Evaluation of Early Medical Abortion (EMA) Pilot Sites

Final Report

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Executive summary

Background

1 This short but intense project was commissioned by the Department of Health to assess the safety, effectiveness and acceptability of early medical abortions (EMAs) in non-traditional settings, and to help establish a protocol to cover the elements and processes required for a safe EMA service in non-traditional settings.

2 Early medical abortion (EMA) is the termination of a pregnancy up to 63 days gestation using a combination of drugs that are administered orally and/or vaginally. Mifepristone is the most widely used drug for EMA; this blocks the pregnancy hormones and causes the pregnancy to be unviable. Most commonly, mifepristone is used in combination with misoprostol, which causes the uterus to contract and expel the uterine contents. While there is some variation in the dosage used and method of administration of these drugs worldwide it is widely recognised, as a result of a large and growing evidence base, that EMA is highly effective, safe, acceptable to women, and advantageous for those providing an abortion service.

3 At the current time in the UK, abortions are permitted only in NHS hospitals and independent sector sites approved by the Department of Health. The power to approve a 'class of place' is vested in the Secretary of State for Health but has been conservatively used in the past. This is in contrast to the practise in various other countries, where Gynaecologists in their private practice not only have the right to perform surgical as well as medical abortion but actually perform most of the abortions. Medical abortions have been performed in these countries in private practice since 2000. There are no reports of increased rates of side effects or complications.

4 Two pilot sites were approved to carry out EMAs in 2004 in 'non-traditional' sites. One is within a community hospital (129 procedures carried out in 2005) and the other is in a stand-alone unit within an acute hospital (576 procedures carried out in 2005).

The Research

5 Three comparator sites were used to assist the evaluation of the pilot sites. Two were selected so as to match the size and local population characteristics of the pilot sites, whilst the third was an independent sector clinic that only performs EMAs.

6 A range of methods was used to collect relevant data, including interviews with staff working at the five sites (n=31), analysis of case notes from the sites (n= 862), client self-completed questionnaires (n=139), client interviews (n=14) and protocol analysis. The questionnaire

returns from two of the sites (one of the pilot sites and its matched comparator site) were very low, so the data from these sites could not be used in analyses of the measures that were obtained solely from the questionnaires.

7 It should be stressed that the pilot sites were in close proximity to hospitals even though they did meet the strict criteria of being 'non-traditional' sites. Similarly, the comparator sites were not 'traditional' in that one used a recently opened hospital ward at times when it was not busy with gynaecological patients, and the other is in a health centre that is physically separate from the main hospital site. The third comparator site was an independent clinic operating to a protocol that differs significantly from the pilot and other comparator sites in that women plan to complete their abortion in a place other than the clinic.

8 The fieldwork took place between June and December 2007.

Key results – safety

9 National HSA4 returns revealed very few reported EMA complications. Amongst the five sites used in this study, ten complications in total were reported during 2005 and 2006, with no site being more likely to report one. The total number of EMAs conducted at the five sites during these two years was in excess of 6500. However, it should be noted that these national returns are completed at the time of the abortion, and so may underestimate the extent of subsequent complications.

10 Of the 862 case notes analysed in the current study, there were six clinical concerns noted but these were all of a relatively minor nature and only one of these was noted at the pilot sites.

11 No concerns were expressed in the staff interviews about the unavailability of drugs or other facilities at the pilot sites.

12 The vast majority of women at all sites felt that they had been given enough information regarding what to do should they experience problems after discharge.

13 From the case notes, over 90 percent of women were given prophylactic antibiotics prior to discharge, with no differences between sites.

Key results – effectiveness

14 From case note analysis, incomplete expulsion of products occurred in fewer than one percent of cases in four sites, and in two cases (out of 64) at the other. There were no variations between the pilot and comparator sites in this respect.

15 Case notes record evidence of expulsion prior to discharge in around 80 percent of cases (not including the third comparator site which sends women home straight after the second drug treatment), with no clear differences between sites.

16 On the questionnaires, a higher proportion of women reported being sure that expulsion had occurred at the pilot site than at the comparator site. The third comparator site, which discharges women straight after the second drug treatment, fell between the other sites on this measure.

Key results – acceptability

17 A considerably higher proportion of women at the pilot site than its direct comparator site reported that they had been given a choice of method regarding their abortion.

18 Amongst those women who reported that they had been offered a choice, the major reported reasons for choosing EMA were *to avoid surgery, to be more natural, so the abortion could be done earlier, it is a less invasive option, and to avoid physical trauma and anaesthetics.*

19 Questionnaire-reported side-effects after the first drug treatment were generally lower at the pilot site than at the comparator sites.

20 On the other hand, reported side-effects after the second treatment were more prevalent at the pilot site than its matched comparator site. This may be linked to the different management techniques adopted (second administration of misoprostol at the comparator site).

21 Compared with what they had expected, reported bleeding was somewhat higher, but reported pain/cramps somewhat lower at the pilot site compared with its matched comparators site.

22 Pain management by the clinic was rated considerably more highly at the pilot site than the matched comparator site. The independent clinic received lower ratings on this measure.

23 Ratings of post-abortion care were very similar between the pilot and comparator sites.

24 The ratings of the quality of information provided throughout the process were very similar at the different sites, although the quality of the verbal information and accuracy of information were higher at the pilot site than its matched comparator site. Ratings on these issues at the third comparator site were very high.

25 Ratings of staff on professionalism, reassurance and warmth were all higher at the pilot site than its matched comparator site. Again, the third comparator site scored highly on these measures.

26 Ratings of physical features (environment, washing facilities, toilets, provisions) at the sites varied quite widely with no clear pattern emerging.

27 Ratings of the comfort of the waiting and examination rooms, and recovery areas at the sites were very similar, although the ratings of the privacy of these facilities were somewhat higher at the pilot site than its matched comparator site.

28 The pilot site received higher ratings on contraceptive advice provided and pre- and post-abortion counselling than did its matched comparator site.

29 Overall, over three-quarters of women at all sites reported that they would, if needed, choose the same method and the same clinic for a future abortion, and would recommend them to a friend in need.

30 There was strong support from staff and clients at all sites for the need for accessible and supportive help after discharge in order to provide reassurance for women still experiencing side-effects and other concerns.

Views on changes to current provision

31 There was generally strong support amongst staff and clients for widening the scope of an approved class of place.

32 Some staff respondents stressed that the quality and training of the staff involved were more important factors than the physical location, subject to certain basic requirements being met.

33 Views on going home straight after the second treatment appeared to be strongly affected by where the women had their own procedure. Of the pilot site clients, 60 percent would choose (if offered the choice) to stay at the clinic, compared with 22 and seven percent of the women at the comparator sites.

Conclusions

34 Subject to the fairly considerable limitations of the current study, and from a range of sources, including medical records, and staff and client views, there are no discernible differences between the pilot sites and their matched comparator sites in terms of the safety, effectiveness or acceptability of non-traditional sites for the administration of early medical abortions. These findings confirm the experience from other countries with longer experience of early medical abortions in non-hospital settings.

35 Detailed protocols and guidelines should be developed to cover staffing requirements as well as clinical aspects of care.

36 Given the importance of reassurance and support throughout the process, the centrality of suitably motivated and skilled nursing staff to any expansion of EMA provision cannot be overestimated.

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1 Background and introduction to study

1.1 Introduction

This short but intense project was commissioned by the Department of Health (DH) to assess the safety, effectiveness and acceptability of early medical abortions in non-traditional settings, and to help establish a protocol to cover the elements and processes required for a safe early medical abortion service in non-traditional settings.

The two pilot sites are at Chalfont and Gerrards Cross (Buckinghamshire) and St Mary's Hospital (Paddington, London). The comparator sites were agreed in consultation with the DH. Additionally a fifth site was included in the assessment to provide an alternative model of provision in the independent sector. The two pilot sites are both in close proximity to hospitals, and so there are no direct data on the provision of EMA in general practice or community-based family planning or contraception clinics.

1.2 Brief literature review

Early medical abortion (EMA) is the termination of a pregnancy up to 63 days gestation using a combination of drugs that are administered orally and/or vaginally. Mifepristone is the most widely used drug for EMA; this blocks the receptors of the pregnancy hormone, progesterone, and causes the pregnancy to be unviable (it has no action on the other pregnancy hormone hCG). Most commonly, mifepristone is used in combination with misoprostol, which causes the uterus to contract and expel the uterine contents. While there is some variation in the dosage used and method of administration of these drugs worldwide it is widely recognised, as a result of a large and growing evidence base, that EMA is highly effective, safe, acceptable to women, and advantageous for those providing an abortion service.

Mifepristone was developed in the early 1980s by Roussel-Uclaf, the French pharmaceutical firm. First licensed for use in France in 1988, and next licensed for use in Britain in 1991, EMA originally met with controversy (in the USA in particular) but is now widely accepted. Its use has been approved in many countries, including the USA (from 2000), Austria, Belgium, China, Denmark, Finland, Germany, Greece, Israel, Luxembourg, the Netherlands, Russia, South Africa, Spain, Sweden, Switzerland, Tunisia, and Ukraine, and is also included in the 'list of essential medicines' of the WHO.

1.2.1 Safety and effectiveness of EMA

Many studies have been conducted worldwide to consider the safety of EMA, including comparisons with early surgical abortion, using a range of outcomes measures such as death rates, infection rates, complications requiring hospital treatment, heavy bleeding, and risk

of miscarriage, ectopic pregnancy, preterm birth or low birth rate in subsequent pregnancies (Von Hertzen *et al.,* 2003, Hausknecht, 2003; Honkanen *et al.,* 2004; Shannon *et al.,* 2004; Gary and Harrison, 2006; Virk *et al.,* 2007). These show that EMA has been used safely and effectively by very large numbers of women (Winikoff *et al.,* 1997; Shaff *et al.,* 1999; 2000; 2001; Jones and Henshaw, 2002; Harvey et al., 2002; Henderson et al., 2005). On balance, EMA is strongly supported by the relevant medical organisations worldwide as the abortion method of choice to end an early pregnancy because any surgical intervention is avoided; the risks of complications associated with surgical intervention and anaesthetic are removed (RCOG, 2004; Hamoda and Flett, 2005; WHO, 2006)). EMA can also be used at an earlier point than can surgical methods and, the earlier the procedure is carried out, the lower is the risk of complications (Ferris *et al.,* 1996).

As use of EMA has increased so too has the variety of regimens, and various studies have explored the relative efficacy of differing regimes building on the established safety and efficacy of the standard regime (Von Hertzen *et al.,* 2003; Creinin *et al.,* 2004; Liao *et al.,* 2004; Schreiber *et al.,* 2005; Ashima *et al.,* 2005; Shannon *et al.,* 2006; Kapp *et al.,* 2006; Gallo *et al.,* 2006; Heikinheimo *et al.,* 2007). Relevant professionals have worked together to pool experience and knowledge about the safety and efficacy of varying regimes and thereby improve practice (Von Hertzen and Baird, 2006).

1.2.2 Acceptability to women and providers of EMA

Emphasis has been placed on features that influence the acceptability of the method for women (Fielding *et al.,* 2002; Berer, 2005). One key issue has been how to best address the experience of EMA for women undergoing the procedure, since it is very different to that associated with early surgical abortion. Specific attention has been paid to pain relief, autonomy of the women and provision of information in advance about what to expect from EMA in order to increase the chances that women's experiences are as positive as possible. The provision of EMA in a way that maximises acceptability to women requires training of the staff involved, and the adoption of approaches and measures that recognise the specific challenges of this particular abortion method (Harvey et al., 2002). Such approaches include, in particular, management of pain and discomfort (cramping, vomiting and diarrhoea are common side effects) and the possibility of seeing the foetus (Henshaw *et al.,* 1993). The longer term emotional effects of EMA and surgical abortion have been assessed and both methods have been assessed positively (Westhoff, 2003).

In relation to acceptability of this method to providers, a number of advantages have been identified. Other than the costs of training to ensure a safe, effective and acceptable service, widespread use of EMA has the potential to increase cost-effectiveness because it minimises the need for hospital staff and associated resources, including those associated with theatre time and clinical specialists including anaesthetists. For these reasons, as well as those which make this method acceptable to women, its provision is strongly supported by abortion providers (Berer, 2005).

1.2.3 Home use

Most protocols adopted worldwide advocate two (and sometimes three) visits to a clinic after the initial assessment. The first two are for the administration of mifepristone and misoprostol respectively, and the third, some days later, to assess the 'success' of the method and deal with any subsequent complications. There has been some attention paid to reducing the required number of clinic visits in order to make the process more patient-centred without sacrificing standards of care. Some years ago, Winikoff (1995) raised the possibility of mifepristone being taken at home prior to a clinic visit, on the grounds that this is a lower risk drug that the prostaglandin (misoprostol); this approach does not seem to have been adopted, however.

A more relevent recent development in the provision of EMA concerns home use of misoprostol. Studies of women who have taken misoprostol at home – in countries that include Vietnam, Sweden, France and the USA – have indicated that clinical supervision can be reduced further without reducing either safety or acceptability to women, and possibly even increasing the latter (Schaff *et al.,* 1997, 2000; Newhall and Winikoff, 2000; Fiala *et al.,* 2004; Ngoc *et al.,* 2004; Clark *et al.,* 2005; Shannon *et al.,* 2005; Clark *et al.,* 2007). Significantly, this approach has been adopted by the Planned Parenthood Federation of America, which provides family planning and abortion services throughout the USA (Hausknecht, 2003; Henderson et al., 2005). However, one large multi-centre study found that women rate home use less positively than clinic administration (Honaken et al., 2004).

In Britain, within NHS hospitals it is usual for women to remain at the hospital following the administration of misoprostol for a three to six hours or until the expulsion of the pregnancy is complete, whichever is sooner. Home use is currently prohibited in Britain by the Abortion Act 1967 (as amended by the Human Fertilisation and Embryology Act 1990) which states that, except in emergency situations, any treatment for the termination of pregnancy must be carried out in a NHS hospital or place specially approved by the Secretary of State. Consequently, independent sector specialist abortion clinics have adopted a protocol that administers misoprostol on licensed premises but then allows women to be discharged to complete their abortion off-site. This protocol was developed in the independent sector and is widely used, including in the third comparator site.

1.2.4 British experience and research

Although Britain was the second country in the world to licence EMA, its use has developed relatively slowly compared to other countries. It is only in quite recent years that provision of EMA has increased. Other countries (for example, Sweden, Switzerland and France) have similar rates of more than 50 percent of all first trimester abortions performed medically. In 2006, roughly 48000 early medical abortions were carried out on UK residents out of a total of around 131000 under ten weeks' gestation. Early medical abortion now accounts for about 37 per cent of procedures in England and Wales before ten weeks, and 25 per cent of the total of all gestation procedures. This is double the percentage of all terminations in 2002, and much larger than the figure for 1997 when only 6.6 per cent of all terminations were by the medical method. Some providers, in the independent sector especially have rapidly increased their use of EMA, and have thus further validated its widespread use in non-hospital

settings. Figures from 2006 show that, of the medical abortions at under ten weeks' gestation, 53 percent occurred in NHS premises, 32 percent in non-NHS settings under NHS agency agreements, with the remaining 15 percent being privately purchased.

The use of EMA in Britain has been the subject of some limited research that has covered the areas mentioned above. The safety and effectiveness of the method have been assessed and confirmed through studies comparing it with early surgical procedures (Child *et al.,* 2001) and through consideration of varying regimens for EMA – in particular, misoprostol dosage (Ashok *et al.,* 2002). Since 'the efficacy of the early medical abortion regimen utilising mifepristone and misoprostol is beyond doubt' (Sharma *et al.,* 2006: 261) recent studies have focussed on the length of time between administration of mifepristone and misoprostol, as well as differences in efficacy according to whether drugs are administered orally or vaginally (Hamoda *et al.,* 2003; Guest *et al.,* 2006; Sharma *et al.,* 2006). Women's need for pain relief has also been thoroughly considered (Penney, 2006). The acceptability of EMA to British women has been confirmed (Abdel-Aziz *et al.,* 2004) and studies have also focussed on comparing different approaches. Self-administration of misoprostol has been validated as safe, effective and acceptable (Kiran *et al.,* 2004, 2006), and as having the advantages of 'demedicalising' provision and decreasing staff workload (Kiran *et al.,* 2004). The importance of preparing women undergoing EMA properly in advance in relation to pain, and the possibility of seeing the foetus has been emphasised (Slade *et al.,* 2001).

Given the legal and administrative context for abortion provision in Britain, home use of EMA has been the subject of less study than it has been elsewhere. It has not been possible to assess women's actual experience of home use, meaning that studies have had to research this issue by asking women undergoing EMA in a clinic if – hypothetically – they would find home use acceptable. Kiran et al., found that while self administration of misprostol would be acceptable to two out of three of the 89 women in the study, only one third were 'willing to try it at home' (2006: 679). However, one needs to bear in mind that this was a purely hypothetical question; women had no possibility of basing their responses on actual facts or experiences. A larger study of women attending four units in England and Scotland found that 76 per cent said 'there was nothing that happened during the abortion they would have been unable to cope with at home'. Thirty six per cent indicated a preference for 'home abortion' and 64 per cent a preference for staying in the hospital. The conclusion was drawn that 'most women would welcome being offered the choice of having medical abortion at home or in hospital' (Hamoda et al., 2005: 781). These results need to be interpreted in the light of experiences from other countries (for example, USA, Sweden, Austria) where home use of misoprostol is a free option, and more than 90 percent of women opt for it (Fiala, personal communication 2008).

As noted above, international practice includes well-established systems of EMA provision by practitioners in specialities other than obstetrics and gynaecology, including family doctors, nurse practitioners, and midwives and, thus, provision in a wide range of community based locations. In the British context, while use of EMA in Britain has increased, at present there is relatively limited provision of EMA in non-hospital places (this is currently almost entirely restricted to independent sector provision because of legal and administrative restrictions). The absence of community provision of EMA is the source of some frustration, and contributes to possible delays in access, since facilities in some parts of the country find

difficulty in coping with the demands at present placed on them (Gupta and Kapepwe, 2007). Further, the woman's option to choose a suitable and appropriate method and location is compromised. Given the international evidence attesting to safety, acceptability, efficacy, and cost-effectiveness, there are clearly grounds for Britain to consider whether to modernise the way that EMA is provided in the community. This study seeks to help achieve this goal, by focussing on work performed in two pilot sites sponsored by the Department of Health for EMA provision in the community.

2 Site summaries

This section contains brief outlines of the five sites used in the study. Fuller descriptions, based on observations and interviews with staff at each site, are provided in Appendices 1 to 5.

2.1 The pilot and comparison sites

Pilot site 1 – Chalfont and Gerrards Cross (see also Appendix 1)

The service was operated in the Family Planning Clinic (FPC) located at Chalfont and Gerrards Cross Community Hospital, and had a dedicated telephone number for referral purposes which was staffed by one of the FPC nurses. Initial appointments took place on a Friday, and involved the women seeing a doctor and a nurse who explained the EMA procedure to them. If the woman[1] chose to proceed with the EMA she had an ultrasound scan to confirm she was fewer than nine weeks' pregnant and routine blood samples were taken. If all was well, she was then given another appointment for the following Wednesday at which she was given the first dose of treatment (mifepristone). The woman was given an appointment to return two days later (Friday) during which time the clinic area was reserved purely for women undergoing EMAs. The women were advised that at this appointment she would need to spend several hours in the clinic. Once the woman had passed the products of conception and her bleeding was satisfactory she was permitted to leave.

The clinic had the capacity to undertake four EMAs per Friday/week. Follow up took place two weeks later, again in the clinic. Women who failed to attend their follow up were reminded by telephone and, if they still failed to attend, their GP was informed (permission to contact their GP had been sought during the initial visit).

In recent months, the clinic has been under staffed (due to recruitment difficulties linked to funding uncertainties and PCT mergers) which resulted in patients requesting EMA being turned away. The clinic ceased operation in October 2007 and is awaiting review and further commissioning.

Comparison site 1 – (see also Appendix 2)

Patients are referred to this service by their GP or a Family Planning Clinic (FPC). At the Hospital they are seen by a doctor in the Out Patient Department; these appointments are only currently available on Tuesdays and Wednesdays. Usually at that visit they will also have a dating ultrasound scan. They will then be seen on the gynaecology ward in the same hospital

[1] The terms 'woman', 'women', 'patient' and 'client' are used interchangeably throughout the report. Some prefer to avoid using the term 'patient' since it medicalises the procedure, while others prefer to use it since it is, after all, a medical procedure!

by a member of nursing staff who will discuss EMA with them in some depth. If the patient decides to proceed with her termination she and the nurse will arrange a mutually convenient date for the woman to return to begin or continue the process. She may be given the first dose of treatment (mifepristone) at that visit; she may have it later in the week. Either way the women then return 48 hours later. From a practical perspective the nursing staff prefer to situate the EMAs in the latter part of the week, as they then have better capacity for service provision since most of the routine surgical patients will have been discharged. They find this may also help women as a Saturday is often a preferable day upon which to arrange child care for other members of their family, and Sundays can be used as well if this is easier for the clients.

Women are advised to expect to stay on the ward for approximately six hours on the day of the second treatment, and are advised as to what to expect. They can bring a friend, read, watch TV, etc. Once they have passed the products of conception they are asked to remain on the ward for at least an hour to ensure the bleeding is settling down at which point they can leave.

Follow up appointments are usually undertaken by the GP (to be arranged by the women) unless there are any complications. Current capacity is four women per week; in the event of the clinic being booked to capacity for EMAs, women are referred to independent sector clinics.

Pilot site 2 – St Mary's (see also Appendix 3)

This pilot site is organised around two main locations. One is at Ladbroke Grove, called the Raymede Clinic. This is an integrated service offering contraceptive provision, sexual health services, abortion consultations and follow up. It has been used this way since around 2000. The clinic is in a residential area. On the same street there is a school as well as housing, and a small hospital (St Charles').

Women are referred here by GPs and FP clinics in Westminster (this covers a large geographical area). They are booked in for appointments by clerical staff. When they attend for their appointment they are seen by a doctor who discusses what they want to do, methods available (the gestation is confirmed by scan) and in detail what each involves. They also can see a counsellor if they wish; they are actively encouraged to if they seem at all uncertain as to what they want to do. Where the woman opts for EMA she is booked in for treatment.

Both drugs are administered at a dedicated unit, the Paintin Unit, about ten minutes' walk from the main building of St Mary's Hospital at Paddington. This unit is used Mondays to Fridays and only for EMA. It is light and airy, and comprises a large room with settees and a TV, for three or four women at a time, with three toilets off to one side. There is a small kitchen for women to use and an office for the nurse who runs the Unit. Women can bring a friend or relative, but space is limited. Both drugs are administered by the nurse and she looks after the women over the time when they are there following administration of misoprostol. Since the unit works through the week, women may attend for mifepristone on the same day as their consultation at Raymede but – should this not be possible – then they will be booked in for the earliest appointments possible. Follow-up takes place at Raymede.

Comparison site 2 – (see also Appendix 4)

Since 2004, all abortion consultations, follow up appointments, and mifepristone administration for EMA have taken place at a modern general health centre located in a residential area about two miles away from the General Hospital. It houses family planning and sexual health services and the abortion service operates as part of this. All consultations for abortion happen here, for all methods and gestations.

Women who live in the area are referred primarily by GPs, FP centres, and a local walk in centre. They call a booking line and get through to the administrator of the service who books their appointment. This person, having established a relationship with the woman, is then a key contact throughout. She is based in an office at the main hospital site, but makes frequent visits to the health centre to check things are running smoothly, greet women as they arrive and take them for their appointment, etc.

Women next attend for a consultation and are seen by a nurse/healthcare assistant, a doctor and often by a counsellor and also the genitourinary (GU) clinic and/or FP doctors (all as part of the same appointment). The abortion decision and issues surrounding methods are discussed with women by the nurse/healthcare assistant and counsellor. The doctor also then covers these areas again, but in the light of confirmed gestation assessed by a scan. The woman then makes her decision about the method of abortion. Where she opts for EMA she is booked in for administration of mifepristone at a Thursday clinic. At the appointment, the nurse/healthcare assistant again discusses the method and its effects and explains there is 'no going back' once the pill has been swallowed.

Misoprostol is administered at a Saturday-only clinic at a day-care centre on the main hospital site (but on a different part of the site to obstetrics and gynaecology) which is used for other procedures through the week, but only by the abortion service on a Saturday. Women arrive at 7 am and leave by 1pm. Most (although not all) will have bled heavily/aborted during the period. All women are again reminded of the help line number and the importance of attending for follow up is emphasised. This is especially strongly emphasised for those who have not bled heavily by the time they leave.

Follow-up appointments are at the original health centre, and women are normally scanned. Both the centres are part of the Hospital Trust.

Comparison site 3 – independent sector clinic (bpas London Central) (see also Appendix 5)

There is just one site involved in this service on Bedford Square in Central London. Women are referred from a variety of sources. They can self-refer as well as being referred by GPs and FP clinics, with NHS funded procedures provided where there is a contract arrangement with a Primary Care Trust (PCT). Many PCTs have arrangements that lead to procedures at this clinic.

There is a central booking service at bpas – Action Line – and appointments are made this way. The women are first seen by an admin counsellor. They discuss the abortion decision, take basic details, and outline the alternative methods and what they entail. Women then see a doctor who dates the pregnancy with a scan and again discusses methods. The woman makes her decision.

For administration of mifepristone and misoprostol the woman will see a specialist nurse (albeit prescribed by a doctor). The mifepristone appointment will be made for a time as soon as possible, which can be the same day. The nurse again discusses the method and issues surrounding it in detail. The client comes back the next day for the misoprostol (the clinic are moving to a system where the second appointment could be on the same day, if the mifepristone was given in the morning). She is given this drug and then sent home immediately, so this appointment is very brief indeed – maybe 15 minutes in all. It is intended that the woman is able to complete her abortion in a non-clinic environment at a place of her choosing; this may be her home, but may be the home of a friend, partner or relative. The approach used at this site is thus completely different from that used at the other four sites in this study.

Throughout, the need for follow up and details of the 24 hour helpline are strongly emphasised. Women are called by the centre between 24 and 48 hours after the second treatment to see how they are (although some women express a preference not to be called). All women are encouraged to attend a follow-up three weeks after the procedure. Where women do attend for follow up they are seen by a doctor. Scanning is routine, and an assessment is made on a case by case basis.

2.2 Comment on comparability of sites

It is clear from these brief descriptions of the sites that the distinctions between the pilot sites and the comparison sites is not as clear cut as it might be. For example, the initial drug administration at comparison site 2 actually takes place on a site that is physically separate from the hospital itself (the general health centre which is part of the NHS Trust). The pilot site at St Mary's Hospital is physically close to the main hospital. Indeed, the patient leaflet for the St Mary's procedure actually makes reference to the EMA taking place at 'the Paintin Unit at St Mary's Hospital', so it is unlikely that the women realise that this is in fact a non-traditional site.

Similarly, at comparison site 1, although this is a fully fledged district hospital with obstetric and gynaecological departments, procedures often take place on a Saturday when the ward is less busy and more relaxed than it is during the week. In many respects, the independent sector clinic is the most 'non-traditional' of all the sites, so its inclusion as a further comparator site is highly relevant despite the protocol being quite different in many respects than in the other sites.

One of the reasons for the lack of differentiation between the NHS sites is that staff at the comparison sites recognised – when they were developing the services – the advantages of encouraging a relaxed atmosphere; there was contact between providers in some of the different sites so each learned from each other. This blurring of the distinction needs to be borne in mind in reading this report.

Indeed, our understanding is that what has been found in relation to the 'control' sites in this study is not at all atypical of provision elsewhere for EMA procedures. In other words, the large expansion of this service (which has to a large extent been catered for by independent sector providers who are, by definition, not 'traditional' sites) has been accompanied by an increase in the use of nursing staff for much of the work, as well as the use of a wider range of facilities.

In terms of the project as commissioned, this means that the initial expectation – to make direct comparisons between the 'non-traditional' pilot sites and more 'traditional' forms of provision – was not possible. Nevertheless, comparisons have been made as originally planned, but these have not provided the 'clean' data that were hoped for. As well as the blurring between 'traditional' and 'non-traditional' sites, there are also differences in clinical regimes between the sites (for example, different protocols for analgesics, administration of a second dose of misoprostol, how long women stay in the clinic after the second drug, etc.). We believe, however that there is still much to be learned from the work, and that the main contribution has been in collecting valuable information regarding what factors contribute to good practice.

Indeed, since commencing work on this project, the researchers have learned from other providers in the country that provision does indeed vary considerably from site to site. Some areas have a primarily nurse-led service in traditional hospital settings where as others have a consultant-led service. Some services keep women in after the administration of misoprostol for six hours or more, whilst others send them home more or less immediately, or offer a genuine choice.

What this blurring means, apart from the inability to take 'clean' comparisons between 'traditional' and 'non-traditional' sites, is that it will be difficult to make clear statements about the acceptability to clients of extending services to a wider range of community settings. Since both of the 'non-traditional' sites were in close proximity to hospitals, we cannot reach any clear conclusions regarding the likely reaction to, say, general practice settings or community-based contraceptive or family planning clinics that are not near to hospitals. We asked women in questionnaires and interviews about how they think they would feel about having the procedure in such settings, but this is not the same as asking about their actual experiences and reactions during the procedure itself. This issue is further discussed later in this report.

OVERVIEW OF PRACTICES AND SERVICES AVAILABLE AT FIVE SITES

Detail	Chalfont and GC	C1	St Mary's	C2	C3
Assessment	fpc clinic in Chalfont and Gerrards Cross community hospital	Gynaecology clinic	Raymede fpc at St Charles Hospital	General health clinic (two miles from hospital)	Various sites
Dating scan	fpc clinic	Maternity clinic	Raymede fpc	General health clinic	Various sites
First treatment	fpc clinic on Wednesdays Mifepristone 200 mg	Gynaecology ward on Fridays Mifepristone 200mg	Paintin Unit near St Mary's (ten minutes' walk) on five days a week Mifepristone 200 mg	General health clinic on Thursdays Mifepristone 200 mg	Central clinic Mifepristone 200 mg
Second treatment	fpc clinic on Fridays PV Misoprostol 800 mcg repeated if no bleed after 4 hours	Gynaecology ward in three single en suite rooms on Saturdays and Sundays Misoprostol 800 mcg	Paintin Unit Misoprostol 800 mcg, repeated after 3 hours	Clinic (day care centre) dedicated for EMAs on Saturdays Misoprostol 800 mcg, repeated after 3 hours	Central clinic, five days a week Misoprostol 800 mcg
Pain relief	Co-codamol, 500/30, 8 tabs maximum dose in 24 hours, or Diclofenac (dose depends on pain level)	Diclofenac pr 100mg Diclofenac (50 mg three times daily), and/or Paracetomol (1000mg, 4-6 hourly, and/or Co-codamol, 1-2 tabs 4-hourly	Paracetomol, followed by codeine if required	Codeine 60mg (one dose), followed by Diclonfenac 50 mg if required	Offered 400mg Ibuprofen before leaving clinic; Women advised to take Paracetomol or Ibuprofen after leaving clinic (not provided)
Evidence of expulsion before discharge?	Yes, normally	Yes, normally	Yes, normally	Yes, normally	No
Follow up	Yes, estimated at 90%; if DNA, GP informed	If no evidence of products of conception - otherwise GP visit encouraged	'Most' attend	Encouraged to call on Monday, and attend after two weeks (but 'few' do so)	48 hour telephone call, three week return visit encouraged. All women given pregnancy test kit for use after three weeks

Detail	Chalfont and GC	C1	St Mary's	C2	C3
Emergency contact after follow up	Dedicated number for office hours, and out of hours service number	Gynae ward number provided	Clinic number provided	Accident and Emergency if over weekend, or Emergency Gynaecological Assistance Services	Telephone helpline
EMA capacity per week	4	4	10	20	60
Number of toilets	2, though not reserved for EMA clients	4	3	3	Not relevant
Physical facilities after second treatment	Private and communal rooms, TV, no shower or washing facilities	Purpose built Gynaecology ward on main hospital site	Large light and airy room with three settees, TV, kitchen	Beds	Not relevant
Chlamydia screen	Offered, 50% take up	Offered	Offered if under 24 years old	Offered	Offered for free if part of PCT contract, available for a fee if not
Pre-counselling	If required via independent sector	Routine by nurse at first treatment and specialist on hospital site if required	Available on request	Available on site, and encouraged	Normal as part of assessment process
Post-counselling	If required via independent sector	Not routine but available if required	Available on request	Appointment made for some, others know it is available if required	Offered but 'low take up'
Routine antibiotics given	Yes PR Metronidazole 1g Doxycycline 200 mg before leaving clinic take home 100mg BD for six days	Yes Doxcycline 100mg twice daily for 7 days, first dose pre-op	Yes Metronidazole and Azithromycin	Yes Doxycycline 100 mg pre-treatment, then 100 mg twice daily for 7 days Flagyl, 400 mg bd for 7 days	Yes Doxycycline TTO (14 tablets, 100 mg, twice daily)
Contraceptive advice provided	Yes	Briefly	Yes	Yes	Yes

3 Data collection procedures and samples obtained

A number of methods were used in this research. Summaries of each of these, together with details of the samples obtained, are provided below. All aspects of the research received ethical and governance approval from the University of Southampton Ethics Committee and Research Governance Office, as well as the clinical leads where appropriate.

3.1 Staff interviews

A total of 31 face-to-face interviews were carried out with key staff involved with each of the sites (between four and eight at each site). These were all tape recorded, semi-transcribed and analysed to extract the relevant information. All staff approached agreed to be interviewed.

Topics covered are shown in Appendix 6, although the relative emphases of topics covered in each interview reflected the staff member's specific role. In some cases, the time available did not permit complete coverage of all the areas listed on the interview schedule.

3.2 Protocol analysis

Detailed protocols were collected from each site as well as, in some cases, other paperwork and records that trace the development of the facilities. Relevant information is used at appropriate points throughout the report and were used to help inform Section 7 of this report.

3.3 Case note analysis

The systems for storing case notes varies considerably between the sites. Different data are routinely recorded, as well as different formats (electronic or paper) being used for the records. Due to issues of confidentiality, staff in some of the clinics preferred to extract the relevant data themselves; in other case, staff from the CSHR were given access to files and extracted the data required. In brief:

Comparator site 1 Hospital used a member of staff to go through records and complete an Excel spreadsheet provided by the CSHR. Sixty four cases drawn from women attending in 2006 and 2007 were entered into the data base.

Chalfont and Gerrards Cross carried out a similar exercise, starting with the opening of the clinic and managed to extract 169 records in the time available (this being carried out over and above the staff's normal duties), and covered a period from 2004 to early 2007.

St Mary's data are stored electronically but the routinely maintained data base does not record much of the information required for this study. A selection of paper records were extracted and the additional data were entered into a file provided by CSHR by the clinical consultant with help from local staff. Two hundred and six usable cases were extracted, covering the period between March and September 2007.

Comparator site 2 Hospital stores the paper case notes in alongside all the other hospital out-patient notes, so to identify and trace the EMA cases for analyses would have been an 'impossible task' in the time available for the study. Accordingly, all records since the start of the project were kept to one side and a member of CSHR staff went through these manually to extract relevant information. This led to 172 records being available for analysis, covering the period between July and October 2007.

Comparator site 3 has an electronic system and many variables (mainly demographic) were obtained readily. However, some of the more detailed information necessitated CSHR staff visiting the clinic and extracting these data by hand from a selected number of cases. These covered procedures carried out in August and September 2007 and 251 cases were extracted.

The level and nature of the data recorded in case notes varies quite considerably between sites, so direct comparison on all variables of interest is not possible. Appendix 7 shows the variables that were extracted from the case notes in the light of what were, in principle, available from the records; however, not all records were completed for each variable. Further, much of the material entered into the case notes will reflect elements of subjectivity, either on the part of the nursing staff or by the clients. For example, the phrases 'heavy bleeding' and 'extreme pain' could be entered into a case note by a member of staff based on direct observation of behaviour or could be entered as a result of a woman's report of such ailments; this latter situation is, of course, inevitable in follow up reports in which the women report on events between discharge after the second treatment and two or three weeks later. Since tolerance to pain is variable, then such case note entries cannot be directly compared or regarded as equivalent across women or sites; no standard definition of levels of bleeding or pain are used.

Strictly speaking, if detailed clinical information is required to enable comparisons across sites, then a prospective study is called for. Such a study would need to ensure that all sites collected data on matched variables, and these would need to be standardised with agreed definitions and criteria.

A further reservation regarding the case note analysis relates to information on subsequent events following the procedure. Since not all women returned for follow up (indeed, one site encouraged visits to GPs rather than the clinic at which the procedure took place) then there is no certain means by which later problems can be identified. For example, a woman who experienced severe problems may have returned to hospital as an emergency case a few days after the procedure (either via her GP or direct as an emergency admission) and it is by no means certain that such an event would have found its way back into the clinic's case notes (even though in theory they should do). Further, data collected from sites where women stayed until expulsion had been confirmed relate to different time-scales from those obtained

from comparator site 3, or from women at other sites who went home prior to expulsion. This is a serious issue in relation to drawing firm conclusions regarding safety of the procedures and sites explored in this study.

All data from the Excel files were transferred to SPSS files for analysis. Since the data collected in the different sites' case notes varied, separate SPSS files for each site were developed as opposed to their being combined into one file for analysis.

The basic demographic and other data from the case note analyses are shown in Table 3.1 below.

Table 3.1: Details of samples of case note samples analysed from each site

Description	Ch	C1	St M	C2	C3
numbers of case notes analysed	169	64	206	172	251
mean age (in years)	28.1	26.6	27.2	26.1	28.1
percentage who were British	86	98	36*	35*	n/av
percentage who were white	88	n/av	29	n/av	62
mean deprivation score of postcodes**	8.2	15.3	38.4	41.2	30.7
percentage who had previous live birth(s)	42	46	37	46	33
percentage for whom this was first abortion	70	71	59	67	68
gestation times					
mean gestation in days at time of abortion	*46.6*	*48.5*	*51.0*	*55.4*	*46.3*
percentage to 35 days	*10*	*11*	*0*	*0*	*16*
percentage 36 to 42 days	*21*	*16*	*7*	*10*	*28*
percentage 43 to 49 days	*35*	*25*	*35*	*15*	*36*
percentage 50 to 56 days	*27*	*30*	*33*	*50*	*20*
percentage 57 days or over	*8*	*19*	*26*	*26*	*1*

Key: CH = Chalfont and Gerrards Cross Hospital (pilot site); C1 = comparator site 1;
St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3
* nationality was not recorded – figure is for women born in GB
** deprivation measured by Index of Multiple Deprivation using the reported postcode
n/av = not available

3.4 Client questionnaires

A questionnaire was distributed to all clinics to hand to clients for completion ten days after the second drug administration and returned direct to CSHR in the FREEPOST envelope provided. In cases where women returned for follow-up, the questionnaire could be completed then. However, for those women who did not return for follow-up, we were reliant on their remembering, and being motivated, to complete this task.

The questionnaire was quite long (taking around 20 minutes to complete on average), but then we were charged with obtaining their views on many aspects of the whole procedure. A

copy of the questionnaire is included as Appendix 8. Prior to its final adoption, it was piloted with 12 women at sites, as well as being sent to the project Advisory Group and staff at the Department of Health for their comments.

The return rates were disappointing, despite efforts made by clinic staff to encourage completion and reminders when contact was made in lieu of return follow-up visits. The total received was 139, but these were unevenly distributed across sites. Particular problems were identified at Comparator 2 (and, to a lesser extent, at St Mary's), where many clients do not speak English as their first language, and where the staff feel that many women do to wish to engage in the process any more than necessary. Returns from Comparator 1 and Chalfont were also particularly poor. It is difficult to calculate precise response rates since we are not sure how many were actually handed out at the clinics; the numbers sent (and returned in parentheses) were Chalfont 80 (4). Comparator 1, 70 (2), St Mary's 110 (43), Comparator 2, 110 (21) and Comparator 3, 220 (69).

Consideration was given (during the project when it became apparent that returns were lower than anticipated) to developing a shorter form of the questionnaire. However, during the pilot phase of questionnaire development, it seemed clear that women would either complete one or they would not, and length was not considered to be the major determining issue. Further, and as mentioned above, a wide range of issues were required to be covered.

Further consideration was then given to splitting the questionnaire such that women completed the section relevant to the different stages immediately after each stage; these could then be matched later according to a coding system. This option was ruled out, however, since it is clear (from staff, from previous research and from the women themselves) that many women are not in an ideal state to complete a questionnaire during, or immediately after, the different procedures. In any event, it was intended to obtain views upon reflection, rather than during the process itself.

It must be stated that staff at the clinics seemingly did all that they could to encourage clients to complete the questionnaires. The relatively low response rate in no way reflects a lack of cooperation on behalf of the clinic staff; indeed some expressed disappointment and apologies at their low level of 'success' in this regard.

Data from the questionnaires were entered into SPSS (version 15), cleaned and fully analysed. Results are reported at relevant places in this report.

Checks were carried out, as far as possible, to ascertain whether the total patient population differed from those completing the questionnaires in terms of demographic background by comparing selected variables against those derived from the case note data. Mean ages were very similar, whereas there were slight indications that those who completed the questionnaires were more likely to be white and to have lower scores on the deprivation index (these two variables are, however, not independent). This probably reflects the English language difficulties mentioned earlier. However, there is a risk that those completing the questionnaire were more disappointed or gratified with their experiences than those who did not complete the questionnaire; it is not easy to resolve this dilemma.

The demographic and other summary details of the respondents are shown in Table 3.2 below.

Table 3.2: Details of samples of questionnaire respondents from each site

Description	Ch	C1	St M	C2	C3
numbers of questionnaires received	4	2	43	21	69
mean age of respondents (in years)	26.8	31.0	25.6	28.1	28.9
percentage of respondents who were white	100	100	45	11	73
percentage who had previous live birth	50	75	26	53	27
percentage for whom this was first abortion	50	50	56	30	66
mean deprivation score of postcodes	8.5	7.0	37.5	38.9	28.4
mean gestation in days at time of abortion	47.8	54.0	46.0	50.9	47.8

Key as table 3.1

The majority of women who completed questionnaires from Comparator 2 were black African (42 percent) and Bangladeshi (16 percent). Non-whites from St Mary's were black African (14 percent) and Asian other (12 percent). About half of all women who reported a previous abortion reported having had a previous early medical abortion.

In view of the low numbers of returns from Chalfont and Gerrards Cross and Comparator 1, these questionnaire data are not discussed further in this report.

3.5 Client interviews

At the end of each questionnaire, women were invited to be interviewed on their experiences. A tear off sheet was attached which could be returned with contact details in a separate FREEPOST envelope. This system was adopted to protect confidentiality in the event of the main questionnaire being intercepted in the post; by using separate envelopes, personal details could not be linked to the questionnaire itself. A coding system enabled the tear off sheets to be matched to the questionnaire once both had been received.

Twenty five women volunteered to be interviewed regarding their experiences; again the distribution across sites was not even. Each of these was contacted by their preferred route; 13 agreed to be interviewed whilst the others either did not respond or reported that had changed their minds about being interviewed. The final numbers were as follows:

Site	Initial agreement	Final numbers
Chalfont & GC	1	1
Comparator 1	0	0
St Mary's	8	5
Comparator 2	2	0
Comparator 3	14	8

Checks were carried out to ascertain the extent to which those interviewed were similar to the general type of clients using the sites. Volunteers and non-volunteers were very similar in terms of mean age (26.8 and 27.8 respectively), index of multiple deprivation score (31.9 and 31.8), whether they were white (60 and 56 percent), whether they had had a previous abortion (36 and 45 percent respectively), whether they had previously given birth (29 and 33 percent), and whether they would recommend medical abortion to a friend (82 and 83 percent respectively) or would choose the same again for themselves (78 and 75 percent). In other words, there are no indications that those who volunteered to be interviewed differed in terms of demographic background, previous experiences of abortions and/or live births or in relation to their overall assessment of the procedures. Again, however, the possibility of self-selection bias exists.

Topics covered in the interviews basically followed the main issues identified in the questionnaire responses, with especial focus on the women's perceptions of how they felt about (a) having the procedure where they did (linked to a hospital or not), (b) how they felt about staying until it was over or going home straight after they had taken the misoprostol, (c) whether they felt they had been given enough advance warning of what it was going to be like, (d) whether the pain relief was sufficient and provided, (e) whether they were clear what to do had anything gone wrong after they had completed the procedure and returned home, (f) how accessible the service was, (g) how they would feel if more clinics were available in more community settings (that is, family planning clinics, GP surgeries, community health centres, etc.) where there may not be acute services readily available should anything go wrong, (h) looking back, were they pleased to have chosen an EMA or would they have preferred a surgical procedure involving an anaesthetic? In all cases, responses were followed up by asking for their reason for their particular responses.

Interviews were tape-recorded, semi-transcribed and analysed, and data are provided at relevant places in this report.

3.6 Site observations

All sites were visited and observations made regarding the general ambience and facilities.

3.7 Summary of data collected

The final sample sizes obtained for the various components of the data collection were as follows:

	Chalfont	C1	St Mary's	C2	C3	total
case notes	169	64	206	172	251	862
client questionnaires	4	2	43	21	69	139
client interviews	1	0	5	0	8	14
staff interviews	6	7	4	8	6	31

4 Key results

The key results derived from the various data sources are presented in this section under three headings: safety, effectiveness and acceptability. However, it must be stated at the outset that comparisons on these measures may reflect the different regimes as much as they may reflect any differences between 'traditional and 'non-traditional' sites.

4.1 Safety

The key objective under this heading was to explore *'… whether early medical abortions at the pilot sites are as safe as those undertaken in NHS hospitals'*. Several indicators were used to address this issue; national data from abortion returns to the Department of Health, comments recorded in case notes at the five sites, and selected items from the client questionnaires and interviews.

4.1.1 National data from HSA4 returns

For 2005 and 2006 for the two pilot sites and the 3 comparator sites, the total complications up until time of discharge, following medical abortion was 10 and no one clinic stood out more than any other.

The total number of EMAs conducted at the five sites during these two years was in excess of 6500. However, it should be noted that these national returns are completed at the time of the abortion, and so may underestimate the actual numbers of subsequent complications.

4.1.2 Case note review

Detailed analyses of the case notes reveal very few cases of serious concerns regarding the outcomes of the procedure.

Specifically, in Chalfont and Gerrards Cross Hospital, there is only one case (out of 169) of a necessary overnight stay (*admitted into hospital that same evening – haemodynamically unstable*), although there are many reports of continued 'heavy bleeding' after discharge. These are not noted as causing concern, however. The fairly high proportion of women who are noted as not attending their follow-up appointment can be interpreted as indicating that they had no concerns and so did not see the need to attend. Although it is, on the other hand, possible that a serious issue had arisen and they had gone elsewhere for help, it is possible (but not guaranteed) that such information would have been received one way or another in the clinic (via the GP or the hospital attended).

In the 64 case notes from Comparator 1, one case is noted of retained products of conception which necessitated a later surgical evacuation which was followed by infection and readmission

for antibiotics. A further case is recorded in which products of conception were passed in the ward, but continued bleeding led to an overnight stay with *lots of analgesia*. She returned to the ward two days later with pain and retained products of conception which necessitated a surgical evacuation, and a Chlamydia test was positive. A third case was retained in hospital needing IV access and was given ergometrine.

No cases of concerns over safety were noted in the 206 case notes from St Mary's Hospital.

Comparator 2's case note 'other comments' section tends to focus on contraceptive advice provided although one case (out of 172) in a separate open ended section of the case notes does refer to a woman who was referred to emergency gynaecology due to *lots of retained products*.

From the 251 case notes from Comparator 3, one case is referred to as having been *admitted to hospital* although no further details are provided. A number of calls to the out of hours service are noted, but the responses to most of these appeared to be reassuring as to what was 'normal' with advice to contact emergency services (or their GP or clinic) if the pain and or bleeding continued. No further information is available.

In summary, from the 862 case notes analysed (and using a liberal interpretation of concern), there are just six cases in which concern was expressed and further action was required (over and above the seemingly routine management of incomplete procedures, pain and bleeding). Three of these occurred in one of the comparator sites (Comparator 1) so there is clearly no evidence that the pilot sites are associated with any greater risk of threats to the safety of the procedure.

In addition to these two key indicators, other potential challenges to safety are concerned with the availability of suitable drugs to treat and/or alleviate certain conditions (for example, anti-D for rhesus-negativity, or analgesics of varying types to manage different degrees of pain). No concerns were expressed in any of the interviews with staff regarding the availability of appropriate medication. Further, not one serious emergency is reported in the case notes available, and few were mentioned in the interviews as ever having occurred. However, since each of these sites (with the exception of Comparator 3) is in very close proximity to well-equipped hospitals, staff did not express concerns regarding access to emergency services had they been required. This issue will, however, need to be considered if the range of sites offering EMA are to be expanded.

In terms of prevention of infection, case notes from all sites reported that over 90 percent of women were provided with antibiotics before leaving the clinic, although the client questionnaires reported rather lower percentages than this (see section 4.3.8). It could be that the women did not realise what all the drugs administered actually were for, so the questionnaires provide an under-estimate.

4.1.3 Client questionnaires and interviews

Although clinical safety is, of course, best defined by the professionals, the extent to which clients were made aware of what to do in the case of problems is relevant to issues of safety. Accordingly, items on the questionnaire that related to this area were explored.

The key items were in Section 8, items 1, 2 and 3, and asked about information provided on discharge about what to do if complications were experienced or suspected. Table 4.1 shows the responses received from the three sites from which questionnaire data were available.

Table 4.1: Reported information provided at discharge (percentages from questionnaires)

Were you given clear information on how to identify potential complications?	St M	C2	C3
yes	71	75	86
no	17	25	5
unsure	12	0	9
n	*42*	*10*	*69*
Were you given clear information on what to do if you experienced or suspected any complications?			
yes	81	86	92
no	15	14	2
unsure	5	0	6
n	*42*	*9*	*69*
Were you provided with a 24-hour emergency contact number?			
yes	83	100	96
no	10	0	3
unsure	7	0	2
n	*43*	*12*	*69*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Overall, a clear majority of clients reported that they were given enough information regarding the identification of complications and what to do about them if they occurred or were suspected, and there were no statistical differences between the sites. Nevertheless, it could be argued that the proportions reporting that they had received adequate advice are somewhat below what they should ideally be. Of course, there may be disagreements in what the clients say and what the staff may say – it could be that some clients who claim that they were not provided clear information had language or comprehension problems, or simply failed to take in the information that was provided. Further, since terms like 'excessive', when applied to bleeding, are somewhat ambiguous, then it may be difficult for some women to report that clear information was indeed provided.

Further analyses were carried out on the data from two sites on these items (although the cell numbers get rather small once data are disaggregated into categories). Amongst the St Mary's respondents, there is a trend for younger women (those below the median age) to report being more 'unsure' if they were given clear information (17 percent of younger and six percent of older women reported this) and a similar trend was noted amongst the Comparator 3 respondents (81 percent of younger women were clear that they had been compared with 90 percent of older women). At St Mary's, but not Comparator 3, those who are less deprived (23 percent of those below the median deprivation score) reported being unsure compared

with eight percent of the more deprived. Interestingly, at neither site was ethnicity a factor in reported clarity of information regarding complications (although, of course, respondents with language problems will have been less likely to have returned their questionnaires).

From the interviews carried out (St Mary's and Comparator 3 only), all women reported feeling safe primarily due to the reassurances provided by staff throughout the process. Two of the Comparator 3 clients reported that they would have felt safer had they been enabled to stay in the clinic for longer after the second treatment since they were worried about events occurring during the journey home (although the interpretation of 'safety' here did not seem to relate to life-threatening conditions, but to comfort and potential embarrassment of bleeding or being in pain while on public transport).

4.2 Effectiveness

The key objective under this heading was to explore '*… whether early medical abortions at the pilot sites are as effective as those undertaken in NHS hospitals in terms of achieving complete abortions without further surgical or medical interventions'*. Several indicators were used to address this issue; comments recorded in case notes at the five sites, and selected items from the client questionnaires and interviews.

4.2.1 Case 2 review

All case notes (with the exception of Comparator 3) recorded whether there were definite indications of the passing of the products of conception during the clinic stay. Table 4.2 shows the results of the analysis of this variable, along with other indicators of the process during the clinic stay.

Table 4.2: Mean times in hours taken to PV bleeding and expulsion, and clarity of POC having occurred after administration of misoprostol at the five sites (a small number of overnight cases have been excluded to avoid skewing the data) (from case notes)

	Ch	C1	St M	C2	C3
mean time to PV bleeding commenced (hours)	n/av	3.6	2.8	n/av	n/av
mean time to expulsion of products where known (hours)	3.5	4.5	3.6	n/av	n/av
mean time from misoprostol to discharge (hours)	5.9	7.7	5.2	3.6	10 mins
definite POC passed in clinic (percent)	70.4	83	80.6	81.8	n/av
unclear POC passed (percent)	7.1	n/av	n/av	n/av	n/av
n	*169*	*64*	*206*	*172*	*251*

Key: Ch = Chalfont and Gerrards Cross Hospital (pilot site); C1 = comparator site 1;
St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3
n/av = not available from case notes
POC = products of conception
PV = vaginal bleeding

These data refer to cases in which products were seen by staff before discharge. Some clients are sent home before complete expulsion has occurred, and these are followed up later and outcomes are recorded (and, in a few cases, expulsion seems to have occurred after just the first drug treatment). Additional data analysis revealed that failed TOPs (using early medical procedures) occurred in fewer than one percent of cases in four of the five sites explored, and in three percent of cases (two cases) at the fifth (Comparator 1). In each of these cases, surgical procedures were carried out to complete the process. The shorter time between the second drug treatment and discharge at Comparator 2 is related to the administration of a second dose of misoprostol if products have not been passed in the first three hours or so.

4.2.2 Client questionnaires

Respondents to the questionnaires were asked about how obvious it had been to them when the products of conception has been expelled, and where they were when it occurred. Table 4.3 shows these data for the three sites from which sufficient questionnaires were obtained.

Table 4.3: Details of awareness, and location, of expulsion of products (from questionnaires)

	St M	C2	C3
mean length of stay in hospital/clinic after misoprostol (in hours)	5.2	3.0	0.25
percentages who thought it was OBVIOUS when abortion actually happened	78	60	70
percentages who were UNSURE where it happened	11	30	20
n	*37*	*10*	*64*
of those who were sure, where they were when it occurred (percentages)			
in the hospital/clinic	97	80	0
on my way home	0	0	10
at home	3	20	90
n	*30*	*5*	*52*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Table 4.3 shows that the majority of clients at the three sites felt that it had been obvious when the expulsion had actually occurred (it also shows, by the way, the reported times of clinic stay which are in close accordance with those recorded in the case notes as shown in Table 4.2).

From comparing responses on other items on the questionnaire, it can be seen that the certainty expressed regarding expulsion was probably, in some case, based on staff informing clients rather than actual direct perceptions or feelings. Table 4.4 below shows the percentages of women who reported that they had been warned to expect to see the products of conception and feeling the actual expulsion itself, along with the percentages who reported actually having done so.

There are two issues to note. First, a higher proportion of women at St Mary's reported that it had been obvious when the expulsion had occurred (81 percent) even though fewer had actually seen or felt the products (68 percent for both). The figures for Comparator 2 and Comparator 3 are more similar, although in both cases more women reported *feeling* than *seeing*. The second point of interest is that the degree of reported distress at seeing the products is not, at first sight, related to whether they had been warned in advance as to what to expect. Women at Comparator 2 were the least likely to have been warned as to what to expect and yet were also the least distressed. This is an unusual result in that most of the data from this study (and indeed from many other studies) point to the benefits of fully informing women in advance in order to ensure more relaxing and acceptable experiences of the procedure. Language difficulties may have affected these results, however.

To explore this further, separate analyses were carried out to investigate the relationship at an individual level. The results are compatible with what would be anticipated, in that women who were warned in advance as to what to expect in this regard were less distressed at seeing and feeling the evidence. Of those who had *not* been warned in advance about possibly seeing

and feeling the products, 41 percent reported being *extremely* distressed at actually seeing them as opposed to 11 percent who were not at all distressed. Similarly, of those who had *not* been warned, 46 percent reported being *extremely* distressed at feeling the evidence compared with 12 percent who were *not at all* distressed. Those who were unsure were again much more likely to report being *extremely* distressed. Increasing gestations were associated with women being more likely to report seeing and feeling the expulsion, but length of gestation was not associated with higher reported levels of distress. (As a matter of interest, one leading abortion practitioner in Vienna has put pictures of five and six weeks' gestational sacs on his clinic's website so as to forewarn women what to expect [Fiala, personal communication, 2008]).

Table 4.4: Information provided in advance about expulsion, and actual experiences (percentages from questionnaires)

Were you told in advance that you might see and/or feel evidence of abortion?	St M	C2	C3
see evidence			
yes	50	31	65
no	41	38	26
unsure	10	31	9
n	*42*	*16*	*65*
feel evidence			
yes	47	27	59
no	38	55	25
unsure	15	18	16
n	*34*	*11*	*64*
did you see evidence of the pregnancy as it was aborted?			
yes	68	57	60
no	20	29	24
unsure	12	14	16
n	*41*	*14*	*67*
did you feel evidence of the pregnancy as it was aborted?			
yes	69	63	80
no	6	25	11
unsure	25	1	9
n	*32*	*8*	*66*
If YES, how upsetting was this for you? (1= not at all, 5 = extremely, mean score shown)	3.42	2.70	3.48
n	*33*	*10*	*58*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2; C3 = comparator site 3

In summary, in terms of effectiveness of the procedures, there appear to be no apparent differences between the sites. All report a very high degree of confirmation of the expulsion of products, either whilst the women are still in the clinic or soon afterwards. Very few cases of necessary additional procedures were noted.

4.3 Acceptability

The key objective under this heading was ' … *to establish the level of acceptability among women visiting the pilot sites for an early medical abortion, and how it compares with acceptability levels for NHS hospital settings. In particular, to assess the degree of satisfaction with [a range of indicators]*' (Initial Research Specification, page 4). Several indicators were used to address this issue, drawn mainly from client questionnaires and interviews. The relevant data are presented according to the abortion temporal pathway, from initial referral through to follow up. Clients' attitudes towards potential changes to abortion provision are reported in Section 5.

4.3.1 Referral, assessment appointment and consultation

Reported routes to the assessment consultation are shown in Table 4.5.

Table 4.5: Details of referral route reported by respondents (percentages from questionnaires)

Referred by …	St M	C2	C3
GP or practice nurse	44	71	55
family planning clinic	37	26	9
pregnancy abortion helpline	0	0	6
contacted clinic directly	17	0	25
other	2	5	6
n	41	19	67

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

The low numbers of self-referrals at Comparator 2 are due to their policy of not accepting direct approaches because of local concerns about assessing entitlement to NHS provision. The data from Comparator 3 include some clients who paid privately, so some of the direct contacts will fall into this category. The St Mary's questionnaire data contains 18 percent who claimed that they contacted the clinic direct, but the case note analysis reveals no direct contacts. Instead, a number are described as being referred from Brook, GUM clinics or from out of area for medical reasons. These misclassifications may result from some misunderstanding on the part of the women involved.

Table 4.6 shows the percentages of women who reported that they were offered a choice of method and, if they were, whether they felt they had been given enough information on which to base their choice of method.

Table 4.6: Respondent reports of assessment consultation (percentages from questionnaires)

	St M	C2	C3
offered choice of method	85	33	90
n	*40*	*18*	*68*
if YES, those reporting that they were given enough information	91	100	87
n	*35*	*6*	*62*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

It would appear that the majority of women accessing abortion through Comparator 2 do not feel that they have been given a choice of method, whereas clear majorities in the other sites do feel that they have, and that sufficient information was provided to enable a choice of treatment.

The various major reasons reported why women chose the method that they did are shown in Table 4.7.

Table 4.7: Reported reasons for choosing early medical abortion (in percentages, multiple responses permitted)

Why did you decide to have a medical abortion?	St M	C2	C3
I was offered no other option	12	60	6
So that I could have someone with me	2	5	4
To feel more in control	20	20	29
To be more natural (like a period or miscarriage)	59	30	54
Involved a shorter hospital/clinic stay	32	20	25
Seemed to be a more private procedure	22	15	26
I wanted to see the aborted pregnancy	5	0	3
So the abortion could be done earlier	54	15	44
To avoid surgery	63	15	65
Recommended by the staff	20	10	10
Recommended by a friend	5	0	7
I could be home sooner	20	15	25
Less invasive option	39	10	44
To avoid pain	15	0	9
To avoid physical trauma	37	10	22
To avoid an anaesthetic	37	10	25
Other reasons	2	0	6
n	*41*	*21*	*69*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

The data from Comparator 2 reflect the apparent lack of choice offered, with all other options being considerably less frequently selected than they were for the other sites. The frequency of selection of reasons – apart from those from Comparator 2 – are remarkably similar between the two other sites. Most reasons were similar across age and deprivation categories, although older women were more likely to report selecting the procedure as being *more natural*, *could be done earlier*, and *being less invasive*.

With regard to the actual clinic to be attended for the procedure, Table 4.8 shows the percentages of women who reported that they were offered a choice, together with, for those who felt they had been offered a choice, the reasons for their selection.

Table 4.8: Percentages of women reporting that they were offered a choice of clinic for the procedure, together with reasons for their choice (if offered)

During the assessment …	St M	C2	C3
… were you offered a choice of hospitals/clinics for the abortion procedure? (percentages saying YES)	25 *(n=40)*	44 *(n=18)*	62 *(n=68)*
… if YES, why did you choose the place that you did?			
only place that could fit me in	0	38	10
more relaxed and informal environment	70	25	17
convenient location	40	25	55
they offered me the earliest procedure	50	13	48
recommended by friend/relative	10	13	10
recommended by a health professional	60	25	5
emergency services at hand should anything go wrong	40	25	5
it offered type of abortion I wanted	40	0	21
other reasons	0	0	16
n	*10*	*8*	*42*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Although the actual numbers of respondents who were offered a choice of location are quite small, it is of interest to note that equal numbers at the pilot and control sites selected the close proximity of emergency services should something go wrong as a reason, although this reason was not selected by many of the Comparator 3 clients.

4.3.2 Experiences of first treatment

Table 4.9 shows the data regarding the first treatment; first, whether the women were accompanied and, second, what physical or psychological side-effects they experienced. The categories *on occasions* and *continuously* have been combined since the frequencies of the latter were very low – fewer than five percent for most symptoms.

Table 4.9: Reported experiences during first treatment (percentages from questionnaires)

	St M	C2	C3
Other than a health professional, did you have anyone with you when you took your first treatment? Percentage YES	33	38	38
n	41	19	69
Did you experience any of the following symptoms (or side-effects) after taking the first pill? (combining 'on occasions' and 'continuously')			
nausea	21	33	40
vomiting	14	22	11
diarrhoea	12	6	6
headaches	12	28	15
dizziness	12	6	26
flushes/sweats	7	6	21
bleeding	26	28	17
stomach cramps/pain	31	33	30
feeling frightened	26	11	27

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

As mentioned earlier, some of these reported symptoms and/or side-effects are rather subjective, so it is not at all clear how much weight to place on them as objective indicators of the quality of care. Further, nausea and sickness may be related to the pregnancy rather than to the effects of the mifepristone itself. In any event, there are no large and consistent variations between the sites in reported effects of the first treatment. Further, there were few differences in responses between women of different ages and those living in areas with different levels of deprivation.

4.3.3 Experiences of second treatment

Table 4.10 shows some practical issues relating to the second treatment, with Table 4.11 showing reported symptoms or side-effects during this stage (the list provided excluded bleeding and pain since these were covered under a later question).

Table 4.10: Aspects of details of second treatment (from questionnaires)

	St M	C2	C3
How long did it take to get to the hospital/clinic? (mean time in minutes)	30	29	60
Did anyone accompany you (percentage YES)	24	33	52
Did you administer the second treatment yourself? (percentage YES)	15	79	75
n	*42*	*18*	*69*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

There are no variations in the proportions who were accompanied to the second treatment (although they are not permitted to remain with the women at St Mary's and they have to wait in the waiting area at Comparator 2), and the time taken to reach the clinic was similar for St Mary's and Comparator 2. The time to travel to Comparator 3 was considerably longer, with 32 percent taking more than one hour and almost 19 percent taking 90 minutes or more (the distribution of travel times here is not dissimilar to that reported in an internal survey carried out in 2000-01 by the organisation, although there are relatively more women reporting longer times in the current study).

There is a large difference in whether the misoprostol was self-administered. An interesting result was obtained whilst exploring whether self-administration had any perceivable impact on outcomes – amongst those women who did not self-administer, 43 percent reported that the bleeding had been not as bad as expected, compared with 27 percent of those who did self-administer. This relationship may be worthy of further examination with a larger sample (using prospective randomised treatment allocation); it may be that the decision as to whether to allow the woman to self-administer is not independent of other factors, so some reverse causality may be present.

Table 4.11: Percentages of respondents who reported side-effects (combined 'on occasions' and 'continuously') after second treatment (from questionnaire)

Did you experience any of the following symptoms or side-effects after having the second treatment?	St M	C2	C3
nausea	52	17	36
vomiting	33	23	18
diarrhoea	36	6	21
headaches	19	6	21
dizziness	36	22	36
flushes/sweats	29	11	38
feeling frightened	29	0	39
other	31	0	11
n	*43*	*21*	*69*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Most of the large number of 'other' responses from St Mary's referred to cramps and bleeding that are dealt with in a later question in the questionnaire. Quite why women at St Mary's report more symptoms is not clear; the staff interviews at Comparator 2 referred to women being routinely offered an anti-emetic drug which could explain the lower numbers reporting nausea, vomiting and diarrhoea. However, the client questionnaires did not reveal any differences in reported medication to alleviate these symptoms and side-effects.

The degrees to which the bleeding and pain were worse, the same, or better than expected are shown in Table 4.12.

Table 4.12: Ratings of bleeding and pain after misoprostol administration (percentages from questionnaires)

	St M	C2	C3
How was the bleeding you experienced?			
worse than you expected	24	13	35
as you expected	36	47	34
not as bad as you expected	41	40	31
How were the pain/cramps you experienced?			
worse than you expected	48	63	38
as you expected	33	13	32
not as bad as you expected	20	25	29
n	*42*	*15*	*68*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

It is not immediately clear why such apparent variations are found between sites (although the distributions are not statistically significant and therefore these findings could have just occurred by chance). It could be related to the extent to which staff prepare women in advance as to what to expect, although there is no evidence that would indicate this from other sources. From the additional comments written on questionnaires, it would appear that these items may have been a little ambiguous in that some seemed to be reporting on the *severity* of the experience whilst others comment on the *length of time* for which the bleeding or pain persisted.

Overall, younger women reported worse bleeding and pain than they had expected, and those living in less deprived areas also reported worse bleeding (but not pain) than expected.

The relative approaches of the clinics to managing pain are described in Table 4.13. There is a clear difference in procedures between Comparator 3 and the other two sites, with St Mary's appearing to be somewhat more proactive in this regard than its compar ator.

Table 4.13: Administration of analgesics (pain relief) at sites (percentages from questionnaires)

Which of the following best describes administration of pain-killers by staff at hospital/clinic?	St M	C2	C3
staff automatically gave me pain-killers	26	17	8
staff told me they could provide if needed	80	67	19
staff did not offer me pain-killers	0	10	43
I had to ask for pain-killers	13	0	0
the hospital/clinic did not provide me with pain-killers	0	8	46
n	*40*	*15*	*68*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

The percentages of women who reported taking some analgesics after the second treatment are shown in Table 4.14, together with the percentages who regarded the pain relief provided by the clinic as being adequate.

Table 4.14: Reported usage of analgesics and adequacy (percentages from questionnaires)

	St M	C2	C3
Percentages who actually took pain relief medication following second treatment?	79	60	87
n	*42*	*15*	*69*
reported adequacy of initial pain relief provided by clinic			
adequate	45	27	17
not adequate	33	33	9
none provided	0	0	59
not applicable – none taken	21	40	14
n	*42*	*15*	*64*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Although a higher proportion of women at the pilot site reported taking analgesics than did so at the comparator site, the level of satisfaction with the management at the former was considerably higher than at the latter site. This could also be related to the longer stay at the clinic amongst women using the pilot site.

Women were also asked if they needed to take further pain relief once they had returned home after the procedure and, if so, who provided the medication. Results are shown in Table 4.15.

Table 4.15: Respondents who took further pain relief at home (percentages from questionnaires)

	St M	C2	C3
Needed to take further pain relief at home	69	50	93
n	*42*	*14*	*66*
OF THESE…			
… analgesics provided by clinic	13	67	14
… analgesics personally bought/provided	87	33	87
n	*23*	*3*	*54*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

A rating scale was included in the questionnaire to ask for assessments of the overall management of pain by clinic staff. The distribution of responses is shown in Table 4.16.

Table 4.16: Percentage distribution of ratings of management of pain relief by hospital/clinic and mean score (among those who required it)

	St M	C2	C3
excellent	44	22	24
good	38	56	19
adequate	9	11	27
poor	9	11	19
very poor	0	0	11
mean scores*	*4.16*	*3.89*	*3.27*
n	32	9	37

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3
* scale ranges from 1=*very poor* to 5=*excellent*

St Mary's clearly receives more positive ratings than the other sites on this measure, although the mean scores are not significantly different; as mentioned above, this could be due to the longer stay at St Mary's than at Comparator 2.

Data are also available from the case note reviews as to which types of analgesics were used in pain management after the second treatment. These are shown in Table 4.17 for four sites; Chalfont and Comparator 1 have been included (since the numbers of cases are sufficiently large) whereas Comparator 3 has been omitted since the question is not appropriate because women were sent home immediately after the second treatment.

Table 4.17: Type of analgesia initially provided after administration of misoprostol at four sites (in percentages from case notes)

	Ch	C1	St M	C2
percentages requiring no analgesia	31	5	35	62
paracetamol only	1	2	30	1
diclofenac only	14	31	2	1
codeine phosphate only	-	-	3	34
co-codamol only	31	-	-	-
percentages requiring two or more analgesics	23	62	30*	2
n	*169*	*64*	*206*	*172*

Key: Ch = Chalfont and Gerrards Cross Hospital (pilot site); C1 = comparator site 1;
St M = St Mary's Hospital (pilot site); C2 = comparator site 2
* second analgesic would normally be stronger than the first, such as diclofenac or codeine

4.3.4 Post abortion care and follow up

Results on aspects of post abortion care relevant to safety issues have been presented earlier (section 4.1.3). In this section, details of follow up arrangements and symptoms experienced after discharge are reported.

Table 4.18 shows responses to items on whether women were offered a follow up appointment and whether they attended (or intended to attend, depending on when they completed the questionnaire).

Table 4.18: Information provided on follow-up and actions taken (percentages from questionnaires)

Before leaving the clinic after your second treatment were you given a follow up appointment to attend?	**St M**	**C2**	**C3**
yes	100	75	88
no, but I was advised to make one	0	25	12
no, and no such advice was given	0	0	0
n	*41*	*11*	*68*
Which of the following best describes your intentions for follow-up?			
I have already been/am here today for it	88	63	52
I am planning to attend	12	38	48
I have no plans to see anybody for follow-up	0	0	0
n	*42*	*11*	*66*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Although all women at St Mary's were given an appointment for a follow up consultation, and all reported either having already been or intended to go, from the case note analysis it transpires that, overall, only 84 percent do in fact attend follow up. The system for storing case notes at Comparator 2 did not permit an accurate assessment of the actual numbers returning for follow up, but staff estimated the rate as being 'very low'. Comparator 3 calls women after 48 hours to ask about progress and also encourage a return visit after three weeks. However, a fairly high number of the case notes examined recorded no answer to the 48 hour call (and/or that women had requested no such call be made), and precise details of the proportions attending for the three week check are not available (one staff interviewed estimated the number as being 10 to 15 percent, with some attending other clinics within the same organisation). Comparator 1 suggests that women contact their GPs if they have remaining concerns, but there is no system for recording how many in fact do so. Finally, Chalfont arrange follow up appointments for all women (either at the TOP service or at the family planning clinic), and report non-attenders to their GP.

The questionnaire included items asking about any problems or complications experienced after discharge, what these were, and from where further help was obtained. At the end of this section, a five point rating scale asked about their overall feelings about the post abortion care offered.

Table 4.19 show the responses for problems experienced since discharge (women were asked to complete the questionnaires about ten days after receiving the second treatment, but there is no assurance that this was always the case).

Table 4.19: Reported post abortion problems and/or complications (percentages from questionnaires)

So far, have you experienced any problems or complications with the abortion	St M	C2	C3
yes	33	31	14
no	67	69	86
n	*42*	*13*	*66*
If YES, what problems have you experienced? (NOTE SMALL Ns)			
excessive or prolonged pain	57	0	33
excessive or prolonged bleeding	57	100	67
an infection	21	0	0
n	*14*	*4*	*9*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Note that the actual numbers of those who experienced problems are fairly low since the proportions reporting problems were relatively low. Thus, the IF YES categories above contain just 14 women from St Mary's, four from Comparator 2 and nine from Comparator 3, so the percentages of the specific types of complications reported should be treated with caution. So, for example, the figure of 21 percent of St Mary's women reporting an infection refers to just three women.

Overall ratings of post abortion care are shown in Table 4.20.

Table 4.20: Overall ratings of post-abortion care (percentages from questionnaires)

Overall, how would you rate the post abortion care you have been offered??	St M	C2	C3
excellent	27	10	33
good	44	70	47
adequate	24	20	14
poor	5	0	7
very poor	0	0	0
mean score (1=very poor to 5=excellent)	*3.95*	*4.00*	*4.03*
n	*42*	*13*	*61*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

There are no significant difference in the mean ratings of overall care between the sites.

4.3.5 Perceptions of information and support provided

Women were asked on the questionnaires how they rated the verbal and written information received regarding the procedures and what to expect. Table 4.21 shows the responses received.

Table 4.21: Perceptions of information provided at two stages (percentages from questionnaires)

Were you given enough information about the abortion and possible side-effects …	**St M**	**C2**	**C3**
… before the first treatment?			
yes	88	93	93
no	5	0	4
unsure	7	7	3
… before the second treatment?			
yes	80	93	90
no	13	0	6
unsure	8	7	5
n	*42*	*15*	*69*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Clearly, there is overall general satisfaction with the quality of information provided, with no clear differences between sites. Although overall ratings were very positive, the ratings of the quality of the written and verbal information were somewhat more varied. The distribution of ratings on a five-point scales used to assess these are shown in Table 4.22, along with the mean scores of the ratings.

Table 4.22: Ratings of written and verbal information provided about what abortion would involve (percentages from questionnaires)

Ratings of information provided ……	St M	C2	C3
written information			
excellent	43	38	57
good	48	63	39
adequate	10	0	5
poor	0	0	0
very poor	0	0	0
none provided	2	0	2
mean score (1=very poor to 5=excellent)	*4.33*	*4.38*	*4.52*
verbal information			
excellent	40	21	64
good	47	57	26
adequate	14	21	10
poor	0	0	0
very poor	0	0	0
none provided	0	0	0
mean score (1=very poor to 5=excellent)	*4.26*	*4.00*	*4.54*
was the information accurate?			
yes	83	63	86
no	0	6	12
unsure	17	31	3
n	*42*	*16*	*67*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Although the quality of the information was regarded as being better at Comparator 2 than St Mary's, the actual content of written information was similar in the two sites, with the verbal information gaining a higher score at St Mary's than at Comparator 2. The information provided by Comparator 3 was regarded as superior for both written and verbal forms. It is not clear from the data available why more women from Comparator 2 were unsure as to whether the information provided was accurate or not.

Details of additional (open-ended) comments on the information provided (and requested) were recorded. Most perceived gaps are related to wanting further detail of procedures and what to expect, although a few women complained that they had been led to believe that it would be worse than it turned out to be.

4.3.6 Perceptions of staff involved

Respondents to the questionnaire were asked to assess the staff involved in the procedures in terms of their professionalism, reassurance and warmth/friendliness. Data are shown in Table 4.23, with the distribution of responses as well as the mean scores for each of these indices.

Table 4.23: Ratings of staff at the sites (percentages from questionnaires)

Ratings of staff for ……	St M	C2	C3
… professionalism			
excellent	64	25	70
good	31	69	25
adequate	2	6	5
poor	2	0	0
very poor	0	0	0
mean score (1=very poor to 5=excellent)	*4.57*	*4.19*	*4.66*
… reassurance			
excellent	64	23	69
good	21	69	22
adequate	8	8	8
poor	5	0	2
very poor	3	0	0
mean score (1=very poor to 5=excellent)	*4.38*	*4.15*	*4.58*
… warmth/friendliness			
excellent	65	20	76
good	18	60	16
adequate	15	20	8
poor	3	0	0
very poor	0	0	0
mean score (1=very poor to 5=excellent)	*4.45*	*4.00*	*4.69*
n	*42*	*16*	*67*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

The staff at Comparator 3 emerge strongly on all dimensions, followed by those at the pilot site (St Mary's) and comparator site 2. Statistically significant differences were obtained between the St Mary's and Comparator 2 mean scores on professionalism ($t=2.81$, $p<0.02$) and warmth ($t=1.99$, $p<0.05$) but not reassurance. All differences between Comparator 3 and Comparator 2 were strongly significant beyond the five percent level, but none of the differences between St Mary's and Comparator 3 were significant.

An open-ended item was included after the ratings of staff which asked for comments on how (if at all) staff could improve. Although the item asked for possible areas of improvement, the many respondents took the opportunity to write comments that were positive about the staff.

For St Mary's, seven of the 16 comments referred to the staff as being *excellent*, *friendly*, *giving lots of support*. More challenging comments referred to a seeming lack of understanding (five comments) and one referred to feeling that the staff were wanting her to *hurry up*. Just one comment mentioned the lack of a doctor being unsettling, and one mentioned that the placenta had been referred to as *the baby*.

Just two of the women at comparator site 2 made extra comments, one referring to the need for more staff, and the other to a wish that there was a check that the 'pills' had been correctly inserted.

Eleven of the 25 comments from clients at comparator site 3 were positive, with one or two of the others each referring to delays in being seen, the doctor being rather clinical (in contrast to the nurses), the lack of provision of pain relief, lack of warning as to how painful the procedure would be, and a wish for a resting room after the second treatment.

4.3.7 Perceptions of physical facilities

Women were asked to rate the physical facilities at the sites. Distribution data are shown in Table 4.24 along with the mean scores.

Table 4.24: Ratings of physical facilities at the sites (percentages from questionnaires)

Ratings of ……	St M	C2	C3
… physical environment			
excellent	38	25	41
good	38	63	42
adequate	21	13	17
poor	2	0	0
very poor	0	0	0
mean score (1=very poor to 5=excellent)	*4.12*	*4.13*	*4.24*
… toilet facilities			
excellent	33	31	36
good	36	69	45
adequate	21	0	15
poor	10	0	5
very poor	0	0	0
mean score (1=very poor to 5=excellent)	*3.93*	*4.31*	*4.12*
… washing facilities			
excellent	30	40	36
good	15	53	42
adequate	39	7	17
poor	9	0	6
very poor	6	0	0
mean score (1=very poor to 5=excellent)	*3.55*	*4.33*	*4.08*
… provisions within clinic (reading material, TV, drinks, etc.			
excellent	38	13	25
good	38	53	41
adequate	17	0	25
poor	7	20	8
very poor	0	13	0
mean score (1=very poor to 5=excellent)	*4.07*	*3.33*	*3.84*
n	*42*	*16*	*67*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Again, comparator 3 emerge strongly on three of the four indices, with provisions within the clinic scoring most poorly. However, the only statistically significant differences related to the poorer scores on washing facilities at St Mary's.

Further items asked about the perceived comfort and privacy of the waiting rooms, examination rooms and recovery areas at the sites. Data distributions are shown in Tables 4.25 (for comfort) and 4.26 (for privacy), together with the mean scores. There were no significant differences between the sites on any of the comfort measures, with just one difference in the

privacy measures – comparator 3 was rated lower than St Mary's (possibly because women do not remain in the clinic for recovery).

Table 4.25: Ratings of comfort at the sites (percentages from questionnaires)

Ratings of comfort in hospital/clinic of ……	St M	C2	C3
… waiting rooms			
excellent	23	18	28
good	47	69	49
adequate	25	6	22
poor	2	6	0
very poor	0	0	0
none available	2	0	0
mean score (1=very poor to 5=excellent)	*3.93*	*4.00*	*4.06*
… examination rooms			
excellent	21	27	33
good	58	60	50
adequate	19	13	17
poor	2	0	0
very poor	0	0	0
none available	0	0	0
mean score (1=very poor to 5=excellent)	*3.98*	*4.13*	*4.17*
… recovery areas			
excellent	33	28	16
good	44	56	44
adequate	21	0	12
poor	2	8	0
very poor	0	0	0
none available	0	9	28
mean score (1=very poor to 5=excellent)	*4.07*	*4.15*	*4.12*
n	*43*	*16*	*66*

K Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Table 4.26: Ratings of privacy at five sites (percentages from questionnaires) (mean scores exclude those who rated 'none available')

Ratings of privacy in hospital/clinic of ……	St M	C2	C3
… waiting rooms			
excellent	20	15	29
good	48	54	35
adequate	15	15	30
poor	10	15	6
very poor	3	0	0
none available	5	0	0
mean score (1=very poor to 5=excellent)	*3.79*	*3.69*	*3.86*
… examination rooms			
excellent	24	33	45
good	60	42	37
adequate	17	17	16
poor	0	0	2
very poor	0	8	0
none available	0	0	0
mean score (1=very poor to 5=excellent)	*4.07*	*3.92*	*4.25*
… recovery areas			
excellent	22	24	28
good	45	39	39
adequate	13	8	15
poor	10	8	0
very poor	8	0	0
none available	3	22	17
mean score (1=very poor to 5=excellent)	*3.68*	*4.00*	*4.20*
n	*42*	*13*	*67*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Additional comments on the physical aspects were recorded. The St Mary's comments (18 in all) covered a range of issues, with the relative lack of toilets and privacy being prominent. Just two comments on comparator site 2 referred to the need for private rooms and a cleaner toilet. Of the 20 comments on comparator 3, there were a number of issues raised about the need for better vending machines, more direction signs and the heating and ventilation.

4.3.8 Other services offered

In addition to the items that related specifically to the abortion procedure, respondents were also asked about other aspects of their treatment. Table 4.27 shows the results for what respondents claimed they had been offered at one or another stage of the procedure.

Table 4.27: Offers during treatment and care (percentages agreeing that offer was made)

Which of the following were you offered during your abortion treatment and care?	St M	C2	C3
antibiotics to prevent infection	83	75	93
chlamydia screening	12	19	39
testing for other STIs	17	38	3
HIV testing	2	13	4
smear test	5	13	1
sanitary protection	31	6	9
post-abortion pregnancy test	13	15	87
n	*42*	*16*	*69*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

As mentioned earlier, the case notes provide somewhat different figures form these in some respects. For example, over 96 percent of the case notes from the three sites report having provided antibiotics; only the women attending comparator 3 concur with this figure. Other services are not recorded in the case notes so comparison cannot be made (other than at comparator site 2 who report STI screens for 65 percent of women, a figure not dissimilar to the total of Chlamydia and other STIs noted above).

Women were also asked to rate the contraception advice they were given, as well as the pre and post abortion counselling. Data are shown in Table 4.28.

Table 4.28: Ratings of other services provided (from questionnaire) (percentages and mean scores exclude those who rated 'none provided')

How would you rate the following services you received …	St M	C2	C3
… contraception/contraception advice			
excellent	48	21	34
good	36	57	31
adequate	14	21	28
poor	2	0	8
very poor	0	0	0
none provided	0	0	5
mean score (1=very poor to 5=excellent)	*4.29*	*4.00*	*3.91*
pre-abortion counselling			
excellent	33	20	47
good	47	70	28
adequate	20	10	21
poor	0	0	4
very poor	0	0	0
none provided	24	11	20
mean score (1=very poor to 5=excellent)	*4.13*	*4.10*	*4.19*
post-abortion counselling			
excellent	40	29	37
good	32	57	33
adequate	24	0	21
poor	4	0	5
very poor	0	14	5
none provided	29	29	32
*mean score (1=very poor to 5=excellent)**	*4.08*	*3.86*	*3.93*
n	*42*	*16*	*69*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

There are no statistically significant differences between the sites.

4.3.9 Overall reflections

Finally, women were asked to provide an overall assessment of their experiences regarding the procedure and the clinic in which they received it; this was phrased in the form of whether they would use the same method and clinic if they needed to in the future, and whether they would recommend them to a friend. Results are shown in Table 4.29.

Table 4.29: Overall feelings on looking back (percentages from questionnaires)

If you needed another abortion in the future ..... would you go back to the same procedure hospital/clinic?	St M	C2	C3
yes	78	73	86
no	8	20	5
unsure	15	7	9
... would you choose a medical (pill) abortion?			
yes	78	77	72
no	5	15	11
unsure	17	8	17
Would you recommend the hospital/clinic to a friend?			
yes	79	93	92
no	7	0	3
unsure	14	7	5
Would you recommend medical abortion to a friend in need?			
yes	88	92	77
no	5	0	8
unsure	7	8	15
n	*42*	*14*	*65*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

Perhaps unsurprisingly, there is a fair amount of uncertainty regarding future plans if the situation arose again since these ratings have been completed within a few days of having been through what can be a painful and distressing experience. Interestingly, on most of the measures, more would recommend the clinics and procedure to friends than would repeat their experiences!

Overall, however, ratings are generally positive and there are no statistically significant differences between sites.

5 Respondents' views on changes to current provision

The opportunity was taken in the client questionnaires and interviews, as well as the staff interviews, to explore views on possible changes to the provisioning of early medical abortion. Specifically, views were sought on widening the range of places at which EMAs could be obtained, remaining in the clinic after the second treatment, and the possibility of taking the second treatment at home. The views of women who have recently undergone the procedure, and staff who deal with them on a daily basis, are potentially of great interest to current national policy discussions. It is important to stress, however, that undue emphasis should not be placed on interview extracts. They are included to provide some examples of the varied experiences and perceptions of those involved, rather than as necessarily being typical or representative views.

5.1 Widening the scope of class of place

5.1.1 Client views

The wording of the questionnaire items are shown below and Table 5.1 shows the results on this issue.

Section 10, item 1. Currently, abortions are provided at hospitals and approved clinics only. The Department of Health is considering making early abortion services more widely available in approved community settings, such as family planning and sexual health clinics.

Table 5.1: Views on community provision of EMA (percentages from questionnaires)

Do you think this is a good idea?	St M	C2	C3
yes	62	87	73
no	12	13	12
unsure	26	0	15
n	*42*	*15*	*67*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2; C3 = comparator site 3

The majority of women agree that this would be a positive move, although a fair number remain unsure. Fewer than one fifth are opposed to the idea. Across all sites, older women were more likely to agree with the suggestion (77 percent as opposed to 61 percent of younger women), as were women living in less deprived areas although the difference was not large (65 percent as opposed to 71 percent). Neither difference was statistically significant.

Within the client interviews, there were consistently clear views about the 'class of place' issue, with all stating that a less 'formal' clinic setting was preferred. For example, from the women who accessed St Mary's, one woman in her early 30s reported that it felt like a clinic rather than a hospital, a woman in her early 40s said that the staff were more important than the actual setting, whilst another woman in her mid 20s felt that the clinic setting was comfortable and homely and not like a clinical setting. It was informal but could have done with some beds. A teenager commented that she had never given any thought to the proximity of services nor anything going wrong with the procedure as it was just taking a pill. She expected to bleed and to have it in a clinc but confidentiality was important and she would not want to see anyone she knew. A woman in her mid 20s remarked that community-based clinics feel *more homely* and made women feel safer and less afraid as larger hospitals settings can be quite daunting. Finally, a woman in her early 40s agreed that more community clinics would be better than hospitals.

One woman in her mid 20s was ambivalent about this issue, saying community provision was good for women in violent relationships but felt that if services were too readily available younger girls may not appreciate the seriousness of unwanted pregnancy and abortion.

Amongst the clients of comparator site 3, although they did not stay in the clinic after the second treatment, there was strong support for more community settings. One woman in her mid 20s provided a list of supportive reasons, which included – peace of mind that it is a simple procedure, more relaxed and less formal than a hospital, pleasant environment, the feeling of guilt is reduced as it is not in a clinical hospital setting, it is more accessible, it is less serious than a hospital. A woman in her mid 30s supported the view that the clinic was a nicer, more homely place than the clinical setting of a hospital adding that anything that made the procedure less complicated was to be welcomed.

A woman in her mid 20s reported feeling more comfortable in a clinic that specialised in abortions on the grounds that she felt, based on previous experience, that hospitals were not comfortable doing abortions. She did, however, express concerns about wider use of GPs to administer the procedure on the grounds that they might not ask the right questions or carry out appropriate checks; for example, her own GP had not carried out a pregnancy test on her before referring her on.

A teenager stressed the importance of having somewhere near to home so as to avoid the fear and uncertainty experienced during the journey from the clinic. Such views were echoed by a woman in her mid 20s who felt that clinics should be easy to get too as it was uncomfortable to travel when feeling unwell especially if you have to travel on public transport when you are in pain and it shows. She also felt that being near to emergency services was not an issue, on the grounds that the staff are professional people who would know what to do; had anything gone wrong they would have been able to ascertain how bad it was and call an ambulance if needed. She felt that the a relaxed quiet atmosphere was more important than the clinical setting.

A woman in her mid 40s who accessed Chalfont and Gerrards Cross did not mind where it was, as long as she could get to and from it with minimum fuss. She didn't really think about

the proximity of emergency services as she felt the procedure was so straightforward that it was unlikely anything could go wrong. She thought that wherever she was (hospital or community) she would have a nurse with her and she found that very reassuring. She also added there needed to be more local clinics where women who do have an unwanted pregnancy can go and be cared for and reassured and to cause as little upset to their lives as possible.

5.1.2 Staff views

The summaries of the staff interviews on this topic are as follows.

Chalfont and Gerrards Cross – There were very mixed views regarding what sort of site would be suitable. One interviewee felt strongly that more GPs should offer the service, whereas others felt that this would not be appropriate, especially for younger women who may be concerned about being recognised. Further, since some women undergoing the procedure make a fair amount of noise due to pain and cramping, it was felt that this would not be popular in GP surgeries. Further, the degree of time needed to go through all the different issues involved – including giving time for the women to decide – was not felt to be conducive to the typical GP surgery.

Community-based clinics (including Family Planning Clinics, sexual health clinics, centres with multiple GP practices and cottage hospitals) were felt to be appropriate sites, as long as they met the basic requirements.

All interviewees, based on their experiences of developing this pilot, agreed that lack of direct access to acute services was not a barrier. Whereas early on in the development there was a view that a cautious approach was preferred, all felt much more confident now about expanding community-based services. The very rare occasions on which real emergencies do occur could be dealt with as is any other emergency – by calling an ambulance and getting the woman to Accident and Emergency departments or by using an out-of-hours GP service.

Comparator site 1 – There were very mixed views regarding expanding the range of places in which EMAs could be carried out. Some were very positive in the light of the safety of the procedure, the greater informality that could be achieved, and the opportunity to have specialised units with dedicated and highly trained staff.

On the other hand, some reservations were expressed, primarily in terms of monitoring of standards and possible emergencies. One interviewee, who has been closely involved in issues regarding the performance of subcontracted work to an independent provider, commented *if you multiply* [those problems] *hundred times, that's difficult.* She felt that a few sites would be preferable so that adequate *counselling and support that needs to be in the communities* could be assured. There were also concerns about confidentiality in cases where facilities were close by to the area in which the women lived.

Although some expressed reservations regarding what might happen in the case of emergencies, they equally acknowledged that emergencies are, in their experience, very rare. One commented that, in her three years of work in the current unit, there had only been two occasions on which a doctor had to be called due to heavy bleeding. Another remarked

that the situation (and level of risk) would be no different from a situation of spontaneous miscarriage, in which emergency services would be summoned.

Some reservations were also expressed about the 'type' of woman for whom a community-based service might be suitable. Younger women were mentioned as a group that may possibly need more specialised monitoring and support, as well as back up and reassurance.

Further concern was expressed about the lack of anonymity provided to clients and staff should terminations be carried out in a small community-based unit where the service is less easily absorbed into the other aspects of a larger service. This was felt to be of particular concern should the service come to attention of pro-life campaigners.

St Mary's Hospital – Being one of the DH pilot sites, all those interviewed here were very positive about expanding the possible environments in which EMA could be carried out. It was stressed that the equipment needs are minimal – an examination room, a communal room with comfortable chairs/sofas and a nice environment, sufficient toilets, tea and coffee making facilities, somewhere for clients to lie down if they wanted, access to emergency services if required (although it was stressed that this is needed very rarely). By using the term 'minimal' however, it was not being suggested that careful planning and suitable modification of premises were not required.

The quality of the staff was also stressed, with a general view that well-trained, experienced and non-judgemental nurses were essential. Healthcare assistants may be useful as support staff, but should not replace nursing staff.

Comparator site 2 – Expansion to other sites was felt to be a positive step as long as they were all equipped with the necessary facilities, including trained scanners, staff with good knowledge, toilets, privacy, etc. A greater range of sites would enable more women to be treated within the EMA period.

Comparator site 3 – There is a strong view that the current legislation is unreasonable and unjustifiably restrictive. A strong view was reported that the actual physical location was of lesser importance than the structures and support mechanisms that are in place. The physical location was important in that adequate privacy, a restful environment (for women who stayed in) and easy access to toilets was essential, but little beyond this.

Some doubt was expressed as to whether some GP surgeries would have the physical space and facilities required, but also whether they would have the capacity to provide the time and support needed both during the procedure and afterwards. Carrying out EMAs on a 'part-time' basis was seen to be risky from these aspects. Further, the quality of staff and their commitment to abortion could be a problem is some community based facilities.

Some interviewees felt that 'class of place' would be better determined in terms of provider competence rather than by physical location.

5.2 Going home straight after the second treatment

5.2.1 Client views

The questions are shown below and the data are shown in Table 5.2.

Section 10.2. Typically, women undergoing an early medical abortion are required to stay in the hospital/clinic for a number of hours after taking the second treatment (the Misoprostol) for the abortion to commence. Some hospitals/clinics are thinking of allowing women to leave much earlier.

2a. Do you think that women should be given the opportunity to go home immediately after taking the second treatment?

Yes ❑ *No* ❑ *Unsure* ❑

2b. If you had been offered the opportunity, would you have gone home immediately after taking the second treatment?

Yes ❑ *No* ❑ *Unsure* ❑ *I was offered the opportunity* ❑

Table 5.2: Views on going home straight after second treatment (percentages from questionnaires)

	St M	C2	C3
Do you think women should be given the chance to go home straight after the second treatment?			
yes	23	57	85
no	63	29	9
unsure	15	14	6
If you had been given the opportunity, would you have gone home immediately after the second treatment?			
yes	29	67	90
no	61	25	7
unsure	11	8	3
I was offered the opportunity	*3*	*18*	*94*
n	*40*	*14*	*66*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2; C3 = comparator site 3

There are widely disparate views on this issue between the women accessed via St Mary's and comparator 2, which are not easy to account for. Responses may reflect the quality of the experience in the clinics accessed, although the differences in reported satisfaction with the two sites (reported earlier) were not as large as the differences in responses to these questions would seem to indicate.

The responses from women accessing comparator 3 are clearly considerably more positive than those from the other sites.

Overall, younger women were considerably less likely to agree that going home was a positive move compared with older women (40 percent of younger women selected no compared with 22 percent of older women (highly significant chi-square=14.7, p<0.001). Similarly, more older women (80 percent) would have taken the chance if they had been offered it than amongst the younger women (47 percent, chi-square=13.1, p<0.001). There were no variations across deprivation area.

Within the interviews, there were mixed views about going home after the second treatment; these to a large extent reflected the women's own experiences. Amongst the St Mary's clients, one teenager did not want to go home since her mother was there, but would have liked to have had a friend to stay with her at the clinic and to have been able to go outside for a walk. As it transpired, she went home after the nurse had said that she thought that the abortion had occurred. Later, however, when she was having a bath to relieve the pain, she expelled a large clot that she found extremely upsetting.

A woman in her mid 20s, who stayed in until the nurse wanted to go home before expulsion had occurred, said she felt more comfortable at home, but would have felt safer staying in the clinic until the process had been completed. She felt that all women should be kept in, on the grounds that they may feel alright for an hour or so after the second drug, but after that the effects can be strong enough to cause a person to collapse.

A woman in her early 40s was happy to have stayed in just in case something adverse had occurred. She had strong pains and was glad for the added pain relief and the comfort of the nurse. Finally, a woman in her early 30s, who had initially wanted to go home after the second drug, was glad that she had stayed since seeing the expelled product was reassuring for her in that she knew the procedure had worked effectively.

The clients at comparator site 3 expressed more varied views. The teenager, who had earlier expressed her fears about the journey home, later said that she glad that she went home straight afterwards so that she could relax and be on her own in the quiet if she wanted and could go for a walk in an area she knew.

A woman in her mid 30s had been told that nothing would happen after the second treatment for at least two hours, but then started to bleed heavily on the bus on the way home and had to run from the bus stop to her home. As a result of this experience, she felt strongly that the second drug should be self-administered at home to avoid the risk of this happening to others, although she acknowledged that this might not be suitable for everyone. She felt that either the second drug should be taken at home, or that women should be kept in for the expulsion to occur and until they are stable – and that, at the first consultation if they feel you are competent and understand the procedure an its effects.

A woman in her early 20s reported having been in two minds – she would have liked to have stayed as she felt very anxious on the way home as she was unsure of exactly what would happen and she suffered a lot of pain after half an hour. She said she would have liked to have stayed just to be reassured that everything was normal and to have someone to prescribe medication if necessary. However, she would not have liked to have share a room with other

women also in pain. She said it was nice to go home but felt that she would have like to have had more information about what was going to happen and the pain.

A woman in her early 30s described her experiences in some detail. She felt they could have given a little more information about what to expect especially on in terms of bleeding although she appreciated that all women would be different. She had big bleeds and thought something was wrong. Once the product had passed, the bleeding was less than a normal period for her.

She claimed that she had not been told how to identify the product and thought that when she first took out the tampon and heard something fall into the toilet bowl she thought that she had expelled the product. The bleeding then got heavier and she felt that she had to urinate and returned to the toilet where she was aware that this time she passed the product without any pain.

She was scared because she was told she may or may not bleed, she started to think that maybe she should do it under medical supervision. She reported feeling anxious, she was given the instructions about when to remove the tampon and was allowed to leave immediately. As she was leaving, she was told to go straight home, which made her feel worried that, if the train, was late, then she would have problems on the journey. This feeling was enhanced by her being on her own. She felt that she should have been kept in for a little longer, and she would have appreciated some more reassurance about what was going to happen.

These experiences contrast somewhat with those of a woman in her mid 20s, who reported that she was told when to remove the tampon (cytotic) between 2 and 4 hours afterwards. But, again, she was told that the pain would start after about two hours – she started to suffer (pain) after half an hour, while on the train going home. She had a one hour journey home – she started bleeding after one hour (as she got home).

A woman in her mid 20s was glad she went home although there was nobody there. She wished that she had confided in a friend and then they could have stayed with her. She thought it was good to be at home and she was more relaxed. She was frightened by the excess bleeding, but did not phone the helpline and just took herself to Accident and Emergency. The reason was that she wanted to talk to someone face to face, she wanted to be in a clinical setting in case there was something really wrong. She found the A and E staff were quite judgemental as if she had had an illegal abortion. The staff were not friendly like the staff at the clinic.

Finally, a woman in her early 40s remarked that she would have preferred to have gone home straight after the second treatment. She wanted to walk around as this helped with the pain, but there was nowhere to really walk, especially in the fresh air (or to have a cigarette). She said she would have felt comfortable going home if she had a number to call where she could talk to someone about what was happening and get reassurance that the blood loss and pain levels were normal.

5.2.2 Staff views

Chalfont and Gerrards Cross Hospital – this issue was not covered in the staff interviews.

Comparator 1 – There were reservations regarding a possible lack of monitoring and reassurance, as well as the fact that some women do not want people in their home knowing what they are going through. As one respondent put it, *I think yes, theoretically, it's a nice idea. I think there are lots of practical issues that argue in favour of this being provided in the community.*

At the time of interviewing plans were being put in place to enable some women to go home after the administration of the misoprostol (second stage of treatment). The criteria these women will need to meet are:

- seven weeks or less gestation
- must live within a defined geographical area
- be of a defined age group
- be medically uncomplicated
- have transport
- be willing to carry out her treatment in this way

St Mary's Hospital – not covered in the staff interviews.

Comparator site 2 – not covered in the staff interviews.

Comparator site 3 – reflects current practice.

5.3 Taking second treatment at home

5.3.1 Client views

Finally, women were asked how they felt about taking the second treatment at home. The questions are shown below and responses are shown in Table 5.3.

Section 10.3. Currently, women in the UK must return to a hospital or clinic to receive the second part of the medical abortion treatment due to legal restrictions. In some other countries women are given the Misoprostol tablets to use at home at the appropriate time.

3a. Do you think that women in the UK should be given the choice of whether they would like to take the second treatment at home or return to the hospital/clinic?

Yes ❑ *No* ❑ *Unsure* ❑

3b. If you had been given the option, where would you have chosen to take the second treatment?

At home…….. ❑

At the hospital/clinic…. ❑

Unsure……❑

Table 5.3: Views on taking second treatment at home (percentages from questionnaires)

	St M	C2	C3
Do you think women should be given the choice to take the second drug at home?			
Yes	36	31	50
No	53	44	32
Unsure	12	25	18
If you had been given the option, where would you have chosen to take the second treatment?			
at home	24	30	40
at the hospital/clinic	69	53	50
Unsure	7	18	10
n	*42*	*16*	*68*

Key: St M = St Mary's Hospital (pilot site); C2 = comparator site 2;
C3 = comparator site 3

There are clearly mixed views on this issue, with just over one third agreeing that the choice should be offered, but also a fair degree of uncertainty as indicated by the *unsure* responses. Interestingly, women from comparator 3 (49 percent) were more in favour of being offered the choice, although fewer (41 percent) would have exercised the choice to take it at home. The clinic or hospital remains the first preferred option for the majority of women at all sites (after omitting those who are unsure).

No differences arose on any of these indices according to the age or deprivation level of the women.

The interviews provided a range of opinions on this issue. Amongst the St Mary's women, most preferred the idea of a nurse administering the second drug. A woman in her mid 20s felt that inserting the second pill was comparable to inserting a pessary treatment for thrush but identifying the product may be harder because women may think that every clot that passes is the product. Although women may initially be unsure, once it passes there is little doubt that the termination has taken place. She would allow the nurses to insert the second pill for her and then gone home if given the option. A woman in her early 40s felt that women should not be allowed to do it themselves or at home as they may not insert it far enough for it to be effective.

A woman in her early 30s also had reservations. She felt that this would not work for everyone as everyone's experience is different. It would not have worked in her case – but would have been ok for the other three women she was with. It would not also work in the cases where the second drug (dose of misoprostol) needed to be given again if nothing had happened (this happened to her and another women at the clinic with her). She felt that a nurse would need to be on call for this to work.

It would be very stressful for the person with you as they would untrained and worried about your symptoms. This may result in ambulances being called unnecessarily. On the other hand, it would be more comfortable at home and privacy would be better. She felt that for this to be satisfactory, you would have to have someone with you after taking the drug. You would need a list of side effects/step by step guide to what should/shouldn't happen. So that you could know when to phone for help or advice. You would need a nurse to be on call so that you could get advice/help.

A woman in her mid 30s from comparator site 3 felt that it was unnecessary to have the second drug in a place that is far away from her home (she had been told it would take two hours before anything happened but seemingly started to abort on the bus) dependent upon how long you had to travel afterwards. If you do not have a long journey afterwards it could be inserted at the clinic but if have a long journey it may be better to insert at home.

Others were also sympathetic to the idea of taking the second treatment at home, but were aware of possible risks, amongst younger women for example, of their not inserting it at the right time or in the right way. One woman stressed that – were this to become more common – a longer initial consultation would be required to ensure that women knew what to do and what would happen.

The Chalfont respondent saw no problem since she had been unsupervised when she administered the second drug anyway, and she did not see any difference.

5.3.2 Staff views

Chalfont and Gerrards Cross Hospital – this was not covered in these interviews.

Comparator site 1 – not covered in staff interviews.

St Mary's Hospital – There were mixed views on this; one interviewee would prefer a complete home service to the current practice of giving the second drug in a clinic and then sending women home on a bus. On the other hand, others felt that there could be problems of people losing the drug, not wanting to have others know about the abortion, and that some women would find it difficult to administer the drug correctly.

Generally, it was agreed that this should be an option, but only for women who are assessed as being suitable and well-informed, and who could be guaranteed to attend for a follow-up check.

Comparator site 2 – There were generally negative views towards moving to a system of home administration of the second drug. Many of those interviewed felt that not enough women would be responsible enough to follow the guidelines properly, and some thought that the drug would be passed to others who were not entitled to it (one even said it would …appear on e-bay the very next day).

Some did say that after a very careful assessment of clients that it would be suitable in some cases, especially if there was a number to call at all times and if a follow-up visit – with scan – could be guaranteed. However, no clear statements were made as to how such selection for suitability could be made.

Comparator site 3 – There was a strong view that – subject to careful assessment at the beginning and careful follow up afterwards – there were no good reasons to prohibit administration of the second drug at home. It was pointed out that this is common in the USA and that, in the UK, children as young as ten years old can be entrusted to administer insulin by themselves.

6 Protocol analysis and development

This section raises a number of considerations that need to be taken into account in developing protocols for new services offering EMA in non-traditional settings. A number of issues are briefly covered, many of which have been dealt with elsewhere in this report and/or accompanying appendices. The aim is not to develop a protocol as such, but to raise issues that have emerged as being relevant. The context in which this is written is an acceptance that the data collected in this study reveal – in line with the published literature – there are no indications that 'non-traditional' sites (in as far as the pilot sites can be called this) are any less safe, effective or acceptable than the more 'traditional' sites. Indeed, on some measures, they can be regarded as more acceptable to many women. The further issues covered in this section are drawn from those identified in the initial Research Specification, but not covered explicitly elsewhere in this report; there is inevitably some degree of overlap in coverage.

6.1 Accessibility to services

The co-location of EMA provision to family planning clinics increases the probability that other issues will be considered during consultations The case notes from St Mary's and comparator site 2 reveal comprehensive coverage of these issues, although it is not clear if the advice given is followed up. Presumably, a fully coordinated service could carry out comprehensive checks on many other aspects of sexual and reproductive health in general, and maintain well-informed records. Since, overall, more than one third of the women attending for EMA in these samples had had previous abortions (44 percent in the questionnaire sample and 34 percent from the case notes), there is some room for more integrated support and care.

There was insufficient data from the current work to be able to say anything with confidence about general practice sites as possible venues for EMA to be provided. Some reservations were expressed by staff about whether suitable space and facilities would be available, especially if the women were to remain in the clinic until the expulsion of products. Mention was made that soundproof spaces would be desirable. There were advantages recognised in holding EMA clinics at times of the week when other uses were low, so this area needs to be explored further. However, of relevance to integrated care, as well as potential locations, it is of interest that in almost ten percent of the independent provider case notes, there is specific mention of the women not wanting their GP to be informed of the abortion.

In terms of preferred days and times of availability, no complaints were made from any clients regarding the restricted availability of EMA clinics that are in place at three of the five sites. It could be inappropriate, however, to read too much into this since women for whom the times were inconvenient may have been forced to wait longer and so be excluded from these samples (that is, they would have required surgical intervention instead). We do not have data on this possibility.

There were reservations expressed by staff at some sites regarding capacity issues. Staff at three of the sites specifically mentioned how demand was higher than they could deal with at the moment, and that this was not cost-effective; women were being turned away and referred to other providers with which the PCT had contracts. It was felt that initial starter costs for a really effective service (including readily available USS facilities, building works (space and toilet provision, for example), staff training, and others, could be more fully justified if more clients could be catered for.

The demographic characteristics of women seeking EMAs covered a wide spread, so it is not at all clear to what extent local profiles need to be taken into account in locating any new services. Specific consideration would need to be paid to young people who do not want their parents to know (and others who may not wish their partner to know), and so who would probably wish to stay in a facility until the process is complete.

The location of services is an important issue; travel times from home amongst the overall sample in this study averaged at 45 minutes, with a range from 5 minutes to four hours. Women accessing comparator site 3 had the longest travel times; the average excluding these was 29 minutes. This emerged as an important issue in the interviews, where a few women reported that they felt that the estimate of two hours before expulsion would occur was not justified. There were strong concerns that expulsion might commence on the journey home.

Location is also important in respect of transportation. Forty percent of women were accompanied to the site for the second treatment, ranging from 24 percent at St Mary's to just over half at comparator site 3; neither age nor deprivation was associated with this. Data are not available on what proportion of the accompanied women had transport provided by partners and/or friends, but it seems reasonable to assume that being accompanied (especially for those who return home straight after the second treatment) reduces feelings of uncertainty and concern.

6.2 Physical environment

Generally, the physical environments in which procedures took place were rated positively in terms of comfort and privacy, although not very frequently as *excellent*. Whereas many women appeared to appreciate the more relaxed atmosphere that a non-clinical setting provided, there were some reservations regarding a lack of places to lie down in some sites, insufficient sofas, and so on. Indeed, even in the control sites, the fact that the settings were reserved exclusively for EMAs (by using weekends) meant that normal ward routines were not encountered.

Many women did specifically comment that they appreciated being separated from other women undergoing other obstetric or gynaecological procedures. At one pilot site where other visitors could share toilets and pass through the waiting area, staff were adamant that this was not ideal and caused some women some discomfort.

Lack of toilets was mentioned frequently as a matter of concern. Given the unpredictable nature and uncertainties of the processes involved, ready access to toilets and washing facilities as and when required was highly valued.

No problems were expressed in any of the material regarding other basic infrastructural features, such as clean water, reliable power supply, ventilation or storage space.

6.3 Supplies and equipment

No major problems were mentioned in relation to the availability of the medications and equipment required. Ultrasound scanners were available at assessment and follow up centres, although the physical distance from this to other services was mentioned as a drawback in one of the comparator sites. One of the pilot sites had purchased its own USS equipment and had trained a nurse to use it. Emergency equipment was available, although it must be borne in mind that the two pilot sites were in close proximity to hospitals. However, the need for emergency equipment was minimal, and many staff felt that routine services (for example, the ambulance service and accident and emergency departments) were sufficient to deal with any unexpected events.

6.4 Staffing infrastructure and training

Staffing issues were regarded by all concerned as being crucial in running an effective and acceptable EMA service. In the sites studied in this project, ratings by clients of staff were generally highly positive, with mean scores falling between *excellent* and *very good* in all sites (with the exception of one that was very close on one specific dimension) and many highly complimentary comments being made in the qualitative sections of the questionnaires and in the interviews. Many of these comments related to the professionalism of the nursing staff, their sensitivity to the issues involved, their reassuring nature, and their warmth.

Indeed, one of the clearest conclusions from the study is the crucial importance of the staff involved in the actual treatment administration. Although of course some clinical skills are crucial as well, the relative absence of clinical complications together with the importance of clear descriptions of what will be happening and the need for reassurance after the drug administration, high quality communication skills are central to the whole procedure. Indeed, as some of the staff who were interviewed reported, beyond a basic level of clinical expertise and the physical infrastructure, there is a strong argument for defining 'class of place' in terms of staff competence and attitudes as opposed to purely physical features.

There was a dilemma in one pilot site regarding staff training. Given the uncertainty surrounding future funding of the facility, the extent to which investment was made in further training was restricted. One nurse had become trained in the use of ultrasound scanning equipment, but the facility could only be used when she was on duty. Given a higher capacity at the facility, then stronger arguments could be made for more extensive training across a wider range of skills and staff.

The uncertain future of the site also affected staff recruitment at this particular site. Other sites mentioned difficulties related to finding sufficient staff who were prepared to be involved in abortion, although there was a view that EMA was less likely to be a barrier than other forms of abortion. Additionally, there was an oft-expressed view that, because the procedure can be

effectively nurse-led, then the seemingly increasing problem of recruiting doctors to work in abortion services poses less of a challenge.

All staff interviewed seemed to be fully aware of the issues surrounding abortion, some of the wider implications and contexts, the legal discussions, and so on. Of course, the staff interviewed were all working in the service (presumably through choice), and so extrapolation cannot be made with regards to other staff who may be brought into the area through expansion of posts and duties (as may happen in greater use of non-traditional settings).

6.5 Staff perceptions and support for improving services

Within the caveat expressed above, there was strong support for expansion of EMA provision across a wider range of outlets, a view that the procedure was more acceptable to a wider range of women, that it avoided the need for more specialist staff such as anaesthetists, and other issues.

Some opinions were expressed that making EMA more readily available might encourage some women to be less careful about using contraception. No empirical support was found for this view in the current project, nor indeed in the wider literature.

6.6 Local stakeholder perceptions and support

In each of the NHS sites, the expansion of the EMA services was led by a committed and enthusiastic person – either a doctor or a member of the PCT – who argued the case and took on a lot of the work to develop the service. Various arguments appear to have been used to support the developments, not least amongst them being an economic argument. Although the detailed financial implications were beyond the scope of this project, there was a view amongst many staff that EMA services save on anaesthetic and theatre time costs, can enable a higher throughput of clients, can be basically nurse led, avoid the need to rely as much on independent sector providers when capacity is reached, etc. and that these features are attractive to commissioners.

Other than these aspects, gaining the views of local commissioners was problematic. In many cases, staff simply did not know who to contact regarding the commissioning process, and recent changes to boundaries and merging of some of the trusts did not assist this endeavour. One of the pilot sites experienced some opposition in the early days from pro-life campaigners (including GPs), but this seemed to have been short-lived and did not appear to cause serious concerns.

6.7 Clinical procedures

Although detailed discussion of clinical procedures is beyond the scope of this project, sites appeared to vary somewhat in the extent to which they were following the Royal College

of Obstetricians and Gynaecologists and Department of Health guidelines regarding blood testing, scanning, drug dosage, the use of prophylactic antibiotics, and contraceptive advice. Counselling provision was less clearly covered in all cases, although this was not identified as a problem in client questionnaires or interviews. The attached protocols provide detailed examples of a wide range of issues to be covered in developing suitable protocols, and appear to deal well with various eventualities.

6.8 Record keeping

Systems for keeping records and integrating these across clinical specialities were varied, and there seemed to be room for improvement in some aspects. For example, contraceptive discussions were included, but little apparent effort to follow through whether advice was followed. The opportunity provided by contact during the abortion process may not be being realised as fully as it might. In developing a protocol for the expansion of EMA services into a wider range of settings, thought could profitably be given to developing a standard system for case notes, preferably using electronic opportunities (subject of course to issues of confidentiality – for example, in cases where women did not want their GPs to know of the procedure).

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Appendices

Appendix 1 – Summary of Chalfont and Gerrards Cross Hospital (pilot site one)

Interviews were conducted with six key staff involved in the EMA service at Chalfont and Gerrards Cross Hospital, now part of the Buckinghamshire PCT (since 1 October 2006 – previously comprised three PCTs: Vale of Aylesbury, Chiltern and South Bucks, and Wycombe), and various papers were consulted.

Brief historical development and current capacity

Historically, much of the abortion service in the various primary care groups (PCGs) and PCTs has been commissioned out to the independent sector. Due to the distances involved in accessing the independent sector sites, and the time involved in gaining referrals and arranging suitable appointments, few women had the opportunity to choose EMAs. One (at the time) lay member of the Chiltern and South Bucks PCG had heard that consideration was being given to establishing pilot sites for non-traditional settings for EMA. In the light of increasing concern in South Bucks regarding the relatively low number of NHS funded terminations carried out in the area, preliminary discussions were held between the DH and the local PCG; some key senior managers at the time were very interested in the idea.

Initially, the local plan had been to establish a few primary care settings but this was ruled out for mainly legal reasons. After a lull, the DH came back with an offer of financial support and the PCG considered various options. Amongst the facilities available (under the PCT's responsibility) were two community hospitals – one at Amersham and one at Chalfont and Gerrards Cross Hospital. The family planning consultant at Aylesbury was already operating an EMA service which covered the north of the county, but this ceased upon her retirement. Although other sites may have been preferable (in terms of geographic coverage), it was decided to start off the pilot in Chalfont and Gerrards Cross Hospital.

During the early days, the PCG structure changed to three PCTs and then eventually to one PCT covering the whole area. Despite various changes of senior management, support was maintained and, apart from a few very vocal opponents, the majority of GP practices in the local area were very supportive of the establishment of the new facility.

During the establishment of the new facility, some of those involved visited other sites – including St Mary's Hospital – to see how the service was being delivered elsewhere. It was stressed during the interviews that they did not regard this development as delivering a new technique, just the same technique but in a new environment; with a need to adapt the service from a hospital setting to a community setting (even though the facility is actually on a hospital site).

Apparently, the initial setting up of the facility in the community hospital met with some resistance from existing staff; there were some objections to the idea of shared use of the staff toilets, as well as fears about possible 'action' from local pro-life organisations.

The clinic currently has the capacity to undertake four EMAs per week, although some weeks it does not meet this capacity due to staffing limitations.

Commissioning process

Being a pilot site, the DH is invoiced directly on an annual basis for the costs of running the service. Amongst the interviewees, there was some uncertainty as to how closely and how frequently the local commissioning arrangements were considered; there was a perception that the frequent changes in structures and personnel has led to a somewhat passive continuation of previous practices.

The finances are made more complex by the additional allocation of direct money from the DH, For example, the additional training needed to provide nurses with ultrasound scanning skills – thereby obviating the need for women to travel to a different site in between referral and the procedure – was paid from the direct DH funding.

It appears that, generally, a higher proportion of abortion services across the area are being commissioned from an independent provider, with the PCT delaying a decision on this pilot site until this current evaluation has been carried out. It was pointed out, however, that the additional travel and logistics of having greater proportions of abortions commissioned out to the independent sector may have led to a smaller proportion being carried out as early medical procedures.

Accessing early medical abortions

Referral and initial contacts

The women are referred by their GP or local FPC to the Family Planning Clinic located at Chalfont and Gerrards Cross Hospital; occasionally, women are referred from GUM or from outside the PCT area coverage. The service provides a dedicated telephone number for referral purposes which is staffed by one of the FPC nurses. Occasionally women may self refer; usually as a result of word of mouth about the service.

Assessment

Here they are seen by a nurse who will explain the EMA procedure to them. If the woman chooses to proceed with the EMA she has an ultrasound scan to confirm she is fewer than 10 weeks' pregnant and routine blood samples are taken. This being so she is then given another appointment for the following Wednesday; and told that she can bring someone with her if she wishes.

Obtaining two signatures is not reported to be a particular problem. When GP calls to book a client in, the receptionist asks them to provide one (or a colleague if they are not willing to). In a small number of cases, women arrive without a signature and two of the family planning doctors are then required to sign the forms.

Stage One – administration of mifepristone

At the Wednesday appointment, women see a doctor to go through some aspects of medical histories, discuss contraception, go through the procedure again, asked if they were feeling nauseous at that time (since the drug may not work effectively if they are), and offered the chance to change their minds. After signing the consent form, they are given the first dose of treatment. They are asked to wait for at least half an hour to ensure that all is well, and then allowed to go home.

The woman will also be given an appointment to return two days later (Friday) during which time the clinic area is reserved purely for women undergoing EMAs. The women will be advised that at this appointment she will need to spend several hours in the clinic.

Stage Two – administration of misoprostol

Women arrive at 9 am. The doctor is not present on Fridays, but available by phone if needs be. Pessaries are provided by the nursing staff for either self administration or nurse administration. A Chlamydia screen is also taken at this time unless the woman refuses. Private and communal rooms are available for resting, watching TV, making coffee or tea, reading magazines, etc. Hot water bottles, analgesia and anti-emetics are all available.

However, the space used is not restricted to the EMA service. There are walk in clinics operating on the site on the same day, so other hospital users walk through and use the toilets. Although screens are put in place, there is not such a sense of privacy as would be found in a more dedicated space. There are no shower or washing facilities which is considered unhelpful.

Women remain in the facility for between two and six hours, after which most have expelled the products. The 'very few' who have not done so by then are sent home.

Discharge

Once the woman has passed the products of conception and her bleeding is satisfactory she may leave. She will be given analgesia and the dedicated telephone number which is available 08:00 – 18:00 Monday to Friday, as well as the out of hours service number. They are told not to drive or take the bus.

Follow up

Follow up takes place two weeks later, again in the clinic. Women who fail to attend their follow up are reminded by telephone and, if they still fail to attend, their GP is informed. Counselling is not available through the unit, although some women do call back for a chat with one of the staff if desired.

Perceived quality of service

Strengths

The major strengths identified referred to the local access, the dedicated staff and the relaxed environment in which the procedures are carried out. The co-location with family planning services was seen as a strength in that a dedicated abortion service may be seen to be stigmatising for some women.

However, despite these perceived strengths, there was a general view that the potential strengths of the service are not being currently exploited to the full.

Shortcomings

At present the clinic is under staffed (due to recruitment difficulties) which is resulting in some women requesting EMA being turned away. Two main reasons were provided for the current staff problems, First, there are restrictions on new recruitment due to general PCT financial challenges.

Second, and more directly pertinent to this pilot evaluation, it was pointed out that the uncertainty regarding the future of the service (due to time-limited funding) has meant that getting trained to work in the facility has not appeared to be an attractive option for some potential staff.

The physical facilities are not regarded as being ideal, for the reasons mentioned earlier; a lack of privacy and insufficient toilets to cater for the demand when the maximum numbers of clients are in attendance.

The location of the site is again not regarded as being ideal. The site is poorly served by public transport; this raises concerns since women are not permitted to drive home after their second visit. This is a particular challenge for women who do not have a friend or partner who can accompany them, and/or who wish to conceal the fact that they had had a termination.

A further issue that was raised in a number of the interviews relates to economies of scale. In its present form, the service may seem to be expensive for what is provided. The equipment needs and the requirement for trained staff to operate this, together with the difficulties in attracting and retaining staff to a limited service with an uncertain future, is regarded as wasteful in many ways. Greater capacity would enable a larger pool of staff, higher use of equipment, and a generally more efficient service operating with a lower unit cost.

Finally, aftercare was felt to be a problem. Initially, a consultant was required to be on call at all hours, even though no calls were ever received for emergencies. Efforts were made to secure the services of an independent provider 24 hour support line, but these discussions did not bear fruit. At present, emergency out-of-hours callers are redirected to a national support service, although there are suspicions that the staff operating the phones are not adequately trained in abortion issues, may have objections, and too easily simply refer on to accident and emergency departments.

Staffing

As mentioned above, attracting and recruiting staff is causing some challenges at the present moment. The current staff feel stretched to capacity and are aware that they could deliver a lot more given more support, a larger pool and better physical facilities. When all the current complement of staff are on duty then they can manage adequately, but any absenteeism due to illness and vacations causes problems. They could certainly not expand the service with current staffing levels; indeed, it was pointed out that the current service relies on the goodwill of the staff being prepared to work late on frequent occasions.

When the facility opened, the initial nurse carried two phones – one for taking calls from GPs, and the other to take calls from patients in distress. Both were on 24 hours a day, even though her salary did not appear to cover this service. When she left the post to relocate with her partner, the staff who took over, not surprisingly, did not wish to continue this arrangement. Currently, the phone for booking is kept open, although cannot be answered when the staff member is busy with client, but the other phone (for clients) is switched through to an out of hours cover service. This was partly a pragmatic decision, but also was felt to be justified by the very small number of calls received. This has caused some dissatisfaction to be expressed by local GPs who, having got used to the original standard of accessibility, now feel it has degenerated. Staff expressed concern that this may have impacted upon referral rates.

At a more general level, comment was made about the need to attract more family planning trained nurses into the profession, and to train more of these in EMA procedures. There was a view expressed that the workforce 'is quite old', and that these areas are not seen as providing a route into a career.

Improvements

As covered above, the main improvements mentioned involved better suited space with more toilet facilities and greater privacy, a more accessible location, greater staffing complement to enable more flexibility, more sessions available during the week, and removal of the uncertainty about future funding so as to attract more suitable staff and to justify expenditure on additional training.

In terms of actual procedures, there is a preference for allowing women to go home if they wish to do so after the second drug. However, since this is a DH pilot, the unit was told to keep them in until the products had been passed. Over the time of the unit's operation, a very small number of women have gone home, but have kept in regular touch with the staff by phone throughout the time. Some women express a strong preference for stating in so as to receive support as and when needed. One interviewee estimated that, given a free choice, around half would opt to return home.

There was also a view that a dedicated phone line would be an improvement, both for GPs and for women to self-refer.

Other considerations

Class of place issues

There were very mixed views regarding what sort of site would be suitable. One interviewee felt strongly that more GPs should offer the service, whereas others felt that this would not be appropriate, especially for younger women ('young people and GP surgeries just don't go together') who may be concerned about being recognised. Further, since some women undergoing the procedure make a fair amount of noise due to pain and cramping, it was felt that this would not be popular in GP surgeries. Further, the degree of time needed to go through all the different issues involved – including giving time for the women to decide – was not felt to be conducive to the typical GP surgery.

Community-based clinics (including FPC, sexual health clinics, centres with multiple GP practices and cottage hospitals) were felt to be appropriate sites, as long as they met the basic requirements.

All interviewees, based on their experiences of developing this pilot, agreed that lack of direct access to acute services was not a barrier. Whereas early on in the development there was a view that a cautious approach was preferred, all felt much more confident now about expanding community-based services. The very rare occasions on which real emergencies do occur could be dealt with as is any other emergency – by calling an ambulance and getting the woman to accident and emergency departments or by using an out-of-hours GP service.

Home administration of second drug regime

This was not covered in these interviews.

Legal review

The majority view was that the scope of a 'class of place' should be widened, and that there was no longer any need for two doctors to sign the forms. Since a signature is required for prescription of medication in any event, it was felt that this should be sufficient. All agreed that greater efforts should be made to encourage women to attend for abortions earlier where this is possible.

Local survey

Questionnaires from a small scale survey carried out by the family planning clinic during 2006-07 were made available to the research team conducting out this project. The items on the survey and the responses obtained are shown below. (The project staff cannot, of course, endorse the quality of this small-scale study but we certainly have no grounds whatsoever for doubting its integrity.)

1 How would you judge the care you have had from the staff here?
- 57 *excellent*
- 2 *good*
- 0 *satisfactory*
- 0 *unsatisfactory*

2 Were you given enough time to discuss any questions you had?
- 59 *yes*
- 0 *no*

3 Did you feel that you had enough information to be as well prepared as possible for the termination?
- 55 *yes*
- 3 *no*
- 1 *did not respond*

4 How important do you think it is to have a 24 hour helpline?
- 37 essential
- 20 important
- 2 don't know
- 0 not necessary

5 If one of your friends needed a termination would you recommend
- 58 were referred to this clinic
- 0 were referred to another service
- 1 had a surgical termination

Additionally, a number of comments were written on the questionnaires or in cards sent to the clinic staff:

- All staff were very friendly and helpful. Couldn't have done it without the support and help they gave.
- We were very impressed with the nurse led service and the efficiency with which USS and the clinical management were done. It is crucial to have an experienced person as there is no onsite emergency back-up.
- Although I would have liked to know more about the side effects of the hormone drugs used. It would be a good idea to give the drug information leaflet to the patient to take away.
- I was very well taken care of and felt comfortable in surroundings and comfortable with the staff. Staff were very helpful and friendly and offered plenty of practical advice. Coming to the clinic was much less daunting that going to a hospital.
- XXX and the staff made me feel welcome, relaxed and also important. They didn't make me feel any different (very caring).
- The whole experience was made a lot better by coming to the Chalfont and Gerrards Cross. Friendly kind individuals with time to discuss all aspects of the treatment.

- Every member of staff at the clinic was very helpful and kind. I never felt rushed or that my questions were silly. The care I received made the situation I was in so much more bearable – and every bit of attention I needed was given without a fuss and with a big smile, A big thank-you to everyone at the clinic.
- I received excellent care from staff. Staff are very friendly and kind and dedicated themselves. Thanks for everything.
- All the staff were extremely kind and caring and made what is a very traumatic experience much easier.
- Appointment system does not seem to run smoothly. Lots of time in between seeing people and getting various medical bits done. Not told to expect to be at clinic for a time except for actual termination day. This makes an otherwise exceptional service miss out on excellence. Very difficult when trying to fit in appointments around a job and young family. Might help reassure patients they have not been forgotten if someone explained at intervals the delay and expected time before they were going to be seen.
- The service that I received was exceptional! For an awkward and difficult experience I felt comfortable and at ease, This was due to the staff. Thank you.
- The staff were all extremely kind and sensitive and this made the process easier.
- Excellent service. Staff were very supportive and kind. Thank you for your excellent care.
- There was plenty of information given, but my miscarriage came out as one pregnancy sac and I wasn't warned of this which made the situation more traumatic. So girls are needed to be warned of this situation.
- I found the staff made the experience as comfortable as it could have been. I had absolute confidence in each of them.
- I did some research on some American medical websites regarding the drugs given. One thing they mentioned which was not in the notes was not to drink grapefruit juice. This may be important to you.
- Thank you very much for your help, support and kindness (card).
- Dear XXX and XXX, I just wanted to say thank you for everything, you both really looked after me through a hard time and great support (card).
- Dear XXX, Just a short note to thank you and your team for the care and concern you showed me last week. You are lovely people (note).
- (drawing entitled *An Angel to Look After the Girls at Family Planning*) To all the staff. Thank you very much for all your help and support. Terminating this pregnancy was a very hard decision to make but you have made it all so much easier for me. Thank you. PS Sorry it's in pen and lined paper. I didn't bring much else. Oh, yes, and sorry for smoking on the premises (lined paper).

Appendix 2 – Summary of Comparator Site 1

Interviews were conducted with six key staff involved in the EMA service at comparator site 1.

Brief historical development and current capacity

Terminations (the preferred term amongst the interviewees) are provided as part of the Gynaecological service. The EMA service started around five years ago. A previous dedicated termination clinic was closed around two years ago and a higher proportion of the surgical work (as well as EMA when capacity is reached) is now commissioned from the independent sector. The reasons for this closure were primarily lack of funding, difficulties in recruiting staff willing to work in termination services and, allegedly, a desire to use the facilities to develop a regional cancer centre. There was agreement amongst staff that this was not ideal, both in terms of their not being able to provide a full service, as well as the impact on women who need to travel further to obtain a termination. Although the proportions of terminations that are EMAs has increased, the actual number has reduced as a result of this more limited capacity, and the current throughput is around four per week.

Commissioning process

The acute Trust is commissioned by the PCT to provide the termination service for the county and, in turn, commissions some of the work from the independent sector. This was felt, in theory, to be a good model in the sense that the Trust is more likely to have the clinical expertise to enable adequate monitoring of the externally-commissioned provision; in practice, however, some problems are being experienced with clinical governance aspects of the independent sector provision. Until fairly recently, some provision was also commissioned from another independent sector provider, but this was stopped when a DH inspector advised against using two different providers in grounds of expense. It was felt that more could be carried out by the Trust if and when more space becomes available and that this would be beneficial in shortening delays caused by the three-week referral process for the chosen independent sector provision.

Accessing early medical abortions

Referral and initial contacts

Referrals are made from GPs (the majority) or the family planning clinic; there is no system of self-referrals. Occasionally, clients are referred by school nurses or sexual health workers in colleges and universities or the GUM clinic. All NHS clients are referred to the service even if they are then referred on to the independent sector. There was a general view that access

through the family planning clinic was generally faster since there may difficulties in getting appointments with some GPs, and some GPs can delay the process.

Assessment

All clients are seen in the hospital outpatient clinic by a consultant or registrar and a scan is conducted (either on the same visit or a day or two before the clinic appointment) and a history taken. These clinics are not dedicated termination sessions, but occur as 'slots' within general gynaecological sessions as long as the consultant on duty is prepared to discuss termination as an option; at present, there are just two clinics per week, one each on a Tuesday and Wednesday. If termination is the preferred option of the woman, then she is sent down to the gynaecology ward for more detailed discussions with the nursing staff regarding options and procedures, and a decision is reached in the light of both client preference and capacity. Then extensive information is provided as to when to attend, what to bring with them, what to expect, and so on. No dedicated counsellor is available (at the time of writing), although nurses are felt to be equipped to carry out this function; a specialist counsellor was expected to be appointed late in 2007. There is a counsellor available in the hospital who can be called if it is deemed to be necessary.

Stage One – administration of mifepristone

There is a care plan specifically for Early Medical Termination of Pregnancies (EMTOPS). Although detailed information will have been provided in the clinic as to what to expect, what clothes to bring in with them, and so on, the staff on the ward repeat it all in case some of the information has not been explained too well, or has not been taken in fully. In some cases, the initial treatment can be taken on the same day as the clinic visit, although this depends on capacity available. There is a preference amongst staff to move the process towards the end of the week since there tends to be more available space at weekends – and some women find it easier to arrange suitable child care at weekends if necessary. During this initial visit, efforts are made to introduce the women to the staff on the ward who will be supporting them through the process in order to try to reduce any anxieties that may be felt.

Prior to the administration of the first treatment, more specific details are provided regarding the likelihood of pain, that different types of pain relief will be readily available as required, that suitable sanitary towels will be readily available, etc. The aim is to ensure that there is as little as possible for the woman to worry about, to anticipate and reduce possible feelings of embarrassment, guilt, or awkwardness. It is made very clear that there is no 'turning back' once the initial drug has been administered.

The mifepristone is administered and women are asked to wait in the ward for about 30 minutes in case they experience nausea, diarrhoea, bleeding, or other reactions. They are then sent home with details of a 24 hour phone line and encouraged to call if they have any concerns whatsoever. Should they pass products of conception during this time (that is, prior to the administration of the second drug) then they are encouraged to bring these products with them so that they can be inspected; this was described as having occurred 'occasionally'. If the products are not seen by the staff, then a further scan is required after ten days to ascertain whether the termination is complete.

Stage Two – administration of misoprostol

Two days later, the women return to the ward, normally around 9.30 in the morning. They are encouraged to bring in a change of clothes, something to keep them entertained, money for the television, and a friend or partner if they wish. Children are not encouraged.

They are, if possible, put in their own side room with its own bathroom. After baseline observations, they have the tablets inserted vaginally by the nurse or, if they prefer, they can insert them themselves after instructions. They are then asked to lie down for two hours or so to prevent the risk of reduced efficacy. After this time, they are free to wander around, go to the restaurant, sit on the outside patio, or what they wish, although it is preferred that they only leave the ward if they have someone else with them. They are told that they can eat and drink as normal.

The vast majority of women will have aborted by mid-afternoon (around six hours after administration of the drug). A bed pan is used to collect all expelled products so they can be inspected. If they have not done so by around 5 pm, they are sent home and advised as to what to expect when the products are eventually expelled. If nothing is passed (or at least if the woman believes that nothing has passed) then they are brought back in for an ultrasound scan after ten days. A small number of women self-discharge after taking the second drug; in these cases, the woman's GP is informed, as they are in the very small number of cases where a woman does not return for the administration of the second drug (although, in this latter case, efforts are made to contact the woman direct by the staff if at all possible within the constraints of confidentiality).

If there were to be any problems during this stage, the consultant team is available and the on-call registrar would be called.

Discharge

Prior to discharge, women are provided with information to what to expect in terms of bleeding and pain, what any signs of infection would be, what sorts of sanitary protection to use, when to resume sexual activity, etc. Although, as one staff interviewee put it, 'some women say they will never have sex again', the staff try to engender an open and more realistic environment for these discussions.

Until the closure (around two years ago) of the family planning clinic that had been associated with the termination clinic, detailed advice on contraception was routinely provided. Now it is described as being covered 'very briefly'.

Follow up

No routine follow up is provided by the service, although women are given a leaflet upon discharge and encouraged to contact the ward if they have remaining queries or concerns. Clients are encouraged to visit their own GP for a check up after two weeks to check that 'everything is ok', although there does not seem to be any system in place to check that this advice has been followed.

Post procedure counselling is not routinely available. Previously, there had been a full time hospital chaplain who had a special interest in miscarriage and abortion, and who apparently developed an 'excellent' service. After she left, she was replaced by a part-time chaplain; it is too early as yet to be sure how this service will develop. However, it was pointed out by some staff that this may not be appropriate for women who are not religious.

Perceived quality of service

Strengths

There was a strong feeling that the physical facilities are good, being part of a modern gynaecological ward that was built 'with women's health in mind, so it's got the privacy and dignity part of it'. Being a relatively small hospital, there are three side rooms with toilet facilities which is suitable for the (normally) four women who are admitted at weekends for the procedure. The women are not then required to be 'in the middle of a ward where there are lots of people running up and down'.

Supplies and equipment are regarded as not being a problem since the unit is in an acute hospital setting.

There was a general view that the service was excellent, based on professional judgement and reported frequent positive feedback from clients.

Shortcomings

Although the physical facilities were generally described as being 'excellent', there was a general view that more could be done if more facilities were available. Comment was made by some of those interviewed that it seemed a poor use of resources and expertise to have to send women out to an independent provider when there were such good facilities available more locally. The restrictions primarily occur due to only being able to offer the EMA service at weekends due to capacity limitations and the general competition for beds given that terminations are not a "target". This situation is further exacerbated by a lack of staff willing to participate in the field.

Further, although the space and privacy aspects were felt to be good, there was a view that a more informal environment would be desirable. At present, women sit or lie on a surgical trolley in their separate rooms, with a chair beside them for their friend or partner; a less clinical atmosphere would be welcomed.

All those interviewed felt that a dedicated and integrated termination and family planning service (as they had before) was much preferred.

Some comment was also made about aspects of the physical layout of the hospital, whereby it would be preferable to have all services closer together. At present, the outpatients clinic is 'at one end of the hospital, scanning is in maternity, and we are way down here'. Ideally, all services would be in an emergency Gynaecology clinic to avoid the need for women to have 'a scan in the obstetrics unit when they are not actually going to continue with the pregnancy'.

Staffing

There were some misgivings regarding the numbers of staff available on the ward, with some recent reductions in numbers and uncertainties regarding future provision. Although those staff in post were described as being excellent and experienced, there was felt to be insufficient permanent capacity. Bank staff were relied upon, although some of these were by now very experienced and sensitive to the issues involved.

There was also a view that there were insufficient gynaecological nursing trained staff in the outpatients clinic.

There have been difficulties with gynaecology staff, both medical and nursing, who have refused on ethical grounds, to participate in the care of women undergoing terminations. This was identified as being an increasingly incurring issue and was partly attributed to the rise of multicultural nature of the UK workforce.

Improvements

Amongst the main areas in which improvements were felt to be needed were

- greater capacity to deal with more clients during the week;
- closer proximity of the facilities required;
- a dedicated member of staff who could coordinate the whole process from start to finish, provide counselling as required, and so on;
- a dedicated termination service, possibly/preferably linked with family planning services;
- greater access through midwifery, on the grounds that they are better able to provide information and support than many GPs; and
- a much clearer patient pathway which is made available to a wider range of people through schools, family planning clinics, SH clinics etc.

Other considerations

Class of place issues

There were very mixed views regarding expanding the range of places in which EMAs could be carried out. Some were very positive in the light of the safety of the procedure, the greater informality that could be achieved, and the opportunity to have specialised units with dedicated and highly trained staff.

On the other hand, some reservations were expressed, primarily in terms of monitoring of standards and possible emergencies. One interviewee, who has been closely involved in issues regarding the performance of subcontracted work to an independent provider, commented 'if you multiply [those problems] hundred times, that's difficult'. She felt that a few sites would be preferable so that adequate 'counselling and support that needs to be in the communities' could be assured. There were also concerns about confidentiality in cases where facilities were close by to the area in which the women lived.

Although some expressed reservations regarding what might happen in the case of emergencies, they equally acknowledged that emergencies are, in their experience, very rare. One commented that, in her three years of work in the current unit, there had only been two occasions on which a doctor had to be called due to heavy bleeding. Another remarked that the situation (and level of risk) would be no different from a situation of spontaneous miscarriage, in which emergency services would summonsed.

Some reservations were also expressed about the 'type' of woman for whom a community-based service might be suitable. Younger women were mentioned as a group that may possibly need more specialised monitoring and support, as well as back up and reassurance.

Further concern was expressed about the lack of anonymity provided to clients and staff should terminations be carried out in a small community based unit where the service is less easily absorbed into the other aspects of a larger service. This was felt to be of particular concern should the service come to attention of pro life campaigners.

Home administration of second drug regime

There were reservations regarding a possible lack of monitoring and reassurance, as well as the fact that some women do not want people in their home knowing what they are going through. As one respondent put it, 'I think yes, theoretically, it's a nice idea. I think there are lots of practical issues that argue in favour of this being provided in the community'.

At the time of interviewing plans were being put in place to enable some women to go home after the administration of the misoprostol (second stage of treatment). The criteria these women will need to meet are:

- 7 weeks or less gestation;
- must live within a defined geographical area;
- be of a defined age group;
- be medically uncomplicated;
- have transport;
- be willing to carry out her treatment in this way.

Legal review

The majority view was that no change is required to time limits, although one favoured a reduction in the upper limit 'for social reasons' (although it should perhaps be noted that the site does not carry our any procedures beyond 16 weeks' gestation). One respondent saw no good reason why the two signature rule should not be relaxed (although it may be seen as being reassuring for women) and felt that nurse practitioners could play a larger role at this stage 'as long as they were informed about some of the more unusual and rare indications'.

Appendix 3 – Summary of St Mary's Hospital (Pilot Site Two)

Interviews were conducted with four key staff involved in the St Mary's Hospital service, which is part of the Imperial College Healthcare NHS Trust (as of 1 October 2007 – this was formed with the merging of Hammersmith NHS Trust and St Mary's Hospital NHS Trust and the integration of Imperial College London).

Brief historical development and current capacity

Early medical abortion has been offered at St Mary's Hospital since around 2000. Initially, women went to the Raymede Clinic for assessment and referral to the day care ward at St Mary's Hospital, where they received the treatments.

Early in 2005, a new unit was opened specifically dedicated to early medical abortions. This is the Paintin Unit, close by the St Mary's Hospital site (around ten minutes' walk from the main site). This Unit was established as a pilot site for 'non-traditional' provision; that is, not located in a traditional gynaecological ward in a mainstream hospital.

At present, the Unit performs around 550 early medical abortions per year. The increase in capacity has led to many fewer complaints about waiting times.

Commissioning process

The hospital has a long history of abortion services and there has been a fairly fixed provision; no woman has ever needed to be turned down, and the costs are very predictable.

Accessing early medical abortions

Referral and initial contacts

Women are referred to the Raymede Clinic by GPs and FP clinics in Westminster and Kensington and Chelsea and surrounding areas (this covers a large geographical area). They are booked in for appointments by the coordinator, told that the initial assessment will take two hours or so, given information leaflets and details of the counselling service if required. The Raymede Clinic is a dedicated contraceptive and sexual health service close by the St Charles' Hospital site in Exmoor Street. There is no self-referral since it was felt that women would not then get the chance to discuss their options fully.

It was commented by some of the staff that some local GPs are unhelpful in referrals, simply saying that they do not support abortion. In some cases, GP surgery receptionists apparently

turn women away without information on where else they can go, so some delays are experienced here. Further, some GPs apparently provide incorrect information.

Assessment

When they attend for their appointment they are seen again by a coordinator, who does the basic paperwork. They are then seen by the nurse who takes blood samples and takes a medical history. They then see a doctor who examines them, performs a scan, discusses what they want do and the methods available and details of what each procedure involves. The women can also can see a counsellor if they wish; they are actively encouraged to if they seem at all uncertain as to what they want to do. Where the woman opts for EMA she is booked in for treatment. Additionally, all women under 24 years are offered a Chlamydia test.

Stage One – administration of mifepristone

Both drugs are administered at a dedicated unit, the Paintin Unit, about 10 minutes' walk from the main building of St Mary's Hospital at Paddington. This unit is used throughout the week, and only for EMA. It is light and airy, and comprises a large room with settees and a TV, for three or four women at a time, with three toilets off to one side. There is a small kitchen for women to use and an office for the nurse who runs the Unit. Women can bring a friend or relative, but space is limited so they cannot wait with the women throughout the process. Since the unit works through the week, women may attend for mifepristone on the same day as their consultation at Raymede but otherwise they will be booked in for the earliest appointments possible.

The various risks and likely experiences are repeated prior to the administration of the drug to ensure that all women understand what is likely to occur; this was felt to be especially important for those whose first language is not English.

Half an hour after the administration of the drug, women are allowed to go home.

Stage Two – administration of misoprostol

When women arrive for the second treatment, they have their blood pressure checked and asked if they have experienced any symptoms since the previous visit. An explanation is then provided of what will happen next and what to expect, how long events may take to happen, and so on.

Women are encouraged to stay, but are able to go home at this stage if they choose to do so; in these cases, they are given the Unit's phone number. Partners and friends are not permitted in the communal room; this was felt to be preferable by staff since it could make some women feel uncomfortable.

Discharge

All women are given the clinic telephone number when they leave.

Follow up

All women are asked to return in two weeks' time for a check. Follow-up takes place at the Raymede clinic; strenuous efforts have been made to increase the proportions of women who do return for follow-up, and the proportion is now described as being 'most' of them. Those who do so see the doctor again are asked about what has happened, and any complications – usually retained products of conception – are dealt with. Failed procedures are very rare.

It is estimated that one in ten has 'significant problems' and so might need counselling; this, in the view of one of the doctors, is a combination of factors, including the physical procedure itself, coming to terms with the decision, personal issues (such as a relationship problems), etc.

Perceived quality of service

Strengths

There was a general view that having a dedicated environment that is pleasant and non-clinical is very much appreciated by clients.

Advantages were also seen with having the Raymede Clinic some distance from the hospital site; two main advantages mentioned were that since the clinic is multi-purpose, it is not clear why women are going there and so is more confidential than if it were a dedicated abortion clinic. Second, since many local residents know people who work in the hospital, having both the clinic and the unit off site is seen as positive for similar reasons of confidentiality.

Similarly, being housed in separate premises means that women do not see ill patients on a ward, and do not need to enter a building with 'abortion' mentioned on signposts.

Shortcomings

The only possible shortcoming mentioned related to the physical distance between the Raymede Clinic and the Paintin Unit. It was felt that integrating these would make the process easier for women and would save time and avoid possible delays.

Further, it could make the duties of the nurses more varied – it was mentioned by some that working full-time administering EMAs was not particularly stimulating. Linked to this, having only one member of staff in the unit can lead to logistical problems during illness and/or holidays.

Staffing

There was a general view that it was getting harder to recruit staff who felt comfortable being involved in abortions, and these areas were specifically raised in interviews so as to be clear that job applicants know what to expect.

Improvements

The only issue raised related to the issue of combining the two sites into one, with perceived advantages for women clients as well as staff.

Other considerations

Class of place issues

Being one of the DH pilot sites, all those interviewed here were very positive about expanding the possible environments in which EMA could be carried out. It was stressed that the equipment needs are minimal – an examination room, a communal room with comfortable chairs and a nice environment, sufficient toilets, tea and coffee making facilities, somewhere for clients to lie down if they wanted, access to emergency services if required (although it was stressed that this is needed very rarely).

The quality of the staff was also stressed, with a general view that well-trained, experienced and non-judgemental nurses were essential. Healthcare assistants may be useful as support staff, but should not replace nursing staff.

Home administration of second drug regime

There were mixed views on this; one interviewee would prefer a complete home service to the current practice of giving the second drug in a clinic and then sending women home on a bus. On the other hand, others felt that there could be problems of people losing the drug, not wanting to have others know about the abortion, and that some women would find it difficult to administer the drug correctly.

Generally, it was agreed that this should be an option, but only for women who are assessed as being suitable and well-informed, and who could be guaranteed to attend for a follow-up check.

Legal review

Not covered in detail, but there was general support for expanding the definition of a class of place within the reservations mentioned above.

Appendix 4 – Summary of Comparator Site 2

Interviews were conducted with nine key staff involved in the EMA service at comparator site 2.

Brief historical development and current capacity

Early medical abortions were initially offered at the site around 2000 when the new guidelines were published; prior to this the main method had been suction. Until 2003, EMAs were carried out on the gynaecological award in the main hospital – there were just two on a Saturday. When the General Health Centre – an integrated sexual health service – opened in 2003, the initial consultation was moved there, but the first drug was still administered in the hospital. After six months, it was arranged with the pharmacy that the first drug could be administered at the General Health Centre, and this is how it has been since then.

Prior to the move to the General Health Centre, the initial referral and counselling were held in another hospital where the general atmosphere was described as 'disapproving', and where the clients had to share a waiting room with 'neurology men' ('.. because it was abortion we were allowed a hole in the wall'). The move to the General Health Centre was seen to be considerably better for patients and staff; it is accessible and a 'valid place with a nice waiting area'.

The move has enabled the service to manage 20 EMA procedures per week.

Commissioning process

Women who live in the area covered by the Trust are eligible, and abortions are carried out up to 20 weeks; after this they are referred on to an independent sector provider.

Accessing early medical abortions

Referral and initial contacts

Women who live in the area are referred primarily by GPs, family planning centres, and the local walk in centre. They call up a booking line and get through to the administrator of the service who books their appointment. This person, having established a relationship with the woman, is then a key contact throughout. For example, if the woman has any concern, wants to book further appointments etc., this is the person she talks to. She is based in an office at the main hospital site, but makes frequent visits to the General Health Centre to check things are running smoothly, greet women as they arrive and take them for their appointment, etc.

Objecting GPs (estimated to be one quarter in the borough) were not thought to be a major problem since there are other local facilities where a referral can be obtained. Some women just turn up but are told they must have a referral; meanwhile, however, an appointment is made so as not to delay the process.

Assessment

All abortion consultations and mifepristone administration for EMA have taken place the General Health Centre. This is a modern general health centre located in a residential area about two miles away from the Hospital. It houses family planning and sexual health services and the abortion service operates as part of this. All consultations for abortion happen here, for all methods and gestations.

After referral, women attend for a consultation and are seen by a nurse/healthcare assistant, a doctor and often by a counsellor and also the GU clinic and/or FP doctors (all as part of the same appointment). The abortion decision and issues surrounding methods are discussed with women by the nurse/healthcare assistant and counsellor. The doctor also then covers these areas again, but in the light of confirmed gestation assessed by a scan. The woman then makes her decision about method. Where she opts for EMA she is booked in for administration of mifepristone at a Thursday clinic. Women are all offered a Chlamydia screen and contraception is discussed.

The staff make a point of emphasising precisely what occurs during the EMA procedure – they commented that some women think that they just need to take a pill and the expulsion will happen immediately; they seem to be confused between EMA and emergency hormonal contraception. In the view of the staff who see the women at assessment, it is vital to prepare the women for the pain that they are likely to experience on the ground that they are likely to cope better if they are prepared. Getting the women to relax is seen as a very important part of this stage. A few (especially younger) women change their minds about methods at this stage and opt for suction instead – either due to not wishing to experience the pain and/or due to wishing to conceal the process from others.

All staff stressed that it was important that all women see the counsellor prior to the procedure. The counsellor makes an appointment for post-abortion support in some cases if she feels it might be needed; others are left with an open option to return to see her later if they wish.

Specific issues were mentioned at the site that were not mentioned elsewhere, including a relatively higher number of women who do not speak English well, and some who are from a different area but 'try it on'.

Some reasons for delays were mentioned, including waiting to see GPs, and seasonal variation was mentioned, with summer holidays and Christmas affecting EMAs 'quite seriously'. Occasionally, additional sessions become available, and it was mentioned that EMA is popular with managers in this regard since theatres are not needed.

Stage One – administration of mifepristone

At the Thursday appointment, the nurse/clinical assistant technician again discusses the method and its effects and explains there is 'no going back' once the pill has been swallowed. Anyone who is still having doubts is sent along to the counsellor for further discussion, and about two or three per week do so. After administering the drug, women are kept in for about half an hour to make sure that they are not sick, and then sent home.

Stage Two – administration of misoprostol

Misoprostol is administered at a Saturday only clinic at a day-care centre on the main hospital site (but on a different part of the site to obstetrics and gynaecology) which is used for other procedures through the week, but only by the EMA service on a Saturday.

Women arrive between 7 am and 9 am; they can bring someone with them if they wish; although there is not enough room around the beds, there is a waiting area. The women see the same nurses that they have seen before, and are given anti-emetics. After a brief reminder of what will happen, the drug is given to them for insertion and analgesics are provided if required. They can walk around the hospital but not leave the premises. Three hours later they are given further misoprostol and most start bleeding. They are given antibiotics as well.

Discharge

Most women leave by 11 am or 12 noon, and told to contact accident and emergency if they experience any problems over and above what they have been warned to expect; if they need admission, they are sent to the gynaecological ward, where their notes will be. Alternatively, they can contact EGAS (the Emergency Gynaecological Assistance Service); if they have retained products of conception, they come in next day to have the evacuation.

Some women prefer to stay until the process is complete.

All women are again reminded of the help line number and the importance of attending for follow up is emphasised. This is especially strongly emphasised for those who have not bled heavily by the time they leave. Women are asked to call on the following Monday to report on how things have gone, and to make a follow-up appointment for two weeks' time.

There is a desire amongst staff to expand the service to enable 24 hour calls in case of problems.

Follow up

Follow-up appointments are at the General Health Centre on Mondays. Women are normally scanned. Failed procedures are very rare. Most problems are associated with retained products of conception (but not failed abortions), and so further medical treatment is required. On a few occasions, surgery is required.

Although the importance of follow-up is stressed at each opportunity, 'few' do return. It is assumed that this is because the women do not perceive any problems and so a return visit is not seen to be necessary.

Of those who do return, some see the counsellor – an issue for many of the women is actually having seen the sac on expulsion, and this needs to be talked through.

Perceived quality of service

Strengths

The physical locations for both parts of the procedure were felt to be a great strength of this service. Neither has large numbers of people attending for other reasons, and being away from the main site enables a sense of confidentiality. Since all the women are attending the General Health Centre for family planning or sexual health-related reasons, and all attending day care centre on the hospital site are doing so for the same reason (on the Saturday clinics) then the possibility of stigmatisation is reduced.

Being nurse led was felt to be extremely important, and there was a general view that the staff are very good at what they have to do. The continuity of staff contact between the various stages was also seen as a very positive feature.

Generally, women were felt to be well-prepared for what they were likely to experience. Further, they appreciated being able to wear their own clothes and walk around, making it as non-clinical an environment as possible.

In the wider context, it was felt that EMA is preferred by many women since it is quicker and simpler, and does not involve a general anaesthetic or admission to a hospital.

Shortcomings

There are only three toilets available in the day care centre on the hospital site, and this is felt to be insufficient for the numbers of women (normally 20) attending the Saturday clinic. More privacy would be welcomed at the day care centre, and some mentioned that two clinics dealing with ten women each would be preferable to one session catering for 20 women.

One of the medical practitioners felt strongly that women should not be sent home before expulsion has occurred, but allowed the option if they wish.

There is a gap in availability of provision between the Saturday lunchtime and the Monday clinic, during which time the women are told to contact accident and emergency; this is felt by some to be weakness in the level of service. This may apply especially to women who have concealed their abortion from others in the home, and may have to suffer a lot of pain without this being obvious.

One clinician felt that routine post-abortion scanning would be a good idea.

Staffing

It was mentioned that it seems harder to get doctors interested in TOPs now than it was a few years ago. Of ten current registrars in the speciality, only two are prepared to be involved.

Specific problems in recruiting nurses was not mentioned, although it was stressed that all those being interviewed for posts are told explicitly that the post will involve some dealing with the abortion service. Some felt that more staff need to be trained to be able to work in EMA clinics. If the service were to be expanded, then it was felt problems in recruiting sufficiently well trained and supportive staff might be experienced.

Improvements

More toilets and more privacy were the main areas in which it was felt improvements are warranted. Other suggestions include having a walk-in service (although the likely unpredictability of demand was recognised, and one interviewee said this would pose an ' … administrative nightmare'), and having a counsellor available for immediate consultation for women who are still unsure of their preferences.

Other considerations

Class of place issues

Expansion to other sites was felt to be a positive step as long as they were all equipped with the necessary facilities, including trained scanners, staff with good knowledge, toilets, privacy, etc. A greater range of sites would enable more women to be treated within the EMA period.

Home administration of second drug regime

There were generally negative views towards moving to a system of home administration of the second drug. Many of those interviewed felt that not enough women would be responsible enough to follow the guidelines properly, and some thought that the drug would be passed to others who were not entitled to it (one even said it would ' …appear on e-bay the very next day').

Some did say that after a very careful assessment of clients that it would be suitable in some cases, especially if there was a number to call at all times and if a follow-up visit – with scan – could be guaranteed. However, no clear statements were made as to how such selection for suitability could be made.

Legal review

These issues were not discussed in detail in these interviews, although the general view is that any barriers to early access should be removed as far as possible.

Appendix 5 – Summary of Comparator Site 3 – bpas London Central

Interviews were conducted with six key staff involved in the EMA service at the clinic. Bpas is an independent sector provider working on a contract basis for NHS services as well as accepting private clients.

Brief historical development and current capacity

The Bedford Square clinic has been run by the provider for seven years, and specialises in early medical abortions. Other bpas facilities in and around London carry out EMAs, and there are plans to open more in the near future.

In the early day of EMA provision, the initial dose of mifepristone was three times the dose used now, and the prostaglandin was a vaginal pessary called servigem which had a number of bad side-effects. Women were kept in the clinic for six hours after the administration of the second drug and expulsion normally occurred in the clinic.

As the drug regimes have become more acceptable, so the method of treating women has changed (around 1999 to 2000). As well as the much smaller dose of mifepristone and the adoption of misoprostol for the second drug, women leave the clinic immediately after the second drug and expel products at home.

Within the past 12 months, further developments have occurred. The time interval between the administration of mifepristone and misoprostol has been reduced markedly, with six to eight hours now being accepted as sufficient; bpas pioneered this move in the UK. The initial tight restrictions on who was allowed to go home before the procedure was completed have now been relaxed with no apparent ill-effects.

The current capacity of the clinic is 60 EMAs per week.

Commissioning process

Women can self-refer (although many commissioners do not like this arrangement) but are more normally referred by GPs and FP clinics, with NHS funded procedures provided where there is a contract arrangement with a PCT. Many PCTs have arrangements that lead to procedures at the clinic and the providers other facilities. There is an increasing emphasis from commissioners to have somewhere local and to increase the relative proportions of abortions that are carried out earlier in the gestation. Some contracts are limited in terms of numbers, which can lead to delays in obtaining authorisation to proceed.

Accessing early medical abortions

Referral and initial contacts

There is a central booking service at bpas – Action Line – and appointments are made this way.

Assessment

The women are first seen (not necessarily at the clinic, but at one of the other bpas assessment centres in the area) by an admin counsellor. The staff discuss the abortion decision, take basic details, and outline the alternative methods and what they entail. Women then see a doctor who – if necessary – dates the pregnancy with a scan, takes a gynaecological history, take blood pressure, etc., and again discusses methods. The woman makes her decision, although the staff feel that in many cases women have already made their decision before this point. Having said this, it was also pointed out that the act of discussion seems to be a ritual that needs to be gone through – many women were reported as appearing to need to justify their decision and seek some sanctioning by others. This takes time, and was felt to be a crucially important issue to consider when setting up services.

Scans can in fact be carried out by nurses and health care assistants after suitable training and monitoring. The scan images are never shown to women unless they specifically request seeing them. Blood samples are not routinely taken if the gestation is under nine weeks. Chlamydia testing is offered for free if it forms part of the contract with the particular commissioner; otherwise women are offered this for a fee but there is a low take up. An assessment under the Fraser Guidelines is made for all under-16 year olds.

Contraception is discussed with all women at this stage and supplies can be provided if necessary.

It is regarded as extremely important at this stage to specify as fully as possible what is likely to occur. There is a view in the service that full 'psychological' preparation is essential, and that such preparation makes the whole process much more manageable by the women.

Stage One – administration of mifepristone

For administration of mifepristone the woman sees a specialist nurse. The appointment will be made for a time as soon as possible after the decision, which can be the same day. The nurse again discusses the method and issues surrounding it in detail. Anti-emetics are given if it is deemed necessary. Checks are made as to how long the woman needs to get home and whether there will be someone there to look after them – this is in preparation for the second visit and drug administration.

Stage Two – administration of misoprostol

The client comes back the next day for the misoprostol (bpas is moving to a system where the second appointment could be on the same day, if the mifepristone was given in the morning). She is given the misoprostol and then sent home immediately, so this appointment is very

brief indeed – maybe 15 minutes in all. About 80 percent administer the drug themselves vaginally.

Discharge

All women are given a pregnancy test kit for use three weeks after the procedure. Throughout, the need for attending a follow-up is stressed and details of the 24 hour helpline are provided.

Follow up

All women are contacted by telephone by the clinic staff between 24 and 48 hours after the procedure to check that all has gone well (that any abnormal bleeding and/or pain has subsided, and that the products have been passed successfully). Some (estimated at 60 percent) return for a follow-up visit; in such cases they are seen by a doctor. Scanning at follow up is routine, and an assessment is made on a case by case basis.

Procedures do fail but most problems relate to retained products. For those who live too far to attend for follow-up, they are encouraged to visit their own GP or local family planning clinic for a check; any such visits are not recorded. If a woman phones before the three week follow up period with a problem, then they can be seen as an emergency follow up.

The helpline recently has been changed from a system whereby calls were routed through to clinics or the action line and the woman would be called back by the nurse on duty (who could have been linked to any one of the clinics). Since June 2007, the service has used Primecare, an out of hours service with walk in centres; they take all calls 24 hours a day. The service uses trained nurses and all calls are monitored to ensure that high standards are maintained.

All women are offered post-abortion counselling but few take it up (although the numbers seeking support from elsewhere are not known).

Perceived quality of service

Strengths

The major advantage of the bpas system is felt to be the specialised nature of the services, with all staff working in this area alone. Being nurse led is felt to be extremely important given the strong need for communication and time to talk, to prepare clients properly, to show an appropriate non-judgemental and inclusive attitude, and to have a broad understanding of reproductive issues. Although it was felt that much of the process could actually be carried out by trained health care assistants, women appear to appreciate there being nurses involved at each stage.

Having an internal counselling service was also felt to be particularly important, especially for new service development.

The 24 to 48 hour follow up phone call is apparently highly regarded by clients as illustrating that the service cares about them.

All interviewees felt that the structure and procedures in this system were thorough and comprehensive, and worked extremely well. It was also stressed that the procedure must not be regarded as being 'quick and easy', and that adequate time for preparing women and going through the process in detail in advance, and in having proactive follow up systems in place. This, of course, has cost implications for purchasers.

Shortcomings

No obvious shortcomings were identified – some physical features of the clinic were regarded as not being ideal, but it is currently being refurbished. The physical space available was felt to be more than adequate.

There was a strong view that the current legal requirements are overly restrictive; this is further discussed below.

Staffing

No current problems in recruiting suitable staff were mentioned in any of the interviews, although there have been times in the past when it was more difficult. All new appointments are fully trained and mentored by experienced staff.

Improvements

All staff felt that the current requirement of administering the second drug on the 'approved' premises was unnecessary in the majority of cases. Given the women stay for – at the most – 30 minutes and then go home immediately, it was felt to be an additional imposition in terms of travel, etc. Further, since the paperwork for registering the abortion is completed at the time of administration of the initial drug, then it was not even clear that a change in the law would be required to enable women to take the second drug in their home.

Other considerations

Class of place issues

There is a strong view that the current legislation is unreasonable and unjustifiably restrictive. A strong view was reported that the actual physical location was of lesser importance than the structures and support mechanisms that are in place. The physical location was important in that adequate privacy, a restful environment (for women who stayed in) and easy access to toilets was essential, but little beyond this.

Some doubt was expressed as to whether some GP surgeries would have the physical space and facilities required, but also whether they would have the capacity to provide the time and support needed both during the procedure and afterwards. Carrying out EMAs on a 'part-time' basis was seen to be risky from these aspects. Further, the quality of staff and their commitment to abortion could be a problem is some community based facilities.

Some interviewees felt that 'class of place' would be better determined in terms of provider competence rather than by physical location.

Home administration of second drug regime

As mentioned earlier, there was a strong view that – subject to careful assessment at the beginning and careful follow up afterwards – there were no good reasons to prohibit administration of the second drug at home. It was pointed out that this is common in the USA and that, in the UK, children as young as ten years old can be entrusted to administer insulin by themselves.

Legal review

All interviewees were in favour of changing the law to remove the need for two doctors signatures, and to expand the definition of class of place.

Appendix 6 – Topics for discussion in stakeholder and staff interviews

Briefing about study

Obtain informed consent from participant

Explain that participant may withdraw consent to participate at any time

Respondent's personal role in the delivery of abortion

Can you tell me a bit about your own personal role in the delivery of abortion services at XXXXXX?

- Job title
- Role and responsibilities
- Length of service
- Previous experience in abortion care

The historical development of the current EMA service

How has the abortion service changed over recent years?

What improvements have you witnessed?

- Greater proportions under 10 weeks
- Greater use/uptake of EMA

The commissioning process

Can you explain to me how the commissioning process works?

What services are currently being provided in the region?

What are the determining factors?

Are there any barriers to the improvement of the current service? Generally/for EMA specifically?

- PCT purchasers
  - Key contacts/commissioners
  - Services provided (medical/surgical)
  - Length of contracts
- Hospitals/sites providing services
  - Time limits
  - Space limitations
  - Other limitations (staff?)
- Other agencies used
  - Marie stopes (location of assessment & procedure)
  - bpas (location of assessment & procedure)
- Costs
  - Supplies/equipment
- Staff
  - Ease/barriers to recruitment

Accessing abortion services

Can you tell me a bit about how women currently access abortion services in the region?

In your opinion, do you think the service is easily accessible

Is the service adequate, are there any problems with the current service?

- Referral pathways
  - Primary care/self-referral
- Criteria for patient inclusion/exclusion
- Procedure for signatures
- Ease of access to the service

Thinking about EMA in particular, are there certain types of women who are seen to choose EMA over the surgical option?

- Who chooses EMA?
  - Surgical vs medical
  - Ages/types of women

The current EMA service provided

Can you explain what happens when a women elects for an EMA?

Where could improvements be made/how do you think the service could be improved upon?

What are the services shortcomings?

- Accessing the service
- Client contact procedure

- Assessment/consultation stage
  - Scans/bloods (methods of dating)
  - Chlamydia testing/other STI tests?
- Information given (verbal and written)
  - Discussion about side-effects/symptoms
  - Discussion about what is going to happen (pain/tissue/clots/products of conception)
- Treatment regime & procedure
- First treatment
  - Treatment of side-effects
  - Provision of anti-emetics?
  - Administration of second dose if vomiting occurs
  - Discharge after how long?
  - Emergency contact details provided?
- Second treatment
  - Accompanying people
  - Provision of anti-emetics?
  - Provision of pain-relief?
  - Contraceptive provisioning (discussion or actual provisioning)
  - Timing of discharge
- Emergency contacts/information
- When EMA goes wrong
  - Notification of complications
- Follow-up procedure
  - Incomplete procedures (rescans/BHcG/ERPC – evacuation of the retained products of conception)
  - Onward referrals
- Post-abortion counseling provided
- Type and quality of information given to clients at all stages

What is the staffing structure? Do you think this is adequate?

- Numbers
- Qualifications
- Training
- How would you personally rate the service provided?
- Physical environment/adequacy of facilities
- Adequacy of supplies/equipment
- Written protocols/guidelines

The granting of a 'class of place'

If 'a class of place' was granted how would you see that working in XXXXXX?

What advantage do you foresee?

What problems do you foresee?

Do you foresee any objections? From whom?

- Key considerations in the provisioning of an ideal EMA service
- What facilities need to be in place for community EMA to work
  - What sites would be suitable
- Safety and effectiveness of EMA
  - When EMA goes wrong
- Staff in community settings objecting to performing EMAs
  - Barriers to recruitment
- How to facilitate access to doctors
  - 2 signatures

Further developments/improvements to EMA provisioning

In your opinion, how could the current EMA service be improved upon?

What more can be done? Nationally/locally?

- Provisioning of second treatment for home administration

Do you support a review of the abortion law?

Thank participant and give a debriefing form

Debriefing Statement

The aim of this research was to find out about the experiences and views of staff and stakeholders on the provision of early medical abortion services. The information you have provided us with will form part of an evaluation of the provision of early medical abortions in non-traditional compared with traditional settings, commissioned by the Department of Health. The information you have provided will be treated with strictest confidence. Results of this study will not include your name or any other identifying characteristics.

If you have questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you may contact the Chair of the Ethics Committee, Department of Psychology, University of Southampton, Southampton, SO17 1BJ, tel: 02380 593995.

Thank you very much for your participation in this research!

Appendix 7 – Case note analysis variable availability

		Ch	Com1	St M	Com2	Com3
DEMOGRAPHICS						
1	ID number	✔	✔	✔	✔	✔
2	date of birth	✔	✔	✔	✔	✔
3	postcode	✔	✔	✔	✔	✔
4	marital status	✔	✔		✔	✔
5	ethnicity/country of birth	✔	✔	✔	✔	✔
6	country of residence					✔
7	live births	✔	✔	✔	✔	✔
8	still births				✔	✔
9	miscarriages				✔	✔
10	ectopics					✔
11	previous TOPs	✔	✔	✔	✔	✔
11a	previous EMA			✔		
12	other obstetric history			✔		✔
FIRST TREATMENT						
13	gestation	✔	✔	✔	✔	✔
14	date mife given	✔	✔	✔	✔	✔
15	time mife given		✔	✔	✔	✔
16	PV between treatments	✔	✔	✔	✔	✔
17	type PV	✔	✔	✔	✔	✔
18	side effects/other comments	✔	✔	✔	✔	✔
SECOND TREATMENT						
19	date miso given	✔	✔	✔	✔	✔
20	time miso given	✔	✔	✔	✔	✔
21	date PV bleeding		✔	✔	✔	
22	time PV bleeding		✔	✔	✔	
23	date POC passed	✔	✔	✔	✔	
24	time POC passed	✔	✔	✔	✔	

		Ch	Com1	St M	Com2	Com3
COMPLICATIONS REPORTED PRIOR TO DISCHARGE						
25	excessive bleeding	✔	✔	✔	✔	
26	excessive pain	✔	✔	✔	✔	
27	nausea	✔	✔	✔	✔	
28	vomiting	✔	✔	✔	✔	
29	other side effects/comments	✔	✔	✔	✔	
30	time of discharge	✔	✔	✔	✔	✔
DRUGS						
31	type of analgesia (1)	✔	✔	✔	✔	
32	time (1)	✔	✔	✔	✔	
33	type of analgesia (2)	✔	✔	✔	✔	
34	time (2)	✔	✔	✔	✔	
35	type of analgesia (3)	✔	✔	✔	✔	
36	time (3)	✔	✔	✔	✔	
37	anti-emetic given (1)	✔	✔	✔	✔	✔
38	time (1)	✔	✔	✔	✔	✔
39	whether antibiotics given	✔	✔	✔	✔	✔
40	whether pain relief for home provided					
FOLLOW UP						
41	attendance at follow up	✔		✔		✔
42	whether failed TOP	✔	✔	✔	✔	✔
43	additional comments regarding procedure	✔	✔	✔		✔
REPORTED COMPLICATIONS FOLLOWING DISCHARGE						
44	whether excessive bleeding			✔	✔	✔
45	comment – time of report/action/outcome			✔	✔	
46	whether excessive pain	✔		✔		✔
47	comment – time of report/action/outcome			✔		
48	whether infection	✔				
49	comment – time of report /action/outcome					
50	other comments/side effects/complications			✔		
51	STI test results				✔	
OTHER ISSUES						
52	whether contraception discussed			✔	✔	
53	whether contraception provided					

Appendix 8 – Client questionnaire

EMA Study

The University of Southampton is conducting a study on behalf of the Department of Health on the provision of early medical abortion (EMA) in different types of settings. Usually, early medical abortions are provided in hospitals and specialist clinics. The Department of Health is, however, considering whether other settings, such as family planning and sexual health clinics, may also be suitable. This study aims to inform their decision. While this study is unlikely to help you, it could be of considerable value to other women in the future who may require an abortion.

This questionnaire asks you about yourself and your experiences of obtaining an early medical abortion at this hospital/clinic. We should be very grateful if you would complete it as accurately as possible at least 10 days after your second treatment (it should take you about 30minutes). We must stress that your participation is voluntary and you don't have to complete this questionnaire or any question in it if you don't want to – it's entirely your choice. Choosing not to participate will not affect your treatment in any way. What's more you can stop at any time.

The questionnaire is completely confidential you will not be asked your name, and nobody you know will ever see the answers you give. Envelopes are provided for you to return your completed questionnaire directly to the research team free of charge. Many thanks for your help.

Completion and return of this questionnaire will be taken as evidence of you giving informed consent to be included as a participant in this study, for your data to be used for the purposes of research, and that you understand that published results of this research project will maintain your confidentiality

If you have any questions or comments please contact:

Professor Roger Ingham, Centre for Sexual Health Research,
School of Psychology, University of Southampton, SO17 1BJ
e-mail: cshr@soton.ac.uk
Tel: 023 8059 7770

This study has been approved by the ethics committee of the School of Psychology, University of Southampton. If you have any questions about your rights as a participant in this research, or if you feel that you have been placed at risk, you can contact the Chair of the Ethics Committee, School of Psychology, University of Southampton, Southampton, SO17 1BJ (tel. 023 8059 3995)

SECTION 1: Information about yourself

1. How old are you? .....years

2. What is your home postcode?..... e.g. SO17 1BJ

(This information is only used to find out what area you live in and how far you've travelled to have your abortion. It will not be released to anyone outside of the research team)

3. What is your ethnic group?

White.....	☐	Indian.....	☐
Black Afro-Caribbean.....	☐	Pakistani.....	☐
Black African.....	☐	Bangladeshi.....	☐
Black Other.....	☐	Chinese.....	☐
Mixed: White & Black Caribbean...	☐	Asian Other.....	☐
Mixed: White & Black African.....	☐	Mixed: White & Asian.....	☐

Other (Please specify: .....)

SECTION 2: Previous pregnancies

1. Have you ever given birth? Yes ☐ No ☐

2. Have you ever had a miscarriage? Yes ☐ No ☐ Unsure ☐

3a. Have you had an abortion before? Yes ☐ No ☐

3b. *If YES*, which of the following have you had previously.
(Please tick all that apply)

Surgical abortion (suction) ☐

Early medical abortion (abortion pill under 9 weeks) ☐

Medical abortion (abortion pill over 9 weeks) ☐

Sections 3 through 8 ask you about the different stages you went through to obtain your abortion (referral, assessment, first treatment, second treatment and follow-up). You are asked for your views about the different places you visited, the choices you made, the people you met and the care you received. Please remember that all the answers you give are completely confidential. Space is also provided at the end of the questionnaire for you to comment further on your experiences.

SECTION 3: Getting your abortion assessment appointment

The following question asks you about how you were referred for your abortion assessment/ consultation appointment after asking for an abortion.

1. How did you get your abortion assessment appointment?

Referred by the GP/Practice Nurse ..... ☐

Referred by the family planning clinic..... ☐

Referred by the hospital ..... ☐

I contacted the hospital/clinic directly..... ☐

I called a pregnancy/abortion helpline..... ☐

Other ☐ (Please specify:.....)

SECTION 4: Your abortion assessment/consultation

The following section asks you some questions about your experiences of the abortion assessment/consultation, the appointment you had prior to actually taking the abortion pill. During this appointment you may have had counselling, a scan, blood tests, STI screening, talked about your options and were maybe asked some questions about your sexual history andpast pregnancies.

1a. During your abortion assessment, were you offered a choice of abortion methods? (e.g. medical or surgical)

Yes ☐ No ☐

1b. *If YES*, do you feel you were given enough information (written and/or verbal) to make your choice of treatment?

Yes..... ☐

No ..... ☐

Unsure ..... ☐

2. Why did you decide to have a medical abortion (i.e. to take the abortion pill)?
(Please tick all that apply)

a.	I was offered no other option.....	☐	i.	To avoid surgery.....	☐
b.	So I could have someone with me	☐	j.	Recommended by the staff	☐
c.	To feel more in control.....	☐	k.	Recommended by a friend	☐
d.	To be more natural (like a period or miscarriage).....	☐	l.	I could be at home sooner.....	☐
e.	Involved a shorter hospital/clinic stay	☐	m.	Less invasive option.....	☐
f.	Seemed to be a more private procedure.....	☐	n.	To avoid pain	☐
g.	I wanted to see the aborted pregnancy	☐	o.	To avoid physical trauma.....	☐
h.	So the abortion could be done earlier	☐	p.	To avoid an anaesthetic.....	☐

Other reasons (please specify).....

3. During your abortion assessment, were you offered a choice of hospitals/clinics to attend for your abortion procedure?

Yes ☐ No ☐

3b. *If YES*, why did you choose to have your abortion at that the hospital/clinic you eventually did? (Please tick all that apply)

a.	Only place that could fit me in.....	☐
b.	More relaxed and informal environment	☐
c.	Convenient location	☐
d.	They offered me the earliest procedure.....	☐
e.	Recommended by a friend/relative.....	☐
f.	Recommended by a health professional	☐
g.	Emergency services at hand should anything go wrong	☐
h.	It offered the type of abortion I wanted.....	☐
i.	Other reasons (please specify).....	

SECTION 5: Your experience of the FIRST treatment

The following questions ask you about your experiences of taking the first abortion pill (the Mifepristone drug).

1. **Other than a health professional, did you have anyone with you when you took your first treatment?**

   Yes ☐ No ☐

2. **According to the hospital/clinic, what was your gestation (how pregnant were you) when you took the first pill?**

   ……..weeks ……..days

3. **Did you experience any of the following symptoms or side-effects after taking the first pill? Additionally, please state if you took any medication to ease or prevent the symptom(s)** (Please tick all that apply)

	Yes, on occasions	Yes, continuously	I took medication
Nausea (feeling sick).....	☐	☐	☐
Vomiting.....	☐	☐	☐
Diarrhoea	☐	☐	☐
Headaches.....	☐	☐	☐
Dizziness.....	☐	☐	☐
Flushes/sweats	☐	☐	☐
Bleeding	☐	☐	☐
Stomach cramps/pain.....	☐	☐	☐
Feeling frightened	☐	☐	

0ther (Please specify:.....)

SECTION 6: Your experience of the SECOND treatment

The following questions ask you about your experiences of taking the second treatment (the Misoprostol drug).

1. **How long did it take you to travel to the hospital/clinic where you took the second treatment?**

   …….hours …… minutes

2. **Did anyone accompany you when you had your second treatment?**

   Yes ☐ No ☐

3. **Did you administer the second treatment yourself (did you insert it yourself)?**

   Yes ☐ No ☐

4. **Did you experience any of the following symptoms or side-effects after having the second treatment? Additionally, please state if you took any medication to ease or prevent the symptom(s)** (Please tick all that apply)

	Yes, on occasions	Yes, continuously	I took medication
Nausea (feeling sick).....	☐	☐	☐
Vomiting.....	☐	☐	☐
Diarrhoea	☐	☐	☐
Headaches.....	☐	☐	☐
Dizziness.....	☐	☐	☐
Flushes/sweats	☐	☐	☐
Feeling frightened	☐	☐	

0ther (Please specify:.....)

5. **How was the bleeding you experienced?**

   Worse than you expected..... ☐

   As you expected..... ☐

   Not as bad as you expected..... ☐

   Please comment if you wish .....

   .....

6. How were the pain/cramps you experienced?

Worse than you expected..... ☐

As you expected..... ☐

Not as bad as you expected..... ☐

Please comment if you wish .....

.....

7. Which of the following statements best describes how pain-killers were administered to you by the hospital/clinic staff? (Please tick all that apply)

Staff automatically gave me pain-killers after my treatment..... ☐

Staff told me they could provide me with pain-killers if I needed them…… ..... ☐

Staff did not offer me pain-killers..... ☐

I had to ask a staff member for pain-killers ..... ☐

The hospital/clinic did not provide me with pain-killers..... ☐

8. Did you <u>actually</u> take pain-relief medication following your second treatment?

Yes ☐ No ☐ (if NO, please skip straight to ***question 12*** on the next page)

9a. Was the initial pain-relief provided by the hospital/clinic adequate in relieving your pain?

Yes ☐ No ☐ None provided ☐

9b. *If NO*, what action was then taken? (Please tick all that apply)

Nothing ..... ☐

They offered me another dose ..... ☐

They offered me another/stronger type ..... ☐

Other ☐ (Please specify:……..)

10. How would you rate the management of your pain-relief by hospital/clinic staff?

Excellent ☐ Good ☐ Adequate ☐ Poor ☐ Very poor ☐

11a. Did you need to take further pain-killers at home?

Yes ☐ No ☐

11b. *If YES*, which of the following best describes your use?
(Please tick all that apply)

I took pain-killers given/prescribed to me by the hospital/clinic..... ☐

I took pain-killers I personally supplied/bought ..... ☐

Other ☐ (Please specify: ……..)

→ If you skipped because you didn't take any pain relief medication, please restart here…

12. How long did you stay at the hospital/clinic after taking the second treatment?

…….hours …….minutes

13a. Was it obvious to you when the abortion had actually happened?

Yes ☐ No ☐ Unsure ☐

13b. *If YES*, where were you when you think the abortion happened?

In the hospital/clinic..... ☐

On my way home..... ☐

At home..... ☐

Other ☐ (Please specify:……..)

14. At the procedure hospital/clinic, how would you rate:

	Excellent	Good	Adequate	Poor	Very poor
a) the staff for…					
Professionalism/competency	☐	☐	☐	☐	☐
Reassurance	☐	☐	☐	☐	☐
Warmth/friendliness	☐	☐	☐	☐	☐
b) the physical environment of the hospital/clinic (decoration, atmosphere)	☐	☐	☐	☐	☐
c) the toilet facilities	☐	☐	☐	☐	☐
d) the washing facilities (baths, showers etc.)	☐	☐	☐	☐	☐
e) the provisions within the hospital/clinic (reading material, TV, drinks etc.)	☐	☐	☐	☐	☐

15. For comfort, how would you rate the procedure hospital/clinic's:

	Excellent	Good	Adequate	Poor	Very poor	None available
a) waiting rooms	☐	☐	☐	☐	☐	☐
b) examination rooms	☐	☐	☐	☐	☐	☐
c) recovery areas	☐	☐	☐	☐	☐	☐

16. For privacy, how would you rate the procedure hospital/clinic's:

	Excellent	Good	Adequate	Poor	Very poor	None available
a) waiting rooms	☐	☐	☐	☐	☐	☐
b) examination rooms	☐	☐	☐	☐	☐	☐
c) recovery areas	☐	☐	☐	☐	☐	☐

17. How (if at all) could the staff at the procedure hospital/clinic(s) improve?
(Please be as specific as possible)

……

18. How (if at all) could the facilities at the procedure hospital/clinic(s) be improved?
(Please be as specific as possible)

……

SECTION 7: Information you were given

The following questions ask for your views on the information you were given during your abortion treatment and care (from your assessment appointment through to your discharge).

1a. Do you feel you were given enough information (written and/or verbal) about the abortion and any potential side-effects?

Before the first treatment Yes ☐ No ☐ Unsure ☐

Before the second treatment Yes ☐ No ☐ Unsure ☐

1b. *If NO*, what additional information would you have liked?

……

……

2. How would you rate the written information you were given about what the abortion would involve?

Excellent ☐ Good ☐ Adequate ☐ Poor ☐ Very poor ☐

I was not given any written information/leaflets.. ☐

3. How would you rate the verbal information you were given about what the abortion would involve?

Excellent ☐ Good ☐ Adequate ☐ Poor ☐ Very poor ☐

I was not given any information verbally…….. ☐

4a. Do you think the information you were given about how the abortion would be carried out and any potential side-effects was accurate?

Yes ☐ No ☐ Unsure ☐

4b. *If NO*, why not?

……

……

5. Were you told in advance that you might see and/or feel evidence of the pregnancy as the abortion happened (i.e. the pregnancy sac)?

i) See evidence: Yes ☐ No ☐ Unsure ☐

ii) Feel evidence: Yes ☐ No ☐ Unsure ☐

6a. Did you see and/or feel evidence of the pregnancy as the abortion happened?

i) See evidence: Yes ☐ No ☐ Unsure ☐

ii) Feel evidence: Yes ☐ No ☐ Unsure ☐

6b. *If YES*, on a scale of 1-5, how upsetting was this for you?
(Please circle one number)

Not at all				Extremely
1	2	3	4	5

Please remember the following questions refer to your entire abortion treatment and care (from your assessment appointment through to your discharge).

7. Which of the following were you offered during your abortion treatment and care?
(Please tick all that apply)

a. Antibiotics to prevent infection ..... ☐
b. Chlamydia screening..... ☐
c. Testing for other sexually transmitted diseases..... ☐
d. HIV testing..... ☐
e. Smear test..... ☐
f. Sanitary protection ..... ☐
g. Post-abortion pregnancy test ..... ☐

8. How would you rate the following services you received?

	Excellent	Good	Adequate	Poor	Very poor	Did not receive any
a. Contraception/ contraceptive advice	☐	☐	☐	☐	☐	☐
b. Pre-abortion counselling	☐	☐	☐	☐	☐	☐
c. Post-abortion counselling	☐	☐	☐	☐	☐	☐

SECTION 8: Post abortion care and complications

The following questions ask for your experiences since having the abortion.

1. Were you given clear information on how to identify potential complications?

Yes ☐ No ☐ Unsure ☐

2. Were you given clear information on what to do if you experienced or suspected any complications?

Yes ☐ No ☐ Unsure ☐

3. Were you provided with a 24hr emergency contact number?

Yes ☐ No ☐ Unsure ☐

4. Before leaving the clinic/hospital after your second treatment were you given a follow-up appointment to attend?

Yes ..... ☐

No, but I was advised to make a follow-up appointment..... ☐

No, no such advice was given/this was not mentioned..... ☐

5. Which of the following best describes your intentions for follow-up?
(Please tick one box only)

I have already been/am here today for a follow-up appointment ..... ☐

I am planning on going for a follow-up appointment ..... ☐

I have no plans to see anybody for a follow-up appointment ..... ☐

6a. So far, have you experienced any problems or complications with the abortion?

Yes ☐ No ☐

6b. *If YES*, what problems have you experienced?

Excessive or prolonged pain ..... ☐

Excessive or prolonged bleeding..... ☐

An infection ..... ☐

Other (Please specify).....

6c. From where have you sought help (by phone or in person)?
(Please tick all that apply)

Clinic/hospital where I had the abortion..... ☐

My GP/Practice nurse ..... ☐

Family planning clinic/sexual health service..... ☐

Accident & Emergency ..... ☐

Dedicated abortion help/phone-line..... ☐

Other (Please specify: ……..……..……)

I haven't sought help yet..... ☐

7. Overall, how would you rate the post abortion care you have been offered?

Excellent ☐ Good ☐ Adequate ☐ Poor ☐ Very poor ☐

SECTION 9: Looking back

1. If you needed another abortion in the future:

a) would you go back to the same procedure hospital/clinic? Yes ☐ No ☐ Unsure ☐

b) would you choose a medical (pill) abortion? Yes ☐ No ☐ Unsure ☐

2. Would you recommend the hospital/clinic(s) to a friend? Yes ☐ No ☐ Unsure ☐

3. Would you recommend medical abortion to a friend in need? Yes ☐ No ☐ Unsure ☐

SECTION 10: Changes to abortion services

1. **Currently, abortions are provided at hospitals and approved clinics only. The Department of Health is considering making early abortion services more widely available in approved community settings, such as family planning and sexual health clinics.**

   1a. Do you think this is a good idea?

   Yes ☐ No ☐ Unsure ☐

2. **Typically, women undergoing an early medical abortion are required to stay in the hospital/clinic for a number of hours after taking the second treatment (the Misoprostol) for the abortion to commence. Some hospitals/clinics are thinking of allowing women to leave much earlier.**

   2a. Do you think that women should be given the opportunity to go home immediately after taking the second treatment?

   Yes ☐ No ☐ Unsure ☐

   2b. If you had been offered the opportunity, would you have gone home immediately after taking the second treatment?

   Yes ☐ No ☐ Unsure ☐ I was offered the opportunity ☐

3. **Currently, women in the UK must return to a hospital or clinic to receive the second part of the medical abortion treatment due to legal restrictions. In some other countries women are given the Misoprostol tablets to use at home at the appropriate time.**

   3a. Do you think that women in the UK should be given the choice of whether they would like to take the second treatment at home or return to the hospital/clinic?

   Yes ☐ No ☐ Unsure ☐

   3b. If you had been given the option, where would you have chosen to take the second treatment?

   At home..... ☐

   At the hospital/clinic ..... ☐

   Unsure ..... ☐

Please feel free to use the space below and overleaf to comment further on your experience of obtaining an abortion (both positive and negative) or to expand on any of the answers you have given in any section of the questionnaire.

Thank you ever so much for taking the time to fill in this questionnaire.
Please return it in the freepost envelope provided.

Would you be interested in taking part in a confidential interview?

The information we get from these questionnaires is extremely valuable, but we also want to conduct some interviews to hear about the experiences and views of women, in their own words, who have accessed abortion services. Would you be willing to take part in a confidential one-to-one interview?

This study is being conducted for the Department of Health to help ensure abortion services are safe, effective, accessible and acceptable to women like you. If you decide to take part, the interview will be arranged at a time convenient to you. You will also receive **£20** for your time and, in addition, we would cover any reasonable travel costs.

If you are interested, please fill in the information requested below, tear off this sheet so your personal details are not attached to your questionnaire, fold and return it separately in the smaller freepost envelope provided.

If you are selected one of our researchers will contact you with further information and to arrange a date and time convenient to you. Filling out this slip does not mean you are committed to participating in an interview as you are free to change your mind at anytime.

Many thanks for your time.

Yes, I am interested in finding out more about this study. My contact details are:

Name:
E-mail address:
Mobile phone no:
Home phone no*:
Address*:
Preferred method of contact: Email/Mobile/Home phone/Post (Please circle one)

* This information is optional if you have already provided an email address and a mobile phone number.

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