unethical use of human data without the full informed consent of its subjects (Barbour et al. 2009).

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Counseling the Abortion-Vulnerable Patient *

ABSTRACT: Induced abortion is defined as a procedure done to end a pregnancy in such a manner as to avoid a live birth ie intentional feticide. Many physicians will encounter patients considering intentional feticide (induced abortion) for various reasons. Such interactions present an opportunity not only to create a lasting bond with the patient, but also to open doors for her to explore possibilities she may not have considered, and thereby enable her to make a life-affirming decision. Given the importance of offering accurate information about induced abortion and continuation of pregnancy, this Guideline provides guidance and resources for the pro-life physician encountering an abortion-vulnerable patient.

Background

Epidemiology

According to the Centers for Disease Control, the percentage of US pregnancies that were unintended declined from 43.3% in 2010 to 41.6% in 2019. Larger percentage declines in unintended pregnancy rates were seen among younger age groups, and those patterns were mirrored for pregnancy rates overall, declining by 52% for teenagers aged 15–19.[1] By 2011 unintended pregnancy rates[2] were highest among those who:

- Were 18 to 24 years of age.
- Had low income.
- Had not completed high school.
- Were non-Hispanic black.
- Never married, not cohabiting.

* AAPLOG Practice Guideline. This dociment was developed by authors on the Research Committee. Practice Guidelines are evidence-based documents informing pro-life prividers with high-quality, peer-reviewed literature.

Stulberg et al reported in 2011 that 97% of practicing obstetrician-gynecologists in the United States encounter patients seeking intentional feticide (induced abortion).[3] Finer et al (Guttmacher Institute) reported:

> ... the two most common reasons (for having an abortion) were "having a baby would dramatically change my life" and "I can't afford a baby now" ... A large proportion of women cited relationship problems or a desire to avoid single motherhood (48%). Nearly four in 10 indicated that they had completed their childbearing, and almost one-third said they were not ready to have a child. Women also cited possible problems affecting the health of the fetus or concerns about their own health (13% and 12%, respectively).[4]

Definitions

The following definitions were modified from *Excellence of Care: Standards of Care for Providing Sonograms and Other Medical Services in a Pregnancy Medical Clinic*.[5]

The *abortion-vulnerable* patient is one who by continuing her pregnancy faces challenges and problems that she may feel unprepared or unable to manage. She may tell her physician that she is considering induced abortion, may feel that abortion is her only or best option, or simply may not have ruled out induced abortion. She may have a medical condition affecting her decision-making.

An *abortion-minded* patient is one who is planning to obtain an induced abortion or who has already initiated the process by making an appointment with an abortion clinic or having had laminaria placed or having taken abortion inducing drugs or herbs.

Although this Practice Guideline uses primarily the term "abortion-vulnerable" for the sake of clarity, the same counseling concepts and techniques may be applied as needed for an abortion-minded patient who is open to having a conversation.

Challenges

The practicing Obstetrician/Gynecologist (OB/GYN) faces several challenges in counseling abortion-vulnerable patients: Clinic time may be limited and patients may require more counseling time than is scheduled.[6-9] Some physicians may feel discomfort, or perhaps an inner conflict stemming from a desire not to condemn or alienate the patient while at the same time feeling an obligation to protect the life of the unborn. Patients themselves may feel uncomfortable discussing their circumstances because of coercion from partner or family, worries about school or finances.

Ethical Responsibilities

In counseling the abortion-vulnerable patient, fundamental values to consider are respect for the dignity of human life and the duty to alleviate suffering and distress by working with community resources to help meet needs and to eliminate obstacles making life-affirming choices as easy as possible for the patient. Previously established ethical systems can be applied to counseling the abortion-vulnerable patient.[10-12]

- *Fidelity* to the patient involves protection of confidentiality, a duty to provide accurate information concerning their health and that of their preborn child, and a commitment to remain available to help and support the patient as she works through her decisions.
- *Autonomy* means that the patient ultimately decides the intended outcome of her pregnancy. The physician counseling her aims to improve her ability to make a well-informed decision. It is important for a pro-life OB/GYN to represent all data honestly.
- *Beneficence* moves the physician to act for the benefit of both our maternal and our fetal patients.
- *Non-maleficence* is the responsibility to mitigate, while still respecting autonomy, any harm to either the maternal patient or her preborn child. This includes patient safety.
- *Justice* means that with utmost respect for the dignity of *all* human life, we should do our best to ensure that all patients have accurate information concerning their health and that of their unborn baby and are offered support and counseling regarding viable options that enable her to continue her pregnancy, regardless of socioeconomic status, sexual orientation, or ethnic background.

General Counseling Technique and Content

Preparation is very important to good counseling of abortion-vulnerable patients. A physician can improve his or her counseling by considering counseling technique, community resources (including in-office literature and relationships with local pregnancy care centers), and evidence before being faced with an abortion-vulnerable patient.

While counseling content may vary from one patient to the next depending on individual patient needs, this Practice Guideline aims to provide the physician with a number of topics which can be considered for discussion. In general, it is wise to start by asking questions, expressing empathy, and learning about the patient's situation.

If the patient has brought up the subject of induced abortion, an appropriate opening question may be "How do you feel about abortion?" Some patients

will express a belief that induced abortion is objectionable. She may say something like, "Well...I never thought I'd even consider it, but..." or "I never believed in it, but..." In this case, the physician may need only to encourage fidelity to her deeply held beliefs, then go on to discuss how to overcome hurdles and challenges that make continuing the pregnancy seem difficult. However, the practicing Ob is likely to see women of diverse faith backgrounds whose situations are complicated, leading to a more complex decision-making process. The physician can help the patient to identify other areas of discussion, including perceived barriers to pregnancy continuation and avoiding coercion, many of which are listed in Table 1.

Table 1. Counseling Topics for the Abortion-Vulnerable
The woman's own feelings about parenting, adoption, and induced abortion
Perceived barriers to continuation of pregnancy
Your role in emotional support, encouragement, and obstetrical care if she continues the pregnancy
Your identity as a pro-life physician (i.e., she can trust you to provide care for her *and* her baby)
Open adoption
Dealing with pressure and coercion, even from people with whom the patient has a positive relationship
Fetal development
Fetal pain
Induced abortion procedures, including induced abortion by surgery or by chemical agent
Risks of induced abortion • Claims that abortion is safer than childbirth highly questionable, drawn from incomplete data • Preterm birth • Effects on mental health • Hemorrhage • Uterine perforation (surgical abortion only) • Injury to surrounding organs (surgical abortion only) • Infection • Particular risks associated with self-managed induced abortion
Abortion pill reversal

Part of comprehensive counseling is to encourage the patient to gather as much information as possible and to take time to understand and consider it carefully.[7-13] Assure her that she does have options and use language of empowerment to specifically advise her to resist coercion, to focus on making a decision that she will be comfortable with for her entire life, and to make yourself available in the decision-making process and for support during her pregnancy. As you listen to and counsel the patient, be aware of signs of human trafficking, listed in Table 2.

Table 2. Red Flags for Human Trafficking

Working and Living Conditions:

- Is not free to leave or come and go as he/she wishes
- Is in the commercial sex industry and has a pimp / manager
- Is unpaid, paid very little, or paid only through tips
- Works excessively long and/or unusual hours
- Is not allowed breaks or suffers under unusual restrictions at work
- Owes a large debt and is unable to pay it off
- Was recruited through false promises concerning the nature and conditions of his/her work
- High security measures exist in the work and/or living locations (e.g. opaque windows, boarded-up
- windows, bars on windows, barbed wire, security cameras, etc.)

Mental Health and Behavioral Conditions:

- Is fearful, anxious, depressed, submissive, tense, or nervous/paranoid
- Exhibits unusually fearful or anxious behavior after bringing up law enforcement
- Avoids eye contact

Physical Conditions:

- Lacks medical care and/or is denied medical services by employer
- Appears malnourished or shows signs of repeated exposure to harmful chemicals
- Shows signs of physical and/or sexual abuse, physical restraint, confinement, or torture

Lack of Control:

- Has few or no personal possessions
- Is not in control of his/her own money, no financial records, or bank account
- Is not in control of his/her own identification documents (ID or passport)
- Is not allowed or able to speak for themselves (a third party may insist on being present and/ or translating)

Other:

- Claims of just visiting and inability to clarify where he/she is staying/address
- Lack of sense of time, or knowledge of whereabouts and/or of what city he/she is in
- Has numerous inconsistencies in his/her story

Modified from the National Human Trafficking Resource Center.

There are a few things to avoid in counseling the abortion-vulnerable patient. Avoid critcism, don't minimize her emotions, and don't try to tell her what to do.[6] If possible, offer to perform (or order) an ultrasound. Dating the pregnancy, determining viability, and ruling out ectopic pregnancy will be necessary regardless of her decision. Ultrasound also affords the opportunity for your patient to actually see the life she is carrying. Women value the information gained from ultrasound.[14] While it is unclear exactly how many women choose life because of ultrasound,[15,16] experience has shown that many women choose to continue their pregnancies when allowed to see an ultrasound.[17,18]

Finally, it is generally useful to offer a follow up appointment to continue your discussions, answer questions that have come up, or repeat the ultrasound examination. You may offer to see the patient and/or her family more

frequently so that she can benefit from your understanding and willingness to listen. Let her know that you will make any referrals needed for her to receive the best care.

Clinical Questions and Answers

Q I am Faced with an Abortion-Vulnerable Patient in My Office now and I Don't Have Time to Sift through Literature or Form Relationships with the Local Pregnancy Care Center. Who Can Help Me Right Now?

AAPLOG.org hosts multiple documents such as this, that condense useful information. It also provides a list of pro-life physicians, who may have additional local resources or may form a referral base.

The following websites and hotlines will be useful The first three sites listed provide comprehensive option counseling and do not refer for induced abortion.

- Optionline.org, call 1-800-712-HELP (4357)
- Options for Women, call 888-652-1140 or text "HELPLINE" to 313131.
- Pregnancydecisionline.org, call 866-406-9327
- Lifetimeadoption.org is devoted to helping women understand and consider adoption.
- Care-net.org and Heartbeatinternational.org are websites devoted to pregnancy care centers, with a Christian emphasis.
- Abortionpillrescue.com provides a telephone hotline and online chat for women who have initiated an induced abortion with mifepristone and are reconsidering their decision. The website also provides information about chemical induced abortion and the reversal process.
- Live Action has a website called Abortionprocedures.com in which Abortionists who have performed hundreds and even thousands of induced abortions describe the most prevalent abortion procedures at every stage of pregnancy, accompanied by medical animations.
- Bravelove.org is a pro-adoption movement dedicated to changing the perception of adoption by acknowledging birth moms for their brave decisions.

When there is a concern about human trafficking, the National Human Trafficking Resource Center can be reached at 1-888-373-7888, or by texting "HELP" TO 233733 (BEFREE). There is also an online chat available at www.humantraffickinghotline.org.

Q How Can a busy OB/GYN begin to Establish Rapport with an Abortion-Vulnerable Patient?

Try to create a suitable environment and a relationship with the patient that makes her feel comfortable and safe to express herself. It is helpful to show empathy, to make an effort to understand her situation from her perspective. The patient must have a sense that the physician counselor is sincere. She must know that she can count on you and your staff to follow through with the support and help you offer.

Q Are Special Laws in Effect for Minors Participating in Sex Work?

Yes. According to federal law, any minor under the age of 18 engaging in commercial sex is a victim of sex trafficking, regardless of the presence of force, fraud, or coercion.

Q What about the Case of the Patient whose Fetus has Anomalies?

Patients and their families who receive a life-limiting fetal diagnosis may choose perinatal palliative care, an active approach that manages symptoms of anxiety and isolation, and openly manages anticipatory grief. Perinatal palliative care has similar rates of maternal complications and maternal regret as induced abortion. Induced abortion has not been found to be an effective way to curtail or prevent grief when a life-limiting perinatal diagnosis is encountered, so parents may readily consider a perinatal palliative care. Retrospective cohort studies demonstrate that perinatal palliative care is readily taken up by patients and healthcare professionals; limited prospective evidence suggests that perinatal palliative care may improve maternal anxiety, communication, and family relationships. Offering perinatal palliative care should be part of every obstetrician/gynecologist's counseling when adverse pre natal diagnoses are made.[19, 20] Please see AAPLOG's Practice Guideline Number 1, Perinatal Palliative Care and Perinatal Hospice.

Q What Language Can be Used to Describe Fetal Development in a Short Time?

The following is an excerpt from the AAPLOG Patient Guide pamphlet: "Your unborn child is a person. At about 22 days after fertilization your child's heart begins to circulate his or her own blood, unique from your own, and has a heartbeat that can be detected on ultrasound. At just six weeks after fertilization, your child's eyes and eye lids, nose, mouth, and tongue can be seen. Then just ten weeks after fertilization your child can make bodily movements. Around week 19-21 your child can hear. During this you should begin to feel movement. From fertilization on, your child is a human being and a human person, uniquely distinct from you. Your child is alive, and every life is a precious and valuable gift."

Q When Can Fetuses Feel Pain?

A human fetus may feel pain by as early as 12 weeks gestation, and fetuses respond to touch as early as 7.5 to 8 weeks.[21, 22] For more information, refer to AAPLOG's Practice Guideline No. 2, Fetal Pain.

Q How much does Induced Surgical Abortion Increase a Patient's Risk of Subsequent Preterm Birth?

Overwhelming evidence from more than 160 studies over fifty years points to a clear dose-response relationship between surgical induced abortion and subsequent preterm birth.

One prior surgical induced abortion is associated with statistically significantly higher odds of subsequent preterm birth, corresponding to a 13-14% risk, compared to the baseline rate of 10% in the United States. Two or more prior surgical induced abortions are associated with significantly higher odds of subsequent preterm birth, corresponding to a 18% risk of subsequent preterm birth, compared to the baseline rate. One prior surgical induced abortion is associated with significantly higher odds of having a subsequent very preterm birth (either 32 or 28 weeks' gestation), corresponding to a 2.3% risk, compared to the baseline rate of 1.5% in the United States.[23-51]

If an induced chemical abortion fails and requires surgical completion, the risk of preterm birth following surgical completion will be at least as high as a primary surgical induced abortion.

Helping patients understand why preterm birth is to be avoided can be helpful. Preterm birth can have both short-term and long-term health risks for the neonate. Short-term risks include the hurdles in respiratory and digestive function that neonatal intensive care patients deal with daily. In addition, preterm birth leads to an increased risk for some long-term complications, such as cerebral palsy, impaired vision and hearing, behavioral and psychosocial difficulties, and impaired cognitive development.[28, 29]

Q Is Induced Abortion Safer than Childbirth?

One cannot state that induced abortion is safer than childbirth. To quote Dr. David Reardon, "It is almost impossible to accurately compare deaths related to induced abortion and deaths related to childbirth in the U.S. due to incomplete reporting, definitional incompatibilities, voluntary data collection, research bias, reliance upon estimates, political correctness, inaccurate and/or incomplete death certificates, incompatibility with maternal mortality statistics, and failing to consider other psychologic causes of death, including suicide."[52] Looking at population research done in other countries,[55-59] "we see a different conclusion, that women are far more likely to die in the year following an induced abortion than they are following childbirth." For more

information, please refer to AAPLOG's Top 10 Myths About Abortion, page 28, "Abortion is Safer Than Childbirth."[52-60]

Q How much does Induced Abortion Increase a Patient's Risk of Mental Health Problems?

It may be important for the abortion-vulnerable patient to understand that although many induced abortions are purportedly done to prevent or reduce mental health risks, the medical literature offers no evidence that induced abortion reduces mental health risk.[61, 62] In fact, while some claim no induced abortion-related mental health risk, there are numerous studies,[61-100] including a carefully designed meta-analyses in 2011,[63] revealing induced abortion as a significant risk factor for mental health problems. Summarizing the medical literature, Dr. Priscilla Coleman has stated, "For a significant number of women, abortion initiates a life trajectory characterized by feelings of grief, loss, alienation from others, and mental health challenges."[101]

Some risk factors place women at especially increased risk for mental health complications after induced abortion. These are detailed in AAPLOG Practice Guideline 7 Abortion and Mental Health. These include:

1) Perceptions of the inability to cope with the induced abortion.
2) Low self-esteem.
3) Difficulty with the decision.
4) Emotional investment in the pregnancy.
5) Perceptions of one's partner, family members, or friends as non-supportive.
6) Timing during adolescence or being unmarried.
7) Pre-existing emotional problems or unresolved traumatization.
8) Involvement in violent relationships.
9) Traditional sex-role orientations.
10) Conservative views of induced abortion and/or religious affiliation.
11) Pregnancy is intended.
12) Second trimester.
13) Pre-abortion ambivalence or decision difficulty.
14) When women are involved in unstable partner relationships.
15) Feelings of being forced into induced abortion by one's partner, others, or by life circumstances.

For more information, please refer to AAPLOG's Practice Guideline number 7, Abortion and Mental Health.[102]

Q Does Induced Abortion Increase a Patient's Risk of Breast Cancer?

There exists evidence that induced abortion of a first pregnancy, especially for teens and women over the age of 30, increases breast cancer risk. The mechanism is thought to be stimulation of stem cell breast tissue (Type 1 and 2) in early pregnancy but lack of terminal differentiation which occurs after

elaboration of human placental lactogen (HPL) by the placenta after 20 weeks gestation. HPL is required for terminal differentiation of breast tissue to lactational tissue, which is cancer resistant. Studies which look at the subset of women who abort prior to carrying a child to term show the strongest association. Studies which look at women who abort after previous term pregnancies do not show as strong an association. There is biologic plausibility as well as epidemiologic evidence[109-128] for a causal association between abortion and-breast cancer. Please see AAPLOG's Committee Opinion, number 8, Abortion and Breast Cancer.[128]

Q What Options are Available for a Patient Who has taken Mifepristone but then Changes her Mind?

For patients who have already taken mifepristone, but not misoprostol, there is as high as 68% chance of saving the pregnancy by following an abortion pill reversal protocol[129] For patients who choose this treatment, she should know that having taken the mifepristone, there is no evidence that her fetus is at increased risk for birth defects.

Utilizing the data from the 2018 Delgado study,[129] two protocols can be recommended for women who change their minds after taking mifepristone and want to halt the chemical induced abortion process.

1) High Dose Oral Protocol Progesterone micronized 200 mg capsule two by mouth as soon as possible and continued at a dose of 200 mg capsule two by mouth twice a day for three days, followed by 200 mg capsule two by mouth at bedtime until the end of the first trimester. Oral progesterone should be taken with food to improve absorption. Micronized progesterone should be avoided in women with peanut allergies.

2) Intramuscular Protocol Progesterone 200 mg intramuscular as soon as possible and continued at a dose of 200 mg intramuscular once a day on days two and three, then every other day for a total of seven injections. This protocol is suitable for women with peanut allergies. Some clinicians may choose to continue intramuscular treatment longer since this recommendation is based on relatively small numbers.

For more information, please refer to AAPLOG's Practice Guideline number 6, The Reversal of the Effects of Mifepristone by Progesterone.[130] Also, you may contact the Abortion Pill Rescue Network: abortionpillrescue.com

Q What Risks should Patients be Made Aware of Who are Considering Self-Managed Induced Abortion?

Currently, more than 50% of induced abortions in the U.S. are induced abortions with chemical agents[131] and self-managed chemical abortion is being actively promoted.[132] In addition to the four-fold increased complication risk associated with chemical induced abortion, principally due to hemorrhage,[133] self-managed induced abortion carries additional significant dangers for pa-

tients. Because errors in gestational age estimation are bound to occur, there is a risk of consuming mifepristone in the second trimester when complication and mortality risk will be much higher. Risk of death from undiagnosed ectopic pregnancy and risk to future pregnancies from Rh incompatibility also present themselves with self-managed induced abortion.[132]

Summary of Recommendations and Conclusion

The Following Recommendations are Based on Good and Consistent Scientific Evidence (Level A):

1) Physicians should encourage the patient to gather as much information as possible, take time to make a decision, and to provide significant support.
2) Patients may be counseled that induced surgical abortion and induced chemical abortions which need to be completed surgically increases risk for preterm birth in subsequent pregnancies.
3) An ultrasound is required prior to a medical/chemical abortion to document estimated gestational age, viability of embryo/fetus, and intrauterine pregnancy to rule out ectopic pregnancy.

The Following Recommendations are Based on Limited and Inconsistent Scientific Evidence (Level B):

1) Patients may be counseled that induced abortion causes increased risk for mental health problems, and possibly breast cancer.
2) For patients who have taken mifepristone, but have not yet taken misoprostol, there is as high as 68% chance of saving the pregnancy by following an abortion pill reversal protocol.
3) Self-managed induced abortion carries significant additional risks to health.

The Following Recommendations are Based Primarily on Consensus and Expert Opinion (Level C):

1) Physicians should prepare ahead of time to counsel abortion-vulnerable patients, in particular by studying the literature cited and by forming connections with local organizations that can offer these patients resources.
2) It is important for physicians counseling abortion-minded patients to listen to the patient and ask her about her own feelings about life, adoption, and induced abortion.
3) Physicians counseling abortion-vulnerable patients should avoid negativity, marginalizing emotions, and paternalism.
4) Experience has shown that many women choose to continue their pregnancies when they see their baby on an ultrasound monitor.
5) Women whose unborn child is diagnosed with a serious or lethal fetal anomaly should be aware of the availability of perinatal palliative care.

6) Pregnancy Care Centers should be used whenever possible.
7) Physicians counseling abortion vulnerable patients should be aware of signs of human trafficking.

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