

Iffy about Mife?: Improving Access to Medical Abortion in Family Practice





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Disclosure / Conflict of Interest

Relationship with Commercial Interests: none



"Try this—I just bought a hundred shares."

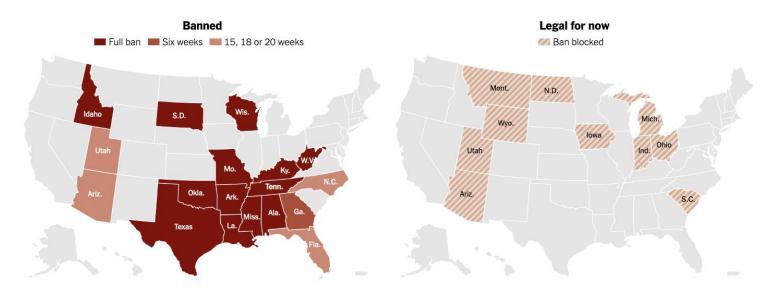
- 1) Discuss ways to implement mifepristone abortion care in family practice
- 2) Assess and counsel patients regarding risks, side effects, and advantages of mifepristone in patients who are interested in medical abortions
- 3) Assess and manage common questions/concerns and complications of mifepristone

Agenda

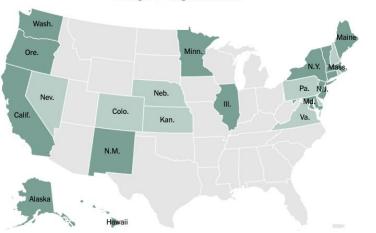
- 1) Introduction
- 2) Overview of mifepristone/misoprostol regimen
- 3) Cases
- 4) Tools and Resources
- 5) Questions and Wrap-up



Tracking the States Where Abortion Is Now Banned



Legal Legal but limited



Abortion in Canada

- ~ 100, 000 abortions/year
- 1 in 3 women has an abortion in her lifetime
- Limited access outside of large urban centers (except Quebec & BC)

Abortion clinic accessibility across Canada (as of July, 2019)

Abortion clinics are mainly located in large urban centres, meaning women who live outside those areas must travel long distances and pay out-of-pocket expenses to access the service. This map illustrates driving times to abortion clinics from cities across Canada

Yukon

B.C. Prince

George

Campbell

Courtenav

Grande

Prairie

Lethbridge



MURAT YÜKSELIR / THE GLOBE AND MAIL SOURCE: HERE TECHNOLOGIES: STATISTICS CANADA Prior to mifepristone ~5% of abortions in Canada were medical (mostly in BC)

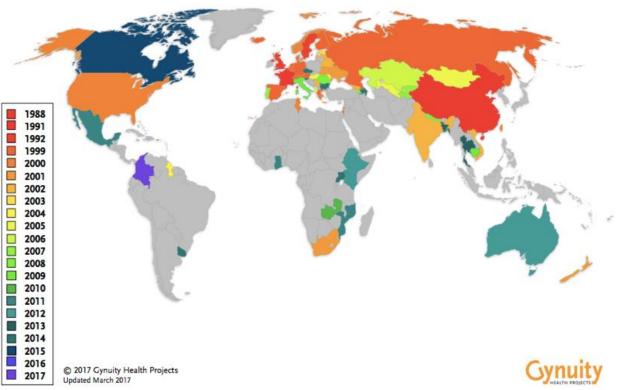
Norman WV, Contraception 2012;85:185-91. Norman WV, Guilbert E, et al. Canadian Family Physician 2016 Sethna C, Doull M. Women's Studies International Forum 2013

Pro-Choice Rally in NB 2014



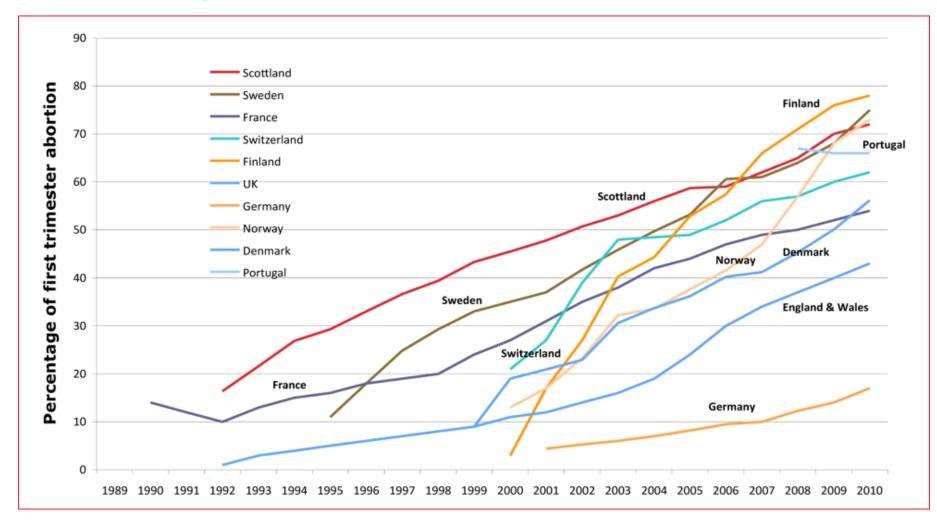
History of Mifepristone for MA

- Ist approved in France in 1988 "RU-486"
- Now gold standard for medical abortion worldwide 1988
- WHO List of Essential Medicines
- 62 countries approved between 1988 and 2015
- Approved by Health Canada mid-2015
 "Mifegymiso" mifepristone + misoprostol
- 4 countries since 2015 (mostly in Africa)



Mifepristone Approved

Use of mifepristone for abortion



Berard V, Fiala C, et al. PloS ONE DOI: 10.1371/journal.pone.0112401

Options for Patients in Countries Without Legalized Abortion





Why Medical Abortion?

Many patients prefer it

- Less invasive/avoids anesthesia
- Rapid/immediate availability
- Patient 'takes charge' of the abortion process

Satisfaction rates comparable to surgical methods

80-95% would choose the method again or recommend the method to a friend

Improved access in areas where there are no surgical abortion services

- Increases number of potential providers
- Requires less infrastructure (no OR/procedure room)

Swica Y et al, (2011) Expert Rev Obstet Gynecol 6.4

July 2015 Health Canada Approval

- Mifegymiso®: mifepristone 200 mg (1 tab) and misoprostol 800 mcg (4 x 200 mcg tabs)
- Indication: Termination of pregnancy up to 49 days gestation
- Available by "limited" prescription only
 - Mandatory on-line training & registration for prescribing physicians & dispensing pharmacists
 - Registered physicians could order and dispense
 - Observed ingestion of mifepristone required.
- Signed informed consent and information sheet required.

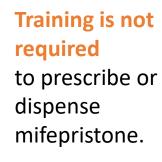
KEY POLICY CHANGES SINCE APPROVAL



Health care professionals are not required to witness a patient when they take medical abortion pills.



Pharmacists may dispense Mifepristone directly to patients like any other drug.





Physicians' personal information cannot be shared with the manufacturer.



Nurse

practitioners may prescribe Mifepristone in Alberta, BC, Ontario, Nova Scotia, Yukon, and Saskatchewan.



....

Universal

coverage of mifepristone has occurred in all provinces and most of the territories.



MIFEGYMISO: ACCESS AND COVERAGE IN CANADA

ACCESS

Since November 7, 2017 all pharmacists across Canada have been authorized to dispense Mifegymiso directly to patients.

PROVINCIAL/TERRITORIAL COVERAGE

Universal Coverage

No coverage

NATIONAL COVERAGE IS LIMITED TO:

- Non-insured Health Benefits Program
- Interim Federal Health Program
- Canadian Forces Health Services
- Programs for Correctional Services of Canada

FOR MORE INFORMATION www.pharmacists.ca

Updated: June 11, 2019

An estimated 86% of Nunavut residents are eligible for coverage through the Non-Insured Health Benefits Program

> CANADIAN ASSOCIATION DE PHARMACISTS PHARMACIENS ASSOCIATION DU CANADA

Current Health Canada Approval November 7, 2017

- Indication: Termination of pregnancy up to 9 weeks (63 days) gestation
- Health professionals are required to :
- Provide the patient with the current Patient Medication Information and a completed Patient Information Card
- Exclusion of ectopic pregnancy and confirmation of gestational age by ultrasound is no longer required (required if ?ectopic or GA uncertain)
- Counsel on the effects and risks
- Ensure patients have access to emergency medical care in the 14 days following administration of mifepristone; and,
- Schedule a follow-up 7 to 14 days after patients take mifepristone to confirm complete pregnancy termination and monitor for side effects.

Approved information and consent

Mifegymiso

Mifepristone and Misoprostol For medical termination of a pregnancy



Patient Information Brochure



linepharma

UK sponsor

Mifegymiso Patient Information Card

To be completed by your health professional. Please keep it with you.

Date and time of treatment:

Step 1 (Green Box):

Step 2 (Orange Box):

If you have a serious symptom or side effect, get immediate medical help. If you have an emergency, go to:

Mifegymiso Patient Consent Form

Mifegymiso (mifepristone and misoprostol) for termination of pregnancy

- I understand the MIFEGYMISO medical abortion process and the possible risks and side effects of the treatment. I have discussed the information with my health professional and he/she answered all my questions.
- 2. I understand that MIFEGYMISD medical abortion is irreversible.
- I understand that once I start MIFEGYMISO, I have to complete both steps. Both mifepristone and misoprostol can cause birth
 defects if my pregnancy is continued.
- I understand that I can decide against having MIFEGYMISO at any time before I start taking the drugs.
- 5. I understand what to expect during the expulsion.
- 6. I understand that I will take the first part of the treatment mifepristone (green box) (Day 1).
- I understand that I will take misoprostol (orange box), 24 to 48 hours after I take mifepristone. I understand it is up to me to decide when to take the tablets within this specified time period. It is recommended that I plan this process to fit within my daily schedule.
- 8. My health professional gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
- Bleeding and cramping do not mean that my pregnancy has ended. I must schedule a follow-up with my health professional within 7-14 days (1-2 weeks) after I take Milegymiso to be sure that my pregnancy has ended and that I am well.
- 10. I know that in some cases, the treatment will not work. This happens in about 2.7-5.1% of women who use this treatment.
- 11. Lunderstand that if my pregnancy continues after any part of the treatment, there is a chance of birth defects. If my pregnancy continues after treatment using Mifeormiso Imifeoristone, misographical Liwill talk with my health professional about my choices.

<u>http://celopharma.com/en/health-professionals</u>

Overview of Regimen

Mifepristone/misoprostol regimen:



- 1. Mifepristone 200 mg PO
 - 2. Misoprostol 800 mcg buccal* 24-48 hours later

*OFF LABEL: vaginal miso has similar pharmacokinetics, may have less side effects, can use 6-72 hours after mifepristone

- Misoprostol Impairs Female Reproductive Tract Innate Immunity against *Clostridium sordellii*
- David M. Aronoff,^{*,2} Yibai Hao,^{*} Jooho Chung,[†] Nicole Coleman,^{*} Casey Lewis,[†] Camila M. Peres,[†] Carlos H. Serezani,[†] Gwo-Hsiao Chen,[†] Nicolas Flamand,[†] Thomas G. Brock,[†] and Marc Peters-Golden[†]

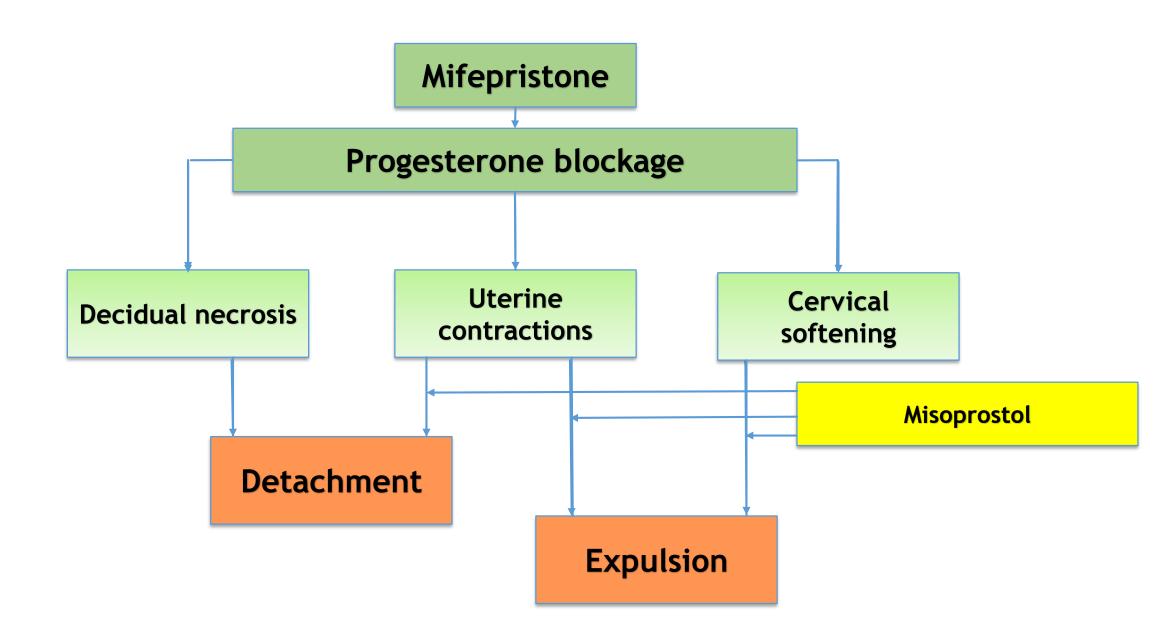
Mechanism of action

Mifepristone - antiprogestin

- Blocks the action of progesterone
- Breakdown of endometrium, cervical ripening
- Increased sensitivity of uterus to prostaglandins

Misoprostol - synthetic prostaglandin

binds to myometrial cells, causes cervical ripening and uterine contractions



Expected Side Effects

Mifepristone:

no side effects or nausea only, occasionally cramping/spotting (5%)

Misoprostol:

Common: cramping - may be severe (7-10/10) bleeding - may be heavy, including large clots diarrhea (2-61%) nausea/vomiting (16-47%) fever/chills (4-48%) headache (2-43%) and dizziness (12-41%)

Chen MJ, Creinin M. Obstet Gynecol 2015

Other drug effects

Teratogenicity

- Mifepristone no evidence of teratogenic effect to date (ACOG, 2020)
- Misoprostol associated with Mobius syndrome (facial paralysis and limb and chest wall abnormalities)

Use in breastfeeding

- Mifepristone excreted in breast milk in very low concentrations (RID = 1.5%)
- Misoprostol excreted in breast milk theoretical potential to cause diarrhea
- Breastfeeding may continue uninterrupted

National Abortion Federation 2016

Outcomes

Efficacy: 95 - 98% successful abortion without the need for surgical aspiration

Ongoing viable pregnancy: 0.4 - 2.9% from < 49 to 70 days</p>

Complications:

- Hemorrhage requiring transfusion: 0.08% (0.04-0.9%)
- Infection: 0.01-0.5%
- ER visits: 2.9-3.7%
- ► Hospitalization: 0.4% (0.04-0.9%)

Chen MJ, Creinin M. Obstet Gynecol 2015

Patient MG

- 26 yo G1P0
- LMP approximately 5-6 weeks ago
- Home urine pregnancy test +
- Wants to terminate

Visit 1 - Unintended pregnancy

- Review options for unintended pregnancy
- Pros/cons of medical vs surgical abortion
- Inclusion & exclusion criteria
- Investigations
- Contraception

Medical vs surgical abortion: decision making

Medical abortion	Surgical abortion
 Pros Avoids uterine instrumentation and anesthesia Private/happens at home Support person can be present Patient 'takes charge' of the abortion May be accessible through primary care/shorter wait 	 Pros Quick and predictable Higher success rate Usually does not require follow up Allows use of sedation Less bleeding and cramping
 Cons May take days/weeks to complete Pain may be severe and bleeding heavy Multiple visits/follow up needed Higher failure rate than aspiration Requires access to emergency care 	 Cons Instrumentation and anesthesia Need to travel to surgical abortion facility (involves time, travel and expense for many)

Visit 1 Inclusion Criteria

- Clear decision to have a medical abortion
- Intrauterine pregnancy less than 9 (10) weeks
- Access to telephone and emergency medical care within the next 7-14 days
- Willing to have surgical abortion/D&C in the event that medical abortion is unsuccessful (2%-5% of pregnancies)

Initial visit Exclusions/Contraindications

Absolute contraindication:

- Confirmed or probable ectopic pregnancy
- Chronic adrenal failure
- Uncontrolled asthma
- Porphyria
- Hemorrhagic disorder or concurrent anticoagulant therapy (aspirin excluded)
- Allergy/Hypersensitivity to mifepristone or misoprostol

Relative contraindications:

- ► IUD (remove)
- Concurrent long-term systemic corticosteroid therapy
- Anemia hemoglobin less than 95

Initial Visit Investigations

Pelvic US

- Gestational age and location of the pregnancy
- Chlamydia & gonorrhea testing
- Blood type for Rh factor if GA >= 8 weeks
- beta-HCG (on day of mifepristone) and follow up 7-14 days later

Consider CBC

Initial visit Contraception post-abortion

- **Rapid return to fertility:** ovulation as early as one week after mifepristone
- Hormonal methods can be started on the day of or the day after misoprostol administration (Return for Depo-Provera)
- Barrier methods can be used as soon as sexual activity is resumed
- Intrauterine devices can be inserted at the follow up visit if abortion complete

Visit 2 Mifegymiso Rx and handouts

- Review investigations, inclusion and exclusion criteria
- Counselling
 - How to take medication
 - Expected bleeding, cramping & side effects
 - Reasons to seek emergency or on-call care
- Informed consent & Patient Take Home Instructions (Linepharma or other) provided
- Prescribe Mifegymiso, pain medication +/- anti-emetic, contraception

Mifegymiso Patient Consent Form

Mifegymiso (mifepristone and misoprostol) for termination of pregnancy

- I understand the MIFEGYMISO medical abortion process and the possible risks and side effects of the treatment. I have discussed the information with my health professional and he/she answered all my questions.
- I understand that MIFEGYMISO medical abortion is irreversible.
- I understand that once I start MIFEGYMISO, I have to complete both steps. Both mifepristone and misoprostol can cause birth defects if my pregnancy is continued.
- I understand that I can decide against having MIFEGYMISO at any time before I start taking the drugs.
- 5. I understand what to expect during the expulsion.
- 6. I understand that I will take the first part of the treatment mifepristone (green box) (Day 1).
- I understand that I will take misoprostol (orange box), 24 to 48 hours after I take milepristone. I understand it is up to me to decide when to take the tablets within this specified time period. It is recommended that I plan this process to fit within my daily schedule.
- 8. My health professional gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
- Bleeding and cramping do not mean that my pregnancy has ended. I must schedule a follow-up with my health professional within 7-14 days [1-2 weeks] after I take Mifegymiso to be sure that my pregnancy has ended and that I am well.
- 10. I know that in some cases, the treatment will not work. This happens in about 2.7-5.1% of women who use this treatment.
- 11. I understand that if my pregnancy continues after any part of the treatment, there is a chance of birth defects. If my pregnancy continues after treatment using Mifegymiso [mifepristone, misoprostol], I will talk with my health professional about my choices, which may include a surgical procedure to end my pregnancy.
- 12. I understand that if the medicines I take do not end my pregnancy and I decide to have a surgical procedure to end my pregnancy, or if I need a surgical procedure to stop bleeding, my health professional will do the procedure or refer me to another health professional wine will.
- 13. I have my health professional's name, address and phone number and know that I can call if I have any questions or concerns.
- 14. I have decided to take Mifegymiso (mifepristone, misoprostol) to end my pregnancy and will follow my health professional's advice about when to take each drug and what to do in an emergency.
- 15. I must ensure that I have access to emergency medical care within a reasonable time-limit in case of emergency.
- 16. I will do the following:
- Contact my health professional as soon as possible if in the days after treatment I have a fever of 100.4°F (38°C) or higher, that lasts for more than 4 hours or I experience severe abdominal pain.
- Contact my health professional as soon as possible if I have heavy bleeding, soaking through two thick full-size sanitary pads
 per hour for 2 consecutive hours.
- Contact my health professional as soon as possible if I have abdominal pain or discomfort, or I am "feeling sick", including weakness, nausea, vomiting or diarrhea, with or without fever, for more than 24 hours after taking misoprostol.
- Take the Patient Information Card with me when I visit an emergency room or a health professional who did not give me Mifegymiso, so that they understand that I am having a medical abortion with Mifegymiso.
- Have a follow-up 7-14 days after taking Mifegymiso to check if my pregnancy has ended. My health professional will talk
 with me about my options if I am still pregnant.

I have made the decision to end my pregnancy labortion) after consultation with my health professional. I have made this decision without coercion and on my own free will and being of sound mind.

Date: __

... Date: ____

Patient name (print): _____

Patient signature: _____

The patient has signed the Patient Consent form in my presence after I counselled her and answered all her questions.

Health professional name (print): _____

Health professional signature:

After the patient and the health professional sign this Patient Consent form, the health professional shall give a copy to the patient before she leaves the office and keep a copy within the patient's medical record.

Visit 2 Counselling - how to take the medication

Mifepristone orally, 24-48 hr later misoprostol buccal for 30 min

• Always take misoprostol whether or not they bleed



UK sponsor	Mifegymiso atient Information Card		gymiso ormation Card	
To be cor	npleted by your health professional. Please keep it with you.		To be completed by your health professional. Please keep it with you.	
Step 1 (Green Bo Step 2 (Orange B	Date and time of treatment: x): ox):	If you have a troublesome symptom or side effect that becomes bad enough to interfere with your daily activities, talk to your health professional.	You must have a follow-up appointment 7 to 14 days after taking Mifegymiso.	
	have a serious symptom or side effect, get immediate medical help. If you have an emergency, go to:	Phone number and address of your health professional, clinic or treatment center:	Follow-up appointment date (MM/DD/YYYY) and time:	
	e emergency contact information above] Card to the emergency health professional.		Distributor in Canada	

MEDICAL ABORTION	Patient Na DOB: Health Car	Age:	
CHARTING FORM	nearth Car	u.	
Counselling Pregnancy options counselling provided Surgical vs. medical abortions discussed Medical abortion protocol explained Reviewed timing of ultrasound, labtests, r Reviewed effectiveness, side effects and p Contra ception plan:	otential com		
2. Determine Eligibility for a Medical Abortion	1		
Confirm All Inclusion Criteria Expresses clear decision to have an abortion No indication of being coerced into abortion Informed consent process completed Understands expected side effects (bleeding, cra Agrees to comply with the visit schedule Agrees to a surgical abortion should pregnancy of Understands when and where to consult in case emergent complications Has access to a telephone, transportation, and e medical care Review of current medications	ontinue of	Absolute Contraindications (exclude all) Chronic a drenal failure Inherited porphyria Uncontrolled asthma Allergy to mifepristone or misoprostol Ectopic pregnancy Coagul opathy or current anticoagulant therapy Consider and Manage Relative Contraindications: Pregnancy of unknown location or gestational age Long term corticosteroid use Anemia with hemoglobin Hb <95 g/L IUD in situ (no lorger a contraindication if removed)	
Allergies:			
3. Physical Exam, Gestational Age, Pregnand	y Location	4. Initial Labs and Imaging	
LMP: / / (date) G: T: P: A: L: Vital signs: BP HR Gestational age on / / is: With a confirmed clinically and with urine test or a confirmed by ultrasound βhCG done or planned [see section 4, Labs] or a flore βhCG not done Follow-up appointment scheduled / /		Lab tests complete d/ results: ABO RH □ Antibody Screen □ 120 or 300 μg Rho(D) IG given □ Hemoglobin □ Baseline βhCG IU on / / □ Gonorrhea and chlamydia Imaging □ Dating ultrasound requisition, appointment on / (date)	
5. Provision of Mifegymiso®			
 Review U/S and labres ults with the patient and Prescribe Mifegymiso[®] (indicate on prescription Planned date for mifepristone:/ Planned date for misoprostol:/ Review how and where to take the medication, to Review pain and bleeding management and side 	a "dispense t _ / (date / (date) timing	before" date appropriate for gestational age) e)	
Provide written information on follow-up, when and where to seek emergency care, and who to call for questions			
Other discussion			
Initial Appointment Signatures Signature of healthcare professional providing cours	elling.	Date:	
Signature of prescribing healthcare professional:		Date:	
Medical Abortion Prescriber Checklin	co an At	1 D 1 2 Non-meter - to Devatives 4.0 International License	

Visit 2 Counselling - expected bleeding and pain

- Bleeding moderate to heavy
- Cramping mild to severe
- Clots (up to lemon size) and possible tissue
- Most will pass pregnancy within 6 hours after taking misoprostol, 90% within 24h
- Average 9-16 days of bleeding
- 8% of patients bleed for >30d, including delayed heavy bleeds
- Recommend patients take off work/dependent care the day of misoprostol, possibly next day

Visit 2 Typical timeline after misoprostol

- Hour 0: take misoprostol
- Hour 2: strong cramps, bleeding heavier than period
- Hour 4-6: strongest cramps and bleeding, pass pregnancy
- Hour 8-72: heavy period-style bleeding
- For 1-3 weeks after: light bleeding or spotting

Visit 2 Reasons to seek emergency or on-call service

- Soaking more than 2 large sanitary pads/hour for more than 2 hours
- Severe abdo/pelvic pain not controlled by analgesics
- Fever >38° C for more than 6 hours or that starts >24h after misoprostol
- Continued vomiting, inability to tolerate fluids for >6 hours
- Lightheadedness, fainting, tachycardia
- Feeling 'sick' with flu-like symptoms (weakness/malaise, nausea, vomiting, diarrhea) in the days after the abortion, *often without fever*

Visit 2 Counseling - analgesia

- 1st Line: NSAID (ibuprofen or naproxen)
 - Naproxen Rx = 500 mg x 10 tabs (most use less)
- > 2nd line: Mild opioid (acetaminophen with codeine)
 - Rx = T3 x 6 tabs (most use less)
- Patients usually use pain medication for first 1-2 days only but some use for longer
- Recommend NSAID one hour prior to taking misoprostol

MG - Review Investigations (Visit 2)

Meets eligibility and has no contraindications

- TVUS: 5.7 week sac with yolk sac
- ► Hb: 130
- ▶ b-HCG 5932
- Blood group O negative
- Does MG need RhIG?

Alloimmunization- What we know

- Red blood cells express Rh antigen starting at 52 days from LMP
- There is sufficient maternal-fetal hemorrhage at 63 days from LMP after surgical abortion to cause alloimmunization
- There is limited evidence for use of RhIG below 56 days
- SOGC: Rh immunoglobulin is recommended to Rh negative women undergoing MA beyond 56 days from LMP
- Patients should be advised that the data on RhIG administration is limited.

Jabara S, Barnhart KT. Am J Obstet Gynecol 2003 SOGC Medical Abortion Guidelines, 2016

Visit 2 Written follow-up instructions

- Linepharma Patient Information Card or other
- Requisition for f/u investigation (quantitative beta-HCG or pelvic US)
- Arrange follow up (virtual or in-person appointment) and discuss no show plan

Visit 3 Follow up visit - in person or by phone

- 7-14 days later
- Assessment of cramping/bleeding, resolution of symptoms of pregnancy, emotional/coping.
- Confirmation of abortion completion
- Repeat serum b-HCG*
 - Abortion complete if level has dropped <u>>80%</u> from baseline (day 8-15)
 - Alternative: <a>>> 50% drop 24h after misoprostol (day 3-4)
- Pelvic exam/ultrasound if concern or if b-HCG has dropped <80%
- IUD insertion/Depo injection if chosen method/Contraception check-in
- Info re: prolonged/delayed bleeding

*required for PUL

MG - Day 7

- Took mifepristone day 1, no side effects
- Took misoprostol day 2 (24 hours later), 2 hours later developed severe cramps and heavy bleeding, passed white tissue 1 hour later
- Fever and chills, diarrhea and nausea x 4 hours
- Bleeding decreased to lighter than a period, slight cramps for 2 days
- Today just spotting, 2 liners/day
- Pregnancy symptoms resolved
- Emotionally feeling well

MG - Day 7

bHCG: 949 (Initial 5932) % Drop = 84% (need 80% drop on day 8)

= ABORTION SUCCESSFUL

Started taking OCP on day after misoprostol

- \circ 33 yo G3P2
- LMP 5 weeks ago, positive home urine pregnancy test
- Requesting a medical abortion
- US: no gestational or yolk sac
- Physical exam: small uterus, no uterine or cervical motion tenderness, no adnexal tenderness or masses

Do you go ahead and provide a medical abortion?

Differential Dx?

- early intrauterine pregnancy
- pregnancy failure
- ectopic pregnancy

Is it an intrauterine pregnancy?

- Ultrasound: yolk sac needed to confirm intrauterine pregnancy
- > Yolk sac: 5.5 wks transvaginal, 7 wks transabdominal
- Most patients presenting for MA without yolk sac on U/S will be early or failed, ectopic is much less likely
- Failure to identify a definite intrauterine pregnancy should not delay abortion care at early gestation

Risk of ectopic with PUL

- Goldstone 2013
- 68 patients with no GS, or GS but no YS or double decidual ring
 - 1 ectopic (1.5%) discovered because initial beta-HCG was
 >10,000
- Schaff 2001
- 30 patients with positive pregnancy test and no GS.
 - 2 ectopics (6.7%) 1 discovered because b-HCG > 2000 and the second because follow-up beta-HCG did not drop appropriately

Medical abortion and pregnancy of unknown location (PUL)

- Medical abortion can be safely provided in a PUL if:
- No risks, symptoms or findings of ectopic pregnancy
- Follow up is ensured
- Serial beta-HCG is used for follow-up

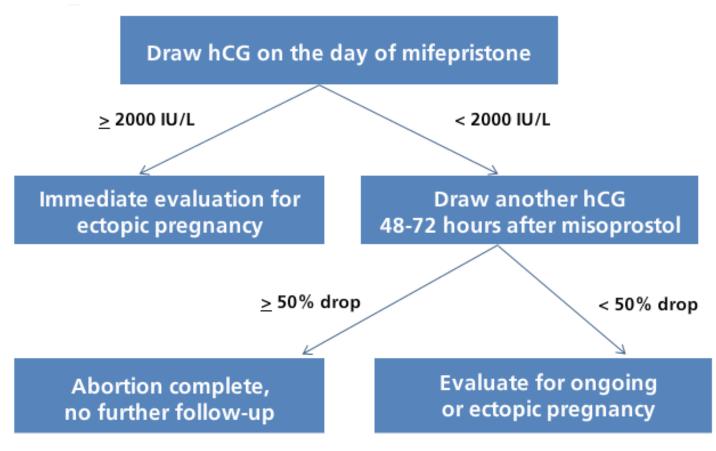
Ectopic Pregnancy

Risk Factors

- Previous ectopic pregnancy
- Previous tubal surgery including tubal ligation
- IUD in place
- History of PID, salpingitis
- Pregnancy conceived with assisted reproductive techniques

- Clinical symptoms
 - Abdominal/pelvic pain
 - Vaginal bleeding
- Ultrasound findings
- Empty uterus with b-HCG of >2000

PUL Management



Courtesy National Abortion Federation

- No ectopic risk factors, symptoms, or signs
- Ultrasound consistent with LMP
- Day 1 b-HCG: 1370
- You proceed with mifepristone abortion
 - Ectopic warning and early follow-up
- RS used misoprostol 1 day later with moderate bleeding and cramping within 4 hours
- Day 4 b-HCG: 380
- Day 7 b-HCG: 96

- 25 yo G1P0
 LMP 7 wks ago
 wants a medical abortion
 Ultrasound is not available
- Can you go ahead and provide a medical abortion?
- Yes but with certain conditions and with the understanding it is off-label.

Pelvic Ultrasound

- Accurately confirms gestational age and excludes ectopic pregnancy
- Confirmation of GA
- LMP alone is fairly accurate if certain and if not on OCP or breastfeeding
 - 2.4% of 3041 women with certain LMP of < 63 days were over 63 days by US
- History and clinical exam by experienced provider correlates to GA within 2 weeks in the first trimester
 - Study of 4008 MA patients 1.6% assessed as eligible by Hx and clinical exam were beyond the 63 day eligibility window

Bracken et al 2011

Mandatory Pelvic US

- Uncertain dates
- Conflicting bimanual exam
- History of pain or bleeding
- Risk factors for ectopic
- CMT or adnexal tenderness

Medical abortion without ultrasound

- Patient has certain LMP and consistent pelvic examination
- No risk factors for ectopic pregnancy
- Informed consent for off-label provision
- Manage as per PUL guidelines
- Provide ectopic warning
- > B-HCG on day of mifepristone
- Follow up with b-HCG (early)
- Ultrasound needed if concerning symptoms or insufficient fall in b-HCG

Mifegymiso® without ultrasound

OFF LABEL:

Product Monograph/HC: ultrasound dating required

- **SOGC:** ultrasound required if:
 - risks for/symptoms of ectopic pregnancy
 - Irregular periods

Otherwise LMP, clinical history and focused exam can be used to date a pregnancy

NAF: "ultrasound is not a requirement for the provision of first trimester abortion care"

• 34F G1P0

- LMP 7 wks ago, wants a medical abortion
- U/S confirms IUP 7w4d
- No contraindications
- Rh positive, Hb 132
- B-HCG 99,770

- Mifepristone/misoprostol taken
- Heavy bleed x 1 day, then lighter x 2-3 days
- Still bleeding like a light period at follow-up visit, but no cramping now
- Pregnancy symptoms resolved
- Day 7 b-HCG 6984 (93% drop)



Pt calls on day 18: still bleeding like a period.Is this normal?

► How do you proceed?



Ultrasound: "Endometrium measures 15 mm, heterogeneous mass with flow consistent with retained products of conception" (RPOC)

Hgb = 109 (baseline 129) - iron supplements

What do you do?

Options for management

Incomplete abortion/Persistent Bleeding/RPOC

- Expectant management with follow-up (can take 2 wks), reassess at 1 wk
- Repeat misoprostol 800 mcg buccal or vaginal, reassess at 1 wk
- Surgical management

Ongoing pregnancy (~1%)

- Repeat misoprostol 800 mcg buccal or vaginal, reassess at 1 wk, if unsuccessful - surgical management
- Surgical management

- Decides to take misoprostol given 2 doses (800 mcg)
- Follow up 1 week later (Day 24):
 - Passed large clot after second dose of misoprostol
 - No further bleeding or cramping
 - ► Hb 116
 - Pt advised to follow up if further heavy bleeding/clots

Common questions on call:

Bleeding:

- I took the misoprostol 6 hours ago and am still having heavy bleeding and passing large blood clots, is this normal?
- I used the misoprostol pills 24 hours ago and I still haven't had any bleeding. What should I do?
- I took the mifepristone yesterday and started to bleed before using the second pills (misoprostol). Do I still need to use the misoprostol?
- I had my medical abortion 3-5 weeks ago and I'm still bleeding.
 What should I do?

Common questions on call:

Pain/other symptoms

- I used the misoprostol 3 hours ago. I have really bad pain and am passing clots. I took one of the pain pills but it only helped a bit.
- I used misoprostol 4 hours ago. I'm vomiting and am shaking. What should I do?

Medication issues

- I vomited after I took the pill and am not sure if I threw it up. What should I do?
- I accidently swallowed the misoprostol pills before the 30 minutes was up. Is this OK?

Other

I took a pregnancy test (after f/u visit) and I'm still pregnant!

Family practice protocol - 3 visits

VISIT 1 (any provider) - review pregnancy options

- Counselling about MA (the process, risks/benefits)
- Review eligibility
- (CBC), Rh, Pelvic US, (b-HCG), urine for GC and Chlamydia

VISIT 2 (MA provider) - review test results and eligibility and prescribe mifepristone

- Informed consent
- Prescribe Mifegymiso® and analgesic, b-HCG, (RhIG)
- Detailed written review of MA process, emergencies, follow-up (Info sheet)
- Contraception plan

VISIT 3 (any provider) - day 7-14 in person or by phone

• Follow up with b-HCG and symptoms, review contraception

Bay Centre (WCH) Protocol: 2 visits

- 1. Screening, options, decision-making by RN/NP
- 2. Pelvic ultrasound
 - gestational age/location of pregnancy
- 3. Bloodwork (baseline BHCG, G&S, CBC); Vitals, urine GC/CHL
- 4. Clinical Assessment by MD/NP
 - Exclude medical contraindications
 - focused PE prn
 - Ensure patient knows what to expect
 - Consent form reviewed and signed
- 5. Prescriptions given +/- RhIG
- 6. Follow up in clinic 1-2 wks or remotely with labwork and phone call
- 7. IUD at two weeks post mife with b-HCG level >48hrs prior

Provincial Billing Codes

Province	Codes
AB (no specific code)	04A (Initial); 03A (Follow-up)
BC	T14545 (\$159.27) - Includes US if done by provider
MB	8428 (\$167.65)
NS	03.03V (\$120); 03.03 (follow-up)
ON	A921 (\$161.15); A921 (\$33.70)
PQ	15313 (\$133.35); US billed extra
Sask	50P (\$387.30)
YT	4116 (\$207.70)

Preparing for mifepristone abortion

Infrastructure

- Timely appointment for suitable patients
- Timely US access, Quantitative b-HCG available
- Access to Rh testing and pathway for RhIG
- Pharmacy that stocks Mifegymiso®
- Mechanism for managing emergencies
 - 24 hr Phone on call
 - ER access
- Referral pathway for failed abortion/complications (D&C)



Online Medical Abortion Training

- 1. Accredited program created through collaboration between:
 - Society of Obstetricians and Gynecologists of Canada
 - College of Family Physicians of Canada
 - Canadian Pharmacists Association
 - 6 modules, 1.5 3 hours to complete, \$50 <u>https://sogc.org/online-courses/courses.html</u>
- 2. Linepharma Training Program: https://www.linepharma.ca/the-use-of-mifegymiso-in-canada/

Further Resources:

Medical Abortion Guidelines:

Society of Obstetricians and Gynecologists of Canada: JOGC April 2016 38(4): 366-389

National Abortion Federation:

https://prochoice.org/resources/clinical-policy-guidelines/

Reproductive Health Access Project (US) https://www.reproductiveaccess.org Join Canada's online community for health professionals certified to provide Mifepristone.

- Exchange tips, resources, and best practices
- Gain feedback from experts
- Locate pharmacies in your region

LEARN MORE

Canadian Abortion Providers Support Communauté de pratique canadienne sur l'avortement www.caps-cpca.ubc.ca



Z CANADIAN ASSOCIATION DES PHARMACISTS PHARMACIENS ASSOCIATION DU CANADA THE COLLEGE OF FAMILY PHYSICIANS OF CANADA



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https://www.caps-cpca.ubc.ca/index.php/Main_Page

