

ABORTION AND CLINICAL PRACTICE

Papers from the **bpas** conference, London, 25 - 26 June 2008

Inside this issue:

Issues in Early Medical Abortion

Mitchell D. Creinin

Issues in second trimester surgical abortion

Eleanor Drey

Abortion research developments

Daniel Grossman

Implementing evidence-based advances in abortion care

Mary Fjerstad

The role of nurses

Kathy French

Who can provide abortion care? The role of the mid-level providers

Marge Berer

INTRODUCTION

By Jennie Bristow, Editor, *Abortion Review*

The groundbreaking **bpas** conference *The Future of Abortion: Controversies and Care* brought together clinicians, academics, policymakers and advocates from the UK, Europe and the USA for a discussion about all aspects of abortion provision. Taking place during a critical Parliamentary debate about the UK abortion law, the conference generated great excitement and presented a number of important research findings and policy suggestions.

In order to maximise the strides made by *The Future of Abortion* conference in taking forward an international, interdisciplinary discussion, *Abortion Review* is producing a series of special editions in which we have published edited transcripts of the presentations. In this third edition, *Abortion and Clinical Practice*, the presentations examine developments in abortion research and practice, and what these might indicate for the kind of abortion service that should be provided.

Professor Mitchell Creinin, MD, Professor of Obstetrics, Gynaecology and Reproductive Sciences at the University of Pittsburgh, examines new issues and developments in early medical abortion, against the backdrop of advances made in the provision of very early surgical abortion. Discussing research into home use of misoprostol, shortening the interval between mifepristone and misoprostol, and post-abortion follow-up intervals that are shorter than two weeks, Professor Creinin indicates the potential for altering some aspects of the classic regimen used for early medical abortion.

Eleanor Drey, MD, EdM, Associate Clinical Professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, discusses several issues related to second-trimester surgical abortion. These include the question of why women seek abortions in the second trimester, the procedures that are used, approaches to anaesthesia and recovery, and the impact of the Partial Birth Abortion Act on the practice of second-trimester surgical abortion.

Presenting on abortion research developments, **Dan Grossman MD**, Senior Associate at Ibis Reproductive Health, examines several aspects of managing early medical abortion, including examining alternatives to ultrasound, women's self-assessment, serum testing, urine testing, the question of who is permitted to provide early medical abortion, and the worldwide availability of mifepristone.

Mary Fjerstad, NP, MHS, Director of Quality and Learning at the Planned Parenthood Consortium of Abortion Providers in the USA, discusses translating research into action, with a particular focus on the way that Planned Parenthood in the

USA has disseminated the discovery of early medical abortion into a large system. From the UK perspective **Kathy French, RN**, examines the role of nurses in abortion care, both in terms of what nurses already do and what roles they could potentially play.

Finally, **Marge Berer**, editor of the journal *Reproductive Health Matters*, places the discussion about 'Who can provide abortion care?' within its international context, through examining the role of mid-level providers throughout the developed and developing world.

Two previous special editions of *Abortion Review*, containing papers from the **bpas** conference, have already been published and can be downloaded for free on the *Abortion Review* website.

Special Edition One: *Abortion, Ethics, Conscience and Choice*. Autumn 2008
http://www.abortionreview.org/images/uploads/AR_SpecialEdition_1.pdf

Special Edition Two: *Abortion and Women's Lives*. Winter 2008/9
http://www.abortionreview.org/images/uploads/AR_SpecialEdition_2.pdf

A forthcoming special edition of *Abortion Review* will examine the theme 'Abortion, Policy, and Law'.

For further information about the 2008 *Future of Abortion* conference, including a summary of the event overall, the programme and full speakers' biographies, please visit:
<http://www.futureofabortion.org>

ISSUES IN EARLY MEDICAL ABORTION

Mitchell Creinin, MD. Professor of Obstetrics, Gynaecology and Reproductive Sciences, University of Pittsburgh

In this presentation I will cover the following topics:

- Very early surgical abortion;
- Home use of misoprostol;
- Shortening the interval between mifepristone and misoprostol;
- Follow-up intervals that are shorter than two weeks.

To begin with, however, I want to start with a definition. Medical abortion is a term that very often has been confusing – even as late as the mid-1990s. I went to an international meeting where we discussed what we would call this, to make sure that worldwide we used the same terms. Medical abortion refers to an early pregnancy termination (usually before 9 weeks' gestation) performed without *primary* surgical intervention and resulting from the use of abortion-inducing medications. This should be differentiated from when abortion-inducing medications are used later in pregnancy, which are labour-induction abortions. When we speak today about Early Medical Abortion, really this is just medical abortion; and we are referring to the use of medications through 9 weeks, though treatment is still effective beyond 9 weeks.

Very early surgical abortion

The manual vacuum aspiration (MVA) system often used in early surgical abortion uses a manual vacuum aspirator with locking valve. It is portable and reusable, and generates a vacuum equivalent to an electric pump. Its efficacy is the same as an electric vacuum (98–99%); and the system uses a semi-flexible plastic cannula.

The MVA system is very helpful for performing very early procedures (less than 6 or 7 weeks' gestation). When I was trained, back in the late 1980s and early 1990s, I was taught that we did not perform surgical abortions at less than 7 weeks; and even in the mid-1990s, when I moved to the East Coast of the United States, there were some areas where providers didn't perform surgical abortions before 8 weeks, because of some poor and outdated data from the 1970s that suggested that such very early procedures had a higher risk of being incomplete, or failing altogether, or having complications.

Technology has changed this dogma so that women don't have to wait, and that medical abortion is not the only answer if somebody is early in pregnancy. The data is plentiful about the safety, efficacy and utility of early surgical procedures.

Figure 1 shows a handful of the major work that has been published about early vacuum aspiration. Some of the studies involve both electrical and manual vacuum aspiration, but most of the data relates to MVA.

Figure 1

Author	Date	N	Gestational Age	Efficacy
Paul et al.	2002	1,132 (MVA+EVA)	<6	98%
Creinin & Edwards	1997	2,399 MVA	<6	99%
Hemlin & Möller	2001	91 MVA	<8	98%
Laufe	1977	12,888	"About 6"	98%

Paul ME, et al. Am J Obstet Gynecol 2002;187:407 -11.
 Creinin MD, Edwards J. Curr Prob Obstet Gynecol Fertil 1997;20:6 -32.
 Hemlin J, Möller B. Acta Obstet Gynecol Scand 2001;80:563 -7.
 Laufe LE. Stud Fam Plann 1977;8:253 -6.

The largest modern study is a work that I published with Jerry Edwards in 1997. (1) Edwards developed the protocol that is most widely in use throughout the world, and which, in the developed world, involves the use of technologies that allow us to be sure that a pregnancy is there.

Our 1997 study involved 2,399 MVA procedures, and changed the way that surgical abortion was performed in the US. This study was performed at the time when performing a procedure at under 7 weeks was considered taboo in most of the US. Women were included if they were less than 6 weeks pregnant. The women all underwent a high sensitivity urine pregnancy test, not available back in the 1970s, and all women had a vaginal ultrasound, which gave us the ability to see a pregnancy as early as four and a half weeks. The products of conception were inspected meticulously immediately after MVA – there was a very little sac that was relatively easy to identify. A transvaginal ultrasound examination was performed immediately after the procedure to confirm removal. The transvaginal ultrasound allowed the surgeon to be sure that there was a pregnancy there beforehand and to help be sure that it was gone after the abortion.

Importantly, 99.2% of the time, that single procedure was completely effective in terminating the pregnancy; a rate that is not different, and if anything is slightly better, than the rates we report at 7 weeks or greater. There were only 6 repeat aspirations (0.25%), and there were 14 ectopic pregnancies (0.6%) that were diagnosed early and treated, all of which

Home use of misoprostol is a hot issue in the UK, but outside the UK it really is not

were recognised because of the protocols in place for the procedure. We concluded that women should not be denied access to a surgical abortion early and only permitted a medical abortion.

Early Medical Abortion

With that little bit of background, I want to turn more attention to medical abortion. The standard, or classic, regimen is mifepristone 600mg followed 36-48 hours later by a prostaglandin analogue, which most commonly is misoprostol 400µg, with a follow-up visit about two weeks later where a clinical assessment was performed, with ultrasound if necessary, and a suction aspiration was performed if the procedure was felt to be incomplete or the pregnancy was continuing.

Research and continued work by people who had wanted to know, 'Can we make this easier? Can we make it less costly? Can we make it more acceptable to the woman?' has been important in helping us provide the regimens that we use today. We know that we can vary the mifepristone dose; we have looked at regimens of misoprostol that are non-oral; we have looked at varying the gestational age limits beyond the 49 days that was used with the standard or classic regimen; we have been trying to play with the timing of misoprostol, the 36-48 hour window, in ways that make it more acceptable to the woman; and we have looked at ways to make follow-up easier.

We are moving away from the oral regimen of misoprostol and the gestational age limits go together. With the oral regimen we are mostly stuck with 49 days, but by moving away from this we are able safely and effectively to go beyond 49 days. I also think that the timing issues are very dependent upon the route. The ability to bring the two drugs closer together very much depends on the way we give the misoprostol. One example of this is given by the research into home use of misoprostol.

Home use of misoprostol

Home use of misoprostol is a hot issue in the UK, but outside the UK it really is not. The majority of trials in North America, and the standard of care in North America, is to provide mifepristone and misoprostol together. So a woman will swallow the mifepristone and be given the misoprostol to take home to use, in whatever way and whatever time that clinic or healthcare provider is using as a protocol. This has high acceptability and high efficacy. It is allowed in the regulatory labelling for mifepristone in the US, and it is the standard of care in North America.

Early studies (2) help us to know with certainty that this is acceptable and safe. Mifepristone was approved in the US in September 2000, so studies that were done in the US prior even to its approval showed us that home use was safe, building on a lot of the data that we had garnered with methotrexate and misoprostol regimens. One of the first studies was by Schaff and colleagues in New York State in 1999, where 158 women were allowed the choice of returning to use the misoprostol or using it at home. Only 3 (1.9%) of 158 women asked the clinician to place the misoprostol in the vagina. This low rate is astonishing given that the research took place in a new environment, where women were uncertain about using this new medicine.

The first few studies that Schaff's group oversaw included more than 4300 women who used vaginal misoprostol at home. Ninety percent found that overall home use was acceptable, which included all the features of it – putting it in the vagina, everything that goes with asking a woman if she finds this acceptable. There was no difference by prior abortion experience, gestational age, or the timing between the mifepristone and misoprostol (1, 2 or 3 days) in terms of acceptability. The adverse events were followed very closely in these studies, and out of 4365 women there were only 4 (0.1%) who had a true emergency. Two women had emergent aspiration for heavy bleeding – neither required a blood transfusion. One woman had vasovagal reaction to cramping, and was treated with intravenous fluids. One woman had a syncopal episode while bleeding, and because of the close quarters of the rooms the women had to stay in, she fell and broke her nose on a sink.

This is significant when you think of all the women in the UK who are made to come back to get their misoprostol, because of the law or whatever concerns might be underlying this law. One out of 1000 women had an episode where coming back and even being observed may, potentially, have been a benefit. So all the women undergoing EMA in Britain are inconvenienced for very rare outcomes.

There have been some studies in Europe of home use of misoprostol. In the UK, there was a pilot study of 49 women up to 56 days' gestation using sublingual misoprostol. (3) For this pilot study all the women used the misoprostol at home; they had to live within 12 miles of the facility; the nurse contacted them every 4 hours, which is probably more nagging than helpful but that was the way this pilot study was set up. There was one woman who, following use of the misoprostol, felt uncomfortable and came back in; the other 98% did fine at home, and 93% said they would use it at home again.

In Sweden and France (4), 130 women up to 49 days enrolled in a study using misoprostol orally at home. Ninety-eight percent said they had no trouble with the regimen, and 98%

Studies have shown that you can give mifepristone and misoprostol simultaneously

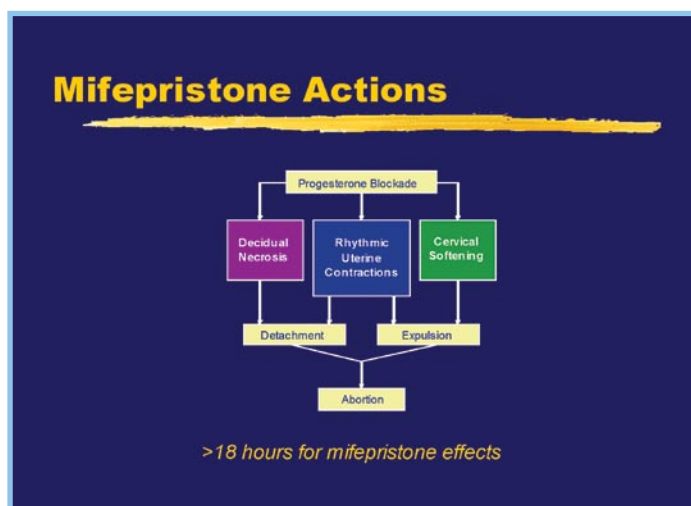
said they would use it at home again. This study, alongside the vast amount of experience in the published literature, led to Sweden changing its regulatory guidelines in 2004 to allow medical abortion at home up to 63 days' gestation.

So I think the literature is abundant in showing that women are not stupid, they know how to use medicines – we send men and women home all the time with prescriptions for cholesterol-lowering agents and blood-pressure lowering agents, and I'm sure they can follow instructions easily for using misoprostol at home.

Shortening the interval between mifepristone and misoprostol

I now want to turn my attention to shortening the interval between mifepristone and misoprostol. This relates to much of the research with which I have been heavily involved over the past decade or so. Much of this research stems from a lack of understanding about how mifepristone really works. Ten years ago, we all thought we knew exactly what mifepristone does; a lot of the research we have done has shown that we don't really know exactly what it does, at least what actions are most important. Ten years ago, we thought that mifepristone's crucial quality was that it weakened the attachment of the pregnancy to the uterus; that it increased the sensitivity of the uterus to prostaglandins; that it increased the natural amount of prostaglandins around the uterus, softening the cervix – all these things happened at least 18 hours after the mifepristone. (See Figure 2) We saw an increase in uterine contractility shortly after that, which was part of the reason why the initial timing between drugs was about 36-48 hours.

Figure 2



I now want to go through some data from many of the studies that look at changing this interval, which will take us back to the issue of what we thought mifepristone did. In summary, I suggest that all the things that happen 18 hours after taking the drug are definitely actions of mifepristone, but may not be exactly what is primarily important in what mifepristone does to allow medical abortion to be effected.

I am going to focus only on vaginal misoprostol; oral misoprostol is effective with an 800µg dose after a 24-36 hour interval, but anything shorter doesn't really work. With vaginal misoprostol, studies have shown that you can go to 24 hours, you can go to 6-8 hours, you can actually give the drug simultaneously and it's highly effective. In relation to buccal misoprostol, there are studies which show you can go down to 24 hours, but you really can't go much shorter than that.

Let's start with looking at bringing the interval between mifepristone and misoprostol down to under 36-48 hours. Schaff and colleagues (5) randomised 2,255 women at 56 days' gestation or less to receiving misoprostol 800 µg vaginally at 24, 48 or 72 hours after mifepristone 200 mg orally. The complete abortion rates were highly effective and equal across all three groups, also regardless of gestational age:

- 98% (95% CI 97, 99%) in the 24 hour group;
- 98% (95% CI 97, 99%) in the 48 hour group;
- 96% (95% CI 95, 97%) in the 72 hour group.

One thing that was certain was that women found it much more acceptable to be in the 24 hour group:

- 86% in the 24 hour group;
- 79% in the 48 hour group;
- 76% in the 72 hour group (p=0.0001).

The idea that less waiting is more acceptable might seem like common sense, but research is always helpful to back up this idea.

We followed that up with some pilot studies to ask the question, 'Can we go sooner?' Misoprostol by itself is effective when given in multiple doses, but a single dose gives an efficacy of about 70-75%. We did a few pilot studies that suggested we could bring that interval closer, and then we did a multi-centre study involving 1,080 women enrolled at 4 centres (4/02 - 6/03). Women were randomised to receiving misoprostol 800µg vaginally 6 to 8 hours later or 23 to 25 hours following the mifepristone 200mg. Follow-up was performed 7 (+1) days and 14 (+2) days after mifepristone, and an ultrasound was done at that time to see if a sac had expelled; that was the only purpose of the ultrasound. Women were given a repeat misoprostol dose at first follow-up if there was no expulsion after one week, and received a follow-up phone call 5 weeks

after mifepristone. This was a non-inferiority study, which means that we were looking to see if the regimens were equivalent. We decided before the study that if the regimens' overall efficacy were within 3% of each other, we would consider that equivalent.

We found that overall there was absolutely no difference. The results are shown in Figure 3. The 6-8 hour group had a 96% overall efficacy, and the 24-hour group had a 98% overall efficacy, and this did not vary statistically by gestational age. The single dose efficacy was 95% and 97%. As I have indicated, a single dose of misoprostol by itself is about 70-75% effective. So this is telling us that the mifepristone is doing something in that very short time that is highly important in causing abortion.

Figure 3

Abortion outcome (%)		
	23-25 hours (n=531)	6-8 hours (n=525)
Complete abortion		
TOTAL	98 (97, 99)	96 (94, 97)
with 1 dose misoprostol	97 (95, 98)	95 (93, 97)
≤49 days gestation	98 (96, 100)	97 (94, 99)
50-56 days gestation	98 (94, 99)	94 (89, 98)
57-63 days gestation	98 (94, 100)	95 (90, 98)

Creinin MD, et al. Obstet. Gynecol. 2004;103:851-9.

Interestingly, we also found that side-effects were significantly lower in the 6-8 hour group than they were in the 24-hour group. (Figure 4) This was just amazing - a finding that we did not expect - an unexpected success.

A single dose of misoprostol by itself is about 70-75% effective

Figure 4

Side effects (%) after mifepristone		
	23-25 hours (n=523)	6-8 hours* (n=518)
Nausea	39	20
Vomiting	14	5
Diarrhea	7	1
Warmth/chills	19	9
Headache	20	10
Dizziness	20	12
Cramping	26	16
Spotting	9	4
Bleeding	5	0.2

*p<0.05
Creinin MD, et al. Obstet. Gynecol. 2004;103:851-9.

Side effects (%) after misoprostol*			
	23-25 hours (n=523)	6-8 hours (n=518)	
Nausea	52	44	p=0.01
Vomiting	30	23	p=0.01
Diarrhea	25	27	
Warmth/chills	53	56	
Headache	37	38	
Dizziness	37	35	
Bleeding			
soaking >2 pads/hour	25	17	p=0.01

*first dose: misoprostol only
Creinin MD et al. Obstet. Gynecol. 2004;103:851-9.

Our findings begged the question: if we could move to 6-8 hours, why couldn't we move to an even smaller interval, and give the misoprostol simultaneously? We did a few pilot studies that showed that this would be a reasonable question to continue to examine. We then performed a study of 1,128 women enrolled at 4 centres (4/04 – 5/06). Women were randomised so that they received mifepristone 200mg followed within 15 minutes by misoprostol 800µg vaginally – they went into the room, put the misoprostol in the vagina, and left the facility – or they were given the misoprostol to take home to insert into their vagina 23 to 25 hours later. Follow-up again was at 7 (+ 1) days and 14 (+ 2) days after mifepristone, and a repeat misoprostol dose was given at first follow-up if the ultrasound scan showed the sac was still present. A follow-up phone call was given 5 weeks after the mifepristone. We also

When you demedicalise medical abortion, your success rates can be much higher

designed this trial as a non-inferiority study.

The results are shown in Figure 5. We had an overall efficacy of 95% in the simultaneous group, and 97% in the 24-hour group, which proved statistical equivalence. There was a small difference statistically with the success with one dose: 91% with the simultaneous versus 94% with the 24-hour regimen. There were no differences by gestational age and overall efficacy. So again, with the primary outcome being complete abortion, there was statistically no difference.

Figure 5

Abortion outcome (%)		
	23-25 hours (n=546)	within 15 min (n=554)
Complete abortion		
TOTAL	97 (95, 98)	95 (93, 97)
with 1 dose misoprostol	94 (92, 96)	91 (88, 93)
<49 days gestation	98 (96, 99)	96 (92, 98)
50-56 days gestation	95 (91, 98)	94 (90, 97)
57-63 days gestation	97 (92, 99)	95 (90, 98)

Creinin MD, et al. Obstet Gynecol 2007;109:885-94.

Conflicting research

One study in the UK followed ours (6), and tried to look at the 6-8 hour window between mifepristone and misoprostol. Interestingly, this study was published even after our simultaneous study was published, but there is no reference to it or even an attempt by the authors to explain the differences. So it is worth looking here at the study, and the differences between this study's results and ours.

The UK study was much smaller, involving of 450 women up to 63 days' gestation, who were randomised to a 6 hour interval (n=225) where they stayed in the clinic, or a 36-48 hour interval (n=225), where they went home and returned for misoprostol. The complete abortion rates were 89% in the 6 hour group, and 96% in the 36-48 hour group. So that 89% is significantly less than what we reported - not only with 6-8 hours in multiple centres in the US, but even less than simultaneous dosing in multiple centres in the US. How can that be?

For one thing, this was a much smaller study (450 vs. 1056). It is important to understand that if you have a disparity in size of this kind, there is going to be a big difference in the power of the study to demonstrate what you're trying to demonstrate. More importantly, there was a difference in how ultrasound was used in the two trials. Sonography was performed at 7 days in the US study, with the only purpose to assess if a sac was present, and if so, a repeat dose of misoprostol was given and women returned in one week. In the UK study, sonography was performed anywhere from 2-7 days after treatment, and the authors stated that they assessed for a gestational sac and also for evidence of 'nonviable products of conception' – a very vague term, which didn't relate just to the question of whether there was a sac present, but an assessment of what the uterine lining looked like.

Women were told that if there was anything that looked like it might not be complete, they could have a suction aspiration or more misoprostol; however, women who wanted another dose of misoprostol were required to remain under observation for 4-6 hours with a follow-up in one week. Obviously, the demands of the protocol could lead women to say, 'If I have to stay 4-6 hours to get another misoprostol dose, I'm not going to opt for that'. There are many ways in which, inherent within the protocol, you can make your efficacy lower. To put it another way: when you demedicalise medical abortion, your success rates can be much higher.

There are other biases in the UK study. The success rates were very different – but again, this goes back to interpretation of what the success rates were. When women in the US study were sent home, came back a week later, and the only purpose of the ultrasound was to see if a sac was present, and then were followed for up to 5 weeks and didn't need any further intervention, 95% of those women were successful. So a success rate of 79% in the UK doesn't beg the question, 'Why were they not successful?' Rather, it begs the question, 'What are we telling so many women they are not successful when in reality they probably are?'

The incomplete abortion rates were double in the UK study (4% vs 2%). Aspiration for persistent sac was much higher (4% vs 0.6%) – again this gets back to what women were required to do if they wanted a second dose of misoprostol, instead of just getting the dose and going home. These findings, all taken together, just mean that there were increased interventions in UK women which were probably not necessary.

Different regimens

With all of this in mind, I wanted to look at these different regimens in terms of the timing of the intervals, and also continuing pregnancy rates. One of the early studies from Schaff and colleagues, which was a very large study with a

48-hour interval with vaginal misoprostol, is useful to look at in terms of continuing pregnancy rates. (Figure 6)

Figure 6

Differences in continuing (viable) pregnancy rate

	interval	rate	interval	rate
Schaff et al (2000)				
≤ 49 d	48h	0.2%		
50-56 d		0.4%		
57-63 d		1.0%		
Creinin et al (2004)				
≤ 49 d	6-8h	0	24h	0
50-56 d		0		0.6%
57-63 d		0.8%		0
Creinin et al (2007)				
≤ 49 d	<15 min	0.4%	24h	0.4%
50-56 d		1.3%		0
57-63 d		0.8%		0

Schaff EA, et al. Contraception 2000; 61:41-6.
 Creinin MD, et al. Obstet Gynecol 2004;103:851-9
 Creinin MD, et al. Obstet Gynecol 2007;109:885-94.

This study shows that continuing pregnancy rates are low, and that they increase slightly as you get up to 63 days. With our 6-8 hour group and the 24-hour group, we had very low rates, equal to or lower what was reported previously with the 48-hour window; and this rate remains low still. Simultaneous dosing does have a slightly higher rate as compared to these, but it is still within the realm of what occurs with use of misoprostol orally up to and including 49 days. So this is within a realm that is acceptable. It doesn't mean that we *should* be using it or that we *have* to be using it. It's important to realise that, statistically, these are all no different because continuing pregnancy is so rare. But it is worth keeping in mind that on a large scale, you might start to see some differences; and then it becomes a question of figuring out with the patient what's going to work best for her within the policies in the area.

Patients and providers need to consider if the slightly higher continuing pregnancy rate might be worthwhile from a convenience and acceptability standpoint of the patient. This is all about choice.

What this really tells us is that the time interval is completely wide open: that we don't have to say to women, 'This is your mifepristone, you have to take your misoprostol at this exact time'. We now know that, based on what's going on in her life, she may want to be at home when she uses her misoprostol, and she may want to do it when her kids are in bed or when her support person is going to be there or when she gets off work. The woman can adjust that time based on what's best for her: she's not stuck with thinking that she has to

The time interval is wide open

leave work early because she has to use the misoprostol at a specific time.

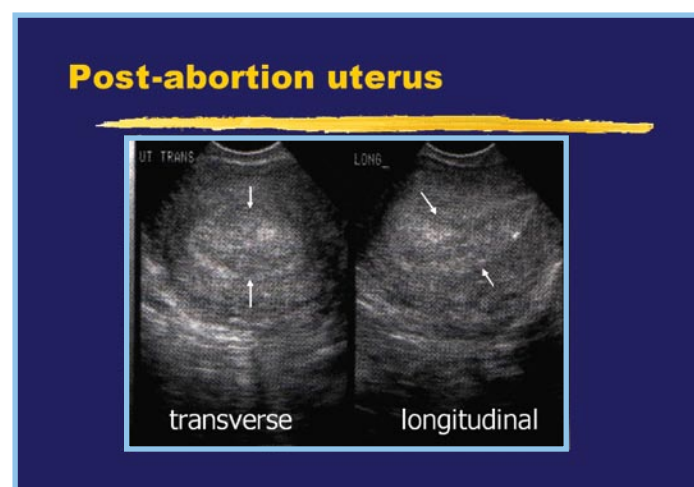
This goes back to our question: 'What does mifepristone really do?' (Figure 2, above). There is definitely high efficacy from the mifepristone, given that misoprostol by itself with a single dose is about 70-75% effective when placed in the vagina. So what these actions of mifepristone are is a great field for further research.

Follow-up intervals that are shorter than two weeks

In looking at follow-up intervals that are shorter than two weeks, studies in which we have followed women for 5 weeks become vitally important. Most studies include follow-up at 1-7 days following treatment. These studies all use transvaginal ultrasound. We need to think about how this compares to follow-up at 2 weeks, primarily using clinical outcomes. Until recently, there have been no studies validating the practice of follow-up sooner than two weeks. Even though we can look with the ultrasound and see whether the sac has passed, does that earlier evaluation potentially result in high rates of later intervention? And what is the best way to use ultrasound?

Figure 7 shows what a uterus looks like following a medical abortion. This is fine – this is wonderful – because there is no sac present. This is a woman who had a complete abortion, and this is what a lot of women who have complete abortions look like. There is nothing here that needs intervention. This is the crucial point that needs to be driven home in relation to using ultrasound.

Figure 7

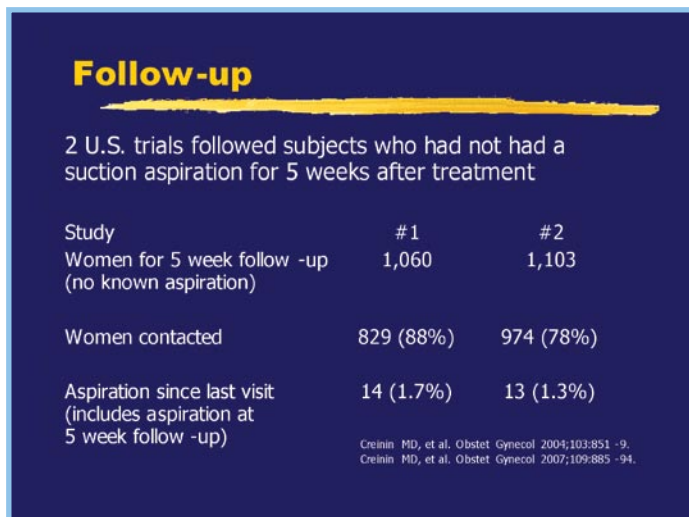


The two US studies shown in Figure 7 followed women for 5 weeks. This enabled us, for the first time, to validate whether looking earlier, at 7 days with ultrasound, has reasonable

History is an incredibly strong predictor

predictability. We had nearly 830 women in the first study and 970 women whom we did actually contact at 5 weeks. In women who were seen at one week, had an ultrasound examination that indicated that the pregnancy was expelled, and then were followed for 5 weeks, about 1.5% of women at some point in the future needed an intervention. So when the ultrasound shows that the sac is gone, the likelihood that the woman will need any further intervention is incredibly low. That is the importance of this data. Using the ultrasound at early follow-up is highly predictive of success: women infrequently need intervention later.

Figure 8



This leads to the question of whether there are other ways to follow-up women after a medical abortion. One of our medical students has done a secondary analysis of one of our large, multicentre studies, to look at whether the patient and clinician can predict the outcome: bearing in mind that this is a treatment that is highly effective to start with. So if at one week the patient tells the clinician what happened, whether she still feels pregnant, whether she thinks she has passed the pregnancy; and the clinician listens to the story and makes a judgement – and then the ultrasound is performed as a test of whether there is a sac there. 95% of the time, both the clinician and the patient feel the pregnancy has been expelled. They are right 99.1% of the time.

History is an incredibly strong predictor – even better than urine pregnancy testing, better than serum HCG – and it is very inexpensive. So now we are conducting a feasibility study of just using the history to indicate if abortion was successful. Can we give women the medicines to take home, along with her contraception, and talk to her at one week? We can send her home with a urine pregnancy test that she will do four weeks later, in addition to starting her birth control. If

both the clinician and the patient feel that the pregnancy is expelled, she can do a pregnancy test after one month, and if the pregnancy test is negative, the process is completed. If either the patient or clinician feels that she hasn't passed the pregnancy, or her pregnancy test is positive at that four week stage, she comes in. The study we are doing right now is to assess if this is feasible. If it is, we can just talk to people – we don't need any testing for primary follow-up, we just talk. We're back to the basics of healthcare.

Conclusion

In looking at the alternatives to the classic regimen, we know that:

- We can lower the doses of mifepristone.
- Women can use the medicines safely at home.
- Misoprostol can be given 800µg vaginally up to and including 63 days' gestation 0-72 hours after the mifepristone.
- We can follow-up within one week using ultrasound – and hopefully, soon we will have the data to show that you can follow up just by talking to people.

References

- (1) Creinin MD, Edwards J. *Current Problems in Obstetrics, Gynecology and Fertility*. 1997;20:6-32
- (2) Schaff et al. *Contraception* 1999;59:1-6. Schaff et al. *Contraception* 2000;61:41-6. Schaff et al. *JAMA* 2000;284:1948-53.
- (3) Hamoda et al. *Journal of Family Planning and Reproductive Health Care* 2005;31:189-92.
- (4) Fiala et al. *Contraception* 2004;70:387-92. Clark et al. *European Journal of Contraception and Reproductive Health Care* 2005;10:184-91.
- (5) Schaff EA et al. *JAMA* 2000;284:1948-53.
- (6) Guest J et al. *BJOG* 2007;114:207-15

ISSUES IN SECOND TRIMESTER SURGICAL ABORTION

Eleanor Drey, MD, EdM

Associate Clinical Professor, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco

Any time I talk about second trimester abortion, I feel I need to back up for a moment and say why second trimester abortion services are so motivating to me. It really comes back to the population we see, women who tend to be extremely marginalised and fairly politically vulnerable as well. And these are people with real lives and often incredibly heartbreaking challenges, women who I think make difficult, very personal decisions. As a physician I feel my role is to provide them with the most safe, most conscientious and respectful care, the most medically careful care, and to try to be as responsible as possible.

All abortion providers tend to be opinionated, and I think that comes down to the fact that what we're doing is largely such a safe procedure, so we tend to think that what we are doing is right and that we are right. So I am opinionated.

In the United States, we talk a lot in the public venue about second trimester abortions, and this is really not when abortions are happening. They are happening, fortunately, increasingly more often at less than 9 weeks, when women could be getting an early, easy aspiration procedure, or an early medical abortion. The proportion of abortions taking place at less than 9 weeks' gestation is increasing, which makes us all very happy. What makes everyone less happy is that there has been incredible stasis at the other end of the extreme, which is during the second trimester – 13 weeks to 21 weeks and over – and that has not really changed since *Roe v Wade*.

We would prefer women to come in at less than 9 weeks' gestation because it is the safest time, and they have an option between a medication abortion and an easy suction procedure. But we also would like to keep them out of the higher level of risk in the second trimester. Even according to the most conservative, positive picture of mortality from childbirth in the US, when you look at all abortion this is a procedure that is ten times safer than childbirth. But you really lose that safety advantage, that mortality advantage, in the later second trimester.

As in England and Wales, in the US about 12% of abortions happen in the second trimester, and only about 1.4% after 20 weeks. About 95% of the procedures in the US are happening by D&E, rather than by induction. And women most commonly don't have a choice between the two. They'll go to a site, and they will have one or the other, depending on what that site provides. But it amounts to a lot of D&Es in the US, so we

do have a lot of experience with them. And perhaps this is a bit dramatic, but in many ways I feel that second trimester services are somewhat endangered.

I am proud and impressed that abortion advocates in Britain have managed to retain the 24-week time limit for abortion: I don't think if we'd had a similar discussion in the US we'd have anything like that happening. I give a lot of credit to those who managed to do the work behind preserving that limit. I worry there generally is a lack of public, political, and medical empathy for these women. Often physicians, nurses and other people can be highly judgemental of the patients we see in the second trimester because often they, like others in the public, seem to express the idea: 'what happened that you came so late? How could you have waited so long?'

There is also the issue that there really are too few providers, and there is a concern that providers are 'greying' in the United States: they are ageing, they are retiring, and will we have a similarly committed group of younger providers to replace them? The problem is compounded for higher risk patients, who are in places that really want to see the lower risk subgroup of the second trimester patients, so women who are obese with previous C-sections, who have medical conditions like hypertension, may have trouble finding a provider. And these second trimester procedures do entail higher risks than those completed in the first trimester.

Why do women seek second trimester abortion?

To return to the issues that Ellie Lee discussed in her presentation (1), my colleagues and I did a study within our own population, looking at who the women are who undergo second trimester abortion, and asking what we could actually say about them that might encourage a greater sense of empathy, and whether, in this optimistic vision, we could find ways to intervene to bring them into the first trimester. (2) What we found was that many of them said that they didn't realise they were pregnant; they had difficulty finding a provider; they had difficulty with funding; and they were unsure of their decisions. Many of them really had more than one reason that slowed them down and that put them in the second trimester, and as Ellie Lee found, a huge proportion of them – almost two thirds – were already in the second trimester by the time they tested for pregnancy. These women didn't have symptoms, such as nausea, vomiting, fatigue, breast tenderness - they didn't have anything that cued them to look for pregnancy. So even if they had had a free pregnancy test in their cupboard, they probably wouldn't have used it. Once they were in the second trimester, which they already were by the time they had tested for pregnancy, they faced immense logistical barriers.

In the United States by far the most common technique in second trimester abortion is D&E

I like to personalise this discussion by trying to think about a representative patient from our clinic. A 21-year-old woman recently came to our clinic, who had three children, all by Caesarean section. She had been a heavy meth-amphetamine daily user for, she reported, nine years; she had had three weeks of being off meth amphetamines, and decided she really wanted a tubal ligation. She had cleaned up her life, she wanted to regain custody of her children. She went to get her tubal ligation, they did a pregnancy test, and she was 20 weeks pregnant. This came as a great surprise to her, and by the time she could find a provider she was 22 weeks pregnant. This is not an unusual story; this is a fairly typical story.

How do we do second trimester surgical abortion?

In the United States by far the most common technique in second trimester abortion is D&E. You need enough cervical dilation to be able to generally use larger instruments, and then you evacuate the fluid with suction and you remove the fetus in parts. In looking at complications, some providers decided it would be better gradually to achieve more cervical dilation so that you could remove the fetus without having to instrument the uterus and without using forceps as often; by using serial dilation, over days, you might be able to remove the fetus entirely, and you may have to depress the calvarium in doing so. The most morbid way of doing a second trimester surgical procedure is a hysterotomy, which is essentially a C-section. This is most morbid as not only is it abdominal surgery, it's also a vertical incision on the uterus that leaves a scar; this means that the woman in the future always has to have another C-section, because you have essentially weakened the part of the uterus that does all of the uterine work of labouring. And so generally, people really try to avoid hysterotomy.

So the basic D&E technique that many providers is to first prepare the cervix. In our clinic we go up to 23 weeks, and we generally use either Dilapan or a combination of Dilapan and Laminaria. On the day of the procedure, which is usually the day after we place the dilators, we remove the dilators, begin ultrasound guidance, check for adequate dilation by passing the forceps into the lower part of the uterus, drain the fluid, remove the fetus in parts under ultrasound guidance while trying to work low in the uterus, and check for completion, then re-aspirate and observe the woman in recovery. My centre is a training centre, so gradually, over the course of 5-6 weeks, our residents can become quite good at doing procedures up to about 23 weeks.

However, even though abortion is safe, we would like to bring down the risk, so most of my presentation will discuss the risks of the procedure and what we know can help bring down those risks. I had some concerns, in putting together this presentation, that people might assume that second trimester

abortion was an unsafe procedure, and it is not. The question is simply, how can we intervene to increase its safety as much as we know how?

There is a combination either of immediate concerns, immediate complications, and delayed complications. Immediate complications may include haemorrhage, surgical injury, fever, perforation, an incomplete procedure, or anaesthesia complications. We also worry about either pre-procedure expulsion of the fetus, or potentially any kind of fetal movement or signs of life in these non-viable fetuses. In relation to delayed complications, the primary concerns are emotional reactions on the part of the patient, the provider, the staff; or any kind of future risk down the road for the woman's later child either spontaneously aborting or being small for gestational age. I am just going to tease apart what we do step by step and go through this.

We start with thorough counselling, because you don't want to place dilators in someone who is not sure of her decision. Even if a woman needs to come back for more counselling, that is preferable than rushing her. Obviously in our clinic, if a woman presents at our limit of 23 weeks plus one day's gestation, she must make up her mind that day or she no longer will have the option of pregnancy termination with us. But ideally, you want to avoid any kind of feeling down the road that she made the wrong decision, so you really want her to be very sure. Then you do pregnancy dating, generally by ultrasound; a medical evaluation; and preparation of the cervix.

Pregnancy dating

Given that some women don't realise they're pregnant until they're in the second trimester, dating by Last Menstrual Period (LMP) in the second trimester is incredibly inaccurate. The women have no idea – it's been a while since their last period, they don't remember their periods, they potentially bled during the pregnancy, which they interpreted as their period - so LMP is really not that useful. And we know, based on large observational studies, that correct dating is essential in avoiding complications. This is particularly true in the second trimester, when it makes a big difference. There are also issues about the limits upon how late providers will perform an abortion. So you need to make sure that you're within the limits of your technical abilities, the limits of your institution, potentially any legal limits, and then there are issues of viability.

In this context, ultrasound dating decreases the risk of complication, and biparietal diameter is generally an adequate marker for gestational duration. But there are exceptions to that, such as anomalies or fetal demise, where the calvarium may be deformed, or if the gestation is very close to the gestational limit, additional measurements may be useful.

The use of hydrophilic dilators is the most common in the United States

Cervical dilation

How do we avoid cervical injury? In the second trimester, we very much worry about the immediate or the delayed complications of cervical injury. So in general, we believe that more dilation is better. Why would more dilation be better? You would not want to achieve dilation in such a way that you suddenly force open a cervix that was not at all soft – from earlier studies, before providers did gentle dilation of prepared cervixes, we know that forcing open the cervix was associated with possible small for gestational age or spontaneous miscarriages in future pregnancies. But if you can safely achieve more dilation, you avoid the need for later mechanical dilation, which makes us nervous about the risk of cervical incompetence in the future, the risk of perforation, and the risk of direct injury to the cervix.

You also would like to do fewer passes in and out of the uterus, using the larger instruments. Why? Because if you use a larger instrument there is less risk of perforation. If you are bumping against a soft uterus with something that is quite small, the risk of passing through the uterus would be greater than if you are bumping against the uterus with something larger.

What are the options to achieve the larger dilation that you need in the second trimester? One option is manual dilation, but this is usually most providers' fallback. The use of hydrophilic dilators is the most common in the United States, much more so than misoprostol alone, especially in the second trimester. Those hydrophilic dilators are either laminaria seaweed sticks, literally a type of seaweed that grows in Japan or Korea, or it's a synthetic Dilapan. You leave those in place anywhere between six and 48 hours, and they will absorb fluid and gradually open the cervix in a gentle way. Or you can use misoprostol. I wish I could say there was an easy answer – but this is really where a lot of the art of D&E lies, because you do have to respect the cervix and you really have to tailor to the individual woman. The cervix might be very different in a young teen, or in a woman who has never had a vaginal delivery, and you have to take that into consideration. The same number of dilators may not achieve the same amount of dilation in a different patient. And this is not predictable.

You then find yourself in a situation where you have to act on your sense of how pliable or how compliant is the cervix, how open is the cervix, and where do we go from here? So I refer you to the Society of Family Planning, which has done two reviews of early second trimester and later second trimester cervical preparation techniques - those both appeared in *Contraception*. (3) Ultimately I don't think there is enough research to act as an exact guide, and even when there are larger trials, there is still going to be a lot of judgement in terms of what you do.

We generally know that you do not want to use manual dilation alone as your cervical preparation; that you really need to have some kind of softening and opening of the cervix before then. We also know that, in terms of hydrophilic dilators, more are better, and the more advanced the gestation is, the more important that is. We know that Dilapan-S will expand more widely than just Laminaria, and we don't have exact guidelines that will tell you exactly how many to place at any particular gestation. So you have these broader views of how many you need. In terms of misoprostol, we have seen that it can be used alone, especially in early second trimester abortions; it's not clear yet how it should be used in the late second trimester, but we do know that 400mcg appears to be an adequate dose.

Anaesthesia

Anaesthesia is another large topic. There are a variety of ways of keeping women comfortable in the second trimester abortion procedure. It is generally a more uncomfortable procedure than a first trimester procedure, and obviously we want women not to suffer from pain. Also, practically, if a woman is in pain she may move and increase her risk, and we don't want that either. So the options are: oral analgesia with a paracervical block; moderate sedation or conscious sedation, which is generally fentanyl and midazolam, and then deep sedation involving propofol. You can go as far as general anaesthesia or regional anaesthesia, such as a spinal or less commonly, an epidural.

The data, which are generally based on older studies, show that you don't really want to use general anaesthesia. The studies relate to older general anaesthetic agents and techniques, where the women were put to sleep and intubated. That was associated with higher complication risks. So I like to use some kind of combination of a paracervical block and either oral sedation or conscious sedation.

However there was a very interesting study, given our understandable skittishness around deep sedation and general anaesthesia in pregnant women, which looked at a huge series of women at Planned Parenthood in New York City, and was presented at the most recent National Abortion Federation meeting. This study looked at over 60,000 women in the first and second trimester having outpatient surgical abortions, and of those about 11,000 were in the second trimester. Only 338 were between 23 and 24 weeks, but 2500 were between 18 and 22 weeks. They were kept NPO, or 'nothing by mouth' according to national anaesthesia guidelines, and what they were using for deep sedation was largely propofol, possibly with fentanyl. In most cases they did not require any kind of airway – less than 1% required an laryngeal mask airway, or 'LMA', most of them breathed on their own, and they only had four hospital transfers that might have been related to

Vasopressin has been shown to be effective in an RCT

anaesthesia complications - and even those were not obviously so. One of them was for asthma, one for hypertension and tachycardia, one for lethargy, where the woman was later admitted to a psychiatric unit, and one for thrashing round. No cases of aspiration were seen, and there were no intubations. So no one ended up being too deeply sedated and unable to maintain an airway.

The study did exclude extremely obese women, women who were actively using cocaine or actually smelt of alcohol on the day of their procedure, women with thyroid disorders, and women who were hyperglycaemic. And what they concluded, based on the fact that they did have no aspiration events, was that given a cohort of this large size one would expect aspiration at the highest part of a 95% confidence interval to be extremely rare, which implies that deep sedation is fine for these patients.

Haemorrhage

What can we do both pharmacologically and surgically to avoid haemorrhage? Ideally you would surgically want to avoid perforation, avoid any kind of trauma to the cervix, complete your abortion, leave nothing behind, do it as quickly as you safely can, and not use general anaesthesia. But pharmacologically, what could we also do? Of the things studied, what has been shown to be effective in an RCT was vasopressin. So going down the steps of our procedure, when you give your paracervical block you may consider using vasopressin.

There was an elegant blinded RCT of paracervical blocks either given with four units of vasopressin or with placebo, and it did show a significant difference between the groups, with less blood loss in the group that was given vasopressin; but the dose response wasn't the dose of vasopressin, which was always held at four units, but the gestational duration. So as the gestational duration increased, vasopressin became more and more helpful to avoid haemorrhage. And since you're worried about blood loss more as you get further along, this is exactly what you would hope to see. The study showed that there was no significant effect on pulse or blood pressure. In other studies epinephrine has not been shown to be equally efficacious; and nor is there convincing evidence of the routine use of ergot derivatives.

Ultrasound guidance

The next issue is whether we should be doing the procedure under ultrasound guidance. There aren't a lot of data about this; however, in terms of actually doing it, basic ultrasound guidance really does not take anyone with a high level of skill. In our clinic, for example, often it is the counsellor who does vocal local, and calms patients. That person will hold the probe

vertically, parallel to the longitudinal axis of the uterus, and if the surgeon felt like he or she couldn't see they could move it around a little bit. This generally gives information about fetal lie and the position of the cannula and forceps within the uterus in relation to the uterine walls. So the evidence on this is quite retrospective, and it was also done in my institution, which is a training institution. It was a combination of highly experienced providers and new trainees, and they did show that after they instituted ultrasound guidance they had fewer perforations.

What has been seen in a more recent series of studies about what people are actually doing in the United States in the second trimester is that about half of providers are using ultrasound guidance, and that younger providers and providers with less experience tend to use it more than older providers. Largely, what you're looking for are things that show up quite well on ultrasound, which are either calcified or metallic. Unfortunately, I would say that ultrasound guidance is especially limited in the lower uterine segment, because down where the speculum is there may be a lot of reflection, and it is often difficult to see there. Unfortunately that can be where you have perforations. So I can't promise you that ultrasound is entirely protective; it's certainly not. But it is one other source of information that can be incredibly useful and may be protective.

Recovery

When women have finished having their procedure, one of the things we do is contraceptive counselling. In our clinic we generally are able to provide them with whatever method they want at the time when they are there. So about a third of the patients we now see leave with some method of Long Acting Reversible Contraception (LARC), and most of those are levonorgestrel IUDs. We are lucky that there's been such a high uptake: it certainly doesn't reflect the use of LARC in the US. All the women either take their first pill or have their patch put on, or they put it on with the teaching of a counsellor, but they get to leave with something in addition to a bag of condoms. But the other thing they leave with in their little brown bag, other than instructions and a year's prescription for contraceptives, is two doses of doxycycline.

Why do we give doxycycline? This is based on evidence that was primarily from the first trimester, which showed that routine antibiotic prophylaxis decreased the risk of fever, and post-abortion endometritis. If you see that a woman has bacterial vaginosis you similarly would want to treat her for that to decrease endometritis. This is based on a meta-analysis of numerous studies, and I would say the most common regimen at this point may be doxycycline, just two doses. This is not a treatment dose for Chlamydia – it really has to do with prophylaxis for the abortion itself. There's also a

The concern over perforation is what drove people to develop the technique of D&X

question of whether you should screen and treat everyone for Chlamydia, whether or whether it would be preferable to screen and then treat that only women in the highest demographic risk group: those who are less than 25 years old.

Perforation

Probably the most frightening complication is that of perforation and incomplete procedure. So what can we do to avoid this? I think this requires a multi-pronged approach. One is intra-operative ultrasound. Another is the importance of accurate dating. My preference would be to have women undergo their abortion procedures earlier, but that's not always possible. We certainly know that later gestations are more at risk for perforation. You really want adequate dilation, and you want to avoid general anaesthesia. The other thing that increases the risk of perforation is working with trainees; however, in a training institution refusing to work with trainees would not further our goal of preparing future abortion providers.

The concern over perforation and the morbidity that can result from that is what drove people to develop the technique of intact dilation and extraction (D&X), to decrease instrumentation of the uterus. When we look at what evidence there is for D&X safety, some of it is just intuitive and logical. If physicians would not have to reach in and out of the uterus as often, then they would not have as many moments where they could make a hole in the uterus. There is one retrospective study that compared intact procedures versus D&Es, and they found no difference between the two groups. This was despite the fact that the intact procedures were at a higher gestational duration, and given that the women in this group should have had more risks but did not have a higher rate of complications, one could conclude that an intact procedure is possibly safer. This was quite a small study, and more studies would be helpful. Unfortunately, because of the Partial Birth Abortion law, and the Supreme Court decision upholding that law, we cannot do any further studies in the United States. So even though a 'Partial Birth Abortion' is not equivalent to an intact procedure, the law essentially bans it. The procedure has been criminalised even before adequate study was allowed to occur.

Feticide and the Partial Birth Abortion Ban Act

Because of the Partial Birth Abortion Ban Act (PBABA) there has been great interest in feticide, and this has become a hot topic in D&E provision in the United States, in part because D&E providers feel they may be in legal jeopardy. In order to study feticide you would really like to do two different types of studies. You would like to do safety studies, to prove that this intervention was safe; and you would like to study whether feticide made the procedure more efficacious or safer for the woman. What are the goals of feticide? One is that patients

or providers may prefer it; another is legal concerns about viability; and another, which should be quite important, is whether it makes the D&E a more safe procedure.

The most common ways to achieve feticide are by injections of digoxin or concentrated potassium, installations of intra-amniotic urea, or dividing the umbilical cord. Not all US providers use pre-D&E routine feticidal techniques, and I'll explain why. We did a safety study, a small pharma-kinetic study where we highly monitored women for 24 hours and made sure that there wasn't significant serum uptake, cardiac rhythm abnormalities, clotting changes, or anything else. We did not see any signs that 1mg of intra-amniotic digoxin was unsafe. There has also been a much larger study with a variety of doses, using either intra-amniotic or intra-fetal routes, and this did not see any signs of lack of safety in the doses that were used. The study did show that about 7% of the time the interventions did not achieve fetal demise, and one of the more concerning things they showed was that about one in 20 women went into labour before her procedure, so they were already starting to have contractions. But all the doses they used were effective in achieving fetal demise in most cases.

However, the safety of the actual injections is only part of the question. What you also really care about with the safety of D&E is whether you are making the *D&E procedure* more safe. The reason why we are not using digoxin in our clinic is that we did a blinded study. Before the study, most of our clinic's doctors had assured me that the procedure was easier when using digoxin, but when they were blinded as to what had been administered there was no difference in ease or duration of D&Es. The only thing that was statistically different between the two groups was that the women who had received digoxin were more likely to vomit.

What about the evidence for feticidal use of potassium? Potassium is more technically difficult to administer, so it is not as widely used. There are safety studies, but they are largely for selective reduction in multiple gestations. There was also a complication case report that showed one cardiac arrest, and the woman was successfully resuscitated. There is no evidence for cord division in terms of making abortion safer. There are no other randomised trials of clinical effectiveness of fetal demise before D&E.

So what effect has the PBABA in the United States had on providers? Many surgeons are sure that feticide makes a D&E easier for them, and safer for them. So then they really feel like they can consent women for these feticidal injections, because they believe clinically that it's better for the woman. But if instead you believe in the blinded study, and you think that you have to give these injections to protect yourself legally, it completely torques the normal consent. Because to consent people for interventions, you then would need to say:

The studies that exist would indicate that it remains safer to do a D&E

'Well, the risks are these, the benefit is I won't go to jail, and the alternative is you won't get the procedure' - so you have to extort them into it, which is not really how you ethically consent someone. In providing 'standard D&Es', you are not breaking the law.

What is the effect of feticide on intact D&X? It makes it more difficult to do an intact procedure, so you may end up doing a standard D&E instead. It limits autopsy information, and the family may not be able to view the fetus. This is all in comparison to second trimester induction abortion, which is an extremely different experience. In the worst scenario, induction terminations may take days, so it's generally not an outpatient procedure. In our hospital they take place on an L&D (Labour and Delivery) unit, so often the nursing support is not as kind or supportive as you would like them to be. L&D units may not be geared up for labour inductions and pregnancy terminations, that's not really what the staff come to work to do. So it can be a very uncomfortable position for the woman having those terminations. Over the hours or days of induction, she may have a lot of pain: essentially she's labouring and delivering a non-viable fetus, and she may not have wanted to go through that experience. Often, the placenta doesn't pass – so even though you manage to have the fetus pass, the woman may still require instrumentation to remove the placenta.

When I think about second trimester abortion, I often think that in terms of the experience, it's not an easy decision for the women having these procedures, and it is not easy for the staff who are involved in them either. But in many ways there is a certain amount of burden involved in second trimester procedures, and by doing an induction, you may shift the burden of the suffering to the woman. Some early studies found that providers preferred induction terminations, but women preferred D&Es. This also was seen in attempt by David Grimes to randomise women to induction versus D&E – he didn't have particularly optimistic goals of being able to recruit patients, and he couldn't even meet those goals, because women didn't want to be randomised to induction.

Grimes, in an article in *Reproductive Health Matters* (4), describes why he thinks D&E is preferable, and he steeps his argument in evolution, evidence, and ethics. He argues that when you look at the way the uterus is designed, in the first trimester when there are chromosomal abnormalities the uterus is designed to expel an early pregnancy. That's why you can have such successful early medical abortions. In later pregnancy, when the uterus is designed to go into labour, you use tiny doses of misoprostol because the uterus is primed to expel the fetus. However, in the middle of pregnancy, you have to use really big doses of misoprostol and a lot of doses, and potentially mifepristone as well, so it can be a difficult, lengthy and potentially unsuccessful effort to expel the pregnancy.

In terms of safety – there aren't enough safety studies and there aren't enough safety studies with modern induction methods with mifepristone and misoprostol, and yet the studies that exist would indicate that it remains safer to do a D&E. Then there is patient preference: D&Es are more convenient, less expensive, potentially less painful and more of the emotional burden of the procedure may be shifted to the provider. So Grimes feels that D&E is more beneficent, that women have more autonomy, and it's something we really ought to be doing. However, this is limited by lack of training, and lack of motivation among medical professionals.

Conclusion

So to sum up: How do we avoid D&E complications? One issue is accurate dating – we really want to make sure we're doing pregnancy terminations that are within our skills, within our competencies, and within the limitations of our institutions. Ideally we really don't want to do them as late, and we can do something about that which is making sure that our referrals are completed as well as possible, so women can get abortions at earlier gestations. We really want good pre-procedure cervical dilation, adequate pain control, vasopressin in the paracervical block, potentially intra-operative ultrasound, antibiotic prophylaxis and really well-trained providers.

In terms of how to refer patients as well as possible: ideally you'd want women to make their decisions as soon as possible, and I don't think women realise that the sooner they get there the better in terms of safety. I don't think this is widely known, and some patients have no concept that a later abortion may be a two- or even three-day procedure. So you want to give unbiased counselling when you do a pregnancy test so the woman doesn't feel inhibited from telling you that she may want to terminate, and you can really help her through that decision-making process. And ideally a woman should not be referred her to a place that doesn't offer the type of anaesthesia she wants. For example, some women in the US, when they realise they want to terminate a pregnancy, go to the Yellow Pages, and they may not realise that one place offers deep sedation and another place offers ibuprofen. Helping the woman work through that referral is important.

Medical conditions or obesity may also keep her out of certain clinics, and so again that can delay her still further. If she has spent the entire day and got all the arrangements necessary to have a two- or three-day procedure - where is she going to stay, who's going to watch her children, how is she going to get the time off work, how is she going to get the money together? – only to then show up and be told, 'You're too heavy, you've had too many C-sections, we won't take care of you' – the woman now has been pushed a week or two later and the barriers and potential risks may have increased significantly.

Obviously, and this is true for all abortion, we would love to avoid unintended pregnancy so whatever we can all do to achieve that would be ideal. But having more providers and more access to abortion remains critical, and while our goal should remain avoiding unintended pregnancy, I never think that we will entirely lose the need for safe and accessible second trimester abortion services.

(1) Lee, Ellie. 'How late is too late for women?' In *Abortion and Women's Lives: Abortion Review Special Edition 2*. http://www.abortionreview.org/images/uploads/AR_SpecialEdition_2.pdf

(2) Drey EA, Foster DG, Jackson RA, Lee SJ, Cardenas LH, Darney PD. 'Risk factors associated with presenting for abortion in the second trimester'. *Obstetrics and Gynecology*. 2006 Jan; 107(1):128-35. Foster DG, Jackson RA, Cosby K, Weitz TA, Darney PD, Drey EA. 'Predictors of delay in each step leading to an abortion.' *Contraception*. 2008 Apr; 77(4):289-93.

(3) Fox MC, Hayes JL; Society of Family Planning. 'Cervical preparation for second-trimester surgical abortion prior to 20 weeks of gestation'. *Contraception*. 2007 Dec; 76(6):486-95. Newmann S, Dalve-Endres A, Drey EA; Society of Family Planning. 'Clinical guidelines. Cervical preparation for surgical abortion from 20 to 24 weeks' gestation.' *Contraception*. 2008 Apr; 77(4):308-14.

(4) Grimes D. 'The Choice of Second Trimester Abortion Method: Evolution, Evidence and Ethics'. *Reproductive Health Matters*, Volume 16, Issue 31, Pages 183-188

ABORTION RESEARCH DEVELOPMENTS

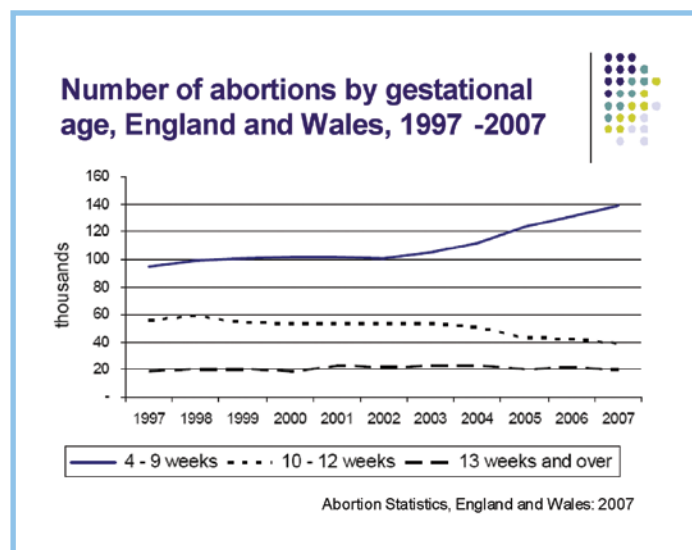
Dan Grossman MD

Senior Associate, Ibis Reproductive Health

Following the approval of mifepristone in 2000, many of us in the United States had high expectations that we would see a very high uptake of Early Medical Abortion (EMA) by providers, that women would start using the method in very high numbers, that there would be more early abortions – and this really hasn't happened yet in the US. The most recent figures estimate that somewhere around 20-22% of eligible abortions, abortions at under 9 weeks' gestation in the US, are done with the mifepristone regimen. While that proportion is certainly higher in some clinic systems, like the Planned Parenthood Federation, we see low uptake of the method among private providers, among OBGYNs in practice, and among clinic practitioners - clinicians who might not otherwise provide abortion. We had hopes that such providers might start providing medical abortion, and that we could improve access to early safe abortion.

The 2007 statistics from England & Wales (Figure 1) have shown a consistent rise in the number of early first-trimester abortions, and something of a decline in the later first trimester abortions. It seems that there has been quite a significant increase in the use of mifepristone here. According to the statistics from 2007, about 48% of early abortions (under 9 weeks' gestation) are now done with the mifepristone regimen in England and Wales, compared to about 20-22% in the US.

Figure 1



There is some evidence that ultrasound may lead to excessive intervention at follow-up

So what are the barriers to uptake of Early Medical Abortion? Why haven't we seen the uptake that we would like to have seen in the US? What are some of the ways that we might be able to simplify the medical abortion regimen everywhere, to increase access to safe abortion and make it a more viable option – not only in places like the United States, but also in developing country settings where we know the vast majority of unsafe abortions occur?

Providing medical abortion

First it is worth looking at some of the aspects of medical abortion that make it complicated to provide. One thing is that, at least as the protocol was originally designed, the method involved the woman making a lot of visits to the provider – three (or more) in some settings. The evidence supports safety and acceptability of home use of misoprostol. (1) Other barriers include the requirement to use ultrasound with the mifepristone regimen – both to confirm gestational age and eligibility before starting the regimen, and to confirm completion. And we have also seen many restrictions in terms of the type of clinician who can provide medical abortion.

Many of these barriers are related to the complexity of the mifepristone regimen as we have put it into place. The real potential of medical abortion is to *demedicalise* abortion - take it out of a clinical environment and make it more accessible for women. But that really hasn't happened yet, certainly not in the US.

Alternatives to ultrasound

Are we too enamoured of our ultrasound machines? Ultrasound is a very useful technique, and if you already have one, you probably aren't going to stop using it. But what about those clinical settings, primary care settings or research centres for example, that don't have one of these machines? For them, if ultrasound use is seen as the standard of care, not having one is a real barrier to implementing the service. In the clinical trials that were done to get mifepristone registered, the regimen was fairly dependent on technology. As we scaled up the regimen, actually put it into service, we tried to keep that technology and that's very difficult, especially in the primary care centres.

So do we actually need ultrasound to determine gestational age and therefore eligibility for the mifepristone regimen? We are focused on whether women are less than 63 days to be eligible for the mifepristone regimen. But of course we know that mifepristone and misoprostol work throughout pregnancy, and providers in Scotland have a lot of experience using this regimen, with a slightly different protocol, in the later first trimester. So even if we're off a bit on gestational age dating, the regimen still works.

What are the alternatives to using ultrasound to determine gestational age? There are a couple of studies that have looked at this. There was a study looking at women in seeking abortion in India and the US to see how accurate in their self-assessment of gestational age was prior to undergoing a medical abortion. (2) It found that actually women were pretty good: approximately 10% underestimated their gestational age and most of those only by one week. Another study, published last year from South Africa, found that clinicians were quite good at making a clinical assessment of gestational age and comparing that to ultrasound. (3) Seventy-four percent of the provider assessments were within two weeks of ultrasound measurement, and only 12% were clinically assessed to be <56 days when they were actually >63 days. In this study, women were less accurate at self-assessing gestational age, but it's a slightly different setting in South Africa: there's a lot of incentive for women to report a gestational age of under 12 weeks, because if they are over 12 weeks they get referred to another service for a second trimester termination.

The other reason we use ultrasound is to determine if the abortion is complete at the end of the medical abortion. We know that there is some evidence that ultrasound may lead to excessive intervention at follow-up, especially when the service is first initiated. (4) So we see things on ultrasound at that follow-up exam that we want to intervene on, when in fact we don't really need to. If a woman doesn't have symptoms of an incomplete abortion, the woman doesn't need further intervention.

The primary aim of active follow-up is to identify ongoing pregnancies, since incomplete abortion is symptomatic, resulting in bleeding and pain. The good thing is that with the mifepristone regimen, ongoing pregnancy is very rare (<1%). (5) The bad thing is that to examine alternative strategies to identify ongoing pregnancy we need very large studies that have the power to see how good they are and how accurate they are at identifying those ongoing pregnancies. But there is some evidence that maybe, some alternative strategies could work to identify ongoing pregnancies that may be as effective as ultrasound and more feasible.

Women's self-assessment

A few studies have looked at how well women can assess themselves whether the medical abortion is complete or not. One small study of the mifepristone regimen in China, Cuba and India (n=222) found that women did a pretty good job. (6) So all women with incomplete abortion (n=17) thought that to be the case when they presented at follow-up. There was a high false positive rate, so a lot of women - 110 - incorrectly thought their abortion was not complete when in fact it was.

A couple of other studies looked at the mifepristone regimen in the US, and these do not look as promising. One large

β-hCG testing is an alternative strategy to determining follow-up and detecting ongoing pregnancy after medical abortion

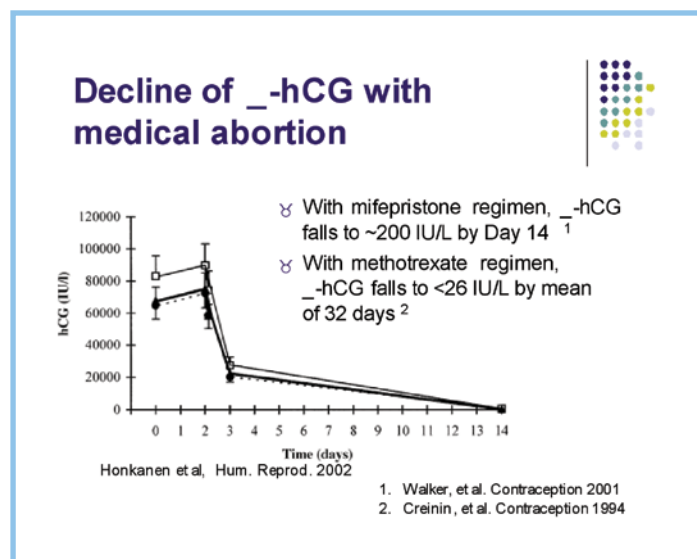
study (n=2,121) was done with the mifepristone register in the US. (7) Women who were less than 49 days' gestational age (GA) were pretty good at assessing whether the abortion was complete, but most of the ongoing pregnancies occurred in those who were over 49 days, and they were not so good at determining whether the abortion was complete. So among women who were >49 days' GA who thought abortion was complete, 4% had ongoing pregnancies. In another study, of 16 ongoing pregnancies, clinical history only detected 8. (8) Another study, of the methotrexate regimen in US (n=50), also revealed that women were not so good at assessing completion. (9) Twenty-eight thought they had aborted by day 9, and 13 of those (46%) had in fact not passed the pregnancy.

There is ongoing research that is looking at this, trying to identify specific signs and symptoms that women might have and to assess their accuracy at assessing whether the abortion is complete. But at this point I think we cannot really say that we can rely on women's symptoms alone as to whether an abortion is complete or not.

Serum testing

One other possible strategy is taking advantage of the fall in β-hCG that we see with a successful medical abortion. Figure 2 shows that after taking the misoprostol dose, there's a rapid fall in β-hCG, but it doesn't immediately fall to zero – in fact there's still a long tail out there. By about day 14 of the mifepristone regimen, the β-hCG values fall to about 200; but with the methotrexate regimen that can take over a month to fall to about 25 or so – something that is near the level of the sensitivity of a highly sensitive pregnancy test, the regular urine pregnancy test that we use.

Figure 2



There are quite a few studies that have shown that the serum hCG level should fall to at least 20% of pre-abortion level by follow-up visit at a week or two weeks, if the abortion is complete. (10) A study (n=151) implementing this protocol in a US clinic, where they used ultrasound as needed or ultrasound according to the preference of the provider, found that using serial hCG measurements was effective and feasible. (11) Sixty-three percent had ultrasound before the treatment, so the rest of them were just dated clinically, and there was no difference in terms of outcome between the women who had a pre-treatment ultrasound and those who did not. All the women who did not receive post-abortion ultrasound aborted successfully. Only 4 of 91 had >20% decline in hCG at Day 7, but all of those four still had a complete abortion. There is of course still the issue of the cost of β-hCG: testing isn't cheap, especially in the United States. But this is an alternative strategy to determining follow-up and detecting ongoing pregnancy after medical abortion.

Urine testing

What about urine pregnancy testing? I mentioned that if using a regular pregnancy test at follow-up, it is highly likely that a pregnancy test that is sensitive to 10 or 25 international units per litre is still going to be positive at follow-up at 2 weeks or so. One study has been published looking at the utility of using a low-sensitivity urine test, sensitive to 2000 IU/L; this found that the test had a high false-positive rate. (12) The Positive Predictive Value (PPV) was only about 1-2%. The study wasn't really large enough to evaluate the accuracy actually in detecting ongoing pregnancy, since there were so few ongoing pregnancies in the study, but if the PPV is so low, it suggests that the test won't be very helpful. Many women with a positive result won't actually have an ongoing pregnancy, and most women will end up getting referred for ultrasound anyway.

A recently completed study that was presented in the US at the National Abortion Federation meeting suggests that a clinic-based low-sensitivity urine test could be useful as a screening test for ongoing pregnancy, but this has not actually been published yet. (13) A dipstick low-sensitivity pregnancy test was recently validated that could be used at home. (14) This was developed in India and may have a somewhat higher sensitivity than the test that was used in the first study, but it still needs to be evaluated in a clinical setting. So the bottom line is that we still need more research looking at the utility of low-sensitivity urine testing to identify ongoing pregnancy.

Providers of medical abortion

One other barrier to the use of Early Medical Abortion that I mentioned was the type of clinician that can provide it. There is a real possibility that medical abortion could greatly improve

There are some innovative provision models being developed

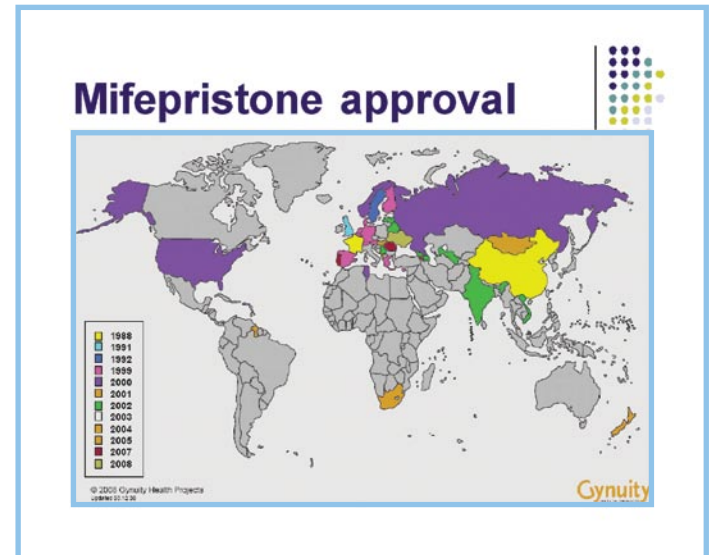
access to abortion because you do not necessarily have to be a highly skilled practitioner to provide the service, so long as there is back-up and referral available. In the US, there are about 15 states where Advanced Practice Clinicians (APCs) - nurse practitioners, physicians' assistants, certified nurse midwives - are allowed to provide medical abortion. In all other states, they are not: those states have physician-only laws, or their laws are interpreted to require physicians actually to provide the abortion. California is one of the few states that actually passed legislation in 2002 explicitly permitting any authorised healthcare professional to provide medical abortion.

There are some innovative provision models being developed to look at how we could potentially extend the reach of physicians to provide medical abortion. One example is a telemedicine system that a Planned Parenthood affiliate in the US is implementing: this is done in a very rural state, where a couple of physicians are based in a city, and a woman can come into an outlying clinic and request a medical abortion, be evaluated by a nurse or nurse practitioner, have an evaluation ultrasound done, and then have an encounter via internet with the physician, located in a city hundreds of miles away. The physician reviews the clinical information from the ultrasound and if she or he determines that the client is appropriate for medical abortion, she or he types a code into a computer that opens a door in the remote clinic and dispenses the medication. This is a very innovative way of using internet technology to provide medical abortion.

Worldwide availability of mifepristone

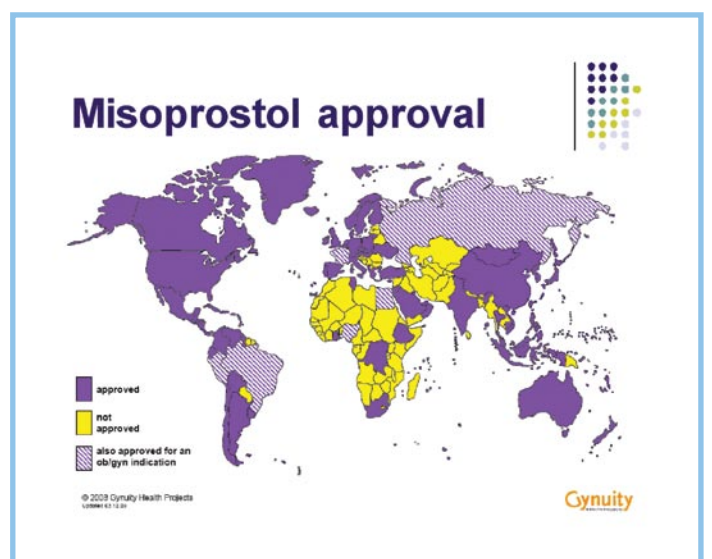
I have been talking about how we could improve access to the mifepristone / misoprostol regimen. One of the biggest barriers in the world to providing the regimen is that mifepristone is available only in a few countries. All the grey countries shown in Figure 3 do not have mifepristone, and in some of the places where it is available, cost is still a barrier to access.

Figure 3



Even misoprostol is not registered in quite a few countries, especially in Sub-Saharan Africa, where a very large number of unsafe abortions occur. (Figure 4) And we know that misoprostol is really a life-saving drug; that it's much safer than other techniques that are used for unsafe abortion.

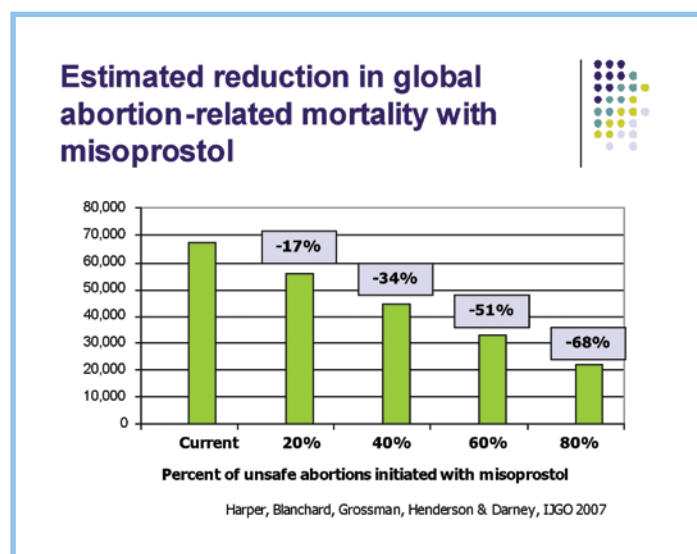
Figure 4



Globally there are approximately 68,000 maternal deaths due to unsafe abortion

Figure 5 shows some modelling work that we did with colleagues at the University of California, San Francisco looking at what the impact could be of increasing use of misoprostol in the developing world at least to initiate abortions, instead of using other unsafe techniques.

Figure 5



As you can see, currently there are approximately 68,000 maternal deaths due to unsafe abortion. If at least 20% of those unsafe abortions were at least initiated with misoprostol, because it is a much safer technique, we would see a 17% reduction in maternal deaths. As we estimate more and more use of misoprostol, there would be a higher and higher reduction in the number of maternal deaths.

Conclusion

In terms of improving access to medical abortion, there are a few strategies where there is good evidence to support their introduction now:

- Home use of misoprostol;
- Ultrasound as needed to assess gestational age, instead of every time;
- Serial serum hCG tests to determine completion and ongoing pregnancy with ultrasound as needed;
- Non-physician provision where feasible.

Other strategies which are promising, but where more research is needed, include:

- Women’s self-assessment of completion;
- Low sensitive urine pregnancy test (or serial urine tests) to screen for ongoing pregnancy in clinic or home.

References

- (1) Clark, Gold, Grossman, Winikoff. *Contraception* 2007
- (2) Ellertson, et al., *Lancet* 2000
- (3) Blanchard, et al., *BJOG* 2007
- (4) Borgatta, et al. *JAMWA* 2000; Suhonen, et al. *Contraception* 2003
- (5) Hausknecht. *Contraception* 2003
- (6) Ellertson, Elul, Winikoff. *Reproductive Health Matters* 1997
- (7) Harper, Ellertson, Winikoff. *Contraception* 2002
- (8) Rossi, et al. *Contraception* 2004
- (9) Creinin, et al. *Contraception* 1996
- (10) Fiala, et al. *European Journal of Gynaecology and Reproductive Biology* 2003; Schaff, et al. *Archives of Family Medicine* 1995; Creinin. *AJOG* 1996
- (11) Clark et al. *Contraception* 2007
- (12) Godfrey et al. *Contraception* 2007
- (13) Bracken et al. NAF presentation 2008
- (14) Grossman et al. *Contraception* 2007

TRANSLATING RESEARCH INTO ACTION

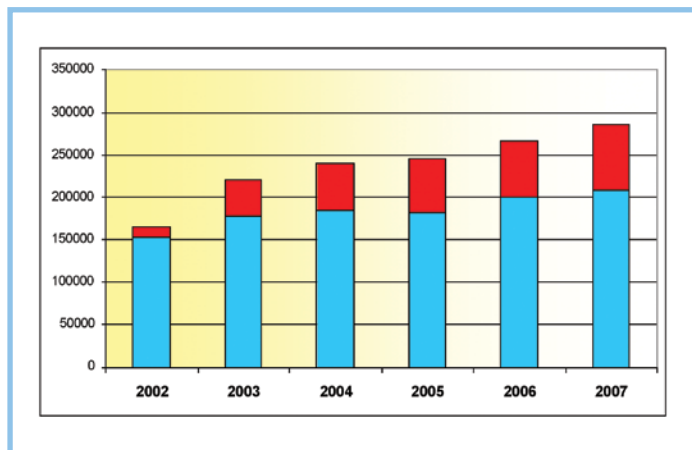
Mary Fjerstad, NP, MHS

Director of Quality and Learning, Planned Parenthood Consortium of Abortion Providers, USA

My paper will focus on taking a discovery – in this case medical abortion – and, from a practical point of view, disseminating it widely into a large system. The system I am talking about is Planned Parenthood centres in the United States – 289 clinics that provide abortion – but it could be a system in a country or a county. I think the same principles would apply in disseminating any new medication, but I am talking about applying it to medical abortion.

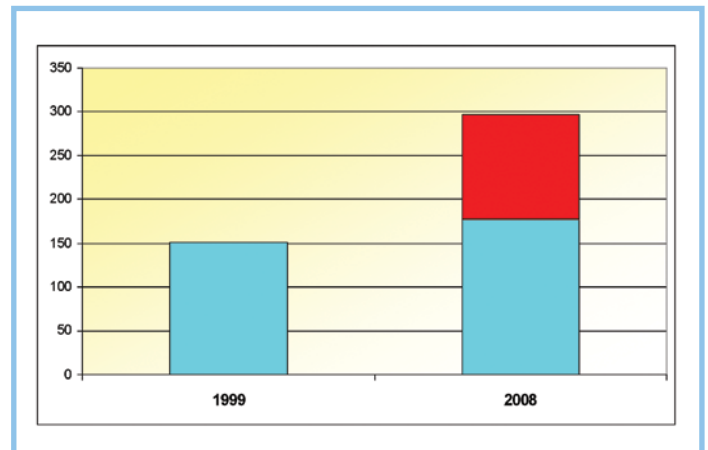
Mifepristone was approved for use in the United States in late 2000, and since then Planned Parenthood has provided 364,000 medical abortions, all with home use of misoprostol. In other words the women get both mifepristone in the clinic and misoprostol to self-administer at home 24-48 hours later. At this point the total system is providing about over 70,000 medical abortions a year.

Figure 1: Number of first-trimester and medical abortions at Planned Parenthood



The blue bar shown on the graph in Figure 1 (above) is first trimester surgical abortion, and these have increased somewhat from 2000 to 2007. However, it has really been the use of medical abortion that has brought more patients to Planned Parenthood and has fuelled growth.

Figure 2: Number of health centres providing abortion



In 1999 we didn't have medical abortion, so 151 clinics provided just surgical abortion, whereas in 2008 the number of clinics providing both surgical and medical abortion grew somewhat. But an amazing growth is shown by the red block of clinics, 119 clinics, which formerly provided no abortion at all but provided contraception. Many of these clinics are located in remote areas, in mountainous areas, in inner cities or college towns, and those clinics now provide medical abortion.

In getting medical abortion into use in the United States, we learned five lessons in how to disseminate a medical innovation. One is, of course, starting with a good scientific innovation and a protocol that is based on very good evidence. But there is a tremendous gap between a great evidence-based protocol and a real-life dissemination and use of a medical treatment. People need to understand how to apply the protocol, need to feel confident in it, and need training. The other lessons relate to training, data, communication, and also some of the unexpected successes. I believe you should always watch out for the unexpected successes, because sometimes that's where you get the most impetus.

Evidence-based protocols

The original trials in the United States, which led to the Food and Drug Administration (FDA) approval of mifepristone, were conducted in 1994, but a tremendous amount of research has gone into medical abortion since then. So it is very important not to be stuck in time, because you want to provide the most efficacious and the most convenient service to women possible. So it is very important to have a system for reviewing and updating protocols based on new evidence. And just to be clear, when the FDA approves a medicine for an indication, it openly permits new indications for that medicine as long as they are based on scientific evidence. So one doesn't have to

You cannot just train the physician and achieve good uptake

go back to the FDA for approval when a regimen is changed based on new science. For instance, now we use 200mg of mifepristone rather than the original dose that was studied in the trials.

The protocol in use at Planned Parenthood clinics today is provision of medical abortion through 63 days (Early Medical Abortion), with 200mg of mifepristone, followed 24-48 hours later by 800µcg of misoprostol by the buccal route. This is home use of misoprostol, self-administered by the woman, and then the woman returns within two weeks for a follow-up visit. Some clinics have the woman return the day after misoprostol, so it doesn't have to be two weeks afterwards. I have audited a clinic where they say to the woman, 'You can return at any time in the two weeks. You can return the day after the misoprostol. That's completely up to you. You decide, you tell us what will work best.' And that clinic had a follow-up rate of 97%. So this let us know that making an early opportunity for follow-up enhanced the women's compliance with the follow-up. When I looked at the ultrasounds of women who came back for follow-up a day or two after misoprostol, I did not see an appreciable difference in how the endometrium looked and what the ultrasound looked like.

So, again based on evidence, we discussed following the success of medical abortion with serum HCG. This can be very effective. One reason is that it can eliminate the confusion of the post-abortion ultrasound. In the United States, there are huge remote areas and women may travel to have a medical abortion for two, even four, hours, and there may be blizzards in the winter. If they have a blood test, a beta HCG test, on Day One they can get their blood run wherever their closest lab is, maybe back at their home area, and comparing those two beta HCG results can determine whether the medical abortion was successful, and save a woman a trip back to the clinic for an ultrasound. Then there is a phone call between the nurse and the woman to determine whether she's feeling well, she's not having any problems, informing her that her blood tests indicate that the medical abortion was successful.

Before we implemented this follow-up with quantitative beta hCG, we looked at the research and we had two mountainous states use this method for 18 months. We gathered the data, looked at the behaviour of the beta HCG results, which was exactly as the literature said it would be. So we found it was a very accurate and successful way to track medical abortion.

The second way we can use beta HCG in medical abortion is in very very early medical abortion. Urine pregnancy tests are so sensitive that women come into clinic very early, and sometimes they are so early that even with a trans-vaginal ultrasound you can't see an intra-uterine pregnancy. Now it may matter a lot to us that we see what we want to see – a gestational sac, or even a gestational sac with a yolk sac – but

it might be psychologically reassuring to the woman that the pregnancy is so early that you can't even see it on ultrasound, and it may be comforting to her to initiate medical abortion that early in pregnancy. So in that application of using serum HCG, the woman would have a beta HCG on day one, receive her mifepristone, and within 48-72 hours after misoprostol, she would have a second beta HCG which would be expected to drop by half.

Training

We have found, and I'm passionate about this, that you cannot just train the physician and achieve good uptake. I was once at a clinic where a receptionist answered the phone, a patient said 'I'd like to have that kind of abortion where you have an abortion pill', and the receptionist said, 'Oh, you're brave'. And I could go on and on about the types of comments that can be made by phone receptionists, nurses, counsellors – it's really the whole team that either inhibits or enhances access.

Whenever I have gone to an agency to provide training, I've always brought somebody with me from another agency. That has a synergistic effect, because people see that this person has come from another clinic like the one they work in, and they are talking about how successful medical abortion is at their agency. Another advantage is that they have got a buddy now they can talk to, and if they're embarrassed to ask the bigwigs they can call their buddy and say, 'We're having a problem, what do you recommend?' This creates a cross-pollination between agencies. Yet another advantage of whole-site training is you really see who the change agents are – somebody who is passionate and understands the implications of offering medical abortion as a choice to women. That is not necessarily the physician: it can be, certainly, but it can also be a respected nurse, a respected counsellor, a clinic manager. So whole-site training has been a real key to success.

Ultrasound

Ultrasound is a very useful tool, but it is not infallible and human beings aren't infallible, and it's an expensive tool. An ultrasound machine costs a lot of money, they break and they don't last forever, and you become very reliant on them. We have had a big training issue in the United States with all the people in our clinics doing scans, so we created a CD called *Ultrasound in Abortion Care*, which has been very useful in bringing up the standard for anybody who is doing scanning. But the problem that I have seen in clinics that I have visited in many countries is the tendency to read too much into the post-medical abortion ultrasound. And if someone from a clinic calls me and says, 'Our intervention rate after medical abortion is 6%, or 8%, or 9%', before the conversation even goes on I know what the problem is. I don't say that – I talk it through with them – but it's almost always because they are agonising

It was crucial for us to collect what I call 'local data'

over the endometrial thickness – is it a clot, is it degree, is it residual tissue- what is it? What do I need to do about it?

As Daniel Grossman indicates in his presentation, the purpose of the ultrasound is to determine that the woman is no longer pregnant. Once you've determined that, the endometrial thickness does not predict the patient's course. And really at that point the best thing to do is to turn the ultrasound off and evaluate the patient clinically, to see if her bleeding is normal and if she feels well, etc. All of us working in the field of medical abortion have reiterated this so many times, but it's still the case that people look at that follow-up ultrasound and try to over-interpret it.

Data

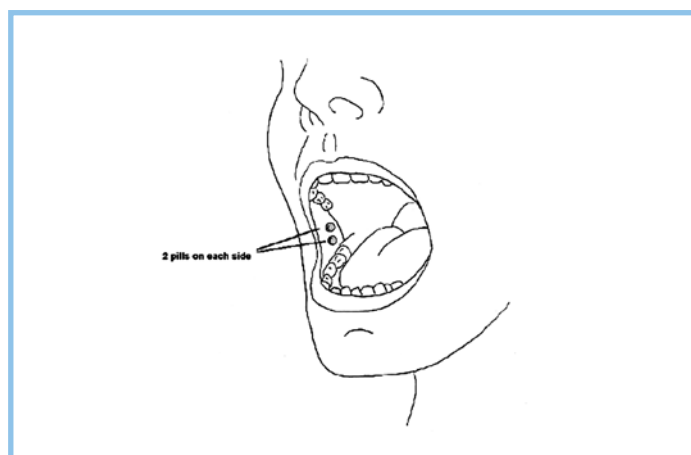
It was really crucial for us, and I believe for any system, to collect what I call 'local data'. Local data may mean different things – for example, if you work in a clinic system, or a clinic in Scotland, that would be your local data. For Planned Parenthood our local data was Planned Parenthood data from across the United States. For one thing we wanted to determine what the uptake of medical abortion was. At this point half of eligible patients at Planned Parenthood clinics in the US are choosing medical abortion. But early on, clinic people would say, 'Oh we're giving a lot of medical abortion'. We would ask them for a number and they would say, 'We're doing two a month'. We needed to start determining what our use is and what our pockets of very high use are, see what they're doing, replicate that, and really track their progress.

In one of our first Planned Parenthood meetings after medical abortion was approved, a very well-respected doctor said, 'These women are going to go home and they are going to bleed like a river'. The only thing that was going to counteract that imagery was data. So since January 2002 we have tracked adverse events – all adverse events are reported centrally, and we also track our dominators, so we know within our system efficacy rates and rates of adverse events, and we have a process to review and analyse those data. So at Planned Parenthood the rate of ongoing pregnancy is 0.5%. Overall, 1.5% of women have a surgical intervention. The transfusion rate is 0.2 per thousand, and the rate of serious infection is now 0.06 per thousand. In this respect, another enormous effort in implementing any medical innovation is communicating progress. We produce a newsletter called *Mife Matters* we distribute it to Planned Parenthood but also to interested parties around the world. And the philosophy behind that is that we provided surgical abortion for thirty years, we had lore and stories about surgical abortion and we had no way to communicate stories and things we learned along the path about medical abortion.

But I cannot emphasise enough how much we've learned about communicating to clients, because these medicines are multi-syllabic, they all start with m – mifepristone, misoprostol – prostaglandin, anti-progestin – patients are in crisis, they can't memorise four pages of single page information and instructions. And also we have to recognise that we have a pretty heterogeneous culture, and for many of our clients English is not their first language, and even people for whom English is their primary language they may not read well. And so we have really worked on developing materials that keep it simple, and that has advantages not only for clients but also it's less intimidating for staff to use tools that make the explanation of medical abortion simpler.

When we started using misoprostol by the buccal route, our staff didn't even know what buccal meant, much less go into this wordy explanation with patients. So a picture is worth a thousand words. (Figure 3)

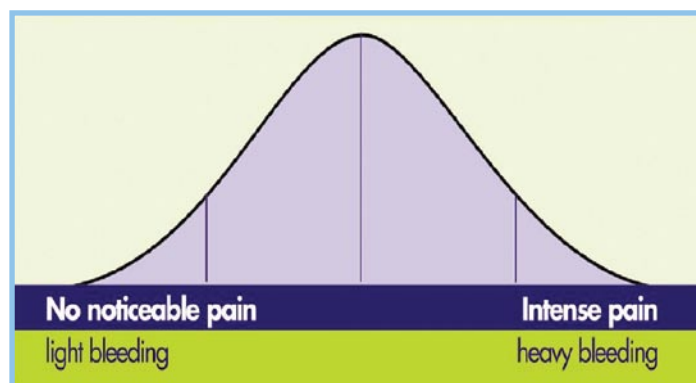
Figure 3



We use such models as the bell curve (Figure 4). There's two ends of the normal continuum – a woman can have a successful medical abortion who doesn't notice cramps and has light bleeding, and on the other end of the continuum she may have heavy bleeding with large clots, and may feel intense cramps. So if those are the two ends of the normal continuum, most women are going to fall somewhere in the middle – that's the nature of the bell curve. And women really understand that this is the range of experience. How much bleeding is too much bleeding? Simple, visual, keeping words down to a minimum, very helpful. We created graphic instructions about how to take your pills.

In 17 US states, nurse practitioners or advanced practice clinicians can provide medical abortion

Figure 4



These women live in little clusters of communities that don't have roads to them, they have dirt paths. So this woman walks an hour down the dirt path and she drives an hour down a dirt road then she drives an hour down a paved road to get to the clinic where she knows the clinic staff, she knows the clinician because she has received care there before, and she gets a medical abortion. She's not going to drive two hours away to a major metropolitan centre – probably nobody within her community has ever been to that major metropolitan centre, it's not in her world. This clinic, at the edge of the Grand Canyon, is within her world. So that is an example of how greater access to early medical abortion has made access to abortion a reality in areas of the US in which it formerly was really not accessible before.

So for people who are going home, and are taking their misoprostol at home, we given them a non-steroidal anti-inflammatory, usually a mild narcotic – all of that is explained in almost like a cartoon type format, and I would encourage people to develop their own materials that are geared to whatever culture or population that they work with. We produce our materials in English and Spanish, because Spanish is the predominant second language spoken in the US.

Unexpected successes

I would call the role of advanced practice nurses in medical abortion a real unexpected success. When we started providing medical abortion we realised in some states that the regulations of nursing are such that advanced practice nurses could provide medical abortion. Much of the time they are the ones who do the scans, they do the counselling, they've seen the patients in their gynaecological care with Pap smears and provision of contraception, so they already know the patients. Unlike in the UK where nursing practice is regulated as a whole nation, in the US it's regulated state by state. So in 17 states, nurse practitioners or advanced practice clinicians can provide medical abortion. And based on the volume of medical abortions given in any particular state, I estimate that about half of the medical abortions provided at Planned Parenthood and provided by nurses with advanced training.

This little anecdote I think brings home the synthesis of the impact of medical abortion. There is a Planned Parenthood clinic in a little town called Flagstaff, Arizona, right at the edge of the Grand Canyon - a vast geographical area, it's very remote; and in this area of Arizona there are huge Native American Reservations, including the Hopi and Navajo Reservations. The nurse practitioner who works in the clinic in Flagstaff provides Pap smears, emergency contraception, colposcopy and women's health care. And she has patients who come from the Native American reservations for medical abortion.

THE ROLE OF NURSES

Kathy French RN, BSC (Hons) Cert Ed, PGDiP, MPH, NT

Without doubt, the role of the nurse in the UK has extended dramatically, and many of the tasks undertaken by doctors traditionally are now undertaken by nurses. Sexual health nurses, for example, provide screening, prescribe medications, insert sub-dermal implants and fit IUDs/IUS. Gynaecological nurses perform colposcopy, hysteroscopies and other procedures. Training, competence and accreditation are key.

My previous post was in south-east London, where I worked with the most incredible team of doctors who supported and trained us to extend our role, obviously within the law. I remember way back in the 1970s when one of our consultants went to the States with his wife, who was a nurse, saying he'd heard about nurse practitioners long before we had them in the UK, and he trained us to fit IUDs. We were the first in the country to do that.

There are many drivers which have assisted nurses in extending their roles in all the different specialities. The NHS Plan (2000) talked about nurses performing 'minor surgery' – though that didn't mean abortion. We have Supplementary and Independent prescribing and now Non-Medical Prescribing, which allows nurses to provide the total package of care for their clients. This is one of the greatest advances for nurses in the UK, but that was a very long and painful path for us. I remember back in 1986 trying to push for prescribing rights for nurses and contraception, and it's taken many many years for that to happen. The many sexual health strategies saw nurses as key to the improvement in the sexual health of the population. But in terms of abortion care nurses must work within the law relating to abortion and this limits somewhat their role.

What do nurses currently do?

The role currently played by nurses depends on the setting in which they work. Some clinics and some providers have different models to the one that I am familiar with. Nurses – and by nurses I include midwives – often perform pregnancy tests when women first present, thinking that she may be pregnant: this is a very common pattern in our contraception clinics. Depending on the skill of that nurse and what additional training she or he has had, the nurse will engage with the woman around choices about where she can go, types of abortion available, who the providers are, etc. That is terribly important. One does hear of women having a pregnancy test done in a certain facility or area, returning two weeks later and the result isn't back from the path lab, so they spend ages going round trying to get the results.

Nurses provide counselling and information to women. I'm not a great fan of the word 'counselling' because many women who come to abortion services know exactly what they want. But they do need information. So we talk about counselling, assessing that woman in very wide terms, and providing information – this is very important. Nurses where I have worked undertake ultrasound scanning to confirm gestation – again, that was an extended role for us. A key issue for nurses working in abortion or a related area is this whole debate around contraception needs and failure. Nurses will discuss and assess this, and prescribe ongoing contraception. Nurses working in sexual health will discuss and assess the risk for Sexually Transmitted Infections (STIs), and also screen for and treat STIs. We perform blood tests. A very important issue is that we will deal with child protection issues that may come up – it is the nurses generally who make those assessments and liaise with Social Services and Child Protection leads, who we get to know quite well in our daily work.

Onwards from that: once the decision is made and the woman is seen, admission is arranged for the chosen procedure, generally by the nurses, depending on where the nurses work. Nurses provide the care needed for women in whatever setting the procedure takes place, and I think that care is very much the essence of the nursing role, and care and procedure can often get confused. I'm talking about the care and not the procedure. However, nurses cannot at the moment prescribe the medication for medical abortion – for a nurse to supply a medication with the intent to procure an abortion without the relevant authorisation would be unlawful. But if nurses could prescribe I could see how that would really help women getting early access to medical abortion. Nurses may or may not want to perform surgical procedures – we don't know, but I think some nurses who work in that area may want to take that step. Currently, however, nurses cannot perform MVAs or any surgical abortion. Nurses are not permitted to sign the notification form (HSA4) but they can seek consent. These two are often confused.

In 2007 an article was published that suggested nurses and midwives could perform abortions in the UK – a personal opinion of the authors. (1) People got quite excited about it, but actually looking at the law it is very very clear that only a registered medical practitioner can perform an abortion, that is the wording that is used. One amendment to the British abortion law discussed in 2008 expressed a desire that the medical practitioner term could be a medical health professional – somebody else who is registered, for example a nurse or a midwife. And I think it's very important that we work within the law. Whilst nurses have extended their roles substantially, many of the procedures do not have Acts of Parliament attached to them: for example we do not have a Colposcopy Act or a Sub-dermal Implant Act. There is no Act that prohibits us from doing these procedures and that is what makes it very different.

The role of the nurse has evolved amazingly

There can be no doubt that nurses, as part of the whole team, provide care to women having an abortion. Care is the essence of the nursing role. The Faculty of Sexual and Reproductive Health has produced a module on abortion for nurses, doctors and social workers, and the aim of this module is that the professions attend all the lectures, and attend the clinical component as well, so the social worker, the nurse and the doctor are very familiar with what our roles are within the rest of that team. Nurses who have an objection to working in abortion units should follow the Nursing and Midwifery (NMC) guidance. The Abortion Act 1967 and the HFEA Act (1990) does not apply to Northern Ireland and therefore the conscience clause of the above Acts does not apply, leaving nurses and midwives in a difficult position. Abortion is permitted in Northern Ireland but only in very limited situations.

What could nurses do?

What could we do if the law was amended? Nurses could prescribe the medication for medical abortion. I think if we could prescribe for Early Medical Abortion in line with the other prescribing rights that many nurses have, it would make quite a difference for the woman. Women could be seen by fewer professionals as part of the pathway. Some nurses may want to perform early surgical abortions (MVAs). Nurses might be able to sign the notification form in place of a doctor – that's a big question mark, or should that remain the job of doctors? Do we need a notification form in the first place? But it is very important to say that abortion should not be part of every nurse's job description, any more than it should be for every doctor.

The evaluation of the Early Medical Abortion (EMA) Pilot Sites (DH 2008) highlighted the role of nurses, who were seen as professional, sensitive to the issues involved, had a reassuring nature, and for their warmth. These were sites that were specifically providing abortion, and we know that may not be the experience of all women seeking an abortion. I came to this country from Ireland, where abortion is illegal, in 1968, and I remember very well the stigma attached to women who were admitted during the evening or at night into wards as a result of poorly performed abortions out there. In addition, women interviewed in the EMA Evaluation also felt that nurses could play a larger role in Early Medical Abortion – it doesn't say what the role is, but the women have said that nurses could have a larger role. But we must wait for a change in the law.

Anything that nurses do in terms of extending their role, they have to have a very long path ahead of them. No one imagined in 1967, when the Abortion Act was passed, how health care delivery might change and the role nurses would play in that change, and that nurses would be doing what they are doing now. And I think the Act was right in 1967 when abortion was

very much a medical procedure, but we have moved on and nurses have changed their role dramatically.

Just to take you back to see how much we've evolved, this is something I found from 1905. And some of this you'll be familiar with and some of it you won't:

Nurses will fill lamps, clean chimneys and trim wicks. Each nurse will fetch a bucket of water for scrubbing and a scuttle of coal to stoke the fire before beginning her rounds. Each nurse is to record her observations carefully and legibly. She must make her pens carefully and she may whittle nibs to her individual taste.

We still have to record, and rightly so, everything about the care that we provide for our clients. The rest we don't do, I am glad to say.

This goes on:

The nurses will be given one evening off each week for courting purposes, or two evenings if they go to church regularly and the provided the superintendent of nursing gives her approval. After 13 hours of work, the nurses should spend their remaining time reading the bible or other good books. Every nurse should lay aside from her pay a goodly sum of her earnings for her declining years so that she will not become a burden of society. The nurse who has performed her duties faithfully and without fault for five years will be given an increase of 0.05p a day in her pay, providing the hospital's situation permits.

For me, the message is that the role of the nurse has evolved amazingly. The law hasn't naturally caught up with it. We do have the Abortion Act, and we must work within that legal framework. But I know there are nurses who would like to have a greater role in giving the whole package of care to women around early medical abortion, and there are some who may want to extend into early surgical abortion – that is working within part of a team supported by medical colleagues, and with appropriate and accredited training. I think that is the vital thing. None of us who have ever extended our role have done it by going off on a folly of our own - we have had to be trained, accredited, and keep the competencies up in order to maintain those skills.

Kathy French has worked in contraception and abortion services in South-East London for many years and was the Sexual Health Adviser at the Royal College of Nursing until July 2007. She is a member of the Independent Advisory Group (IAG) or sexual health at the Department of Health.

References

(1) Argent, V and Pavey, L (2007) Can nurses legally perform surgical induced abortion? *Journal of Family Planning and Reproductive Health Care* 2007 33 No 2 p 79-82

(2) Department of Health (2008) *Evaluation of early medical abortion (EMA) pilot sites: Final report*. Available here: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_084618?IdcService=GET_FILE&dID=164800&RenderItem=Web

WHO CAN PROVIDE ABORTION CARE? THE ROLE OF MID-LEVEL PROVIDERS

Marge Berer

Editor, Reproductive Health Matters

I am first going to discuss the efforts to modernise the 1967 Abortion Act in the UK, and I am speaking in that sense for Voice for Choice – a coalition made up of Abortion Rights, Antenatal Results and Choices, bpas, Brook, Doctors for a Woman's Choice in Abortion, Education for Choice, fpa, MSI and Reproductive Health Matters, who have been working in this area.

The Human Fertilisation and Embryology Bill in 1990 amended the Abortion Act to reduce the time limit from 28 to 24 weeks. When a bill modernising the Human Fertilisation and Embryology Bill was tabled in Parliament in 2008, several anti-abortion MPs attempted to occupy this space by attempting to reduce the time limit further – an attempt that did not succeed. Pro-choice amendments, issues around which Voice for Choice has been campaigning for at least five years, involved:

- The necessity of two doctors' signatures for every abortion;
- Enabling suitably trained health care practitioners, including nurses, to carry out first trimester aspiration abortions and manage first and second trimester medical abortions independently;
- Home use of misoprostol, which is standard practice in a number of other countries; it's about extending the locations where early abortions can take place to other suitable clinical settings, including primary level;
- Extending the 1967 Abortion Act to Northern Ireland, which Voice for Choice considers the biggest priority here, in order to end 40 years of discrimination against women in Northern Ireland.

The government did not see fit to consider our amendments to the HFE Act, perhaps because it would have forced them to consider some 25 anti-abortion amendments as well (though they gave other reasons at the time), but these remain priorities and will continue to be campaigning issues for us.

My presentation here looks at provision of abortion by providers who are not physicians, but are suitably trained to provide abortion. So this paper is about policies on type of abortion provider, comparative studies of safety with different cadres of provider, provider perspectives, and some programmatic experience in France, Sweden, the United States, South Africa and Viet Nam: countries that in some cases have more resources than this country and others considerably less, but all of whom are involved in this.

Abortion has become one of the safest and most frequent clinical procedures used by women

Changes in abortion methods

In the 1960s and 1970s, when laws like the 1967 Act were written, abortion procedures, both surgical (dilatation and curettage (D&C), dilatation and extraction (D&E) and hysterotomy) and medical (intra-amniotic, extra-amniotic) and intra-muscular (urea, saline, various PGs and ethacridine lactate), required a trained physician in order to be safely carried out. But in the past 40 years - and 40 years is a long time in the development of medical technology these days - the methods became safer and simpler (both surgical and medical methods) and at the same time, the laws in Europe, North American, Australia, and Cuba also made abortion accepted medical practice. Abortion today has become one of the safest clinical procedures used by women and also one of the most frequent.

I always find it a bit bemusing that people talk about making abortion 'rare', because it seems to me the only way to make abortion rare is to make women rare, and I don't think we would want to accept that.

The World Health Organisation (WHO) currently recommends three main methods of abortion:

- Vacuum aspiration (VA) up to 14-15 weeks of pregnancy, in skilled hands. In the early weeks that can include manual vacuum aspiration (MVA), which was used initially in developing countries that had no steady access to electricity in their clinics, and electric vacuum aspiration, which we are used to in the UK.
- Mifepristone and misoprostol in appropriate doses for the first nine weeks, and then a changed regimen from 9-13 weeks' gestation, and again a changed regimen from 13 – 22 weeks.
- Dilatation and evacuation (D&E).

What I would like to show in the way of evidence is that the first two of these methods are already being carried out by trained non-clinicians in several countries, and I would even argue that D&E also could be done by non-physician clinicians trained in obstetric surgery.

Why change policy?

There are several very good reasons to change policy on abortion:

- Current policy needs to catch up with technical innovation. When you pass a law you have to be ready to live with it for a long time, because the law is very slow to change compared with other things in the world such as medical advances.

- To provide highly accessible, good quality abortion services at low cost.
- To make up for the lack of physicians willing to take on abortion. The United States is a shining example of a country where, because of the political activity against abortion and the level of nastiness, including murder and threats to doctors' lives, fewer physicians are prepared to do abortions. I don't think it's quite so bad in the UK, but I do think you see evidence that lots of physicians are not queuing up to offer the procedure.
- There is a huge crisis in human resources for health care in low-resource countries.

What is interesting about looking at these issues from an international level is to see how the needs of developing countries can actually inform our practice here, and vice versa, even though the situations are so different.

The World Health Organisation (WHO) in 2003 prepared safe abortion guidance that recommends that:

- Abortion services be provided at the lowest appropriate level of the health care system;
- Vacuum aspiration can be provided at primary care level up to 12 completed weeks of pregnancy and medical abortion up to 9 completed weeks of pregnancy;
- Mid-level health workers can be trained to provide safe, early abortion without compromising safety;
- Training includes bimanual pelvic exam to determine pregnancy and positioning of uterus, uterine sounding, transcervical procedures, provision of abortion and skills for recognition and management of complications.

The WHO guidance says that the cadres of mid-level provider who should be able to do this safely with appropriate training include:

- Midwives;
- Nurse practitioners, advanced practice clinicians (a term from the US);
- Clinical officers/surgical technicians (a cadre of provider in Southern Africa: a non-physician clinician who has had substantial surgical training);
- Physician assistants.

In each country these titles, and the training that stands behind them, are somewhat different, so those have to be adapted on a country-by-country basis.

A colleague of mine from India wrote a paper in 2005 about the meaning of de-medicalisation. I think this is a very important thing to take on board, not just in relation to abortion, but in relation to a great deal of other kinds of healthcare:

Regulations in Great Britain are already interpreted to allow nurses to administer medical abortion drugs

'Measures for de-medicalising primary health services include: adoption of simpler technology and service protocols, authorisation and training of less qualified providers, simplification or elimination of facility requirements, establishment of robust referral links to hospitals, increasing user control and self-medication.' (Iyengar S. *Reproductive Health Matters* 2005;13(26):13-19.)

Every one of these applies to early medical abortion.

International comparisons

Now to the evidence. In the United States, physician assistants, certified by the Board of Medical Practice in the US, have been permitted to carry out early abortions in the states of Vermont and Montana since 1975. (Freedman MA et al, 1986) As of January 2005, trained advanced practice clinicians were providing medical, and in some cases, early surgical abortion in 15 US states. (Joffe C, Yanow S, 2004) Since 2005, two additional states have joined that list.

Now, having to see both a physician and a nurse for early medical abortion is a bit like musical chairs. In the US, in the 35 states (in 2007) where mid-level providers do not have the legal authority to administer the drugs, the mid-level clinician assesses the woman's over-all health, dates the pregnancy, and reviews the choice of a medical vs. surgical procedure. The physician comes in to briefly meet the patient and administer the mifepristone. The mid-level provider then reviews with the woman how and when to take the misoprostol at home, and sends her home with the pills. So we're talking about a very narrow definition of what the physician actually does in the situation, until and unless a serious complication arises, which occurs only rarely.

In Sweden, by 2001, physicians' main role in the provision of medical abortion was to estimate the duration of pregnancy by ultrasound and to serve as consultants and supervisors. For the rest, midwives are responsible for counselling women and administering the drugs.

In France, both medical and surgical abortions must be performed by a physician. However, in practice, physicians' involvement in medical abortion is minimised, thereby reducing staff costs. (Jonsson IM, et al. 2001) Physicians now confirm the pregnancy and conduct the follow-up visit, but nurses are otherwise responsible. (Hassoun 2001)

Regulations in Great Britain are already interpreted to allow nurses to administer medical abortion drugs – as long as a physician prescribes them. As a result, medical abortion services are largely supervised by nurses, with physicians available if needed. This includes second trimester medical abortions.

Going to the developing world: South Africa and Viet Nam were, until fairly recently, the only two developing countries where it is permitted in law for mid-level providers to do aspiration abortions. Nurse practitioners and physician assistants have been permitted to provide first trimester abortion services in Viet Nam since 1945 and in South Africa since 1997, when the law was reformed there to make abortion legal in any case. (Warriner IK et al, 2006)

South Africa has recently updated its abortion regulations to allow trained mid-level providers to manage the whole medical abortion procedure as well. A programme was initiated to train registered midwives throughout the country to provide abortion services at primary care facilities, with an important impact on availability and accessibility for woman. (Sibuyi MC, 2004)

According to South African Nursing Council requirements, midwives are considered for certification in abortion care after 80 hrs of theoretical training and 80 hrs of clinical training under the supervision of experienced, practising physicians in accredited hospitals. The clinical training must be completed within three months of the theoretical training. (Dickson-Tetteh K & Billings DL, 2002)

Safety studies

Figure 1 is a summary of four different comparative safety studies between mid-level providers and doctors. These are all in relation to aspiration abortion; they are not to do with medical abortion, mainly because everywhere where early medical abortion is provided, nurses are so much involved, even though the doctors are in charge, it's very difficult to do a controlled trial between doctors on their own and nurses on their own. WHO's Human Reproduction programme was going to attempt a randomised controlled trial, but when it was discussed it became very clear that the randomisation process would be to nurse working alone, without the presence of a doctor unless complication occurred, compared to a situation in which the doctor was in charge but minimally involved and the nurse was doing most of the work, as I described takes place in Europe. So it's an unusual randomised controlled trial.

The obstacles to increasing the role of the mid-level provider apply to many countries

Figure 1

Year	Country	No. women	Method	Safe?
1986	USA	2,458	1st tri aspiration	yes
2004	USA	1,353	1st tri aspiration	yes
1999-2000	S Africa	27 public health facilities	MVA	yes, 75% good clin practice
2006 (RCT)	S Africa and VietNam	1,160 SA 1,734 VN	MVA	yes

Of the four studies shown in Figure 1, which cover 20 years, two took place in the US. The earliest one, in 1986, found that first trimester aspiration abortion was as safe with nurse practitioners as it was with doctors; in 2004, again, safety was comparable. The study in South Africa at the turn of the 21st century was in 27 public health facilities, the procedure was manual vacuum aspiration (MVA), and in 75% of the cases it was found that the nurses used good clinical practice and it was as safe as with the doctors: primarily where it fell down was in relation to giving antibiotics to prevent infection prophylactically. The last study was the only randomised controlled trial that anybody is aware of yet, and that took place in South Africa and Viet Nam, which studied MVA and compared mid-level providers and doctors, and this also found that the safety was comparable.

Provider perspectives

Now, what do the providers think? Recent surveys in three US states showed a substantial interest among mid-level providers in obtaining abortion training. (Joffe C, Yanow S, 2004) A survey of 1,176 licensed advanced practice clinicians in California found that 25% desired training in medical abortion. The most frequently cited reason for not providing/assisting abortions was lack of training opportunities. (Hwang AC et al, 2005) Just to prove the lack of training opportunities, a study in 2000 of the 486 programmes nationally for nurse practitioners, physician assistants and certified nurse-midwives, found that of the 202 programmes replying to a postal survey, only 53% reported didactic instruction on surgical abortion, manual vacuum aspiration or medical abortion, and only 21% reported including at least one of these in their routine clinical curriculum. (Foster AM et al, 2006)

A rather swingeing editorial in the *Lancet* in 2006 said:

Any proposal to use non-physicians for surgical procedures or any medical role is unlikely to be widely accepted without substantial scepticism and some level of professional turf protection. (Chong Y-S, Mattar CN, *Lancet*, 2006)

Now I think this raises serious questions for gynaecologists, and this is a debate in Britain that is waiting to be had in the Royal College of Obstetricians and Gynaecologists (RCOG). It is not a frivolous question, because if gynaecologists start handing over a lot of the simpler, technical procedures that they're doing, what are they going to do instead? I don't think the intention here is to make them all unemployed or redundant, or to send them all into doing cosmetic surgery in the private sector, which seems to be what quite a few of them are doing. So a really important question is: what does the RCOG have to say about the role of mid-level providers in abortion, and what do its members on the ground have to say about it?

However, in the USA between 1993 and 2002 the acceptance among gynaecologists of mid-level providers being permitted to do medical abortions rose extensively, from less than a third to upwards of 80-85%. That's good news for mid-level providers who want to take up this training. In 1993, obstetrician-gynaecologists in the USA opposed allowing nurse practitioners to provide routine gynaecological services. In 1998, one third of obstetrician-gynaecologists and GPs surveyed believed that advanced practice clinicians (APCs) should be allowed to do medical abortions. In 2002, 80-85% of experienced abortion providers interviewed believed APCs were qualified to provide medical abortions. (Kowalczyk EA, 1993; Kaiser Family Foundation, 1998; Beckman LJ et al , 2002) Since 1999, the American Public Health Association has endorsed permitting advanced practice clinicians to provide first trimester surgical and medical abortions (APHA, 1999).

The main obstacles

The obstacles to increasing the role of the mid-level provider apply to many countries. Ipas, an international organisation promoting MVA and more recently medical abortion, in 2002 identified two major obstacles: training and authorisation to perform abortions, which are restricted to physicians in practically every country:

The principal obstacle preventing nurses, midwives ... and other mid-level providers from helping meet women's needs for safe abortion-related care is that ... training and authorisation to perform abortions ... are restricted to physicians. Even where policies or regulations do not explicitly include such restrictions,

The concept of mid-level provider has been given an upgrade recently by the WHO

opportunities for non-physician health care providers to learn clinical and other skills needed for abortion care are scarce. (Ipas, 2002)

In relation to Mozambique, Tanzania and Malawi, there are three studies in the BJOG from the past several years, led by the Swedish gynaecologist Staffan Bergström. Because these countries have such a lack of surgeons, including gynaecologists, they increased the training for these surgical technicians so they could do some quite complicated surgery. A study of major surgical obstetric procedures during 2002 of TCs and doctors in 34 hospitals in Mozambique found that non-physicians conducted 57% of 12,178 operations scrutinised in tertiary hospitals and 92% of 3,246 operations in district hospitals. Clinical officers in Malawi are doing similar surgery. (Pereira C, et al, 2007; Chilopora C, et al 2007) If these providers can safely do C-sections, obstetric hysterectomies and laparotomies for ectopic pregnancy, I feel then surely they can also do D&E if trained.

The whole concept of mid-level provider has been given an upgrade recently by the World Health Organisation, which has created a category called 'task shifting', defined as:

...the rational redistribution of tasks among health workforce teams. Specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health.

I think this raises some concerns, but task shifting involves for abortion developing an appropriate cadre of provider, in the UK primarily among nurses, as Kathy French has described; bringing training and experience opportunities in; including appropriate clauses into the abortion law and regulations; and creating clinical guidance to make it very clear what they can and cannot do.

My conclusion is that it is both safe and beneficial for suitably trained mid-level health care providers, including nurses, midwives and other non-physician clinicians, to provide first trimester vacuum aspiration and medical abortions. Given the experience in several European countries, where this is also already happening, although unfortunately has not yet been documented (apart from anecdotally), it is also safe for these practitioners to manage second trimester medical abortion independently.

Note

This presentation is based on Berer, M. 'Provision of abortion by mid-level providers: international policy, practice and perspectives.' Bulletin of WHO. 2009 Jan;87(1):58-63. DOI: 10.2471/BLT.07.050138.