Mifepristone for Unintended or Failed Pregnancy

Wesley Medical Center
Department of Obstetrics and Gynecology

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University of Pennsylvania
Division of Family Planning

May 29, 2019
Disclosures

- I have nothing to disclose
- I will be discussing evidenced-based, off-label use of medications
Goals

- Landscape of abortion and pregnancy loss
- History of mifepristone in the US
- Medical management of first and second trimester abortion and pregnancy loss
Outline

- Background and history of medical abortion
- First trimester medical abortion
- Medical management of early pregnancy loss
- Medical management of second trimester abortion and pregnancy loss
Background: Pregnancy outcomes in 2008

Total of 6,578,000 pregnancy outcomes

- Pregnancy losses: 17%
- Induced abortions: 18%
- Live births: 65%

2.3 million women experienced pregnancy loss or abortion in the U.S. in 2008
Abortion in the US

- Nearly half of pregnancies are unplanned
- 1 in 4 women will have an abortion
- 926,200 abortions performed in 2014

Jones et al. Perspect Sex Repro Health, 2014
In 2014, the U.S. abortion rate reached a historic low.
Abortion is increasingly concentrated among poor women

% of abortion patients

1987: 30%
1994: 26%
2000: 26%
2008: 49%
2014: 26%

Below federal poverty level
1-2x federal poverty level

gu.tt/Abortion2014 ©2017
Abortion rates continue to vary by race and ethnicity

Lack of access to health insurance and health care plays a role, as do racism and discrimination

Abortions per 1,000 women aged 15–44
Who Has Abortions?

U.S. Abortion Patients

INCOME
75% poor or low income

RELIGION
62% religiously affiliated

FAMILY SIZE
59% already have a child

AGE
60% are in their 20s (only 12% are teens, of which 4% are minors)

RACE
39% White
28% Black
25% Hispanic
6% Asian/Pacific Islander
3% Other

guttmacher.org ©2016
Background: when women have abortions

80% of pregnancy losses occur in the first 12 weeks of pregnancy

*In weeks from the last menstrual period.

www.guttmacher.org
Top Three Reasons for Abortion

- Responsibility to other individuals
- Inability to afford a child
- Interference with work, school or other responsibility

Finer, 2005
Safety of Abortion

- One of the safest medical procedures
- No risk to future reproduction
- No risk of breast cancer
- No increased risk of depression

- The strongest risk factor for abortion related mortality is gestational age

Earlier Is Safer

Medical vs procedural management

Up to 40% of women offered medical and surgical management of miscarriage will choose medical management

Jones RK and Jerman J, PSRH, 2017; Schreiber et al, NEJM 2018
# Medical vs Surgical

## Characteristics of Early Abortion Methods

<table>
<thead>
<tr>
<th>Aspiration Abortion</th>
<th>Medical Abortion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly effective</td>
<td>Highly effective</td>
</tr>
<tr>
<td>Procedure brief</td>
<td>Process takes one to several days to complete</td>
</tr>
<tr>
<td>Involves invasive procedure</td>
<td>Avoids invasive procedure</td>
</tr>
<tr>
<td>Allows option of sedation or general anesthesia</td>
<td>Avoids anesthesia</td>
</tr>
<tr>
<td>Usually requires only one visit</td>
<td>May involve two visits or more</td>
</tr>
<tr>
<td>Lighter perceived bleeding</td>
<td>Heavier perceived bleeding</td>
</tr>
<tr>
<td>Requires clinical setting</td>
<td>May occur in privacy of home</td>
</tr>
</tbody>
</table>

Paul, 2009
First Trimester Medical Abortion
Medical Abortion

- Accounted for ~ 31% of all abortions in 2014

- Mifepristone + Misoprostol
  - 92-98% effective in inducing abortion

- Safe
  - < 0.3% chance of complication requiring hospital

Jones, 2017
Mifepristone

- Derivative of Norethindrone
- Antiprogestosterone

- World Health Organization
  "Essential Medication"
Mechanism of Action of Mifepristone

1. **Progesterone Blockade**
   - **Decidual Necrosis**
   - **Rhythmic Uterine Contractions**
   - **Cervical Ripening**
     - **Detachment**
     - **Expulsion**

2. **Abortion**
Misoprostol

- PGE$_1$ analogue
- Oral, vaginal, buccal, sublingual, rectal
- Inexpensive
- Widely available
- Stable at room temperature
New F.D.A. Guidelines Ease Access to Abortion Pill

Demonstrators at the Supreme Court building on March 2 when the court heard arguments in a major abortion case. The F.D.A. on Wednesday eased some requirements for taking a medication that induces abortion. Gabriella Demczuk for The New York Times
<table>
<thead>
<tr>
<th>September 2000</th>
<th>March 2016</th>
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<tr>
<td>Day 14: Follow up in clinic</td>
<td>7-14 days after Mifeprex: Follow-up with healthcare provider</td>
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</table>
Twice as many abortion patients are eligible for medication abortion following the 2016 FDA label change.

**ORIGINAL FDA LABEL**
Up to 49 days' gestation

Percentage of eligible abortion patients

**NEW FDA LABEL**
Up to 70 days' gestation

Based on distribution of U.S. abortions by gestation in 2012

Jones, 2016
# Mifepristone Dosage

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*September 2000* to *March 2016*
Decreasing the dose of mifepristone

- Double-blind RCT of 1589 women in 17 centers
- Through 49 days gestation

**600 MG ORAL MIFEPRISTONE, FOLLOWED IN 48 HOURS BY 400 MCG MISOPROSTOL**
- Success 88%
- Failure 12%

**200 MG ORAL MIFEPRISTONE, FOLLOWED IN 48 HOURS BY 400 MCG MISOPROSTOL**
- Success 89%
- Failure 11%

WHO Task Force. BJOG, 2000
## Misoprostol Route

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**Misoprostol route**

- **Oral**
  - Lower bioavailability
  - Fast peak = ↑ side effects

- **Sublingual**
  - Most rapid absorption and highest peak = ↑↑↑ side effects
  - Highest bioavailability

- **Vaginal**
  - High bioavailability
  - Slower absorption, more gradual peak = ↓↓↓ side effects

- **Buccal**
  - Effects on uterine tone and activity similar to vaginal

- **Rectal**
  - Quick peak
  - Less total bioavailability

_Tang, 2007_
Misoprostol Route

Zieman et al. Obst and Gyn, 1997
Winikoff et al. Obst and Gyn, 2008
Misoprostol: Buccal vs Vaginal

- Open-label RCT
- Through 56 days
- Mifepristone 200 mg → 800 mcg of miso 1-2 days later

<table>
<thead>
<tr>
<th></th>
<th>Buccal</th>
<th>Vaginal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete Abortion</td>
<td>95%</td>
<td>93%</td>
</tr>
<tr>
<td>Continuing Pregnancy</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

Middleton et al. Contraception, 2005

p = 0.51
<table>
<thead>
<tr>
<th>Gestational Age Eligibility</th>
</tr>
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Effect of Gestational Age

- Systematic review
- Mifepristone and buccal misoprostol

<table>
<thead>
<tr>
<th>Gestational Age</th>
<th>Complete Abortion (%)</th>
<th>Ongoing Pregnancy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 49 days</td>
<td>98.1 [97.9, 98.3]</td>
<td>0.4 [0.3, 0.5]</td>
</tr>
<tr>
<td>50-56 days</td>
<td>96.7 [96.1, 97.2]</td>
<td>0.8 [0.6, 1.2]</td>
</tr>
<tr>
<td>57-63 days</td>
<td>95.2 [94.2, 96]</td>
<td>1.8 [1.3, 2.5]</td>
</tr>
<tr>
<td>64-70 days</td>
<td>93.1 [89.6, 95.5]</td>
<td>2.9 [1.4, 5.7]</td>
</tr>
</tbody>
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Chen et al. Obstet and Gyn, 2015
## Timing of Misoprostol

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</table>

"MAB through 49 days" and "MAB through 70 days" denote the duration of the abortion process.
Simultaneous dosing of vaginal misoprostol

- Randomized controlled trial of 1,128 participants

- UP TO 63 DAYS

- Statistically noninferior

- Can give mifepristone and vaginal misoprostol at the same time

Simultaneous dosing of **buccal misoprostol**

- Pilot study
- Simultaneous 200 mg mifepristone and 800 mcg buccal misoprostol

_Simultaneous buccal misoprostol **NOT** an option_
Current FDA-approved protocol

- 200 mg mifepristone orally
- 800 mcg of misoprostol buccally 24 hours later
- OR vaginally with no timing delay
- Follow up with a healthcare provider after 7-14 days

<table>
<thead>
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<th>FDA labeling March 2016</th>
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<tbody>
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<td>MAB through 70 days</td>
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<tr>
<td>24-48 hours later: 800 mcg misoprostol buccally</td>
</tr>
<tr>
<td>7-14 days later: Follow-up with healthcare provider</td>
</tr>
</tbody>
</table>
The follow-up visit: two criteria for completion

- 1) Lack of gestational sac on ultrasound
- 2) Resolution of symptoms
  - History consistent with passage of tissue
  - Resolution of pain
  - Decreased bleeding
- Endometrial thickness is not a clinically useful predictor of the need for subsequent uterine aspiration

First trimester spontaneous abortion
1 in 4 women will experience a miscarriage in their lifetime
Early pregnancy loss management

- Four options for a clinically stable patient:
  - Medical management
  - Procedure:
    - Uterine aspiration with anesthesia (OR)
    - Uterine aspiration with local (office)
  - Expectant management
Patient-centered care

- All management options are effective, with equivalent safety & patient acceptability = clinical equipoise

NSFG 2004; Chen 2007; Wieringa-de Waard, 2002; Zhang, 2005; Trinder 2006
Standard regimen

- 800 mcg misoprostol vaginally

- 15-40% of women will require a second dose
Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss

Courtney A. Schreiber, M.D., M.P.H., Mitchell D. Creinin, M.D., Jessica Atrio, M.D., Sarita Sonalkar, M.D., M.P.H., Sarah J. Ratcliffe, Ph.D., and Kurt T. Barnhart, M.D., M.S.C.E.
Mifepristone + Misoprostol for SAB

- RCT of 300 women diagnosed with early pregnancy loss
- Multi-site comparative effectiveness trial

Arm 1:
Misoprostol 800 mcg

Arm 2:
Mifepristone 200 mg + Misoprostol 800 mcg

Follow-up Day 3, Day 8 PRN
Comparative Efficacy

- Success with combined regimen 25% higher than with misoprostol alone by day 3

<table>
<thead>
<tr>
<th></th>
<th>Total (n=297)</th>
<th>Miso Alone (n=149)</th>
<th>Combined (n=148)</th>
<th>RR (95% CI)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success by</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All successes</td>
<td>224 (75.4%)</td>
<td>100 (67.1%)</td>
<td>124 (83.8%)</td>
<td>1.25 (1.09, 1.43)</td>
</tr>
<tr>
<td>Required Procedure</td>
<td>48 (16.2%)</td>
<td>35 (23.5%)</td>
<td>13 (8.8%)</td>
<td>0.37 (0.21, 0.68)</td>
</tr>
</tbody>
</table>

Women receiving combined treatment are 63% less likely to need a procedure (NNT=7)

*All successes by day 3 were with 1 dose and no additional interventions (primary outcome for the trial).

**All p-values are ≤ .001

Data are presented as n (%).
## Serious Adverse Events

<table>
<thead>
<tr>
<th></th>
<th>Total (n=300)</th>
<th>Miso Alone (n=151)</th>
<th>Combined (n=149)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion</td>
<td>4 (1%)</td>
<td>1 (&lt;1%)</td>
<td>3 (2%)</td>
<td>0.31</td>
</tr>
<tr>
<td>Infection</td>
<td>4 (1%)</td>
<td>2 (1%)</td>
<td>2 (1%)</td>
<td>0.99</td>
</tr>
<tr>
<td>Interim Visit</td>
<td>45 (15%)</td>
<td>26 (17%)</td>
<td>19 (13%)</td>
<td>0.28</td>
</tr>
</tbody>
</table>

Data are presented as n (%)
Conclusions

- Combined treatment improves rapid success by 25%

- Combined treatment avoids one procedure for every 7 women treated

- Safety is not compromised

- Combined regimen should be standard of care
INTERIM UPDATE: This Practice Bulletin is updated as highlighted to reflect recent evidence regarding the use of mifepristone combined with misoprostol for medical management of early pregnancy loss. This Practice Bulletin also includes limited, focused updates to align with Practice Bulletin No. 181, Prevention of Rh D Alloimmunization.
REMS Criteria

- Prohibits prescription through pharmacy
- Providers must complete provider agreement form
- Complete Danco patient agreement form
- Provide medication guide to patient
Mifepristone Tablets, 200 mg, are indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To set up your account to receive Mifepristone, you must:
1. complete, 2. sign, and 3. fax page 2 of this form to the distributor.

If you will be ordering for more than one facility, you will need to list each facility on your order form before the first order will be shipped to the facility.

Prescriber Agreement: By signing page 2 of this form, you agree that you meet the qualifications below and will follow the guidelines for use. You also understand that if you do not follow the guidelines, the distributor may stop shipping Mifepristone to you.

Mifepristone must be provided by or under the supervision of a healthcare provider who prescribes and meets the following qualifications:
- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information of Mifepristone. The Prescribing Information is available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, www.earlyoptionpill.com.

In addition to meeting these qualifications, you also agree to follow these guidelines for use:
- Review the Patient Agreement Form with the patient and fully explain the risks of the Mifepristone treatment regimen. Allow any questions the patient may have prior to receiving Mifepristone.
- Sign and obtain the patient's signature on the Patient Agreement Form.
- Provide the patient with a copy of the Patient Agreement Form and the Medication Guide.
- Place the signed Patient Agreement Form in the patient's medical record.
- Record the serial number from each package of Mifepristone in each patient's record.
- Report deaths to Danco Laboratories, identifying the patient by a non-identifiable patient reference and the serial number from each package of Mifepristone.
PATIENT AGREEMENT FORM

Healthcare Providers: Counsel the patient on the risks of Mifeprex*. Both you and the patient must sign this form.

Patient Agreement:

1. I have decided to take Mifeprex and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.

2. I understand:
   a. I will take Mifeprex on Day 1.
   b. My provider will either give me or prescribe for me the misoprostol tablets which I will take 24 to 48 hours after I take Mifeprex.

3. My healthcare provider has talked with me about the risks including:
   - heavy bleeding
   - infection
   - ectopic pregnancy (a pregnancy outside the womb)

4. I will contact the clinic/office right away if in the days after treatment I have:
   - a fever of 100.4°F or higher that lasts for more than four hours
   - severe stomach area (abdominal) pain
   - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
   - stomach pain or discomfort, or I am “feeling sick”, including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol

5. My healthcare provider has told me that these symptoms could require emergency care. If I cannot reach the clinic or office right away my healthcare provider has told me who to call and what to do.

6. I should follow up with my healthcare provider about 7 to 14 days after I take Mifeprex to be sure that my pregnancy has ended and that I am well.

7. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.

8. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.

9. I have the MEDICATION GUIDE for Mifeprex. I will take it with me if I visit an emergency room or a healthcare provider who did not give me Mifeprex so that they will understand that I am having a medical abortion with Mifeprex.

10. My healthcare provider has answered all my questions.

Patient Signature: ____________________ Patient Name (print): ____________________ Date: ____________________
Second Trimester Abortion and Pregnancy Loss
Mifepristone for IOL

- **14-21 weeks, live fetus**

**Day 1**

**Day 2**

Q 3 h up to 5 doses

Buccal misoprostol
400mcg

If no fetal expulsion 3 hr after last dose, D&E

If placenta in but fetus out, one more dose of miso and wait 6 hr before D&E

Mifepristone for IOL

Study arms
- Misoprostol alone
- Mifepristone and misoprostol

Cumulative survival

Time to completion (hours)
Mifepristone for IOL

- RCT
- Median induction time 8.6 h vs. 18.2 h
- No difference in side effects

Mifepristone for IOL

- 14-24 weeks, live or demised fetus

Time 0  

36 hr  

Expulsion of fetus after 36 hr

Vaginal misoprostol  
800mcg  
+ 400mcg PO q 3 x 4

High-dose pitocin (150 mU/min)

Mifepristone for IOL

Fig. 2. Kaplan–Meier time curve for induction to expulsion of fetus for the two study groups. Time until expulsion was shorter in misoprostol group compared with oxytocin treatment (hazard ratio 2.53, 95% confidence interval 1.76–3.65, \(P<.001\)).
Mifepristone in second-trimester pregnancy loss

- Randomized, placebo-controlled trial in India
- IUFD of GA 20 weeks or greater
- Mifepristone 200 mg, 100 mcg misoprostol vaginally every 6 hours

<table>
<thead>
<tr>
<th></th>
<th>Mife+miso N=53</th>
<th>Placebo+miso N=52</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful delivery</td>
<td>49 (92.5%)</td>
<td>37 (71.2%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean induction time (h)</td>
<td>9.8 ± 4.4</td>
<td>16.3 ± 5.7</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

- Data for previable PPROM is scant: but minimal harm in adding mifepristone to induction regimen

Dosing interval

- Induction time vs. total procedure time
Dosing interval

- RCT, n = 509
- Mifepristone 24 h before vs. at the time of first misoprostol dose

<table>
<thead>
<tr>
<th></th>
<th>24 h before</th>
<th>Simultaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete abortion at 24 h</td>
<td>94.4%</td>
<td>85.0%*</td>
</tr>
<tr>
<td>Complete abortion at 48 h</td>
<td>96.8%</td>
<td>95.7%</td>
</tr>
<tr>
<td>Median induction time</td>
<td>7.7 h</td>
<td>13.0 h*</td>
</tr>
<tr>
<td>Median total procedure time</td>
<td>32.3 h</td>
<td>13.0 h*</td>
</tr>
</tbody>
</table>

* Statistically significant difference
Simultaneous Mife and Miso

- Prospective study of 150 patients
- Mife 200 mg + Miso 400 mcg → Miso 200 mcg every 4 hours
- End point was expulsion of placenta

- Mean induction time 13 hours
- 96% complete by 24%
- 100% by 32 hours
Guidelines

♦ Preferred regimen
  (efficacy, speed, side effects)
  • Mifepristone 200mg PO
  • 24-48 hr interval
  • Misoprostol 800mcg vaginally
  • Misoprostol 400mcg vaginally or sublingually q 3 hr
  • Max 5 doses
  • If not complete, rest 12 hr and restart
Guidelines

❖ Combined is ideal
  • Mifepristone 200mg
  • 24-48 hr interval
  • Misoprostol loading dose 600-800mcg vaginally
  • Misoprostol 200mcg q 3 h (vaginal or sublingual)

❖ Pregnancies with a fetal demise may be treated similarly; may need lower doses and have a shorter induction time

❖ Routine placental removal is not warranted
Mifepristone for Cervical Preparation

Alternative to osmotic dilators at 14-16 weeks

Adjunct to osmotic dilators over 19 weeks
The Fellowship in Family Planning, based in 30 leading departments of ob-gyn, is the only fellowship in the nation that provides the opportunity to develop high-level research and clinical skills in contraception and abortion.

- Advanced clinical and research training
- Generous funding package, including Master's degree tuition and meeting attendance
- Research funding
- Fully funded global health opportunity
- Post-fellowship academic career opportunities and funding support
- Connection to a national network of over 300 family planning specialists

For more information and to apply online, please visit www.familyplanningfellowship.org
FELLOWSHIP IN FAMILY PLANNING PROGRAM SITES

30 programs in departments of Obstetrics & Gynecology in 17 states, DC & 1 Canadian province

03/2018
The Ryan Program provides resources and technical expertise to help departments of ob-gyn improve resident training in abortion and contraception.

THE FOLLOWING SUPPORT AND RESOURCES ARE OFFERED:

- Start up funds for faculty, staff and equipment
- Technical support to establish an opt-out rotation
- Didactic curriculum focused on evidence-based practice
- Annual meetings, workshops and webinars

RESIDENTS AT A RYAN PROGRAM SITE CAN EXPECT:

- A formal, required clinical curriculum in abortion and contraception
- Extensive training in all methods of contraception (including LARC insertion) and managing the contraceptive needs of medically complex patients
- Comprehensive training in outpatient first trimester surgical and medication abortion, with the opportunity to learn D&E procedures
- Complete exposure to options counseling, procedure counseling and early gestational ultrasound training
RYAN PROGRAM SITES

90 PROGRAMS IN 32 STATES

Current Ryan Program
No Ob-Gyn Residency
No Ryan Program