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The "No-Test Medication Abortion" Protocol: Experimenting with Women's Health

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A trend of mounting concern is occurring in abortion provision. When elective induced abortion was legalized in the United States in 1973, one oft-cited motivation was to improve abortion's safety, as it was frequently claimed that many women were injured and sometimes died from illegal abortions. Recently, abortion advocates have changed their strategy. Whereas once they claimed they wanted abortion to be "safe, legal and rare," now they favor immediate access and convenience to abortion for all women experiencing unintended pregnancies, regardless of whether it might be more dangerous for a woman, or whether the law prohibits it. Thus, they have begun encouraging women to seek more dangerous, "self-managed" abortions.

A recent peer-reviewed article, "No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond," seeks to leverage the COVID-19 pandemic to promote chemical abortion without the current safeguards that the U.S. Food and Drug Administration (FDA) has placed on its use. Some state guidelines designed to decrease demands on medical systems have resulted in limits on elective abortion access, which these abortion advocates are using as an excuse to recommend removing all the evidence-based recommendations that have governed the usage of chemical abortion for the past 20 years. The authors represent several well-known abortion advocacy organizations: Planned Parenthood Federation of America (PPFA), National Abortion Federation (NAF), Advancing New Standards in Reproductive Health (ANSIRH) of the Bixby Center for Global Reproductive Health, Gynuity Health Projects, and Danco Laboratories (distributor of mifepristone).[1]

Following are key recommendations this protocol endorses:

Criteria for inclusion:

1. Patient report of pregnancy by urine or serum BHCG or ultrasound
2. Last Menstrual Period (LMP) started < 77 days before mifepristone ingestion
3. None of the following symptoms or risk factors for ectopic pregnancy:
    a. Vaginal bleeding or spotting within the past week
    b. Unilateral pelvic pain or significant bilateral pelvic pain within past week
    c. Prior ectopic pregnancy
    d. Prior permanent sterilization or other tubal surgery
    e. IUD in uterus at conception or currently
4. None of the following contraindications to chemical abortion by history:
    a. Hemorrhagic disorder or anticoagulant therapy
    b. Chronic adrenal failure
    c. Concurrent long-term systemic corticosteroid use
    d. Inherited porphyria
    e. Allergy to mifepristone, misoprostol or other prostaglandins
5. No strong preference for ultrasound, pelvic examination, or lab evaluation

Rh typing and administration of anti-D immunoglobulin (Rhogam)

1. Not needed if mifepristone ingestion date is <70 days from LMP, reports Rh positive, desires no future children, or declines anti-D immunoglobulin
2. Anti-D immunoglobulin should be considered for those not meeting these criteria

Treatment: Administer:

1. Mifepristone 200 mg orally
2. Misoprostol 800 mcg x 2 buccally or vaginally
3. Analgesics, anti-emetics per protocol
4. Patient instruction sheet and health facility emergency contact information
5. Two high-sensitivity pregnancy tests (HSPT)

The patient should take mifepristone 200 mg orally followed by misoprostol 800 mcg buccally or vaginally 24-48 hours later. Patients with estimated gestational age (EGA) > 63 days should take a second dose of misoprostol if not bleeding 24 hours after the first dose or if instructed by a clinician.

Follow-up:

1. Plan a follow-up contact one week after dispensing treatment.
2. If the patient reports indicators of continuing or ectopic pregnancy evaluate with ultrasound or serum human chorionic gonadotropin levels (HCGs).
3. Otherwise, instruct the patient to perform the first high-sensitivity pregnancy test (HSPT) 4 weeks after taking misoprostol (not earlier) and to contact the abortion provider if the result is positive.
4. If the patient has indicators of continuing or ectopic pregnancy, evaluate with ultrasound or serum HCGs.
5. If the first HSPT is positive but the patient has no such indicators, instruct the patient to perform the second HSPT in one week.
6. If second HSPT is also positive, evaluate with ultrasound, serum HCG, additional urine testing, or uterine aspiration.

Sample instruction sheet:

1. Call your abortion provider if you:
    a. Vomit within 30 minutes of taking medication
    b. Have a fever of 100.4 or higher more than 24 hours after taking misoprostol
    c. One week after taking misoprostol, you have any of the following:
        i. You have not had cramping or bleeding heavier than a period
        ii. Your bleeding is not getting lighter
        iii. You do not feel that you have passed the pregnancy
        iv. Your pregnancy symptoms are not resolving
    d. At any time, you have any of the following:
        i. An increase in pain/cramps or bleeding more than 24 hours after taking misoprostol

   ii. Severe pain or cramps that don't get better with pain medicine, rest, or heating pads
   iii. Enough bleeding to soak two maxi pads an hour for more than two hours
   iv. Dizziness or vomiting for more than two hours
   v. Weakness, nausea, or diarrhea lasting more than 24 hours
2. Perform one urine pregnancy test 4 weeks after taking misoprostol. Call your abortion provider if the result is positive or invalid. Use the second test if instructed to do so by your abortion provider.

This protocol is a cavalier approach to distributing a drug (mifepristone) that was deemed by the FDA to be too dangerous to approve without restrictions. It demonstrates the abortion industry's prioritization of widespread abortion access over the health and safety of women and girls. These recommendations are in direct contradiction to the results of a 2017 survey of abortion-providing members of the Society of Family Planning, which found that one third had seen complications as a result of "self-managed" abortion, and only half felt it was safe.[2]

On mifepristone's initial FDA approval in 2000, it was assigned a Risk Evaluation and Mitigation Strategy (REMS) and this was reaffirmed in 2016 when a supplemental application was approved extending chemical abortion use from 49 days to 70 days estimated gestational age. The REMS is a safety strategy applied to medications that have a known or potential serious risk associated with them, and it is designed to minimize complications. These current FDA regulations require prescribers of mifepristone to be able to assess the duration of pregnancy accurately, diagnose ectopic pregnancies, and provide surgical intervention in cases of incomplete abortion or severe bleeding. The recommendations in this no-test protocol discount all of these requirements.[3]

There have been recent coordinated efforts by abortion advocates to promote the use of chemical abortions more widely, and chemical abortion's rapid expansion is readily documented. Chemical abortions accounted for 6% of all abortions in 2001, 17% in 2008, 31% in 2014, and 39% in 2017.[4] There are many reasons to expect this rise to continue, including chemical abortion's lucrative nature, the dwindling numbers of physicians willing to carry out surgical abortions, the closure of many financially precarious abortion facilities, and the rise of laws placing restrictions on surgical abortions.[5]

The American Civil Liberties Union (ACLU) and the American College of Obstetricians and Gynecologists have sued the FDA for removal of the Risk Evaluation Mitigation Strategy.[6] These abortion-promoting organizations pursued this action so that even physicians who are not registered to carry out abortions can prescribe mifepristone, with the eventual goal of achieving its over-the-counter status. If this lawsuit succeeds, all physicians will be pressured to prescribe, and all pharmacists will be pressured to distribute, abortion drugs, even if it violates their conscience.[7] This will also lead to

telemedicine, on-line, and mail order provision of chemical abortions.[8] These actions could also override common-sense, state-level laws favored by the majority of Americans, such as parental notification laws, waiting periods, and informed consent requirements for women seeking abortion.[9]

Addressing the errors behind these recommendations

It should be noted that the abortion advocate authors of this protocol frequently reference their own biased studies as evidence for their recommendations. An example of the widespread pro-abortion bias in academic medicine is the 2018 National Academy of Sciences, Engineering, and Medicine (NAS) book, *The Safety and Quality of Abortion Care in the U.S.,* which asserted that abortion is rarely if ever followed by complications. The study was commissioned and funded by six outspoken abortion advocacy organizations: David and Lucile Packard Foundation, Grove Foundation, JPB Foundation, Tara Health Foundation, William and Flora Hewlett Foundation, and Susan Thompson Buffett Foundation. These researchers performed an extensive literature review but excluded an extraordinary number of studies for perceived defects.[10]

Not surprisingly, by primarily using studies performed by fellow abortion advocates, they concluded that serious complications or long-term physical or mental health effects are virtually nonexistent. In fact, they reported that abortion is so safe that the only deterrent to its safety is legislative limits enacted by the states that may prevent a woman from accessing an abortion immediately, "creating barriers to safe and effective care." It has been well documented that U.S. abortion complication and mortality rate calculations are flawed due to voluntary complication reporting requirements, privacy considerations, and disparate funding sources.[11] Less biased and more accurate abortion complication data can be obtained in two ways: records-linkage studies in countries with single-payer healthcare so that all procedures and interventions associated with them are accurately recorded, and meta-analysis studies which analyze all available studies on a topic.

Patient determination of gestational age is frequently incorrect

Although this protocol assumes that a woman will be able to accurately diagnose her unborn child's gestational age based on a last menstrual period (LMP) calculator, clinical experience suggests otherwise. Increasing obesity in the American patient population has led to a high incidence of polycystic ovarian syndrome causing irregular menses. Sometimes a woman will have implantation bleeding which she assumes is a normal period even though she is already pregnant. Thus, it is a frequent occurrence for a woman to underestimate gestational age by a month or more. One study found almost 15% of Atlanta women were in error by more than two weeks when calculating gestational age based on LMP.[12]

A review of over 33,000 chemical abortions revealed that failures requiring surgical completion steadily increase as gestational age increases. Nearly 2 percent (1.9%) failed at < 7 weeks, 3.3% failed between 7-8 weeks, 4.8% failed between 8-9 weeks, and 6.9% failed between 9-10 weeks. Only 332 women were studied at the 9-10 week-range, and their ongoing pregnancy rate was almost 3%. Nearly 12% of these women experiencing chemical abortions found their experience "unsatisfactory."[13] Another meta-analysis of over 45,000 chemical abortions revealed an overall failure rate of 4.8% and ongoing pregnancy rate of 1.1%. The risk of failure was much higher at gestational ages greater than 8 weeks.[14]

But rather than err on the side of caution, these advocates are willing to extend the gestational age beyond the FDA guidelines into inadequately studied gestational ages. They state that a woman should be confident of her LMP (within a one week time frame), but rather than lower the limit to account for overestimation, they extend it, approving use of these drugs potentially up to two weeks past the studied limit, even if a woman is accurate in estimating her gestational age. If she is in error, as often happens clinically, she may be many weeks past the gestational age where the use of this drug is effective and be much more likely to have a failure resulting in severe complications.

If a woman miscalculates her gestational age and has entered the second trimester when she ingests mifepristone and misoprostol, the likelihood that she will require surgery increases dramatically. A Finnish records-linkage study of over 18,000 women comparing first-trimester to second-trimester chemical abortions found 38.5% of second-trimester abortions required surgical completion (versus 7.9% in the first trimester). Additionally, 4% of the later abortions were complicated by infections (versus 1.9% of the earlier ones).[15]

These failure rates are not negligible, particularly when medical resources need to be conserved during a pandemic. Most of the women with failed abortions will present to an emergency room bleeding heavily, where they will often require immediate surgery and sometimes hospitalization for blood transfusion or intravenous antibiotics. The assumption that a woman will follow up with the abortionist for her emergency has not been the typical U.S. experience. Often the abortionist will charge an additional fee for the surgical completion, so many women will present to the emergency room, giving the impression that it was a miscarriage rather than abortion that caused the complication, so that health insurance will cover the additional costs of the surgery.

Failure to diagnose an ectopic pregnancy is a serious and often deadly medical error

Ultrasound has always been considered the gold standard for diagnosis of an ectopic pregnancy. The lack of an identifiable gestational sac in the uterus at a certain gestational age or HCG level necessitates additional testing until the location of the developing embryo can be determined.[16] Even with routine pre-abortion ultrasound, ectopic pregnancies are

sometimes missed. Omitting ultrasound entirely will increase the likelihood of failing to make the diagnosis. Mifepristone exerts its effects on the uterine lining, so when an embryo is implanted in another location, the chemical abortion regimen has no effect. Continued growth may cause the Fallopian tube to rupture, or cause bleeding if the embryo is implanted on another vascular organ. Catastrophic hemorrhage in these situations sometimes leads to maternal deaths.

The limited list of ectopic risk factors included in the protocol leaves out many other risk factors. The American College of Obstetricians and Gynecologists' (ACOG) website also lists: previous pelvic or abdominal surgery, certain sexually transmitted infections (especially chlamydia, which is diagnosed in 5% of women age 15-24[17]), pelvic inflammatory disease, endometriosis, cigarette smoking, age older than 35 years, history of infertility, and use of artificial reproductive technology. ACOG's website also states that half of women with ectopic pregnancies do not have any of these risk factors.[18]

The 2018 ACOG practice bulletin on ectopic pregnancy states, "Tubal ectopic pregnancy in an unstable patient is a medical emergency that requires prompt surgical intervention."[19] The recommendations of this protocol (which allow an asymptomatic woman up to four weeks after the abortion to determine if a pregnancy continues) are starkly unconcerned about the time-limited need to diagnose an ectopic pregnancy, which occurs in 2% of recognized pregnancies but accounts for 13% of maternal deaths.[20]

A woman who experiences ectopic warning symptoms, such as pain or bleeding, while undergoing a chemical abortion may be less likely to report them to a health care provider, because she has been warned to expect just such symptoms as a sign that the abortion drugs are working. A woman is 30% more likely to die from an ectopic while undergoing an abortion than if she had an ectopic but had not sought an abortion.[21]

There are distinct disadvantages of a chemical abortion compared to a surgical abortion

This no-test protocol fails to warn patients who may not be good candidates for chemical abortion. As noted, chemical abortion is being increasingly promoted to women for reasons that benefit the abortionist, but not the woman. A surgical abortion is less likely to result in complications and is completed in a much shorter period of time. The average woman undergoing a chemical abortion bleeds for nine to 16 days, and eight percent will bleed longer than a month. If a pregnancy continues until birth, teratogenic effects such as clubfoot, cranial nerve anomalies, and limb abnormalities related to misoprostol are sometimes seen.[22] The side effects of cramping, vaginal bleeding, hemorrhage, nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness occur in almost all women.[23]

A Finnish records-linkage study of more than 42,000 women published in 2009 and comparing chemical to surgical abortions documented that complications were four times more frequent after chemical (20%) than surgical abortions (5.6%). Hemorrhage (15.6 vs 2.1%) and incomplete abortion (6.7 vs 1.6%) were the most common complications.[24]

This protocol lists only a few contraindications to chemical abortion, but in their 2014 practice bulletin on chemical abortion, ACOG also lists the following situations where chemical abortion may be dangerous: hemoglobin < 9.5 g/dL, severe liver, renal or respiratory disease or uncontrolled hypertension or cardiovascular disease (angina, valvular disease, arrhythmia or cardiac failure). Women with these conditions were excluded from chemical abortion studies, so there is no available data on risks this treatment may pose to these women. Additionally, ACOG states that women are not good candidates for chemical abortion if they are unable or unwilling to adhere to care instructions, desire quick completion of the abortion, are not available for follow-up or cannot understand the instructions because of comprehension or language barriers. None of these cautions are given in the protocol.[25]

Many women suffer from anemia due to iron deficiency from poor nutrition or heavy periods, or hemoglobinopathies such as sickle cell anemia, sickle cell trait, or thalassemia. These women are likely to have a baseline hemoglobin below the 9.5 g/dL cutoff. This protocol does not even prompt the provider to query the patient about potential anemia, even though the extreme blood loss that can occur with a chemical abortion may bring an anemic patient perilously close to hemodynamic compromise.[26]

Additionally, there are other known risk factors for increased likelihood of failed chemical abortion: advanced maternal age, advanced gestational age, multigravity, prior miscarriages, and prior induced abortions.[27] Counseling women about additional risk might compel them to choose a surgical abortion instead, or perhaps if they were thoroughly counseled about all the potential risks of abortion, they might choose to continue their pregnancies.

There is no discussion in this protocol about counseling a woman on options other than abortion. Planned Parenthood's annual report documents that 96% of their pregnant clients obtain an abortion, demonstrating the clear inadequacy of face-to-face counseling by many abortionists.[28] Remote counseling is likely to be even more limited in discussion of other options.

This protocol fails to consider or screen for reproductive coercion

Current FDA regulations require a woman seeking abortion to consume the mifepristone in the presence of the abortionist. One reason for this limitation is to make sure a woman has been counseled and desires the abortion. Potential for misuse and

coercion is high when there is no way to verify who is consuming the drug and whether she is doing so willingly.

ACOG and the National Abortion Federation have documented that women seeking abortions are at risk for reproductive coercion defined as "partner using threats and coercion to enforce his will about the pregnancy outcome," but these abortion-promoting organizations ignore the opportunity for sex traffickers, domestic abusers, and men who do not want to become fathers to surreptitiously give abortion pills to women when these drugs can be easily obtained by anyone.[29]

It has been documented that many women experiencing sex trafficking have been forced into multiple abortions. Interaction with the health care system is an opportunity for these women to be identified and helped, but ready availability of chemical abortion pills to their abusers will remove this opportunity for intervention.[30]

Standard recommendations about anti-D immunoglobulin (Rhogam) are ignored

This protocol exempts women from Rh screening who: are less than 10 weeks' gestational age, state they do not desire children in the future, or who decline anti-D immunoglobulin. Yet, desiring no future children at the time of abortion is not a guarantee that a woman will not actually have future pregnancies. Additionally, clinical experience has demonstrated that most women will agree to receive anti-D immunoglobulin when its importance to their and their future children's health is explained.

This recommendation ignores the 2017 ACOG practice bulletin on alloimmunization which states, "Rh D immune globulin should be given to Rh D-negative women who have a pregnancy termination, either medical or surgical."[31] Additionally, the 2014 ACOG practice bulletin on chemical abortion states, "Rh testing is standard of care in the United States, and Rh immunoglobulin should be administered if indicated."[32]

A 2003 review on alloimmunization demonstrated that nearly all medical societies recommended Rh D immune globulin in Rh-negative women undergoing abortion, because termination of pregnancy may lead to transplacental hemorrhage. It is estimated that fetal blood volume is 0.33 ml at eight weeks' gestation. Risk of isoimmunization in Rh-negative women after first-trimester surgical abortion appears to be 4.6% without Rh D immune globulin but no studies are available examining the risk after chemical abortion.[33]

The consequence of failing to prevent anti-D alloimmunization is great in a subsequent pregnancy. Fourteen percent of untreated, affected infants are stillborn, and one half of liveborn infants suffer neonatal death or brain injury. Approximately 15% of the U.S. population is at risk, and current recommendations of providing anti-D immunoglobulin to at-risk women have reduced the risk of alloimmunization from 13-16%

to 0.14 to 0.2%.[34] The recommendations of this abortion advocacy protocol have the potential to result in catastrophic complications in future pregnancies.

Follow-up recommendations of performing a repeat pregnancy test no earlier than four weeks after mifepristone ingestion delays diagnosis of an ongoing pregnancy by an additional month

If a second abortion must be carried out at a later gestational age due to failure of the first, a woman's risk of complications increases exponentially. Studies have documented the risk of abortion-related mortality increases 38% for each additional week beyond eight weeks' gestation.[35]

Incomplete warning signs of complications are given

This advocacy protocol ignores the FDA black box warning that a fever may not occur in a serious post-abortion infection: "Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following Mifeprex use. *Atypical Presentation of Infection:* Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis. *Bleeding:* Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed."[36]

The immediate complications of chemical 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, particularly when necrotic tissue is retained in the uterus. Misoprostol also has a known immunosuppressive effect.[37] In addition, mifepristone releases inflammatory cytokines that 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.[38] To date at least 24 maternal deaths have been reported in the U.S. from chemical abortions, many from an unusual Clostridium sordellii sepsis.[39]

It is not uncommon for abortion advocates to counsel women utilizing chemical abortions to withhold this knowledge from medical staff if they should present to the emergency room with a complication, leaving the health care provider without all the information he or she needs to adequately care for the patient, or to consider the possibility of atypical infection.[40] Many abortionists do not maintain hospital admitting privileges, so care is often provided by other physicians who may be unfamiliar with the

specific risks of mifepristone.[41] A frightened, hemorrhaging woman is more likely to present to an emergency room than to return to the abortionist who gave her the chemical abortion pills.

This protocol does not address how women will obtain the abortion pills

Will they be prescribed by telemedicine? This will clearly decrease the safety of chemical abortion for rural women if there is limited access to emergency services.[42]

Will they be ordered over the internet? 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 drugs obtained demonstrated that some misoprostol pills contained only 15 percent of the advertised amount, often the packages arrived damaged, and no instructions were contained in any of the packages.[43]

Will they be obtained over the counter from a pharmacy? An Indian study examining the feasibility of providing chemical abortion pills over the counter found that 27% of the 40 women consumed the pills past the recommended gestational age cutoff (nine weeks), with 17% consuming them more than three weeks past the cutoff. This resulted in excessive hemorrhage in 77% of the forty women, surgical evacuation in 68%, severe anemia requiring transfusion in 12%, and 5% presenting in hemodynamic shock.[44]

Will women have access to skilled care should a complication occur? As noted above, catastrophic complications sometimes occur, and emergency care may not be readily available in remote areas. Since there is no therapeutic relationship with a health care provider in this scenario, women may have no one to turn to should adverse events occur.

Chemical abortion utilizing mifepristone and misoprostol is documented to be far less effective than surgical abortion. It is known to have the potential for complications including failure to end the pregnancy, failure to completely evacuate the uterus, hemorrhage, infection, anti-D alloimmunization if immunoglobulin is not given when indicated, ruptured ectopic pregnancy if extra-uterine pregnancy goes undiagnosed, and misuse by those other than a woman who may desire to end her pregnancy. The recommendations in this no-test protocol will increase the risk of these adverse events occurring and are not in the best interests of women undergoing abortion. The resulting complications will increase utilization of precious emergency resources, which is precisely what state limits on non-essential procedures during the COVID-19 epidemic are designed to avoid. It is imperative that these recommendations be viewed skeptically. These abortion advocates do not prioritize the health and safety of women, merely the promotion of abortion.

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