

PRACTICE BULLETIN 8

EVIDENCE DIRECTING PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS

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Medical Management of Elective Induced Abortion

The advent of mifepristone abortion has been heralded by the abortion industry as the solution to the problems of declining numbers of abortion providers and the increasing requirements that abortion facilities comply with standard medical requirements. Seldom are women given accurate information that there is at least a four-fold increase in immediate complications, including of hemorrhage, retained tissue and subsequent ER visits, with complications increasing exponentially for increasing gestational age. It is important that medical professionals understand the increased risk presented to women from medical abortion in order to appropriately provide accurate informed consent.

Background

Medical abortion, which involves the use of medication rather than surgery to induce an abortion, has been commonly used in the U.S. since 2000 and is currently approved until 70 days of gestation (calculated from the first day of the last menstrual period). Whereas the total numbers of abortions are declining in the U.S., the numbers of medical abortions are increasing.¹ In 2004 only 14% of abortions were performed medically, but currently 39% of abortions in the U.S. are induced by medication.² There are many reasons to expect this rise to continue, including the lucrative nature of medical abortion, the dwindling numbers of physician abortionists^{3,4} and the rise of laws placing restrictions on surgical abortions. Given

the expected increase in prevalence, it is important for physicians to be aware of the health risks associated with these medications.

In the U.S., the only Food and Drug Administration approved medical abortion regimen is induced with the provision of two medications: mifepristone and misoprostol. Mifepristone, (Mifeprex or RU486), a norethindrone derivative, binds to progesterone receptors but does not activate them, functioning as an anti-progesterone.⁵ Blocking the hormonal support for the pregnancy results in disruption of the endometrial implantation site and fetal death.⁶ Misoprostol (Cytotec), a prostaglandin E1 analogue, is taken 24-48 hours later to induce contractions to expel the pregnancy tissue.⁷ Buccal, sublingual and

vaginal misoprostol administration appear to be more effective than oral administration.⁸ Other medications such as methotrexate, tamoxifen⁹ and letrozole have been used in place of mifepristone on occasion, but almost all reported medical abortions in the U.S. currently are initiated with mifepristone.¹⁰

History of Medical Abortion in the U.S.

It is instructive to examine the circumstances in which mifepristone was approved, as they illustrate the ways in which abortion provision is held to a different standard from other medical procedures in the U.S. In an unprecedented move, then President Bill Clinton wrote the French manufacturer, Rousell Uclaf, asking them to file a new drug application with the FDA. When they were hesitant to do so due to legal concerns, Rousell Uclaf then ceded the rights to manufacture and distribute in the United States to “Planned Parenthood/Population Council”. The Population Council gave manufacturing permission to a company created for this specific purpose, Danco,¹¹ whose assets were lodged in the Cayman Islands. Danco then hired Hua Lin pharmaceuticals in China to manufacture mifepristone. Hua Lin was at that point under discipline from the FDA for faulty quality control.

The FDA failed to follow its own rules on numerous occasions in order to approve this drug. A new drug must have at least two randomized, blinded placebo-controlled trials documenting its safety and efficacy, but the submitted trials had no placebo groups.¹²

Mifepristone was approved under a special category, “Subpart H: Accelerated Approval Regulations” which are intended for serious/life-

threatening illnesses such as advanced cancer and HIV.¹³ Also, the FDA based approval on the combined action of the mifepristone with misoprostol, because mifepristone does a poor job of completely evacuating the uterus on its own. They mandated the use of misoprostol over the objections of its manufacturer, Searle.¹⁴ The FDA is required to test a drug in a pediatric population but waived this requirement without explanation despite adolescent women comprising 1/4-1/3 of its users.¹⁵ Finally, the approved regimen does not mimic clinical trial conditions as it lacked a required ultrasound, experienced surgeon dispensing, and nearby hospital admitting privileges.¹⁶

The FDA approved Mifepristone for U.S. distribution in 2000 under SubPart H, which was the only mechanism at the time which allowed FDA to require post-marketing restrictions of drugs considered at high risk for complications if not used in accordance with the FDA label. In 2006, the FDA instituted a Risk Evaluation Mitigation Strategy (REMS). This is a safety strategy applied to medications that have a known or potential serious risk associated with them.¹⁷ Under this strategy, the risk of complications such as ruptured ectopic pregnancies, hemorrhage, infection and retained pregnancy tissue, which require surgery in as many as one in 20 women,^{18,19} might be minimized. To decrease the likelihood of these negative effects, Mifepristone was initially only approved up to 49 days gestational age, the provider was registered after specific training, it was only to be dispensed in certain healthcare settings and the patients were to be informed of the risk of serious side effects. Mifepristone abortion providers were required to be able to accurately determine the gestational age, confirm an intrauterine location of the pregnancy,

and intervene surgically if the abortion was unsuccessful or a complication resulted (or alternatively the abortionist could have an agreement with another doctor and facility capable of providing this care). Complication reporting was mandated, as was a 14-day follow-up visit for the woman.²⁰

Finally, a black box warning was assigned. “If mifepristone/misoprostol results in incomplete abortion, surgical intervention may be necessary. Prescribers should determine in advance and give clear instructions whom to call and what to do in case of emergency. Medical abortion is contraindicated if there is no access to medical facilities for emergency services.”²¹

Reality of Medical Abortion for women

Women often choose a medical abortion as a result of intense marketing of the assumption that it is more natural, private and safer than a surgical procedure,²² but physicians and patients alike may be unaware that it takes much longer, involves far more bleeding and pain, and complications occur four times more frequently from medical as compared to surgical abortions.²³ The average woman bleeds for 9-16 days and eight percent will bleed longer than a month.²⁴ Approximately one percent will require hospitalization for serious complications, one percent will have ongoing viable pregnancies (it will fail to kill the fetus), and surgery for incomplete abortion will be required in three to eight percent.^{25,26} The rate of all of these complications increase exponentially as gestational age increases.^{27,28} If a pregnancy continues to birth after taking misoprostol, the second drug in the regimen, teratogenic effects such as clubfoot, cranial nerve anomalies (Möbius syndrome) and limb abnormalities related to misoprostol are

sometimes seen.²⁹ The side effects of cramping, vaginal bleeding, hemorrhage, nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness occur in almost all women.³⁰

Within a few years of mifepristone’s approval, four deaths from sepsis caused by *Clostridium sordellii* causes the FDA and CDC to investigate the potential for immune suppression and sepsis from mifepristone and misoprostol. Both mifepristone³¹ and misoprostol are capable of profound immune suppression. This information led Planned Parenthood to change from vaginal to buccal administration of misoprostol. Unfortunately, buccal administration was also associated with septic deaths.³² Currently there are over 5000 complications reported to the Adverse Event Reporting System.³³ To date, 24 deaths have been reported, many from an unusual *Clostridium sordellii* sepsis³⁴ or from ruptured ectopic pregnancies, because mifepristone has no effect on a pregnancy that is not implanted in the uterus. A previously healthy 21-year-old woman had a heart attack.³⁵ A new black box warning was generated: “Watch for atypical presentation of infection, prolonged heavy bleeding, ensure the patient knows who to call and to alert the ER of mifepristone use if she presents there.”³⁶

Despite the high reported complication rates, a supplemental application was approved by the FDA in 2016 which loosened these restrictions. The use was extended until 70 days gestational age, despite very few studies and much higher failure rates in higher gestational ages.³⁷ There was modification of the dose, timing and route of administration.³⁸ It was no longer required to report a complication unless it resulted in a woman’s death, nor was it required to have a follow-up visit.³⁹

Contraindications to medical abortion include hemoglobin < 9.5 g/dL, ectopic pregnancy, intrauterine device in place, long-term corticosteroid therapy, chronic adrenal failure, coagulopathy or anticoagulant therapy, and allergies to the medications. It is also not recommended if the woman has the inability to follow-up or is likely to be non-compliant.⁴⁰

What do studies say about medical abortion safety?

In examining the peer-reviewed literature on medical abortion, the alert reader will notice two disparate trends. Studies performed internationally or by non-biased researchers often find that failures and complications after medical abortion are common. Meanwhile, studies performed by vocal abortion advocates tend to find much lower incidences of adverse outcomes. These trends merit examination.

Many of the studies which conclude that medical abortion is extremely safe are published in *Contraception*, a journal affiliated with the Guttmacher Institute and Planned Parenthood, or *Obstetrics and Gynecology*, a journal published by The American College of Obstetricians and Gynecologists. These organizations are well known for their abortion advocacy.^{41,42,43} Many studies are performed by researchers such as Daniel Grossman, Diana Greene Foster, Ushma Uphadhyay, and David Grimes, who are affiliated with the Bixby Center for Global Reproductive Health at the University of California, San Francisco, which describes itself as a “leader in clinical research to develop methods of abortion and improve abortion care.”⁴⁴ Additionally, many of the most prolific researchers are paid employees of companies that profit from medical abortions:

Mitchell Creinin is a consultant for Danco, the company that manufactures Mifepristone.⁴⁵ Elizabeth Raymond is employed by Gynuity, a company which seeks to provide medical abortions by telemedicine.⁴⁶

In 2018, the National Academy of Sciences, Engineering and Medicine published a book: *The Safety and Quality of Abortion Care in the U.S.*, which made the assertion that abortion is extremely safe for women, and this publication has been widely referenced. The researchers’ bias is immediately apparent because it was funded by Packard, Buffett, and Hewlett Foundations, three of the top international funders of abortion advocacy.⁴⁷ These researchers performed an extensive literature review but excluded an extraordinary number of studies for perceived defects. Not surprisingly, by primarily utilizing studies performed by fellow abortion advocates, they concluded that serious complications or long term physical or mental health effects are virtually non-existent. In fact, they reported abortion is so safe that the only deterrent to its safety is legislative restrictions enacted by the states that may prevent a woman from accessing an abortion immediately, “creating barriers to safe and effective care.”

They concluded that abortions can be performed safely in an office-based setting or by telemedicine without the need for hospital admitting privileges. No special equipment or emergency arrangements are required for medical abortions. Medical abortions do not need to be performed by physicians; they can safely be performed by trained certified nurse midwives, nurse practitioners, and physician assistants. They reported that abortion has no long-term adverse effects, and abortion specifically does not increase

the risk of preterm delivery, mental health disorders or breast cancer. However, when one examines the research studies they used for their conclusions, the poor quality of the literature regarding long-term complications becomes apparent. For many questions, there were very few or no studies that met their inclusion criteria, and they disqualified many studies due to perceived study defects. Thus, in all cases, there were less than five studies on which they based their definitive conclusion of “no long-term impact.” To make this determination, however, they rejected hundreds of other published peer-reviewed studies.^{48,49,50,51,52}

A closer glance at some of the large studies the NAS referenced show that they also contain many flaws. One study reported a very small percentage of emergency room visits for abortion complications but ignored the reality that documentation specifying medical abortion complications is very difficult in the ICD-10 system.⁵³ Another study documented a very low incidence of serious abortion complications by reviewing Planned Parenthood’s database, ignoring the fact that most abortionists do not maintain hospital admitting privileges or care for their own complications. A woman suffering a complication from medical abortion must be cared for by any emergency facility to which she presents due to EMTALA (Emergency Medical Treatment and Labor Laws), so many women receive post-abortion complication care by non-abortion providers. Thus, serious events would be unlikely to be documented in their clinic records.^{54,55} Finally, another study reported that 99.6% of medical abortions were successful although 2.1% of the women in their clinics required surgical aspiration. The need for surgery, by definition, would indicate the medical abortions were

unsuccessful. Incidentally, that study examined over 30,000 women over two years who had abortions in one clinic system (Planned Parenthood) in one city (Los Angeles). The experiences of such high-volume abortion providers may not necessarily be comparable to other inexperienced or poorer-quality abortion providers.⁵⁶

Immediate complications from surgical abortions usually occur due to a surgical misadventure such as cervical dilation creating a false passage, instrumental uterine perforation or incomplete evacuation of pregnancy tissue. The immediate complications of medical abortions are commonly attributed to hemorrhage or infection from incomplete uterine evacuation and retained pregnancy tissue. But recent research suggests that mifepristone itself may also cause complications of infection and mental health issues through direct pharmacologic effects. Mifepristone also blocks glucocorticoid receptors which may contribute to an impaired inflammatory response, increasing the risk of infection.⁵⁷ In addition, it causes the release of inflammatory cytokines which have been implicated in causing depression. In a rat model the mifepristone termination group had significantly decreased body weight, food intake, locomotor-related activity, and sucrose consumption, which are all animal proxies for depression and anxiety.⁵⁸

There are less biased studies available internationally that give a far different picture of the safety of medical abortions. Epidemiologic studies in Finland are of better quality than those in the U.S. because single payer healthcare and meticulous medical record keeping ensure that all pregnancies and all medical events are accurately recorded. A study of over 42,000 women receiving abortions at <7 weeks gestational age documented

that adverse events occurred in one in five women who had medical abortions and almost 6% required surgery. The rate of complications was four times higher in medical than in surgical abortions.⁵⁹ Another Finnish study of 18,000 women found an 8% rate of surgery for medical abortion failures in the first trimester, and almost 40% surgery rate in the second trimester.⁶⁰ Finally, a meta-analysis of all available Mifepristone/Misoprostol studies worldwide including over 47,000 women found a 4.8% treatment failure rate, and 1.1% ongoing pregnancies.⁶¹

Data limitations of abortion complication and abortion-related maternal mortality rates

When considering the safety of abortion in the U.S., it is important to realize that there are many data limitations affecting the accuracy of these statistics. Due to privacy concerns and payment apart from insurance coverage for most abortions, there is no accurate central database that tracks this procedure. As reported earlier, recent studies documenting apparent low complication rates have been performed by high volume abortionists and do not reflect the quality of all abortion providers in the U.S. The data regarding abortion related maternal mortality is even more compromised. A widely reported study asserted that abortion is 14 times safer than childbirth by using four disparate and difficult to calculate numbers, with non-comparable denominators. Abortion-related deaths were compared to the number of legal abortions. Maternal deaths were compared to the number of live births.⁶² Only live births can be accurately measured due to mandated birth certificates. Yet, only 2/3 of maternal deaths occur in association with a live birth.⁶³

It is well documented in the U.S. that at least 50% of maternal deaths are not reported as pregnancy related on death certificates.^{64,65} Mortality from events in the first half of pregnancy, which are unable to be linked to a birth certificate, are even more difficult to detect, but reliable records-linkage studies from Finland document that 94% of abortion-related deaths are not documented as such on the maternal death certificate.⁶⁶ This is particularly true for mental health related deaths that occur remote from the end of the pregnancy.⁶⁷ Maternal mortality encompasses all deaths occurring while a woman is pregnant, and within a year after the pregnancy ends. The authors of this misleading study are vocal abortion advocates who knew how limited the CDC data drawn primarily from death certificates was, because one of the authors was the former Chief of the CDC Abortion-Surveillance Branch.⁶⁸ This study was clearly performed for propaganda purposes.⁶⁹

In the U.S., we don't even accurately know the number of abortions that occur. The estimated number of abortions are only voluntarily reported to the CDC by state health departments. In 2017 the states reported 638,169 abortions, but several states, including the state with the largest number (California), do not report any data.⁷⁰ By comparison, in 2017, the Guttmacher Institute, which receives their information directly from the abortion providers, reported 926,000 abortions.⁷¹ Only 28 states require abortion providers to report their complications, but there is rarely an enforced penalty for noncompliance. Only 12 states require other physicians, coroners or emergency rooms to report abortion-related complications or deaths for investigation, and frequently these other providers are unaware of the reporting requirements.⁷²

Multiple epidemiologic studies demonstrate that a woman is more likely to remain alive one year following term childbirth than following abortion.^{73,74} Finnish studies show that following an abortion, a woman was two to three times as likely to die within a year,^{75,76} six times as likely to commit suicide,⁷⁷ four times as likely to die from an accident,⁷⁸ and 14 times as likely to be murdered.⁷⁹ Danish studies and California Medicaid studies demonstrate similar findings.^{80,81,82} It appears that a term birth is protective by reducing risk taking behavior, whereas an abortion may lead to increased social disruption and increased risk-taking behavior increasing the likelihood of death within a year.

Medical abortion current advocacy

Abortion advocates have changed their strategy. Whereas once they claimed they wanted abortion to be “safe, legal and rare,” they now favor immediate access and convenience, regardless of whether it might be more dangerous for a woman or whether the law prohibits it. Recent recommendations by pro-choice advocates illustrate this concerning trend, as there have been coordinated efforts to promote the use of medical abortions more widely.⁸³ Abortion advocates have stated that state level restrictions on abortion procedures place barriers to access for women who desire abortion, and they warn that women will resort to unsafe illegal procedures if they cannot readily access an abortion.⁸⁴ Conversely, they then recommend that women pursue medical abortions illegally if they encounter barriers.^{85,86,87}

In 2017, the American Civil Liberties Union sued the FDA for removal of the Risk Evaluation Mitigation Strategy (REMS).⁸⁸ The FDA REMS is

the only real barrier to over the counter distribution of mifeprax. It would shortly follow that all pharmacists will be pressured to distribute abortion drugs, even if it violates their conscience.⁸⁹

There are efforts underway to force taxpayer payment of abortion even though surveys consistently demonstrate that most Americans oppose such actions. This could be accomplished in several ways: through repeal of the Hyde Amendment which prohibits federal funding of abortion,⁹⁰ increasing state Medicaid provision of abortion beyond the 15 states that will currently pay for this eugenic action,⁹¹ and legislative mandates for university health systems to provide abortion pills to students.⁹²

Although a physical examination and ultrasound⁹³ are standard care when evaluating a woman seeking an abortion, and counseling can best be performed in a face-to-face interview, telemedicine is also being promoted to women, especially those who live remote from an abortion clinic. This will clearly decrease the safety of medical abortion for rural women if there is limited access to emergency services.⁹⁴ One survey of abortion providers found that 1/3 had seen women experience complications from self-managed medical abortion, and only 1/2 felt it was safe.⁹⁵ Nonetheless, a clinical trial of telemedicine provision by Gynuity is ongoing in the U.S.⁹⁶ Mail order provision of abortion pills is also sought by abortion advocates.⁹⁷ A study on obtaining abortion pills from international distributors found that no prescription or clinical information was required, the pills averaged two weeks to arrive, analysis of the medications obtained demonstrated that some misoprostol pills contained only 15% of the advertised amount of medication, the packages often arrived damaged, and no instructions were

contained in any of the packages. Nonetheless, these pro-choice researchers concluded that it was “feasible” for women to obtain medical abortion pills on-line.⁹⁸

Because of the restrictions that govern mifepristone prescriptions, sometimes abortion advocates will recommend that women obtain the second abortion pill component only, because it is more readily available. Misoprostol is also used to treat ulcers, so it can be prescribed by any physician. It is easily obtained over the counter in nearby countries such as Mexico. But unfortunately, misoprostol alone is a very poor abortifacient. Studies consistently demonstrate that one in four women will have a failed abortion that requires surgical completion with the use of misoprostol alone.^{99,100,101}

Finally, we see promotion of so-called “menstrual regulation.”¹⁰² This refers to providing the abortion pill to women who report a late period without first ruling out pregnancy. This euphemism allows women to procure an abortion while avoiding the “stigma” of abortion.

There are many potential negative consequences to these recommendations which ultimately demonstrate abortion advocates’ disregard for the health of women. For example, underestimation of gestational age may result in higher likelihood of failed abortion. Undetected ectopic pregnancies may rupture leading to life-threatening hemorrhages. Rh negative women may not receive prophylactic Rhogam resulting in isoimmunization in future pregnancies. Potential for misuse and coercion is high when there is no way to verify who is consuming the medication and whether they are doing so willingly. Sex traffickers, incestuous abusers and coercive boyfriends will all welcome more easily available medical abortion. Catastrophic complications can occur, and

emergency care may not be readily available in remote areas.

Summary of Recommendations and Conclusion

The following recommendations are based on good and consistent scientific evidence (Level A):

1. Abortion with mifeprex and misoprostol has four times the risk of complications as compared with surgical abortion.

While there is heated disagreement in the U.S. about whether elective induced abortion should be legally permitted at all, presumably all would agree that if abortion is allowed, it should be performed in such a way as to optimize safety for the woman obtaining the abortion. Recent trends affecting the provision of medical abortions demonstrate that the woman’s safety may no longer be a priority for some abortion advocates. Medical abortions are consistently documented to have four times the complication rates of surgical procedures. However, due to decreasing number of abortion providers, the abortion industry is increasingly encouraging women to choose this option, which minimizes abortion provider time and risk. Vocal abortion advocates are aggressively using the court systems and pro-choice media sources to advocate for removal of safety restrictions on medical abortions.

2. Post-marketing restrictions are necessary to minimize the inherent dangers of abortion with mifeprex and misoprostol.

The abortion industry is aggressively working for complete over the counter access for mifeprex. They have also begun to advocate for illegal use of mifepristone and misoprostol when restrictions are in place despite the demonstrated increase adverse events that occur when these medications are used

without close medical supervision. The FDA REMS should be strengthened, not removed, in order to ensure that the risks of mifepristone abortion are minimized.

The following recommendations are based on good and consistent scientific evidence (Level B):

Abortion industry marketing interferes with research and adequate informed consent for women.

Biased studies performed by those who profit from abortion provision seek to downplay the common nature of complications. A review of the history of mifepristone's FDA approval demonstrates that

abortion provision abides by a standard different from other medical interventions. Medical providers who seek to advocate for their female patients' best interests should become aware that medical abortions result in complications far more often than its proponents advertise.

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