

Medical Abortion

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Confusion with EC

| Medical Abortion | Emergency Contraception |
|--|---|
| Ends an early pregnancy and causes it to expel | Prevents ovulation. Slight “back up” impairment of implantation |
| Take pills in first 9-10 week of pregnancy | Take pills or use copper IUD within days of unprotected sex |
| Usually causes heavy bleeding and cramps | Mild side effects, if any |
| Stops pregnancy about 98% of the time | Decreases chance of pregnancy by 60-90% |

45% of news articles from 1992 to 2002 on Emergency Contraception (EC) confused it with medical abortion

Why medical abortion?

Where safe abortion is available

- The decision to have an abortion is much more than a decision to have a simple, safe medical procedure.

Where safe abortion is NOT available

- Even when medications are used suboptimally, MAB is safe and effective and saves lives. Women often can get safe care if bleeding.

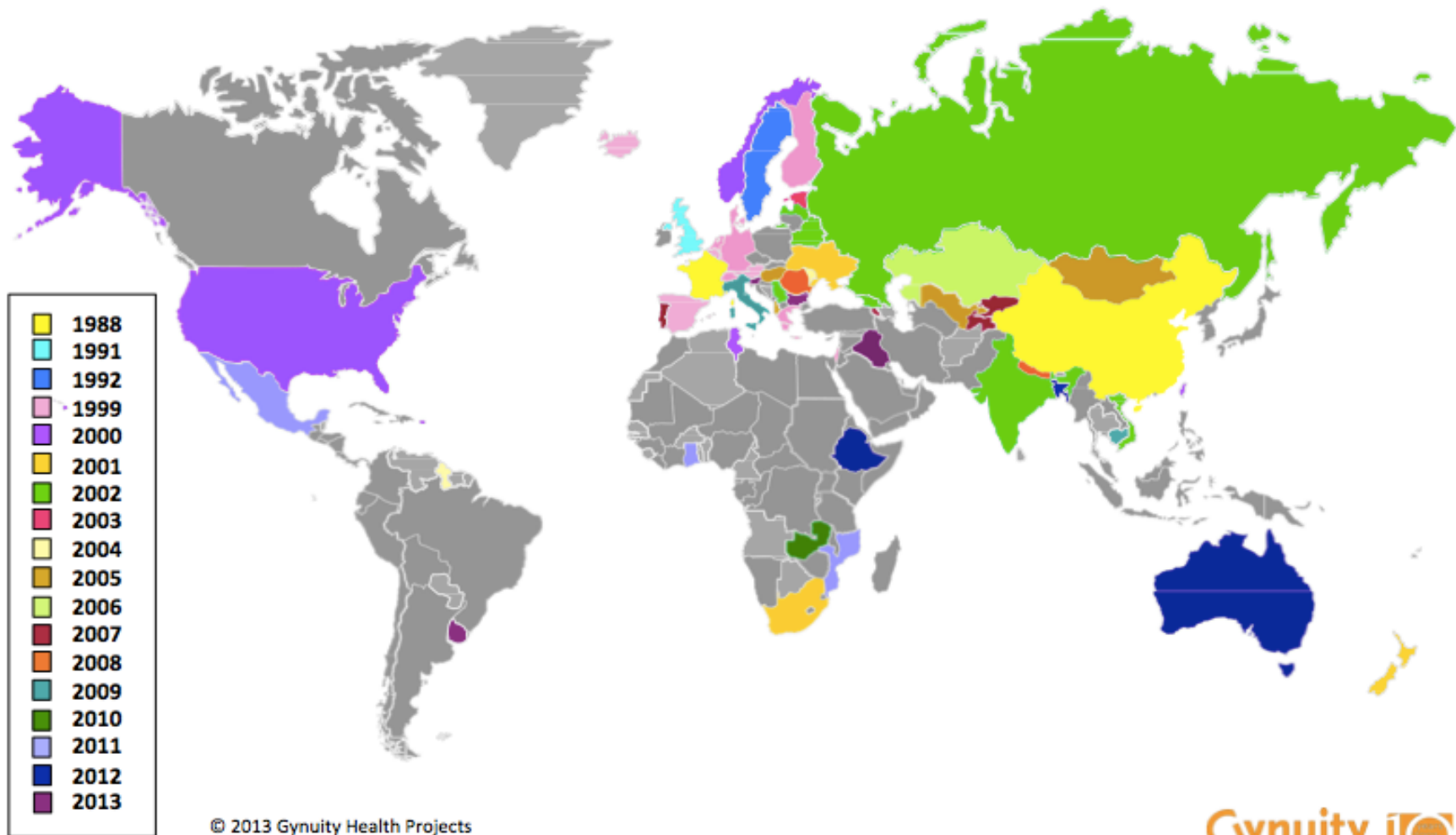


Medical Abortion Worldwide



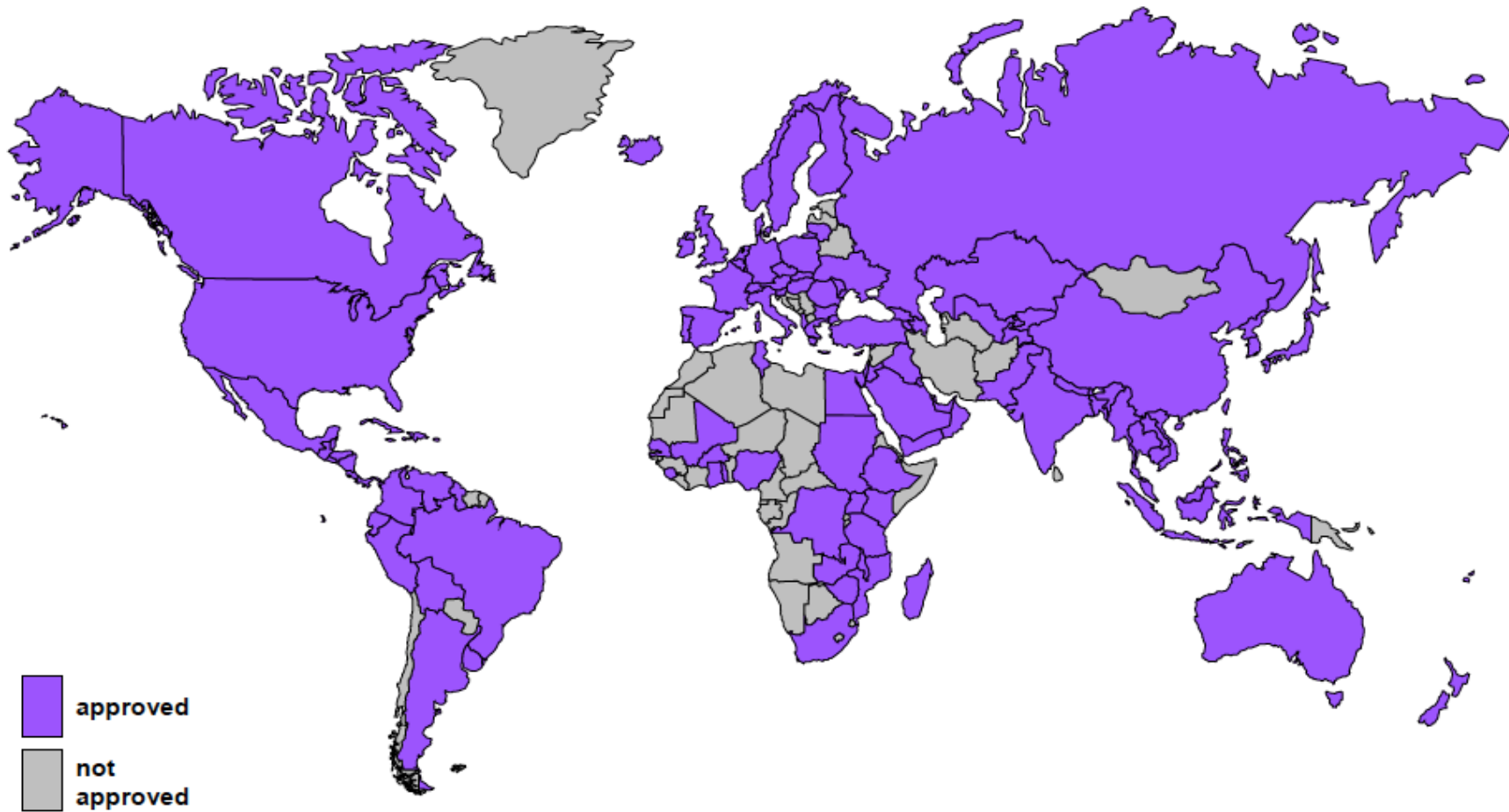
- MAB used for over 60% of outpatient abortions in several European countries
- Abortions occur earlier where MAB widely available

Mifepristone Approved



Gynuity HEALTH PROJECTS

Misoprostol Approved



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Gynuity Health Projects tracks formal drug registration and government approval of misoprostol throughout the world. This map reflects our latest information. If you become aware of registration or approval in new countries, please write to pubinfo@gynuity.org.



Acceptability of Medical Abortion

- In U.S. Multi-Center Trial (n=2121)
 - 96% would recommend procedure
 - 91% would choose procedure again
- Women who desire medical abortion are very satisfied. Women with no preference are less so.

Advantages of Aspiration Abortion

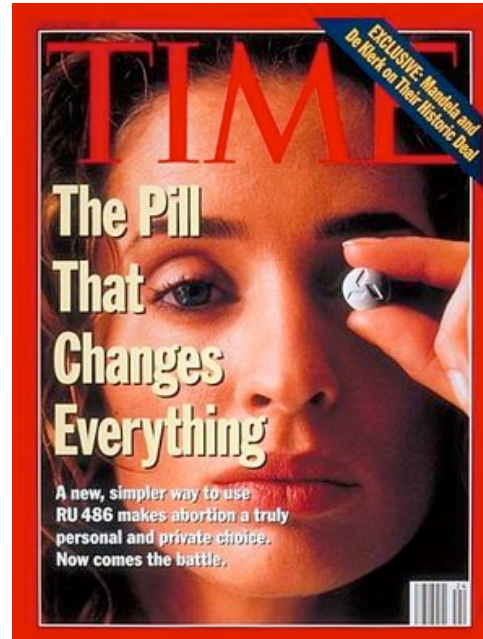
- More effective (similar rates of continuing pregnancy)
- Can be performed later in gestation
- Convenience: Shorter time to completion
Fewer visits (usually)
Fewer days of bleeding
- No exposure to teratogens (for the 1% of pregnancies that continue after MAB)

Advantages of Medical Abortion

- Availability without a skilled clinician
- Privacy
- Potential psychological advantages:
 - greater sense of control
 - abortion of an early embryo
 - abortion at home
- More “natural,” like a miscarriage
- Avoid waiting until 6+ weeks gestation
- Avoid surgical and anesthetic risk/experience

Mifepristone (RU-486, Mifeprex™)

- Anti-progesterone
- Derivative of norethindrone
- Tightly binds to progesterone receptors and prevents progesterone from sustaining pregnancy
- 200 mg mife saturates the receptors



Misoprostol

- Prostaglandin E1
- FDA approved for prevention and treatment of gastric and duodenal ulcers
- Heat stable (does not need refrigeration)
- Inexpensive
- Widely available
- Causes cramping, bleeding
- Side effects: chills, fever, N/V/D

Medical Abortion Regimens

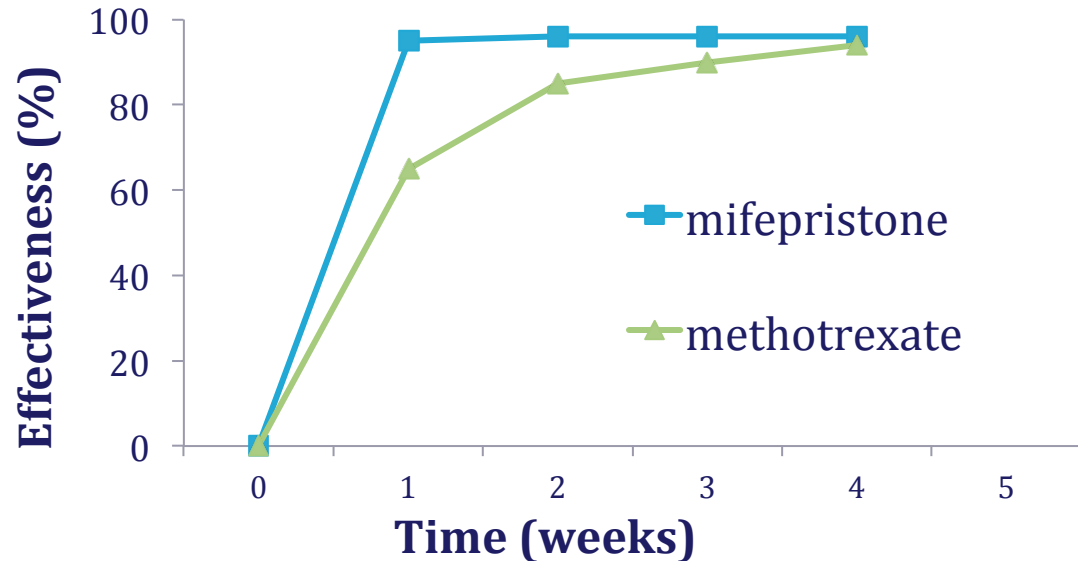
- Mifepristone + misoprostol to 9+ wks.
 - Most effective if available, 95-99%
 - Several effective regimens
- Methotrexate + misoprostol to 7 wks.
 - 92-96% effective within 4 weeks
 - 50 mg/m² IM + 800 mcg miso 3 - 5 days later
- Misoprostol alone to 9 wks.
 - 75-90% effective within 2 weeks
 - 800 mcg every 3-24 hours for 1 to 3 doses

Misoprostol Alone

- 800 mcg buccal, vaginal or SL (not orally)
- 1-3 doses every 3-24 hours
- Safe & effective through 9 weeks
- www.Gynuity.org/resources for directions in multiple languages
- www.ipas.org/resources for a miso-only information and dating wheel

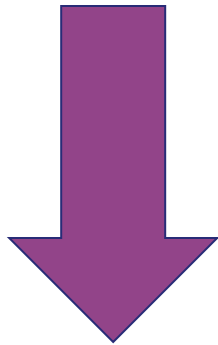
MTX + Misoprostol

- 50 mg/m² IM + 800 mcg miso 3 - 5 days later
- Blocks dihydrofolate reductase, needed for DNA synthesis
- More effective than miso alone
- Less effective than mife + miso, but approaches the same efficacy with time



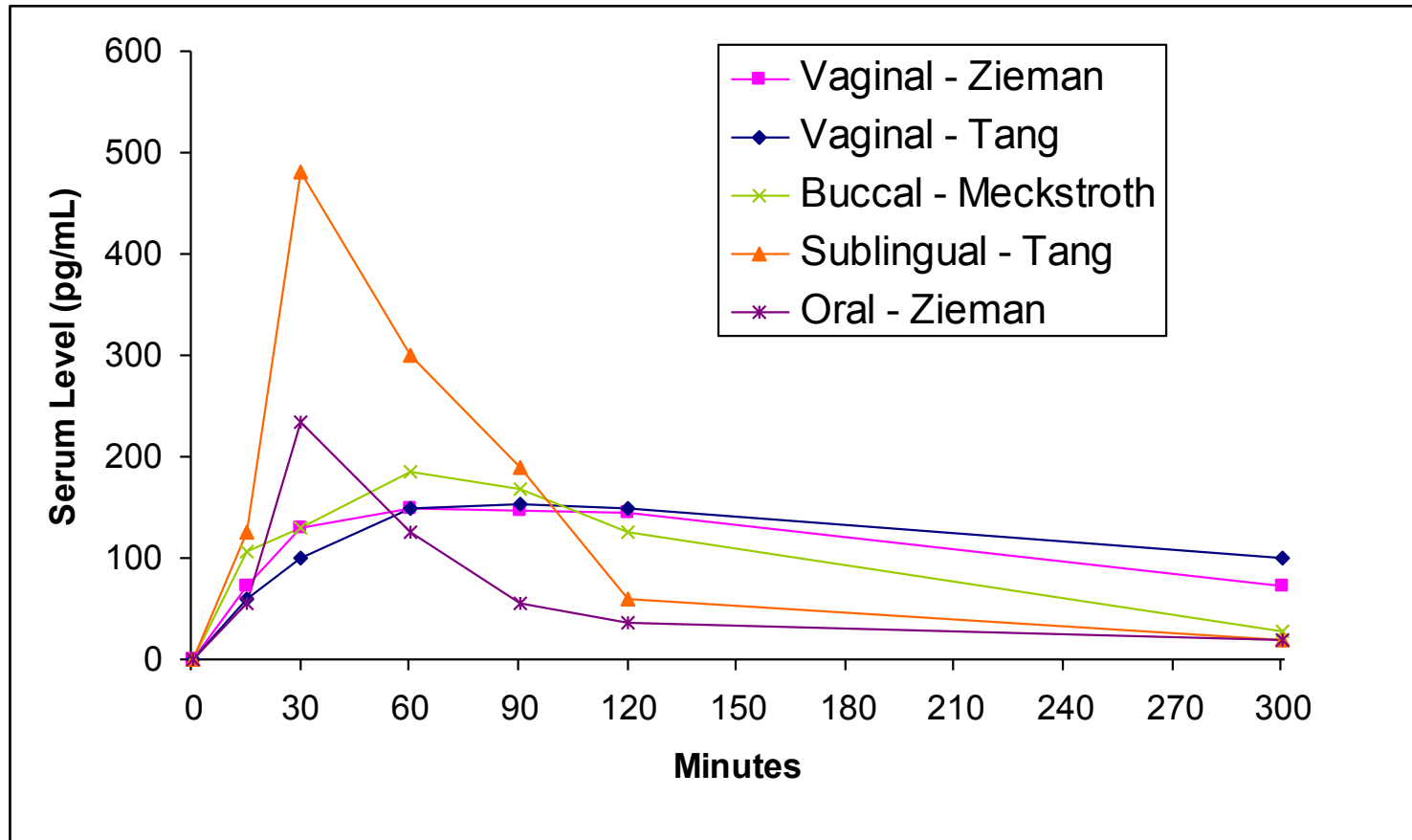
Mife + Miso Regimens

- 200 mg mife orally



- Interval of 24-48 hrs ideal
 - One study of 6-8 hrs - same efficacy
 - Simultaneous 4% less effective
 - Few studies - may extend to 72 hrs
- 800 mcg vaginal or buccal or 400 mcg sublingual
 - To 9 weeks gestation
 - New evidence of safety and acceptability to 10 weeks gestation

Serum Level Comparison



Professional Organizations with Respected Guidelines & Protocols

| Organization | Route of misoprostol |
|-------------------------|------------------------|
| Planned Parenthood..... | buccal |
| ACOG..... | oral, PV, buccal or SL |
| NAF..... | oral, PV, buccal or SL |
| RCOG..... | PV, buccal or SL |
| FIGO..... | PV, buccal or SL |
| WHO..... | PV, buccal or SL |

ACOG=American Congress of Obstetricians & Gynecologists; NAF=National Abortion Federation; RCOG=Royal College; FIGO=International Federation of Gynecology and Obstetrics; WHO=World Health Organization

Systematic Review 2013

Mifepristone 200mg +

Misoprostol 400, 600, or 800 mcg

- Systematic review by Gynuity in Contraception
- 87 trials included 47,283 subjects

Results

- Median ongoing pregnancy: 0.7%
- Median “failure” (intervention needed): 4.8%

Systematic Review 2012 (cont.)

- Higher failure for
 - More women in 9th week
 - 400 mcg miso (worse than 600 or 800)
 - < 24 hours between mife and miso
 - Oral miso (PV = buccal = SL)
 - Ultrasound not used to confirm success
- Home use = clinic use in safety and efficacy

Contraindications

Known allergy to med

- Mifepristone or PG allergy is extremely rare

Bleeding disorder

- Risk of hemorrhage in an unsupervised setting

Systemic steroid use/
adrenal failure

- Mifepristone has antiglucocorticoid effects

Suspected ectopic
pregnancy

- Mifepristone/PG's not effective treatment. (Management protocols for methotrexate treatment are often different)

IUD in place

- Remove before MAB

Inherited porphyrias

- Progesterone implicated in acute attacks. (Studies in chick embryos)

MAB at Very Early Gestation

- Delaying until yolk sac precludes major advantages of MAB
- Benefits:
 - Less pain and bleeding
 - Psychological benefit
- Disadvantage/Risk: Ectopic pregnancy
- Considerations
 - Exclude women with ectopic risk factors or sx
 - Additional consent for low risk of ectopic?
 - Earlier follow-up?



Side Effects with MAB

| | <u>% of women</u> |
|---|-------------------|
| Bleeding longer than 30 days..... | 9 |
| Bleeding before misoprostol (after mife)..... | 21 - 47 |
| Passage of pregnancy before misoprostol..... | 4 |
| Abdominal pain requiring narcotics..... | 29 - 73 |
| Nausea..... | 20 - 65 |
| Vomiting..... | 10 - 44 |
| Diarrhea..... | 3 - 29 |
| Chills or fever..... | 7 - 44 |
| Headache..... | 27 - 32 |
| Dizziness..... | 12 - 38 |

usually self-limited and of short duration

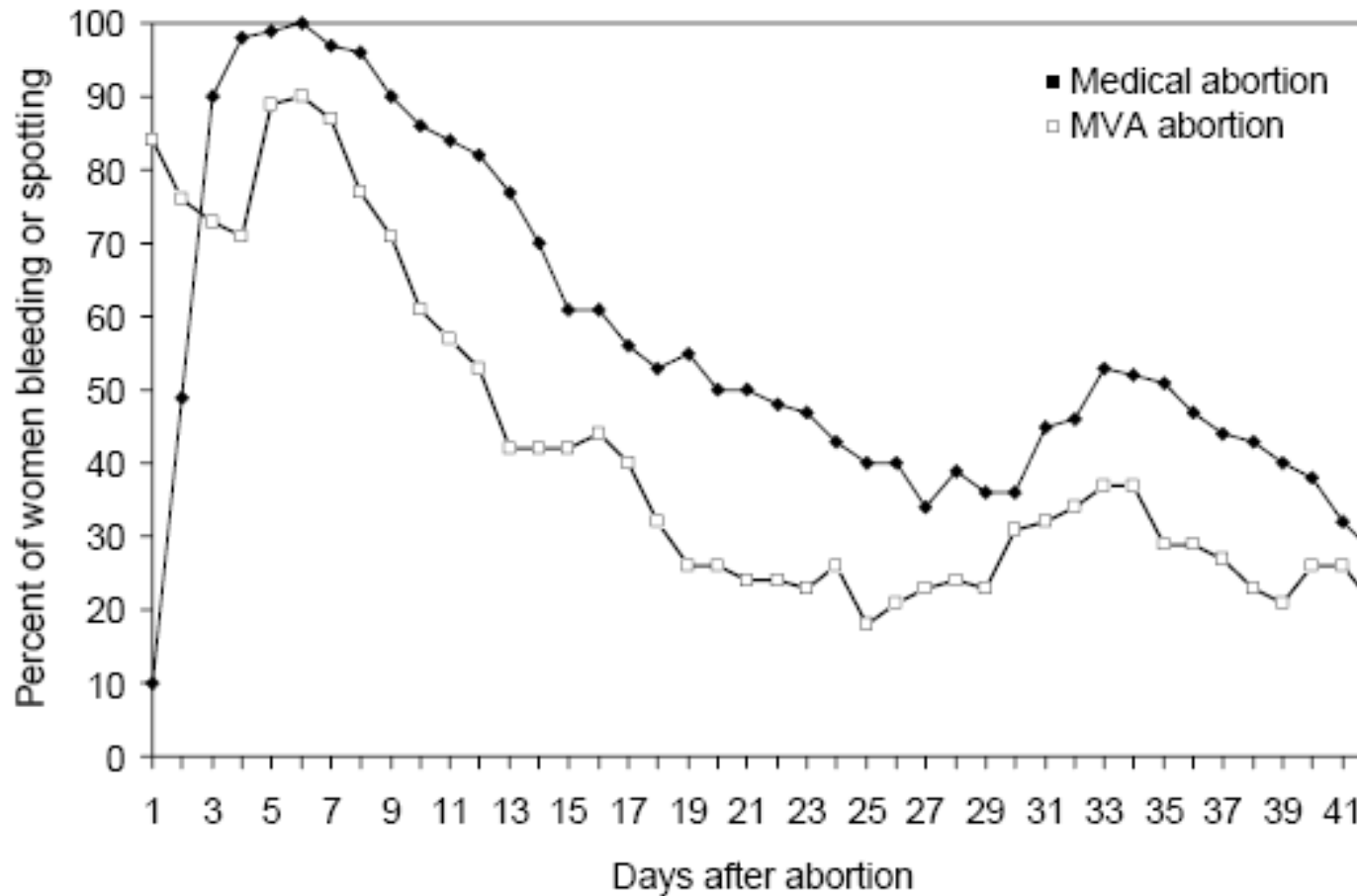
Symptom Management

- Women who receive a description of the sensations to expect have less distress¹
- Provide narcotic initially
- Offer anti-emetic
- Detail pain medicine usage in handout
- Recommend NSAID as soon as cramping starts
 - NSAID not associated with decreased success in RCT
 - Multi-center study with lower success where told to take ibuprofen with miso
 - Routine NSAID associated with less need for opiates

Parameters for 'Normal' Bleeding

- Moderate to heavy bleeding for 1 to 4 hrs.
- Clots from size of dime to orange
- “2 maxi pads per hour for 2 hrs. in a row”
- Average duration 2 weeks
- Lighter bleeding may last even 8 weeks
- Sometimes a second episode of bleeding, 1-3 weeks after the initial passage

Bleeding or Spotting after Medical or Aspiration Abortion



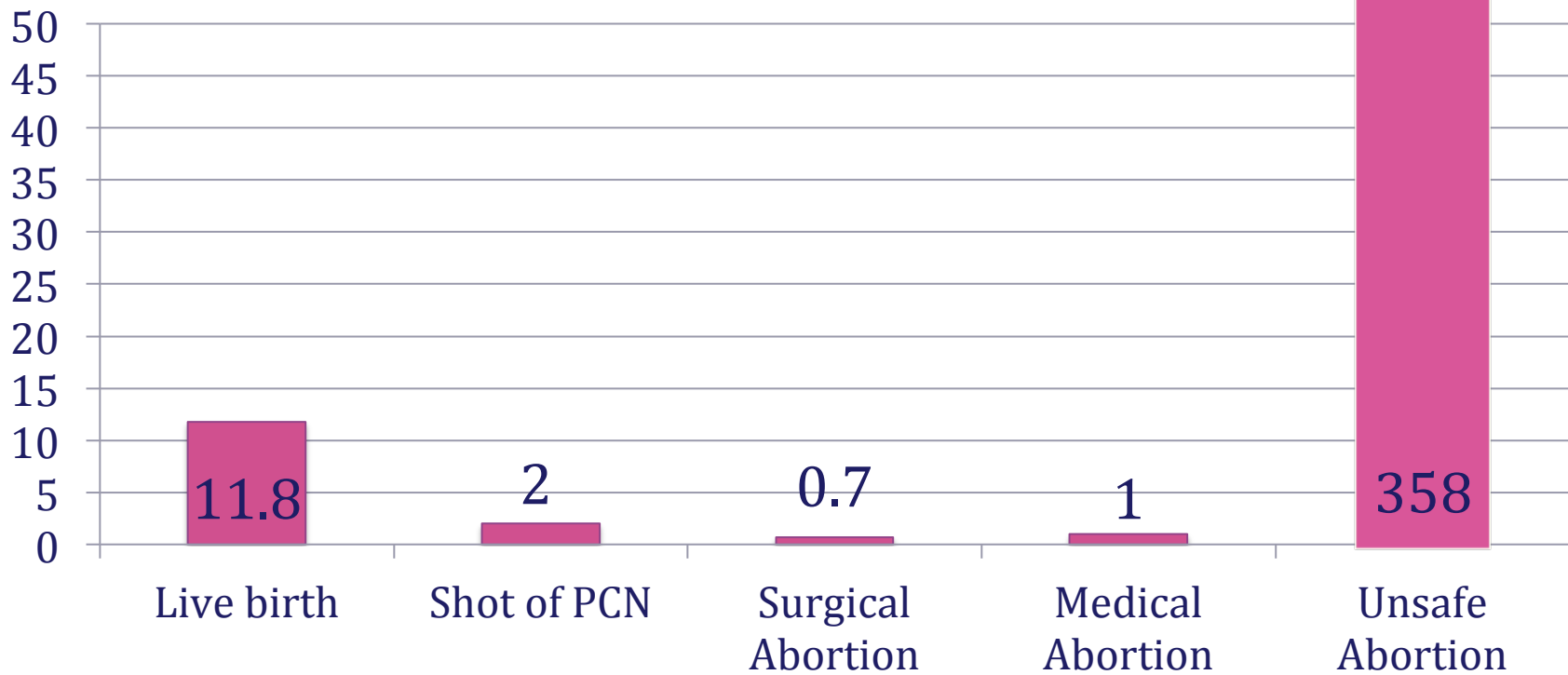
Hemorrhage after MAB

| | |
|---|-------------|
| Hospital inpatient or ER treatment | 0.1% - 0.2% |
| About half from heavy bleeding requiring no transfusion | 0.13% |
| Heavy bleeding + transfusion | 0.05% |

Infection after MAB

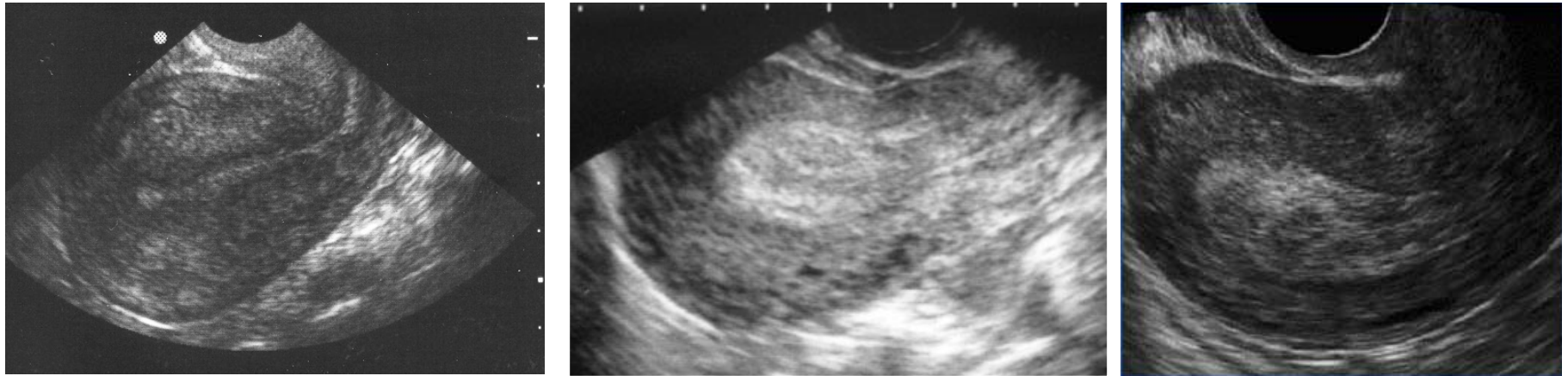
- Infection less common than with aspiration abortion, 0.02%
- 93% decline 0.025% → 0.006% in serious infection with:
 - Change from vaginal to buccal misoprostol
 - Adding prophylactic antibiotics
- NNT: Treat 5000 to prevent 1 infection
- Clinical practice varies

Deaths per 100,000 Women



Death mostly from rare clostridial infection or ectopic, ~ 1/100,000

Endometrial Thickness after MAB



- Thick, irregular endometrial stripe c/w success
- Thickness of endometrium NOT predictive of need for future intervention
- Mean 1cm, PPV < 25% to 3 cm thick

Alternatives to Sono to Confirm MAB Success

- Ongoing pregnancy is rare, but need to identify in timely way
- Women often accurately assess failures (68%)
- H + P: missed 1.3% with incomplete MAB
- Telephone follow 1 wk. & 1 month + urine preg after 3-4 wks. missed none
- Serum hCG:
 - 80% drop by day 6 after miso: **PPV 99.5%**

Providing Medical Abortion

- ✓ Adapt recognized guidelines for setting
- ✓ Arrangement for emergencies
- ✓ US: Sign Danco form, report adverse events



- ✓ Determine appropriate patients
 - Assess early gestational age
 - Evaluate for ectopic pregnancy
- ✓ Counsel, consent and prepare patient
- ✓ Determine outcome