A PATH TO OVER-THE-COUNTER MEDICAL ABORTION

Nathalie Kapp, MD, MPH
Associate Medical Director

Ipas
Health. Access. Rights.

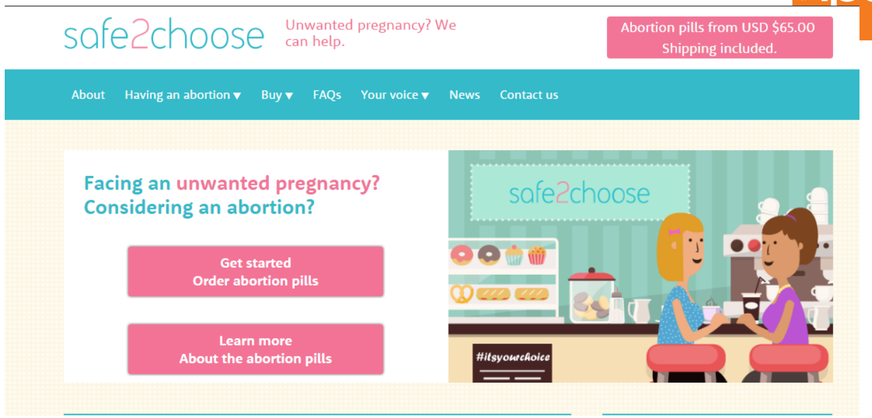
Background

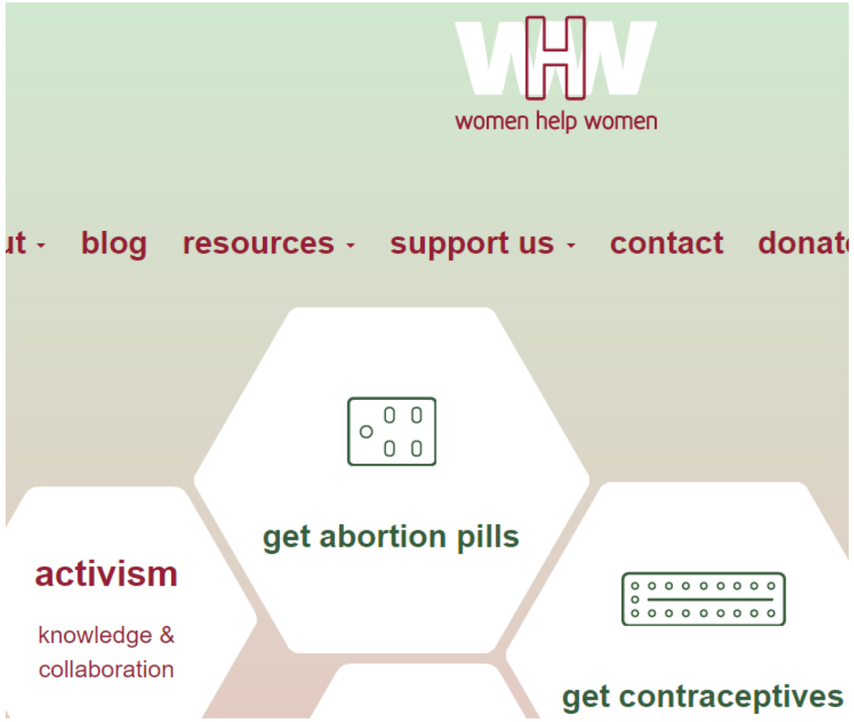
- In current clinical services, women manage most of the medical abortion process on their own
  - Taking misoprostol at home
  - Managing cramping, bleeding, expulsion and pain
  - Follow-up generally not required -- women seek additional care if needed

Changing landscape for medical abortion

Increasingly, women are accessing medical abortion through non-traditional routes

- Telemedicine/ websites
- Hotlines





Telemedicine results/ publications

Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland

Abigail R A Aiken,[1,2] Irena Digol,[3,4] James Trussell,[5,6] Rebecca Gomperts[7]

[1]LBJ School of Public Affairs, University of Texas at Austin, TX 78713, USA
[2]Population Research Center, University of Texas at Austin, TX 78712, USA
[3]Women on Web International Foundation, Amsterdam, Netherlands
[4]Centre for Reproductive Health and Medical Genetics, Chisinau, Moldova
[5]Office of Population Research, Princeton University, NJ 08544, USA
[6]Chalmers Centre, University of Edinburgh, Edinburgh EH3 9ES, UK
[7]Women on Web International Foundation, Amsterdam, Netherlands
Correspondence to: A Aiken araa2@utexas.edu

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ABSTRACT

OBJECTIVES
To assess self reported outcomes and adverse events after self sourced medical abortion through online telemedicine.

DESIGN
Population based study.

SETTING
Republic of Ireland and Northern Ireland, where abortion is unavailable through the formal healthcare system except in a few restricted circumstances.

POPULATION
1000 women who underwent self sourced medical abortion through Women on Web (WoW), an online telemedicine service, between 1 January 2010 and 31 December 2012.

MAIN OUTCOME MEASURES
Successful medical abortion: the proportion of women who reported ending their pregnancy without surgical intervention. Rates of adverse events: the proportion who reported treatment for adverse events, including receipt of antibiotics and blood transfusion, and

RESULTS
In 2010-12, abortion medications (mifepristone and misoprostol) were sent to 1636 women and follow-up information was obtained for 1158 (71%). Among these, 1023 women confirmed use of the medications, and follow-up information was available for 1000. At the time women requested help from WoW, 781 (78%) were <7 weeks pregnant and 219 (22%) were 7-9 weeks pregnant. Overall, 94.7% (95% confidence interval 93.1% to 96.0%) reported successfully ending their pregnancy without surgical intervention. Seven women (0.7%, 0.3% to 1.5%) reported receiving a blood transfusion, and 26 (2.6%, 1.7% to 3.8%) reported receiving antibiotics (route of administration (IV or oral) could not be determined). No deaths resulting from the intervention were reported by family, friends, the authorities, or the media. Ninety two women (9.3%, 7.6% to 11.3%) reported experiencing any symptom for which they were advised to seek medical advice, and, of these, 87 (95%, 87.8% to 98.2%) sought attention. None of the five women who did not seek medical attention reported experiencing an adverse outcome.

What about pharmacy provision?

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Review article

A research agenda for moving early medical pregnancy termination over the counter

N Kapp,[a] D Grossman,[b] E Jackson,[c] L Castleman,[a] D Brahmi[a]

[a] Ipas, Chapel Hill, NC, USA [b] Advancing New Standards in Reproductive Health (ANSIRH), Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California San Francisco, Oakland, CA, USA [c] Independent Consultant, Los Angeles, CA, USA
Correspondence: N Kapp, Ipas, 300 Market Street, Chapel Hill, NC 27516, USA. Email kappn@ipas.org

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Given the overall safety profile and increasing availability of medical pregnancy termination drugs, we asked: would the mifepristone–misoprostol regimen for medical termination at ≤10 weeks of gestation meet US Food and Drug Administration regulatory criteria for over-the-counter (OTC) approval, and if not, what are the present research gaps? We conducted a literature review of consumer behaviours necessary for a successful OTC application for medical termination at ≤10 weeks of gestation and identified crucial research gaps. If we were to embark on a development programme for OTC or more generally, self-use of medical termination, the critical elements missing are the label comprehension, self-selection and actual use studies.

Keywords First trimester, medical termination of pregnancy, mifepristone, misoprostol, pregnancy termination. over-the-counter.

Tweetable abstract Considering medical pregnancy termination through the over-the-counter regulatory lens clarifies critical evidence gaps.

Linked article This article is commented on by K Chaturachinda. To view this mini commentary visit https://doi.org/10.1111/1471-0528.14684.

Evaluating self-use using FDA framework for OTC

Combined regimen (mifepristone and misoprostol) meet many OTC requirements, including:

1. Non-toxic, non-addictive
2. Indication is self-diagnosed
3. Misoprostol is self-administered

We conducted a review to assess the evidence for the following consumer behaviours:

1. Demonstration of self-administration of mifepristone
2. Assessment of gestational age as eligible
3. Identification of eligibility for the medicines
4. Identification of complications/ need to seek care

Ability to self-administer mifepristone and misoprostol outside of clinic

Multiple studies demonstrate women can administer misoprostol at home with similar effectiveness and greater satisfaction

Newer data show women can take mifepristone (followed by misoprostol) at home*

-over 1/3 chose to self-administer

-most (82%) took it when they told the provider they would do so

-none took it over the gestational age limit

Mifeprex label updated (2016) to allow home administration

*Chong, 2015; Conkling, 2015; Platais, 2016

Self-assessment of gestational age

Eligibility for medicines is assessment of pregnancy <70 days gestation

Table 1. How women can self-assess gestational age eligibility in varying contexts

Setting	What women can do	Results	Population/ Source
Research study at termination clinics	Assess whether last menstrual period was certain to have been within 56 days	99% correctly identified as being eligible (<70 days) if their last menstrual period was certain to have been <56 days prior 0.6% >70 days	Studies from UK/ USA Most data from women seeking medical termination at ten sites in USA[1] Raymond 2015: combined data from three studies[17]
Telemedicine: seeking medical termination drugs online (restrictions on service availability in country)	Assess if within 63 days (by obtaining an ultrasound or by last menstrual period) 74–82% had ultrasound for dating	All were within 63 days When followed up (83%), not all women were eligible (<63 days): 67% were <63 days 23% were 70–84 days 10% were ≥13 weeks	Global data[8] Brazil[7]

Self-assessing eligibility for medicines

Eligibility Checklist		Yes	No
1	Did you have unusually light bleeding during your last period?		
2	Do you have any serious illnesses or conditions?		
3	Are you taking any prescribed medicines?		
4	Do you have bleeding problems? (Example: very heavy bleeding after childbirth or miscarriage, cuts that don't stop bleeding, or frequent severe nosebleeds)		
5	Have you ever had an ectopic (tubal) pregnancy?		
6	Have you had your tubes tied (female sterilization)?		
7	Do you have an IUCD now (Example: Copper T)?		
8	Do you have pain or bleeding today?		
9	Have you ever had an allergic reaction to medical abortion pills?		

For mifepristone-misoprostol:

Screen out few contraindications to medicines, including risk for ectopic pregnancy

Online services (Women on Web) provide yes or no screening questions which are reviewed by the service/physician

An eligibility checklist in Nepal found 71% agreement between women's interpretation and the researchers

- limited generalizability due to low(er) literacy

*Andersen, Fjerstad, et al 2017

Identifying when to seek medical care

In clinical practice, follow-up generally not required

Table 2. Complications following use of mifepristone and misoprostol for induced termination obtained through telemedicine services

Context	What women can do	Results	Population/ Source
Telemedicine: seeking medical termination drugs online (restrictions on service availability in country)	Recognise ongoing pregnancy	1.9% (<9 weeks) 1.7% (<13 weeks) 6.9% (>13 weeks)	Brazil[7]
	Seek care for concerns/ complications	20.9% had a surgical intervention for the following indications: No reported complication (42%) Pain (10.9%) Heavy bleeding (12.5%) Fever (3.1%) Not enough bleeding/pain (9.4%)	
		1.6% had ongoing pregnancy	Global data[8,33]
		12.4–13.6% had a surgical intervention (indications not reported)	

Conclusion

Research gaps to move to OTC

1. Label comprehension: How well can people read and understand an OTC label for a combined product?
2. Self-selection: How well can women seeking medical abortion accurately determine they are eligible?
3. Actual-use: How well can women use the label information to correctly (or incorrectly) self-use a combined product for medical abortion ?
4. Demonstration women can understand how to identify a pregnancy <70 days

Desire for expanded availability

Recent, representative U.S. survey of > 7000 women aged 18-49*:

- 37% supported OTC access to abortion pills
- 45% of those who had experienced barriers to reproductive health care supported OTC
- Specifically valued the privacy and convenience, and opportunity to use earlier

*Unpublished study. Briggs and Grossman

Coming next….

Finishing a pilot label comprehension study in South Africa this month

- Results to inform U.S. study

We expect challenges!

-Mifepristone already over-regulated

-Political area where science is often secondary or dismissed

-Laws in many countries (including the US) that specifically require provider involvement