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Original research article

Developing a forward-looking agenda and methodologies for research of self-use of medical abortion

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In December 2016, following the "Africa Regional Conference on Abortion: From Research to Policy," a group of 20 global abortion researchers, representing nine different international organizations and universities, convened to discuss current and future research on medical abortion self-use (http://abortionresearchtopolicy.org). While recognizing the meaning of "self-use" to be evolving, we considered women's self-use of medical abortion as provision of drugs from pharmacies, drug sellers or through online services or other outlets, without a prescription from a clinician, followed by a woman's self-management of the abortion process, including care-seeking for any complications.

Research has not kept abreast of women's self-use of medical abortion, leaving many gaps in the scientific literature regarding the ideal conditions for safe and effective use. Therefore, our main objectives were to assess the research gaps highlighted during the conference, identify specific challenges to conducting research on medical abortion self-use and share promising research methodologies to advance this research. Although there are overlaps with the recommended and well-researched practice of women's self-management of the abortion process at home after receiving medical abortion medicines, screening and information from a clinician [1], our intent was focused on the emerging practice of self-use.

The challenges laid out in this document — a list of identified research gaps and methodologic considerations in addressing them — are intended to inform both ongoing and future research by the participants in this meeting; in sharing them, we hope to inform and validate not only our future work but also that of other researchers.

1. Research gaps

Women and adolescents are increasingly obtaining abortifacient medicines through informal routes including online services, pharmacies, hotlines and drug sellers [2–6], although this trend and the current incidence have not been well documented. Such access is more common

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in settings where abortion services are either restricted or difficult to access [7]. Women themselves and different cadres of providers are developing and implementing innovative access strategies faster than they can be formally evaluated. We agreed that the role of research in this area would be to document this practice in restrictive and less-restricted settings with an aim to determine where interventions could increase safety, efficacy and access to services, and to maximize meeting women's preferences and comfort with medical abortion self-use. Restrictive settings are those where legal abortion indications are generally only for maternal health or life; however, settings which are nonrestrictive do not guarantee ready access to services and may pose similar difficulties for women to obtain safe abortion services. Thus, we considered that these research questions are relevant for a range of legal settings.

Research gaps can be summarized in three broad categories: women's preferences and experiences with self-use of medical abortion, the distribution and provision of medical abortion information and drugs, and clinical outcomes following self-use. For each of these three broad groups, we identify specific research questions varying in level of detail by the contexts they reflect.

1.1. Questions related to women's preferences and experiences using medical abortion

We know very little about women's needs, wants and experiences with respect to medical abortion self-use. Women are most satisfied when they receive the abortion method they prefer if they have choices between methods [8,9], but in contexts where choice is limited, they are more likely to pursue other methods of abortion of varying degrees of safety to terminate a pregnancy [10]. Understanding how medical abortion and particularly its self-use are perceived by women can facilitate interventions to shift care-seeking from less safe to safer methods. Quality research in this area would lead to the development and testing of interventions to address women's perspectives and misconceptions around medical abortion and to mitigate barriers, within legal constraints, to preferred care.

Many questions relating to women's preferences remain unanswered. As these preferences are better studied, they may also inform how to improve clinic-based or surgical services in restricted settings. These research gaps include:

- Women's awareness of potentially available safe abortion methods and in what way it influences their abortion decision making.
- How, or if, women understand the efficacy and risks of different abortion methods, including traditional ones, and how it influences decision making.
- Why women choose self-use and if they would do so even if all other options/technologies were available.
- What would be an ideal self-use experience from women's point of view.
- How women's preferences are influenced by differences in experienced and internalized stigma in facility-based care versus self-use or some other combination.

Generally, we know little about how women want to receive information on abortion, where and from whom. We know even less about how literacy level and the quality of information received make a difference to a woman's experiences and outcomes with medical abortion, and whether this differs from other medicines accessed from a pharmacy. Research gaps that focus on the experiences of self-screening and self-managing the abortion include:

- Whether women are aware of the importance of estimating the gestational age of their pregnancy prior to medical abortion, and what support or tools they need to do so.
- The extent to which self-use of medical abortion is happening in later gestations, particularly in the second trimester, and the resulting clinical outcomes.
- How women who are self-using manage side effects like pain and bleeding, what kind of support they prefer to receive during the process (hotlines, texting, smart phone applications or phone number of pharmacist/chemist) and how they decide to seek medical assistance.
- Whether specific counseling or information could assist women to manage their bleeding and products of conception, particularly those without access to a private toilet or absorbents.
- How self-use of medical abortion affects subsequent use of postabortion contraception, and how women would prefer to receive contraceptive information.

1.2. Questions regarding the provision of medical abortion drugs and information

Increasing availability of high-quality medical abortion drugs requires an understanding of how to best positively influence a range of distribution systems. Research in this area has the potential to inform policies around procurement and distribution to ensure that quality products are available as almost all settings have some legal indications for abortion-related care.

Research has assessed, in some settings, the role of pharmacists and other drug sellers in providing medical abortion, but little is known about how to improve the attitudes, knowledge and practices of pharmacists and drug sellers or about how to address the attitudes and comfort level of clinicians towards pharmacy provision without a prescription.

Unanswered questions regarding the distribution or provision of mifepristone and misoprostol include:

- Whether registration of mifepristone and misoprostol and/or inclusion on a country's Essential Medicines List or by WHO prequalification affects drug availability and quality.
- Through which outlets medical abortion pills are distributed, the quality of available drugs and how sellers decide which products to stock and price.

- What regimens are provided and whether they differ from the evidence-based regimens.
- How can sellers ensure and promote the provision of quality medical abortion drugs and information, and how can purchasers know the quality of the drugs and whether this is different from other medicines.
- How women determine the options for procuring drugs for medical abortion in their community or online.

1.3. Questions regarding clinical outcomes following self-use

The safety and efficacy of mifepristone followed by misoprostol at gestational ages ≤10 weeks have been well established when provided from a clinic setting with women self-managing the abortion process at home. Whether it differs among those obtaining the drugs without a clinician's advice or prescription is not known: eligibility screening, provision of emergency services or provision of accurate information about how to take the pills and when to seek additional care may impact women's experience and management of complications, as might the nature itself of clandestine self-use. If clinical outcomes and women's experiences reflect or improve upon those obtained in facility-based care, then the policy implications would support (1) changing the legal status of medical abortion drugs, (2) developing interventions to promote the role of pharmacy workers and to support and promote hotlines and (3) developing understandable drug labeling.

Investigating the outcomes of self-use should include assessments of the experiences, outcomes and proportions of patients who present for incomplete abortion care and, conversely, the outcomes and experiences of those women who do not present at facilities. Other research gaps include:

- Whether there is a difference in the clinical outcomes depending on where women receive their medical abortion drugs, information and counseling (provider versus pharmacist or drug seller).
- What is needed for women to self-screen eligibility for medical abortion.
- Identifying objective measures of abortion-related complications to assist interpretation of women's self-reported outcomes.

2. Moving forward with research on self-use of medical abortion

There are inherent methodological challenges in studying self-use of medical abortion, not the least of which is the reluctance of some governments, policy-makers and ethical review bodies to approve research in this area. We identified methodological challenges broadly related to recruitment, follow-up of research participants, resulting health outcomes, ethical concerns and securing ethical approval. Below, we describe the various challenges we identified and, in some cases, methods which may address them.

2.1. Recruiting research participants

Due to the clandestine nature of medical abortion self-use in most settings, an obvious challenge is recruitment of women who use medical abortion drugs in this manner, particularly if they are satisfied users. Unlike conducting traditional clinical studies, where care and study recruitment take place in a health facility, recruitment of women using medical abortion completely outside of this formal setting requires different strategies. Pharmacies, drug sellers, community health workers or hotlines are all potential locations where recruitment could take place, but require that researchers understand where and how medical abortion drugs are available and accessed in the local setting.

Advantages of working with drug sellers or community health workers who are distributing medical abortion drugs and/or information include the fact that they are often known and trusted by women already using their services. Alternatively, recruiting through call centers, hotlines and internet sites of sale may be successful in specific settings where women commonly use these routes. Innovative community-based recruitment strategies are needed to understand some of the ways women self-use medical abortion drugs and their experiences.

Researchers who have engaged with pharmacists to study self-use noted that pharmacists who are knowledgeable and motivated to participate in research may not be representative of the general population of pharmacists. Placing research assistants in the pharmacy to recruit women may be more efficient than relying on pharmacists or drug sellers to recruit; however, the cost and time implications may be prohibitive, and there is a risk that their presence may discourage some people from purchasing medicines. Research should be designed to mitigate this effect, as women may shift to less safe approaches rather than going to another pharmacy.

An additional recruitment method is respondent-driven sampling (RDS). RDS attempts to leverage a small nonrandom sample of point people (i.e., seeds) within social networks engaging in hidden or stigmatized behaviors to recruit others within their networks. Through a systematized version of snowball sampling and appropriately adjusting samples for potential selection bias, this approach can generate a prevalence estimate of the behavior of interest within the target population. Like any statistical methodology, RDS has its limitations — specifically, the accuracy of estimates can be influenced by recruitment dynamics and the distribution of the behavior within the network [11] — however, recent evidence suggests that rigorous formative research to identify appropriate initial seeds can improve the accuracy of estimates [12]. This recruitment method proved successful in the first RDS study of abortion where women were recruited with experience in abortion outside of the formal health system in Cape Town, South Africa [13].

2.2. Following women who have self-used medical abortion drugs

Another methodological issue for research of services taking place outside of clinics is tracking women who obtain abortifacients from pharmacies or drug sellers who are unlikely to return to these sites postabortion. Text messaging or a smart-phone application is one way to keep in contact with women as they self-manage their abortion and can provide a mechanism to inform the investigator of their clinical outcomes and experiences. An interactive application could also provide prompts for when to take a dose, reminders about expected bleeding, use of painkillers, tracking of bleeding, postabortion contraception and to indicate available sources for health care services, if needed [14]. The provision of hotlines or phone numbers for women to call a knowledgeable person (e.g., trained counselor, nurse-midwife or pharmacist) for support and information may also provide a method for keeping in contact.

The uptake of contraception postabortion likely differs among women who self-use medical abortion compared with those who receive facility-based care. Whether bundling the cost of both contraceptives and medical abortion drugs in a pharmacy setting increases contraceptive uptake, which methods women choose postabortion and their subsequent contraceptive continuation are all questions for research studies to better understand women's preferences.

2.3. Outcomes

For self-use of medical abortion, the process of cramping, bleeding and pregnancy expulsion is necessarily self-reported. Objective measures to distinguish between complications and normal side effects are currently lacking or difficult to implement even with facility-based care. Assessment of final medical abortion outcomes should rule out a continuing pregnancy within an appropriate time frame. Phone follow-up requires arranging convenient times to speak, avoiding revealing the study participation to other phone users, establishing trust on the phone so that she can share her experiences, ensuring privacy of the respondent so that she can answer the questions in a secure environment and limiting the length of contact time to decrease any possible risk to the woman.

2.4. Ethical concerns

All research methodologies in this area of study must grapple with ethical issues pertaining to women's self-use. Research settings should be one where there are some legal indications for abortion and participants (women and drug sellers) would not risk prosecution from taking part in the study. In more regulated settings, it may be necessary to use mystery clients or to avoid collecting identifying information on the women or drug providers. Seeking local ethical approval, as for any research, is best practice as ethics committees offer local cultural perspectives, may advise on the study approach of extralegal behaviors which affect public health in their setting, are mindful of local public health priorities and encourages local buy-in for use of research findings.

Age limits for assenting to a procedure or participating in research vary and might affect the design and participants who can be enrolled. In most settings, adolescents experience unintended pregnancy and seek induced abortion, including through self-use of medical abortion, but they can be particularly difficult to identify, recruit, enroll and follow-up. If unable to legally recruit women <18 years, one method to study adolescent experiences is to ask young adult women to recall their abortion experiences at these ages. In places where adolescents can consent to participate in research, recruitment through social media platforms may increase responsiveness but may overrepresent study participation to more urban, wealthier adolescents.

3. Conclusion

Although increasing numbers of women are seeking medical abortion outside of formal health systems, the global research agenda has yet to address the topic systematically. Self-use is likely expanding access to induced abortion, especially in legally restricted settings, and may reflect some women's preferences; however, it may also reflect the only way for a woman faced with an unintended pregnancy to access a comparatively safe method of abortion, especially in more restricted settings or where formal health settings have fallen short.

Establishing self-use of medical abortion as a legitimate or recommended approach calls for rigorous research and collaborative work. Cross-organizational research or joint proposals taking advantage of cross-discipline, cross-sector and multiple expertise would be beneficial, particularly because of the level of rigor required to address abortion-related stigma, misconceptions and the common biases held against women's use of reproductive technologies.

To advance an agenda of impactful research on the topic of self-use, we identify the following priority areas of study: (1) rigorously establishing the safety and efficacy of self-use compared with outcomes following facility-based medical abortion care; (2) identifying how to best inform and support women in various settings in using the medicines safely and effectively; (3) documenting how to effectively facilitate the community distribution of high-quality medical abortion drugs and information and, finally, (4) determining the preferences of women in how they obtain induced abortion care to inform future interventions to meet their needs. Moving forward with this agenda has the possibility to transform women's ability to access safe abortion for unintended pregnancy, ultimately decreasing the recourse to unsafe abortion and resulting morbidity and mortality.

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