

**Shorter time interval treatments for Early Medical Abortions: A Mixed Methods
Research Approach**

By

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Abstract

Purpose This dissertation focuses at assessing the efficacy of shorter time intervals in the treatment of medical abortions along with the use of various follow up methods.

Methods This initial part of dissertation was carried out as an extensive study of literature, followed by observational study on shorter time intervals and follow up methods for the feasibility of the study. The main dissertation met its research aims through an RCT of 121 women comparing shorter to standard time intervals and assessing the various follow up methods at the end of 2 weeks. The qualitative component of the study was achieved by conducting in-depth interviews of women undergoing medical abortion on various aspects of medical abortions with emphasis on shorter time intervals and follow up.

Findings This research produced a number of key findings: the RCT showed that both treatments have equal efficacy and acceptability with minor differences in their side effects however the sample size was small to generalise the findings; the follow up methods showed varied responses with preference to confirmatory investigations at 2 weeks follow up.

Conclusions

The main conclusions drawn from this research were that shorter time intervals can be offered as an alternative to standard treatment intervals in well informed women, however a larger RCT is needed. In order to provide these treatments as outpatient robust follow up methods will need to be incorporated into the abortion services.

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List of Abbreviations/definitions

Mife	Mifepristone
Miso	Misoprostol
USS	Ultrasound
TVS	Transvaginal ultrasound
EMA	Early medical abortions
TIMES	Time intervals for medial early abortions
β hCG	beta- human chorionic gonodotrophin
RCT	randomised controlled trial
RCOG	Royal college of Obstetrics and Gynaecology
GP	General Practitioner
FPC	Family Planning Clinic
RPOC	Retained products of conception

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FORWARD: WHY RESEARCH MEDICAL ABORTIONS?

Abortion treatments have gained importance through many centuries, both for women and for service providers. Treatments that began as crude abortifacient methods have developed into the current methods through rigorous research. Newer methods are continuing to be developed to provide women with safe and effective methods. Interestingly not all methods are acceptable to all women and therefore the question of patients' preferences and acceptance poses a clinical dilemma.

Of historical significance was the development of medical methods which met the requirement for a non-invasive method of carrying out the abortion treatments, this saw a change to the service provision allowing a more specialised care with an effective referral system. Most units in the UK provide social gynaecology services that have a referral system integrated with the primary care, family planning clinics and secondary care providers. Each unit requires input from sonographers, day surgery, in patient and emergency services. The challenges then posed by these services can therefore be many, especially while dealing with complications.

Abortion treatments are perhaps one of the most prominent areas in the speciality of obstetrics and gynaecology reflecting changes within the society thereby forming part of social medicine. For example, the rates of abortions reflect the uptake of contraception. In May 2010, the Department of Health released the latest abortion statistics.¹ Total number of abortions in England and Wales were 189,100 in 2009, compared with 195,296 in 2008, a fall of 3.2%. Abortion rate was highest at 33/1000 for women aged 19-21, whilst rates under-16 and under-18 were lower. 91% of abortions were carried out <13 weeks gestation, 75% <10 weeks. Medical abortions accounted for 40% of the total. It is clear from the above data that abortion treatments continue to be provided on a large scale.

Another example is the indirect representation of rates of abortions to economic status, awareness and familial relationships within the society. Of interest is also acceptance and attitudes of women towards abortion treatments.

The decision to choose this particular topic for research was triggered upon seeing the varied practice across different units and more importantly trying to understand women's' experience with medical abortions. It was challenging to counsel women with their requests for quicker and faster methods of medical treatments that they may have had some information about. In the process I began to ask myself "What do women actually want while they are making one of the most difficult decisions in their journey through womanhood".

The basis for this thesis was therefore based on the facts of testing shorter time intervals for medical abortion regimens by understanding women's attitudes towards medical abortions with regards to shorter time intervals and very early abortions- The TIMES study (Time Interval for Medical Early Abortions).

INTRODUCTION: STRUCTURE AND OUTLINE OF THE THESIS

Main focus of this thesis is to address the clinical and practical issues concerning early medical abortions. This thesis includes two studies (quantitative and qualitative) approaching the topic from different perspectives. In this chapter on overview of the thesis, aim is to summarise various aspects of thesis and to briefly discuss how the chapters are connected together.

Part One: Literature review

Medications used for medical abortions have gone through many laboratory and experimental studies to reach the current approved methods. For this reason, the first chapter on literature review gives a historical account of these medications.

To understand how treatments for medical abortions work, what would be essential to know is how treatments act at molecular level. Chapters two and three review literature on the pharmacokinetics of mifepristone and misoprostol. The combined clinical effects of mifepristone and misoprostol are given in chapter four. It also includes a review of different studies for dose and routes of mifepristone and misoprostol. The lessons learnt from these chapters have important implications on understanding the current methods of medical abortions.

Chapter five focuses on the currently used methods of medical abortions for the design of the randomised controlled trial.

Chapter six takes a step back from the clinical aspects of medical abortions and considers the attitudes of women towards medical abortions.

Part Two: Meta-analysis

Part two of the thesis focuses on the evidence from randomised controlled studies on use of mifepristone and misoprostol at different time intervals including their adverse effects.

Part Three: Observational study

Part three of the thesis includes two retrospective studies conducted from April 2008 to March 2009. Data from these studies involves assessing efficacy of shorter time intervals and follow up rates in a non-research setting. Although these studies reflected on the clinical practice of shorter time intervals and follow up, they were not adequate to change practice. However these observational studies have retained their relevance by providing valid information on feasibility of conducting an RCT within the context of an out-patient clinical setting.

Part Four: Mixed methods

Mixed methods is relatively a new concept in research. This chapter explains use of mixed methods in research particularly in relation to this study. The chapter also rationalises the purpose of using both the quantitative and qualitative methods. Both methods have been discussed with the objectives in view that form the basis of this study.

Part Five: Intervention study

Main focus of this thesis is the randomised controlled trial of shorter time intervals. This was designed in the light of results of the observational studies study and set out to find out whether women who had medical abortions at the shorter time intervals had similar treatment outcomes, with fewer side effects and found the treatments more acceptable. Women were recruited from the independent health care abortion service provider and those allocated to either of the treatments received follow up 2 weeks following their treatments to assess efficacy and acceptance.

Part Six: Women's' perspectives

Part six reports a qualitative analysis of women's perspectives on medical abortions, based on in depth interviews. Participants were asked open ended questions on their views, attitudes and experience with medical abortions. Aspects that were key to the randomised controlled trial,

shorter time intervals and very early medical abortions, were explored. These were analysed thematically to identify key concepts which described information, advice and support that women wanted with medical abortions.

Part Seven: Conclusions and summary

The final section draws together findings and considers their implications. It suggests offering medical abortions considering women's preferences and makes suggestions for further research.

PART 1

LITERATURE REVIEW:

WHAT DO WE KNOW ABOUT MEDICAL ABORTIONS

Chapter 1.1

History of Medical Abortion Treatments

Historical evidence suggests that medical abortions date back to centuries when surgical abortions were not known. The use of agents such as herbs, chemicals and drugs for abortion although may reflect old concepts, medically proven regimens have only emerged during the last 50 years i.e. since the 1980's.

Georges Teutsch, a chemist at Roussel-Uclaf, synthesized mifepristone for its glucocorticoid receptor antagonists properties; its progesterone receptor antagonist properties were also discovered then.²⁻⁶ In 1981, Étienne-Émile Baulieu (endocrinologist) from Roussel-Uclaf and Walter Herrmann (gynaecologist) at the University of Geneva's Cantonal Hospital reported successful results following use of mifepristone for medical abortion.⁸⁻⁹ Subsequently authors of various research studies reported complete abortion rates of 60%-80% with mifepristone only.^{10, 11, 12}

In the 1970s natural prostaglandins, such as prostaglandin (PG) E2 and PGF2 α , found their place for clinical use as being effective at inducing abortion in early pregnancy when administered intravaginally or transcervically.¹³ However, these highly effective analogues were also found to cause severe gastrointestinal side effects. With further research into prostaglandin analogues, more stable preparations were considered to have better efficacy with lesser gastrointestinal side effects.^{14,15}

The first analogue that was widely researched and used in abortion treatments was gemeprost (16, 16-dimethyl-trans- Δ^2 - PGE1 methyl ester). 1mg of gemeprost administered as intravaginal suppository in repeated doses of 3 hours for a maximum of 5 doses resulted in complete abortion in 87% to 97% of women at ≤ 56 days' gestation.^{15,16,17} As side effects continued with gemeprost, another injectable prostaglandin analogue, sulprostone (16-phenoxy-tetranor-PGE2

sulfony-lamide), was shown to be effective but had similar side effect profile as any other prostaglandin analog.¹⁸

In order to improve the efficacy of mifepristone for the purpose of inducing abortions, researchers in 1985 began to add small doses of uterotonic agents on the last day of mifepristone treatment to improve efficacy.^{11,12,19} This led to the combined use of mifepristone and prostaglandin analogue minimising side effects by reducing the dose of prostaglandin without compromising the efficacy. Following the research of combined effects of Mifepristone and prostaglandin analogue, France in 1988 became the first country to license mifepristone for use in combination with a prostaglandin analogue for early abortion.¹⁹

Research on the combined effects continued into 1991, when investigators from France and the United Kingdom demonstrated that misoprostol a prostaglandin analogue had the desired effect of increasing the uterine activity in early pregnancy and that the combination of mifepristone-misoprostol was potential benefits for its use in early medical abortion.²⁰

The first report on efficacy of mifepristone and misoprostol regimens for abortion was from a study by Peyron et al, a study in France that 873 women at ≤ 49 days' gestation.²² The investigators reported a complete abortion rate of 96.9% - 96.9%.

Another multicenter trial in the United States²³ involving 2121 women at ≤ 63 days' gestation used 600 mg mifepristone orally followed 2 days later by 400 μ g misoprostol orally, showed that the overall effectiveness of this treatment was significantly better for women with earlier gestations: 92% at ≤ 49 days' gestation, 83% at 50 to 56 days' gestation, and 77% at 57 to 63 days' gestation.

Initial studies of mifepristone on optimal dose and dosing schedule, showed that oral therapy was no different within a dose range of 50 mg to 400 mg daily in single or divided doses over 4 days.^{24,25} In 1991, Thong et al²⁶ and McKinley et al²⁷ demonstrated that 200 mg mifepristone followed 48 hours later by 600 μ g misoprostol orally was 92% effective.

Use of 800 ug of misoprostol intravaginally was first demonstrated by El-Refaey et al ²⁸ in 1994. Complete abortion occurred in 95% of women in intravaginal misoprostol group compared to 87% with oral administration with lower incidences of side effects.

Although research on optimising the combined use of mifepristone and misoprostol for medical abortion continued, researchers wanted to improve the acceptability of medical abortion by evaluating home self-administration of the misoprostol. Schaff et al ^{29,30} were the first to evaluate home intravaginal self-administration of misoprostol for women at ≤ 56 days of gestation. The complete abortion rate was found to be 97% with no difference in efficacy at various gestations.

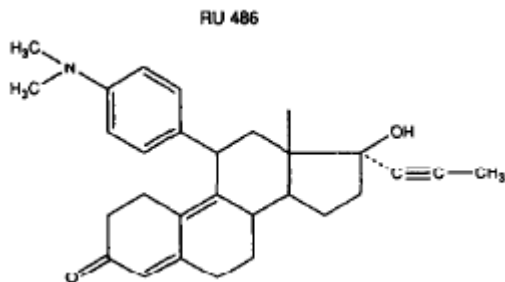
In July 1996, US Food and Drug Administration granted preliminary approval to mifepristone; till further information was available on manufacturing, labelling, and distribution.¹⁹ With the widespread use of combination treatment of mifepristone and misoprostol, it became a universally adopted regimen, however because of political, cultural and economic restrictions these medical abortion regimens were yet to be introduced as routinely available treatments.

Methotrexate as an alternative was tried as an abortifacient after its use in extra uterine pregnancy. Efficacy although acceptable, time taken for the effect of methotrexate was found to be longer compared to mifepristone and prostaglandin regimens.³¹

Chapter 1.2

Pharmacokinetics of mifepristone

Mifepristone (RU486) a derivative of norethindrone is a synthetic 19-nor-steroid. Its chemical composition is 17 β -hydroxy- 11 β -(4 dimethyl aminophenyl)-17 α -(1-propynyl)-estra-4,9- dien-3-one. ^{9,32} Mifepristone acts as an antagonist to progestational and glucocorticoid functions due to its strong binding properties to progesterone and glucocorticoid receptors.



1.2.1 Absorption and distribution of mifepristone

Following oral ingestion, mifepristone is rapidly absorbed to reach its peak serum levels (t_{max}) in 1–2 h. ^{33, 34, 35} The t_{max} values are similar for the dose range of 200–600 mg of mifepristone, analysed by specific RIA or HPLC. ^{36,37}

Whereas the peak concentrations (C_{max}) rise according to the dose of mifepristone. This has been found to be maximum within the dose range of 2–25 mg. ³⁷ At higher doses of 100–800 mg, C_{max} values do not differ significantly, this has been explained due to the saturation of the serum binding capacity for mifepristone. ³⁸

Sarkar et al ³⁹ showed that concentrations of mifepristone were lower in myometrial but higher in abdominal adipose tissues at 12–15 h after oral administration of 200 mg RU486, compared to serum concentrations. Although the absorption of mifepristone by oral route were found to be high (about 70%), its bioavailability was found to be reduced to about 40% due to first-pass

metabolism by the liver.⁴⁰ Absorption following vaginal route have not been shown to be significant for any clinical effect.³⁸

1.2.2 Serum binding characteristics of mifepristone

The main clinical effects of mifepristone depend on serum binding capacity, 94–99% of mifepristone of which is protein bound.^{38, 41} The highly significant correlations between serum levels of mifepristone and serum transport protein AAG (a1- acid glycoprotein) had been suggested by Grimaldi in 1992.⁴² When the concentration of mifepristone exceeds the binding capacity of AAG, it is metabolised, hence the serum concentrations of the metabolites increase the effects of the oral dose of mifepristone. In contrast, doses more than 100 mg do not lead to higher plasma levels.^{34,38}

1.2.3 Metabolism of mifepristone

Apart from the time taken to reach peak serum levels, elimination of mifepristone is equally important for appropriate timing and administration of misoprostol. The elimination phase half-life of mifepristone ($t_{1/2}$) has been reported to vary between 24 and 48 h when analyzed by high performance liquid chromatographic determination (HPLC).^{43,44} However, with radioimmunoassay (RIA) or radioreceptor assay (RRA) $t_{1/2}$ values were reported to be between 54 and 90 h^{33,45}, the most likely reason for this observation was the result of cross reacting of metabolites of mifepristone. Plasma levels of these metabolites were found to increase dose-dependently and exceed the level of mifepristone especially with single oral dose administration of 400 mg or more.^{46,47}

1.2.4 Mode of action

Mode of action of mifepristone depends on its receptor binding. Mifepristone and its metabolites exhibit antagonists properties by binding to its receptor progesterone. Its binding affinity for progesterone receptor has been shown to be 2. 5–5 times that of progesterone.^{47,48}

Mifepristone is regarded as an almost pure progesterone antagonist, however minor agonistic actions have also been reported.^{40,49,50,51} In the 1% of the women where the treatments have

failed when used to terminate pregnancy, it has been suggested that this could have been due to the genetic variation in the progesterone receptors.⁵²

The other probable explanation was that metabolites of mifepristone have a lower affinity to the progesterone receptor, ranging from 9–21% compared to mifepristone.^{46,48,53} The conclusions drawn from the data on pharmacokinetics and binding affinity of these metabolites suggested that they could contribute to 23–33% of the antiprogestagenic effects of mifepristone. Therefore, the biological actions of mifepristone are now considered as a combined effect of mifepristone and its metabolites.^{46,54} At molecular level, mifepristone reverses hyperpolarization of the cell membrane and progesterone-induced inhibition in gap-junction formation.⁵⁵ It can also cause an increase in decidual prostaglandin release and reduce activity of prostaglandin dehydrogenase.⁵⁶

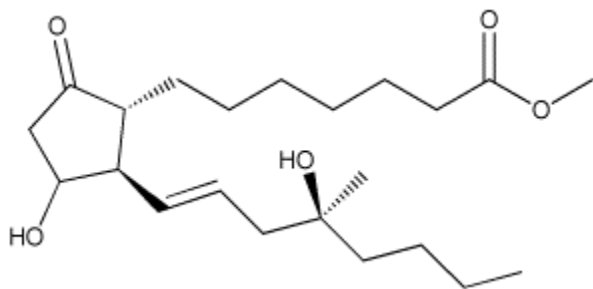
Mifepristone therefore reverses the actions of progesterone in pregnancy by increasing uterine contractility, and sensitizes the myometrium to prostaglandins. By its biochemical actions mifepristone clinically can cause the detached of the gestational sac from the uterine lining as well as softening and dilating of the cervix. Mifepristone is commonly available under the brand names Mifiprex, Mifegyne or Mifegest, and under several other brand names all around the world.¹⁰¹

Chapter 1.3

Pharmacokinetics of misoprostol

Misoprostol (15-deoxy-16-hydroxy-16-methyl prostaglandin E1) is a synthetic prostaglandin E1 analogue. It was initially introduced by Searle in 1973, for the treatment and prevention of peptic ulcer.⁵⁷ It has both uterotonic and cervical priming action. Although misoprostol is not licensed for use in abortion, it has been extensively used off label as an abortifacient in many parts of the world.⁵⁸

Misoprostol is derived from its naturally occurring prostaglandin E by addition of a methyl ester at C-1, a methyl group at C-16 and a hydroxyl group at C-16. This increases the duration of action and improves the safety profile of the drug when taken orally compared to the other prostaglandins E analogues.^{59, 60}



Following the oral administration of misoprostol, it is rapidly and completely absorbed from the gastrointestinal tract. The drug however goes through extensive and rapid first-pass metabolism (de-esterification) in the liver to form misoprostol acid, the principal and active metabolite of the drug.⁶¹

Misoprostol is mainly metabolized in the liver, and less than 1% of its active metabolite is excreted in urine. Misoprostol is not known to cause any drug interactions as it does not induce the hepatic cytochrome P-450 enzyme system.⁵⁸

1.3.1 Bioavailability of misoprostol following various routes of administration

Various routes of Misoprostol administration such as oral, Sublingual, buccal and vaginal have been researched. Pharmacokinetic studies on misoprostol have shown that the peak concentrations are highest following sublingual administration,⁶² whereas the vaginal administration has the advantage of a prolonged time to peak concentration and a slower decrease, in comparison to other routes.^{62,63,64,65,66}

Zieman et al⁶³ performed the first pharmacokinetic study comparing the oral and vaginal routes of administration. Various pharmacokinetic properties such as the peak concentration, time to peak concentration and area under the serum-concentration-vs-time curve after vaginal or oral administration of 400 mcg of misoprostol were compared. With a single oral administration the plasma misoprostol levels increased rapidly and reached a peak at 30 min, plasma levels also declined rapidly by 120 min and remained low thereafter. In comparison, with single vaginal administration, plasma concentration gradually increased, reaching maximum levels after 70–80 min and declined slowly with detectable levels present beyond the 6 hours. The study showed that the peak concentration achieved following oral administration was higher than that following vaginal administration. However, the coefficient of variation of the AUC after vaginal administration was greater than that after oral administration. Based on their findings the researchers concluded that the absorption of misoprostol through the vaginal route was less consistent compared to the oral route among different individuals.

Although vaginal absorption was slower and peak concentration achieved by the vaginal route were lower than that of the oral route, the serum level of misoprostol was sustained at a low level for a longer period of time, this is because the first-pass liver metabolism could be avoided by vaginal route. This property allows for prolonged stimulation of the myometrium resulting in uterine contractions.^{64, 83} It also explains the fewer side effects of vaginal administration as the peak concentration of misoprostol after a single dose of vaginal misoprostol is less when compared to oral misoprostol.

Vaginal route however has variation in its absorption as the tablets may not fully dissolve. Absorption of vaginal route can also be affected by variation in the pH value of vaginal discharge and variation in the amount of bleeding during medical abortion. This can affect the overall efficacy of vaginal administration. This debatable property of vaginal misoprostol has been answered by RCTs on various routes of administration of misoprostol. Other alternative to improve absorption as wetting the tablets or gel form have been tried.

In the study by Zieman et al ⁶³ the AUC₃₆₀ values after oral and vaginal administration were similar. In a similar the study by Tang et al ⁶¹ comparing vaginal to sublingual routes, the absorption of vaginal route was less compared to sublingual route. This difference in the findings on the bioavailability of these two studies was found to be due to wide variation in absorption of misoprostol through vaginal epithelium among different women.

It is available under the brand name of Cytotec, Oxaprost or Cytoprost.⁹⁷ and was originally registered for treating gastric ulcers.

Chapter 1.4

Clinical effects of combined mifepristone - misoprostol regimens based on their Pharmacokinetics

The discovery of combined effect of mifepristone and a prostaglandin analogue on uterine contractility was made in 1985 by Kovas et al ⁶⁷ and Bygdeman et al.¹² Mifepristone increases uterine contractility and sensitises the myometrium to prostaglandin. Recommended combination of drugs for medical abortion is mifepristone followed by misoprostol. ^{95, 96}

1.4.1 Dose of mifepristone

Earlier research on the effective dose of mifepristone suggested that 200-mg dose of mifepristone was as effective as a 600-mg dose.^{26,27,68,69,70,71,30} Later multicentre randomized studies showed that 200-mg dose of mifepristone in combination with prostaglandin was more effective than a 50-mg dose in pregnancy abortion.^{72,73,74,75} Some studies have reported that 100-mg dose of mifepristone might be acceptably effective ¹⁹ based on pharmacokinetics of mifepristone.

In more recent Cochrane review ⁷⁶ six studies were included in the meta-analysis to compare 600mg versus 200mg, 200mg versus 100mg, and 200mg versus 50mg of mifepristone.^{27,72,73,74,75,77} Failure to achieve complete abortion was similar between higher versus the lower dose mifepristone groups (RR 0.90 95% CI 0.77 to 1.05). There was no difference in failure to achieve complete abortion between 200 mg and 600 mg of mifepristone (RR 1.07 95% CI 0.87 - 1.32).

1.4.2 Dose of misoprostol

The same effects were achieved when dose of prostaglandins were reduced to five times lower than used, thus reducing side effects.⁷⁸

Two trials compared different doses of oral misoprostol after 200 mg of mifepristone. Coyaji et al ⁷⁹ compared 2 groups-misoprostol 400mcg to 800mcg given orally (800mcg was administered as a repeat dose of 400mcg after 3 hours), and Shannon et al ⁸⁰ compared 3 groups-misoprostol

400mcg, 600mcg and 800mcg. Failure rates and side effects were found to be similar between the compared groups. There were fewer ongoing pregnancies in the 800mcg compared to the 400mcg group (0.10 95% CI 0.01 to 0.76).

1.4.3 Route of misoprostol

The use of vaginal administration of misoprostol was explored by El Refaey et al.^{81, 82} Most of the current trials involve vaginal dose of misoprostol, however oral misoprostol regimens may be preferable, both due to more acceptability and better understanding of the side effects.

Cochrane review identified six randomized controlled trials that evaluated different routes for their efficacy. Two trials with a total of 1407 women were included in the Cochrane meta-analysis.^{82,84} El-Refaey⁸² used 600mg mifepristone and Schaff⁸⁴ used 200mg mifepristone. Both studies compared 800mcg misoprostol given orally or vaginally after 48 hours⁸² and 24 hours⁸⁴ after mifepristone. The failures were found to be significantly more with the oral route (RR 3.05 95% CI 1.98 to 4.70). Similarly side effects as nausea and diarrhoea were also found to be more in the oral misoprostol group (RR 1.80 95% CI 1.49 to 12.18).

Alternatively buccal routes have been used for their better absorption due to their pharmacokinetic properties. Hamoda et al⁸⁵ and Tang et al⁸⁶ found no difference in failure rates. In the study by Hamoda et al⁸⁵ women received additional doses of misoprostol if abortion was incomplete at follow-up. In another trial⁸⁷ that compared buccal misoprostol to vaginal misoprostol there were more women with diarrhoea in the buccal group compared to the vaginal group (RR 1.51 95% CI 1.12 to 2.03). Failure to achieve complete abortion was similar in both groups.

Tang et al⁸⁶ in 224 women compared sublingual to vaginal route of 800 mcg of misoprostol reported no difference in the failure rates. Women in the sublingual group experienced more side-effects: nausea (RR 1.67 95% CI 1.21 to 2.29), vomiting (RR 2.93 95% CI 1.69 to 5.06), diarrhoea (RR 2.5 95% CI 1.55 to 4.04). More women were dissatisfied with the sublingual method⁸⁵ (RR 2.81 95% CI 1.15 to 6.87) compared to the vaginal group.

1.4.4 Time intervals of administration

The maximum clinical effect was achieved when prostaglandins were administered 36 to 48 h after mifepristone.⁸⁸

Several studies have shown that the complete abortion rates achieved by using 200 mg of mifepristone followed by 800 mcg of vaginal misoprostol administered 48 h later was 95–98% in up to 63 days of gestation.^{12,89,78,90}

Earlier studies on the uterine effects of mifepristone suggested that the peak action on uterine decidual cells was at 18 h after administration.²² However, Murthy et al⁹¹ suggested that the addition of mifepristone to misoprostol, even when administered at the same time, was effective. The exact time at which the clinically relevant physiologic effects of mifepristone occur is not clear. Based on the available evidence on the pharmacokinetics of both mifepristone and misoprostol, mifepristone serum levels peak between 1 ½ and 2 1/2 h after it is taken orally,⁹³ its half-life is 19 h, significant circulating levels of mifepristone remain for more than 48 h.^{91, 92} Misoprostol, when vaginally administered, peaks about 1 h after administration, and serum levels remain constant for 4 h.⁶³ It is therefore biologically plausible that their actions would overlap in the first few hours after administration making it the possible to narrow the time intervals between mifepristone-misoprostol administration to same time, 6-8 hrs or 24 hr intervals.

1.4.5 Single and repeated doses of misoprostol

While many trials explored various routes and doses of misoprostol, researchers have used either single dose or divided doses of misoprostol. This could possibly alter the efficacy of the combined regimens. As shown in the Cochrane review, El Refaey et al⁸¹ in their study of 150 women of < 56 days of gestation compared the efficacy of 800 mcg of misoprostol to 2 doses of 400 mcg 2 hours apart. There was no significant difference in failure rates between administration of 800 mcg of misoprostol as a single dose or by 2 doses of 400 mcg, 2 hours apart (RR 0.70 95% CI 0.21 - 2.39). Side-effects were found to be less in the two- dose group but were not statistically different. Two other randomised controlled trials analysed the use of

repeated doses of misoprostol.^{62, 94} Tang et al in their study used repeated doses of misoprostol (400mcg) on day 4 and 10 either orally or vaginally following 800mcg of misoprostol 3 days following use of mifepristone, more women failed to achieve complete abortion in the oral group compared to the vaginal group (RR 1.60 95% CI 1.00 to 2.57).

Chapter 1.5

Overview of Currently Available Medical Abortion Methods

1.5.1 Mifepristone and Misoprostol: dosages and regimens at different stages of pregnancy

Mifepristone 200 mg is given orally. The dosage, route and the number of subsequent doses of misoprostol change at different stages of pregnancy. Misoprostol can be inserted vaginally or taken by mouth. For the vaginal route of administration, vaginal insertion is ideally done by a provider (nurse or midwife as well as a physician). However if women prefer vaginal tablets can also be inserted by the woman herself up to nine weeks of pregnancy.⁹⁹

With the combination of mifepristone and misoprostol, the regimens recommended by the Royal College of Obstetricians and Gynaecologists (RCOG) National Clinical Guidelines 2011 (**Appendix 1.5.1a**) change at 4–9 weeks, 9–13 weeks and 13–24 weeks.⁹⁹

According to the RCOG recommendation combined mifepristone and misoprostol can be used from the first day of the last menstrual period (LMP) up to 24 weeks of pregnancy.⁹⁹ The mifepristone–misoprostol regimen is more effective if used earlier in the pregnancy: <7 weeks of their last menstrual period (LMP) experience a complete abortion of 95%. Success rates decrease to about 80% at 9 weeks. The side effects of these combined medications for medical abortion have been found to be more significant at later duration of pregnancy.⁹⁸

Contraindication to medical treatments are few^{96, 97, 98, 100} (**Appendix 1.5.2a and b**)

The combined regimen can be provided as inpatient or as outpatient procedure. The outpatient or home use usually involves²³ three clinic visits. On the first visit, the woman takes oral mifepristone and returns to the clinic for administration of misoprostol. 5% of women may however expel products of their pregnancies before the second visit. In some centres where women are treated as outpatient, women are observed for 4-6 hours, as in two-thirds of women abortion can occur within the first 4 h after prostaglandin administration.

For inpatient treatments women remain in the hospital or clinic till the process is confirmed to be complete.

According to the RCOG guidance on abortion care the timing of follow-up visits also varies. Some protocols require women to return to the clinic as early as 3 days after the initial misoprostol administration. Others suggest that women return 1 week after misoprostol administration. Women usually return to the clinic after about 2 weeks for follow-up to ensure that abortion is complete.

If a woman has not had a complete abortion by the first follow-up visit (based on bimanual vaginal examination or vaginal ultrasound), they are offered an additional dose of misoprostol or a surgical option. For those accepting an additional misoprostol dose, most protocols would recommend weekly follow-up appointments for up to 1 month, or longer, if the woman opts to keep waiting for abortion to occur without surgical intervention.

The combined actions of mifepristone and misoprostol intend to induce cramping and bleeding to cause the abortion, 80% of women report cramping and bleeding. Pain is managed with paracetamol or paracetamol with codeine phosphate. It is a common practice to avoid giving aspirin or ibuprofen as these analgesics are known to have antiprostaglandin properties and may counteract the effects of the misoprostol, a study by Creinin et al ¹⁰⁴ however found no empirical support for this practice. Bleeding is common and may seem significant to women but the amount of bleeding is rarely considered to be significant clinically. ¹⁰⁵

Chapter 1.6

Literature review for follow up following treatments for Early Medical Abortions

It is generally recommended that women who have had medical abortions should have a follow-up to confirm complete abortion and the absence of complications. The common complications of incomplete medical abortion are increased risk of infection, persistent or recurrent bleeding and abdominal pain.¹⁰⁶ Early identification of women with retained products of conception following medical abortion treatments is therefore essential for early intervention.

Ectopic pregnancies although rare should be considered for any patient with suspicious findings at the time of follow-up as mifepristone-misoprostol regimen is not considered a medical management for this condition. There are also proven risks of teratogenicity although less and therefore adequate follow-up is necessary to exclude ongoing pregnancies early in pregnancy.

¹⁰⁷

There is no uniform consensus on the ideal time for follow up, vastly because of the different methods employed for follow up and partly service provision. In those services where in-patient treatments are provided, confirmation of complete abortion is by identifying pregnancy products at the time of abortion by clinicians. In those women where outpatient services or self-administration of misoprostol are employed; confirmation is by either USS or clinical examination at the end of 2 weeks. In order to minimise the complications it is recommended to diagnose a failed medical abortion as early as possible, preferably 2 weeks after treatment.⁹⁹ This review discusses the role of clinical assessment, hCG assays, and ultrasonography in medical abortion practice for follow up.

1.6.1 Monitoring medical abortion

The various methods used for confirmation of abortion of the pregnancy:

(a) Clinical assessment including history of vaginal bleeding and expulsion of the pregnancy at the end 2 weeks

- (b) Serial measurement of the decline in human chorionic gonadotropin (hCG) urine or serum
- (c) Sonographic assessment to demonstrate an empty uterus

From earlier research on the behaviour of hCG following mifepristone-misoprostol administration, the conclusions drawn were that β hCG levels increased initially followed by a precipitous decline after administration of misoprostol.^{109,110,111,112} In 1987, Das et al¹¹³ through his in vitro studies demonstrated the inhibitory effect of mifepristone on the placental trophoblastic tissue that could be the reason for a decline in the placental hCG and progesterone levels. This theory however could not explain the initial rise in serum hCG levels as seen in up to 2 days following mifepristone administration in in vivo studies.¹¹² It was suggested by Swahn et al⁷⁸ that the fall in hCG levels following misoprostol administration could most likely be secondary to the abruption of the placenta as a result of uterine contractility. Van der Lugt et al¹⁰⁸ in their research carried out daily measurements of urine and plasma β hCG levels for 2 weeks in women undergoing induced abortions by surgical aspiration. The authors demonstrated that the plasma b-hCG concentration fall was bimodal, with an initial fall in the first 2 days and a further fall in the subsequent 14 days. The decline in the detectable levels of HCG from urine was exponential and gradual; therefore the quantitative analysis of a urine pregnancy test with a sensitivity of 1 IU/ml would almost be negative at the end of 2 weeks after abortion and a positive test 4 weeks after abortion would therefore indicate a high probability of incomplete abortion or persistent trophoblast. Based on the findings of decline in the levels of serum hCG by walker et al¹¹¹ the authors proposed serum hCG measurements as means to monitor the clinical outcome of medical abortion.

The most efficient method of assessing outcome after medical abortion has been transvaginal ultrasonography. Ultrasound assessment has been performed as soon as 4 hours after administration of misoprostol for women being monitored in outpatient setting or the next day in those who self-administered misoprostol at home,³⁰ or most often at the first follow-up visit 2 weeks later.²³

If ultrasonography was performed pre-procedure to confirm an intrauterine pregnancy and gestational age, then absence of the gestational sac on follow-up would confirm a complete

abortion.¹¹⁴ However in those women who had not undergone ultrasonographic examination pre-procedure but reported bleeding after administration of the medical abortion treatments, then the absence of a gestational sac on follow-up ultrasonography most likely would indicate that abortion has occurred.¹¹⁴ In few women of very early gestations where ultrasonography has not confirmed an intrauterine gestational sac, but have undergone treatments with less than significant amount of bleeding; then a differential diagnosis of an ectopic pregnancy or an ongoing pregnancy has to be considered. Ultrasonographic findings consistent with retained clots or chorionic-decidual tissue are common after medical abortion. Most often women expel this tissue in the next few days or so. Therefore early follow up ultrasonography or in those women who are clinically stable, may lead to unnecessary intervention. Alternatively, Wong et al¹¹⁵ proposed that endometrial thickness may be another useful ultrasound parameter in diagnosing incomplete abortion after a first trimester spontaneous abortion.

Most randomized controlled trials on medical abortions have relied on ultrasound to confirm completion of the procedure.⁹⁴ Few cohort studies in the developing countries have used protocols that relied on clinical assessment to assess success of the treatment regimens^{116,117} however these have not been included in the systematic reviews. As these procedures are provided worldwide¹¹⁸ there is ongoing research to find a feasible and acceptable method of follow up.

1.6.2 Methods

A systematic search strategy of electronic databases were searched: MEDLINE (2000 to December 2009), EMBASE (2000 to December 2009), Cochrane Central Register of Controlled Trials). The following terms were used: ("abortion, induced"[MeSH Terms] OR ("abortion" AND "induced" OR "induced abortion" OR "abortion "AND follow up. Language restrictions on publication data were not applied. Cross-references of the selected studies were checked to identify other studies. Relevant abstracts were selected and full text articles were studied. Randomized controlled trials comparing different mifepristone regimens with either misoprostol or gemeprost were included. The outcome was a complete abortion not requiring surgical evacuation.

1.6.3 Results

The literature search identified 352 articles. Among these, nine studies that compared two or more follow-up modalities, including women's self-assessment, clinicians' assessment, serum human chorionic gonadotropin (β hCG) measurements, urine hCG and combinations of the above were included.

A summary of the current evidence on the various methods of follow up to assess treatment outcomes following medical abortions has been shown in **Table 1.6.3a**.

1.6.3.1 Clinical assessment

The review identified three studies that compared clinical assessment of ongoing pregnancy or retained gestational sac with ultrasound. Rossi et al ¹¹⁹ compared both clinical assessment and women's self-assessment of ongoing pregnancy with ultrasound, and the study by Parashar et al ¹²⁰ compared clinical assessment and serum β hCG with ultrasound. Pymar et al ¹²¹ compared clinician's assessment with ultrasound alone.

Pymar et al ¹²¹ were the first to evaluate the ability of the clinician to predict abortion outcome after using mifepristone and misoprostol without ultrasonography. In their study of 40 women \leq 49 days gestation were administered 200 mg mifepristone orally followed by 800 mcg misoprostol vaginally 6–8 hrs later. The ability of the clinician and the participant to correctly predict the passage of the gestational sac at the first follow-up was 90% compared with ultrasound in 85%. The diagnostic sensitivity of the clinician was found to be 95%, specificity 67%, positive predictive value 95%, and the negative predictive value 33% when compared with ultrasound examination. The study was however very small and only reported the clinician's and not the woman's ability to predict outcome.

Rossi et al ¹¹⁹ conducted a multicentre study in 2002–2003, 931 US women pregnant \leq 63 days gestation were administered mifepristone 200 mg orally and misoprostol 800 mcg vaginally 6–8 or 24 h later. In their study the women were asked if they felt they had passed the pregnancy at the end of 6-8 days after the mifepristone treatment. The authors found that women and

clinicians were very accurate at determining expulsion of the gestational sac without ultrasonography or a physical examination. The study however did not include a standardized list of questions to assess if expulsion had occurred. Additionally, the two groups were not comparable as relatively fewer women did not expel the gestational sac compared to a larger group of women who expelled the gestational sac.

Fielding et al ¹²² in their study evaluated clinician's assessment and showed that expulsion of the gestational sac could be predicted in 60% of the women without the need for an ultrasound examination but in 29% of women in whom clinicians believed that sonography was not indicated the gestational sac was still present. The authors concluded that the high sensitivity and positive predictive value supported that women and clinicians can recognize gestational sac expulsion without a physical examination or sonography. It was also suggested that 99% of women would not need a follow-up examination with the positive predictive value of completeness of abortion by the women. However, in situations where the clinician or women were not confident that expulsion occurred, alternative adequate and cost effective outpatient methods for follow- up may be indicated. The authors suggested that telephone method of follow up, the advantage of this form of follow up was speculated to increase accessibility by decreasing both the need and cost associated with follow-up office visits and ultrasonography. It was suggested that if such a policy was adopted then contraceptive counselling would have to be provided at the time of mifepristone administration.

1.6.3.2 Urine hCG

The commonly available urine pregnancy tests are highly sensitive have a threshold of detecting 10–25 IU/L of hCG in the urine.²¹² Previous studies on urine hCG testing following medical abortion treatments have reported the mean number of days of urine pregnancy test to be negative was 31 days after starting the procedure and this was found to be longer than the mean duration of 14 days for transvaginal ultrasound follow-up assessment.¹²³

Two studies that compared urine hCG with other modalities were identified. The first study to examine the accuracy of low-sensitivity (2000 mIU/mL hCG) and high-sensitivity (25 mIU/mL hCG) urine pregnancy tests compared to ultrasonography in a medical abortion trial was by

Godfrey et al.¹²⁴ The authors in this study reported that both tests had very high negative predictive values (96–100%), with very low positive predictive values (1–2%), this was due to the high proportions of false-positive results. The authors also observed that the low sensitivity test performed one week following medical abortion had a lower likelihood ratio and thus was found to be a better test than the high sensitivity assay to determine expulsion of the gestational sac. This finding confirmed that a low sensitivity assay with a negative result would likely allow the clinician or woman to conclude that her abortion has occurred. The authors were however not able to assess the sensitivity of urine testing to detect the outcome of medical abortion treatments as there were very few cases of ongoing pregnancy. Therefore the final conclusions by Godfrey et al.¹²⁴ was that urine testing after medical abortion was of limited clinical value, although a negative test result could exclude a proportion of women from further evaluation.

A semi-quantitative urine dipstick pregnancy test (Orchid Biomedical Systems, Goa, India) that has a positive control, a band sensitive to 10 IU/L and another sensitive to 1000 IU/L was evaluated by Grossman et al.¹²⁵ This prospective study compared the diagnostic accuracy of semi-quantitative urine test to serum β -hCG measurement. The authors reported that semi-quantitative urine test was found to have a higher specificity (71%) than that reported for low-sensitivity test (39%) at days 12–16 following mifepristone.¹²⁴ Interestingly, the study found that the rate of decrease of urine hCG was found to be less than that of initial decrease in serum hCG in women after having a surgical aspiration. The authors concluded that a urine pregnancy test with a sensitivity of 1000 IU/L was most likely be negative 2 weeks after abortion.

1.6.3.3 Serum β hCG

Four studies compared medical abortion regimen of hCG follow-up with ultrasound. Thonneau et al.¹²⁶ in their retrospective analysis found a significant decrease in serum β -hCG levels 2 weeks after mifepristone-misoprostol medical abortion. 23 of 25 women with a failed abortion either due to retained tissue or continuing pregnancy had a serum β hCG level of greater than 500 IU/L, the authors therefore found a correlation between unsuccessful abortion and the continued elevation of β hCG.

In the study by Walker et al ¹¹¹ a 94% decline in β -hCG levels by Day 8, and 1% by Day 14, was found. After expulsion of the pregnancy, the β hCG levels were found to fall precipitously, with the fastest rate of decline in the first 2 days of expulsion of pregnancy.

In a third study by Honaken et al ¹¹², 34 women who underwent mifepristone-misoprostol medical abortion treatments, β hCG levels had declined by >99% by Day 14. The correlation between the pre-treatment β hCG level and final outcome could not be evaluated with the limited number of subjects with failed treatments. Although the percentage decline in serum β hCG levels from days 2 to 3 was inversely and significantly correlated with the time taken to abort the overall correlation between the peak β hCG level and the time taken to abort was found to be non-significant. The conclusion drawn from this study on the kinetics of serum mifepristone were shown to be similar to those in previous studies.¹²⁷

1.6.3.4 Combination tests: USS and endometrial thickness

Rorbye et al in 2004 ¹⁰⁶ found that the prognostic value of serum β hCG and ultrasonography as predictors of late failure were poor. Earlier published predictive analysis on the fall of hCG levels by Creinin et al ¹²⁸, concluded that a decrease in serum β hCG of <50% within 24 h after misoprostol administration was associated with an increased risk of failure of treatments, however the study did not assess the positive and negative predictive values. The authors also reported that the endometrial thickness was significantly higher in late failures than successes after medical abortion. Creinin et al in their study therefore concluded that none of these parameters were found to be clinically useful as a diagnostic test in predicting late failure after medical abortion.

Later Parashker et al ¹²⁰ reported that the endometrial thickness at follow-up varied from 2 to 31 mm 25–35 days post-abortion. For the three failures detected on days 31 or 32, the authors found a correlation between endometrial thickness and serum β hCG levels, but the numbers were too few to support and standardise this type of follow up. The study concluded that the endometrial thickness was not a reliable correlation to clinical outcome.

1.6.3.5 Ultrasonography

The importance of ultrasonography for diagnosing completeness of medical abortion was evaluated by Fielding et al.¹²² In their study of evaluating serial plasma hCG level pre and post treatment, by using 20% decrease in the initial value as cut-off, the authors were able to predict successful abortions in 98.5% of women undergoing medical abortions.¹²⁹ In contrast, ultrasound assessment was found to be reliable in only 89.8% of successful outcomes.

1.6.4 Discussion

Diagnostic value of a test to confirm whether treatments have been successful depends on the clinical situation, consequences of a positive test result, and risks associated with an undiagnosed condition.¹⁰⁶ Failed medical abortion often leads to surgical intervention performed under general anaesthesia. To avoid such unnecessary interventions, positive predictive value of the applied test must be high, specificity should not be <0.95.¹⁰⁶ The diagnostic test should also be simple, cost effective and acceptable.

Studies included in this review show that clinical assessment is an unreliable method for detection of incomplete abortion or ectopic pregnancy. This is mainly due to large individual variation in the time taken to expel the products of conception. Moreover, women's post treatment experiences that are used as indicators for confirmation of abortion treatment can be subjective and there are no validated questionnaires or tools to confirm this.

Biochemical maker for pregnancy-hCG, both in the urine and serum have been explored. Studies that have evaluated semi quantitative methods of urine testing for levels of hCG post treatment have shown that the potential disadvantage of his method is that the results can be either positive or negative making interpretation of the test in the context of determining if further surgical treatment is needed difficult. An inexpensive high-sensitivity (HS) urine pregnancy tests (detection threshold, 25–50 mIU/mL hCG) is likely be negative or faintly positive at 2 weeks after an uncomplicated medical abortion but have also not been found to be clinically useful to determine completion after medical abortion. However the authors have also

stated the potential advantage of urine testing to be more cost effective and a reliable alternative to clinical assessment.

Researchers that have evaluated serum β hCG have reported that the clinical importance in the decline of serum β hCG levels is that it is inversely correlated with the time taken to abort as reported by Honkanen et al.¹¹² This relative drop in serum β hCG makes serum β hCG testing a useful marker to determine successful abortion with mifepristone and misoprostol. Several studies have suggested that serum β hCG drops dramatically within 1–2 weeks.^{106,111,112} However, a complete abortion is also possible despite elevated levels of hCG observed at 2 weeks following mifepristone and misoprostol treatment.¹¹² Also as mentioned in previous research¹²⁴ there are large variations in the β hCG value at the beginning of the treatment depending on the gestational age. This makes it difficult to interpret the threshold for the decline in the β hCG levels at follow-up for that particular gestational age to assess completeness of the treatments.¹²⁶ A longer duration of serial serum β hCG measurements may be therefore be necessary and this would be practically not feasible. A more acceptable suggestion had been a drop in serum β hCG of >50% by 24 h and by >99% by 14 days to be consistent with a complete medical abortion.¹¹¹ Fiala et al¹²⁹ quoted a 20% fall of the initial value as the cut-off at follow-up as having a high sensitivity and predicted correct diagnosis in 98.5% of the patients with successful expulsion. β hCG measurements can therefore have its potential uses for clinicians who require objective evidence with no access to sonography. The other advantage of follow-up serum β hCG is that it can be used to determine an ongoing pregnancy earlier.¹²⁶ It has the additional benefit that it might be more convenient for the woman than a more invasive ultrasound examination. Furthermore this test either urine or serum β hCG does not have to be performed in the same institution that provided the medical abortion, it can be performed most places such as at home, family planning clinics or the GP practices.

The evidence on whether serum β hCG is a sufficiently good marker for evaluation of completeness of medical abortion is inconclusive^{106,111,112}, however a persistently high or increasing serum β hCG level suggests an ongoing pregnancy, even when extra uterine.

A physician's decision to use sonography at the initial visit to assess gestational age or the follow-up exam is based on a range of clinical variables and regional practice variation.¹²²

Ultrasonography has been considered to be an accurate and gold standard method of confirming successful treatments. It gives immediate results in most cases and is inexpensive where available. Women may experience relief as an objective successful outcomes of their treatments. However, the limitations are that ultrasound is not reliable in very early pregnancy i.e. before the yolk sac is visible¹²⁹, but could be useful to in such cases to exclude a persisting extra uterine pregnancy after treatment. Although useful in diagnosing incomplete abortions, the thickened homogenous appearance of the endometrium¹²⁹ in many cases following medical abortions could lead to unnecessary surgical intervention exposing the women to additional risks. The use of ultrasound to determine the outcome of medical abortion and possible need for surgical intervention requires advanced knowledge and skills involving training of the medical staff.

As a result of the lack of uniform consensus on the ideal method of follow up, further studies explored combination tests such as clinical examination with serum β hCG levels and ultrasonography only when indicated.¹²⁰ Other studies combined serum β hCG and endometrial thickness to predict completeness of abortion. The combined quantitative assessment of threshold levels of serum β hCG and endometrial thickness proved to have high positive predictive values with a low sensitivity and were found to be helpful in uncertain clinical diagnosis of completeness of medical abortions. These combined tests therefore have value mainly as adjunct to clinical assessment.

A summary of the factors that determine whether ultrasound examination or serum β hCG measurement is more suitable for follow up was explained by Fiala et al.¹²⁹ **Appendix 1.6.4a.**

1.6.5 Conclusion

Depending on the service provision, follow-up can take place anytime between 1–4 weeks following the treatments. The time interval between treatment and follow-up has an impact on

the findings at clinical assessment, hCG levels and ultrasound. Although all the follow up methods whether on their own or combined are effective methods, a delay until follow up has to be factored when considering the most acceptable method of follow up by women. No study has been published so far evaluating these aspects. From the logistics of various follow up methods, it can be predicted that women would prefer to know the final outcome of the treatments sooner than later and would prefer fewer follow-up visits. The gestational age at the beginning of treatment has to be taken into consideration when considering the appropriate method used at follow-up.

Being able to diagnose pregnancy failures earlier would optimize the medical abortion procedure. It is therefore important to establish post medical abortion guidelines to prevent unnecessary surgical intervention. Scheduling a follow-up visit for a test for confirmation of complete abortion could be used as an opportunity for contraceptive counselling. An ideal test would be that which is cost effective and avoids clinic visits. So far, no standard has been described for the evaluation of successful treatment for the various methods used in clinical practice. Therefore the follow-up protocol should be based on the gestational age and individualised to the patient's requests. The current evidence suggests that fall in serum hCG/urine hCG at 2 weeks is reliable irrespective of gestational age. The use of clinical assessment and women assessment in the form of telephone follow up may seem as an alternative. An earlier and rapid method of confirmation of these treatments therefore warrants further investigation.

Chapter 1.7

Literature review on qualitative aspects of Abortions

This chapter is literature on the various social aspects of abortions that have an effect on the clinical aspects of abortion either directly or indirectly.

This review begins by exploring the attitudes of women towards abortions finding out if there is a temporal trend in the attitudes of general population - men and women over the past few years. Research has shown that women go through a difficult decision making process, this literature review seeks to find out what factors influence women in choosing different abortion methods. This chapter also provides a background on the qualitative aspects of medical abortions tested in the randomised controlled trial. The process of having a medical abortion is complex involving interaction with various medical staff and a literature review on women's experience as they undergo this procedure is highlighted in this chapter. Lastly this chapter defines the long term consequences and emotional aspects of having a medical abortion.

The chapter concludes by connecting this review to the randomised controlled study as part of mixed methods study.

1.7.1 Literature search and methodology

A literature review of MEDLINE, Psycinfo, CINAHL and EMBASE with search terms that included "abortion, induced" OR "abortion" AND "induced" OR "induced abortion" OR "abortion" AND acceptance AND "surgical procedures, operative" OR "surgical" AND "procedures" AND "operative" OR "operative surgical procedures" OR "surgical" AND medical yielded 772 studies. Another search using "abortion, induced" OR "abortion" AND "induced" OR "induced abortion" OR "abortion" AND qualitative identified 668 studies.

The search focused on the period from 1980- 2010 as it was during this period that the medical abortion research had begun and became established in practice.

Those studies that included either medical or surgical methods were used for pretreatment analysis for preferences and reasons for choosing specific form of treatment. For the purpose of

post treatment analysis only comparative studies were considered. Language restrictions were included and limited to only English language. As indicated through citations those studies that included induced abortions for medical reasons as fetal anomalies were excluded from the review.

The search identified sixteen quantitative and six review articles related to medical and surgical abortion treatments. Ten qualitative studies ^{130, 131, 132, 133, 134, 135} and two review articles ^{136,137} assessing women's experience, reasons and decision making process of abortion treatments were identified. Four of these qualitative studies compared medical to surgical treatments. ^{138,139, 140, 141} The search also identified Ipsos MORI survey and National Facility-based Abortion Study 2006 from Nepal, these surveys have been included in the literature review.

1.7.2 Results

1.7.2.1 Attitudes towards Abortions

According to the association of qualitative research an attitude ²⁸⁷ describes a set of beliefs or views held about a concept. It consists of three related elements: knowledge, beliefs and associations regarding the object as emotional attachment that can be positive or negative evaluation; and behavioural intentions towards the object such as purchasing intention, or willingness to become involved. Attitude towards abortion is a classical example about which people can easily form opinions without great technical knowledge and for this reason many social sciences researchers have been interested in public attitudes toward abortion for more than 30 years.

Abortion opinion is interesting for many reasons. Firstly worldwide there are different opinions on abortion. Secondly majority of women from various ethnic and cultural backgrounds feel that the issue is important and personal to them.

In the 2000 National Election Studies in US, 98% of respondents voiced an opinion on abortion. 57% indicated that the issue was "extremely" important, 36% felt that it was "very" important and only 15% said that the issue was "not too important" or "not important at all".

In the research conducted by Ipsos MORI on behalf of BPAS in May 2006, the findings of the survey on awareness of and attitudes towards abortion 63% respondents agreed that the option of having an abortion should be available to women if she did not have to continue with her pregnancy, 18% disagreed and 19% were neutral or had no opinion. The study also looked at the change in trends over the last 5 years, the overall public support for women's rights to abortions seemed to have been unchanged over the last years, 63% agreed in 2006 as compared with 65% in 2001. The proportion of people who agreed very strongly had fallen from 19% in 2001 to 13%. Equally, the proportion who disagreed very strongly had also fallen from 6% in 2001 to 3% in 2005.

The survey also evaluated the response among different age groups, a difference in agreement was noted among the older respondents over 55 years of age, where they were less likely to agree with the legal provision of abortion. Among the group of men, 54% of men over the age of 55 agreed with the legal provision of abortion compared with 63% of men aged 15-34 and 62% aged 35-54. In the group of women, 49% of women over the age of 55 agreed, compared with 62% of women aged 15-34 and 64% aged 35-54.

Apart from the characteristics of the population, the study also analysed approval for abortions under different circumstances. 64% respondents were more likely to approve of abortion where there was evidence that the child would be born with serious physical disabilities and 55% agreement when the child would have serious learning difficulties. 60% of people approved of abortion in circumstances where woman is under 16 years old, however the respondents were least likely to approve in circumstances when the woman did not wish to have a child (48%). Overall significant variation in approval of abortion was seen under different circumstances across sub-groups. Women were more likely than men to disapprove of abortion when a woman did not wish to have a child (42% compared with 34% of men). When analysed according to deprivation levels, very deprived respondents were less likely to approve of abortion where the woman was under 16 (46% compared with 57% who are affluent and 69% who are very affluent). The study also showed that better educated respondents were more likely to agree than those who have no formal qualifications.

The question of whether a woman should have the right to terminate a pregnancy intentionally has been a source of intense controversy for over a generation. Abortion issue has therefore been termed as a “condensational symbol”¹⁴² which means that it derives much of its emotional force from the fact that it exists at the intersection of many fundamental human concerns involving questions of moral theology, human life, gender roles, and sexual morality.

The argument between Roe vs. Wade in 1973, was the origin of significant antiabortion influences. Abortion till then was seen as a solution to a problem pregnancy, often the result of an unplanned pregnancy. At the same time with the emergence of feminist movement and industrialization, there were social changes to reduce the family size. This phenomenon has been characterized by social scientists as demographic transition.¹⁴³

In the Ipsos survey on the legal availability of abortion; 59% agreed, 27% disagreed and 14% were either neutral or had no opinion that abortion should be made legally available to all who want it. In the survey, those belonging to the social classes ABC1 (62%) were more likely to agree that abortion should be made legally available for all who want it where as those from social classes belonging to C2DE 56% agreed to the concept of legal availability of abortions for those who wanted them. Age was found to be another determinant for the opinions regarding legal availability of abortions, those ages over 55 years were less likely to agree with the legal provision of abortion than younger groups. Single people were least likely to disagree that abortion should be legally available (22%) compared with 28% who were married or cohabiting and 54% who were divorced/separated/widowed. Compared with results from 2001 and 2006, the support for legal availability of abortion had fallen from 62% to 59%. The reasoning behind this change in the 5 year period was suggested to be due to the recent developments in medicine and science that could have raised ethical issues relevant to abortion and may have caused some people to change their views.

Culture has also been found to play a role in the decision process. Several studies explored this aspect in their research, Fielding et al¹⁴⁴ explored the significance of culture, religion and political aspects in their study. Lee et al¹⁴⁵ found that American students were less likely to

favor infanticide compared to students in China. Trent et al ¹⁴⁶ had shown that religion had a stronger influence on the legal availability of abortions with Catholicism or Islam displaying a decreased trend in the legal acceptability. A comparative abortion analysis by Hoff et al ¹⁴⁷ in Ireland, Poland, and the United States showed that the cultural had a powerful influence over the legality and acceptability of abortion.

1.7.2.2 Process of decision making

In the process of decision making of having abortion; both social and historical contexts are known to deeply influence women.¹⁴⁴ However, society cannot expect compliance to a social norm as people can act contrary to social expectations. In a pilot study, Astbury et al ¹³⁰ found that majority of women in their study made the decision to have an abortion based on practical and pragmatic concerns, such as a belief in their right to fertility control, having support through the process, and/or the simplicity of the procedure.

Several studies have found one or more of the attributes of women such as age, social, employment and economic status, along with religion, ethnicity and marital status to play a significant role in deciding to have an abortion ^{148, 149, 150, 151}

In a prospective trial by Creinin et al ¹³⁹ on the reasons for women undergoing abortion, authors concluded that the most common reason were not wanting a/another child (63.5%), financial constraints (35.4%), desire to stay in school (16.5%), problems with partner (16.1%), “not married” (6.3%), medical indication or physician advice (3.9%), wanted an abortion because the pregnancy was the result of sexual assault (2.1%), and fear of losing their jobs if they continued their pregnancies (1.8%).

Apart from the other surrounding factors, who women talk to before having an abortion can influence their decisions. In a study by William et al.¹⁵¹ women deciding to have an abortion, were more likely to have talked with friends or relatives. The study found that moral grounds and less pragmatic issues were secondary to personal reasons in decision making.

Personal relationships have a major role to play in the decision process.¹⁵² Some researchers found a involvement with a sexual partner was associated with the use of contraception but when it came to decision making of having an abortion this association was less likely.¹⁵³

In a study by Sihvo et al ¹⁵⁴ the authors explored various personal factors that could have determined women's decisions for an unintended pregnancy. Being single, higher education of the partner, student status of both the woman and their partner, unemployment, work situation, problems in relationships, and number of pre-existing children were all statistically significant in the decision to terminate the pregnancy. They hypothesised that the impact of these factors differed depending on the stage of the life course of the woman.

Multivariate models from the study confirmed that factors influencing the decision to have an abortion in unintended pregnancy varied by age. In the younger age group (<25 years) of women, unintended pregnancies were more commonly terminated when the educational level of a woman and her partner was high, or either one of them was a student. Younger women's abortion decisions were also related to being single or it being an unsuitable time to get pregnant because of her work situation. Among the 25–34 years of age group of women, having an abortion was associated with their reproductive history. Women with no children and women with one child were less likely to be inclined towards having an abortion compared to women who already had two or more children. Similarly, an unstable relationship and a partner's higher education level increased the likelihood of abortion. Among the older women (>35 years), an unstable relationship was associated with an increased likelihood of abortion along with other attributing reasons such as unsuitable work situation, higher education, and being single. The authors reported that the results were not affected by period effects and they remained the same when “years from last unintended pregnancy” variable was added into the models.

The study also reported that worldwide, there was no statistically significant differences among women wanting to terminate or continue an unintended pregnancy based on nationality, religion, income, financial difficulties or work commitments.

In another qualitative study by Kumar et al ¹³² on decision making process prior to abortions, the reasons stated by women for choosing an abortion included an inability to care for a child due to

financial reasons or because they felt too young to provide a stable environment. Lack of family and partner support, educational and financial pursuits were the other reasons stated by women in this study.

In 100 patients interviewed by Saha et al in 2007¹⁴¹ the commonest reason for abortion was unwillingness to have additional children (60%) followed by youngest child being too small or short spacing between pregnancies (21%). Less common causes were economical burden 2%, hyperemesis 1% and pregnancy with pain abdomen 1%. The 2006 national facility based abortion baseline survey in Nepal, reported that nearly all married women with high parity (three or more children) had sought abortion since they had no desire for additional children.¹⁵⁵

1.7.2.3 Surgical vs Medical abortion: Acceptability

Choice of abortion method is important both for women and their providers. Both medical and surgical methods are known to be well accepted. Although both may be acceptable, there are various aspects of the methods that make them more acceptable over other methods when women are given a choice.

The preferences of women and their reasons for preference from studies are summarised in **Table 1.7.2.3a**. The studies were conducted in many countries throughout the world, including the United States and those in Europe, Central America and Asia. Most of the studies included were either observational studies or randomized controlled studies. In the four studies that included qualitative analysis the methods used for data collection were interviews in two studies and open ended questionnaires in the other two studies.

In 1995, one of the earliest review on acceptability of medical abortion in first trimester looked at 12 trials across different cultures and countries.¹⁵⁶ In their review, the authors concluded that there was a strong preference for medical methods. In most trials that offered participants a choice between surgical and medical abortion, 60-70% of patients chose the medical method.

Henshaw et al ¹⁵⁷ in their study combined patient choice and random allocation between medical abortion and surgical abortion, women who were eligible for both methods were asked if they were willing to be randomly assigned to a method, and those who were not were given their choice. 53% were willing to be assigned and those who declined to be assigned strongly preferred one method—surgical abortion (26%) or medical abortion (20%).

In a more recent prospective study of 100 women by Saha et al ¹⁴¹ 74% of the patients opted for surgical abortion in comparison to 26% patients who opted for medical abortion. These results were quite different from earlier reported studies where 84% preferred medical abortion ¹⁵⁸ , 69% medical abortion ^{159,160} and in the study by Bachelot et al ¹⁶¹ 59% had chosen to undergo medical abortion.

Various methods have been used to assess which methods of abortion were preferred by women. Closed questionnaire method was found to be the most common way of assessing acceptability of medical abortion. The most often asked questions were whether they were satisfied with the procedure, whether they would choose the same abortion method again in the future and whether they would recommend medical abortion to a friend. Other approaches were semantic differential rating technique ¹⁶¹ for long term outcomes (2 years) where a pair of opposite adjectives (for example, good-bad) as endpoints on a Likert scale and assessment tools such as the McGill pain questionnaire ^{157,163,164} to correlate acceptability were used. Very few qualitative studies involving interviews were found in the literature search.

Post treatment acceptability and preference are shown in **Table 1.7.2.3b**.

Rosén ¹⁵⁸ and colleagues in their study on acceptability in a randomly allocated sample of women undergoing medical abortion treatments showed that women found self-administered medical abortion method more acceptable and associated their experience more positively. In order to determine if clinical practice reflects the attitudes of the general population, Rosén et al ¹⁵⁸ interviewed both patients and non-patients regarding their preference for medical or surgical abortion. The non-patient groups had equal preference to either method, however those in the

patient group (women actually undergoing abortions) had strong preference for the medical method. Most patients said they would select the same method if they needed a repeat abortion, a slightly stronger preference among women who had a medical abortion (75%) than among those who had a surgical abortion (68%) was reported. Interestingly, medical abortion users who switched preferences (16%) after treatment did so because of pain, amount or duration of bleeding and prolonged length of the procedure. When women who had a surgical abortion were interviewed after treatment, 31% said they preferred medical abortion because it was more natural, involved less risk of infection and required no hospital admission.

In contrast Urquhart and Templeton ¹⁶³ in their study on acceptability of different methods, women who had a surgical abortion were more likely to prefer their method than were those who had a medical abortion. Authors suggested this shift from the normal trend may have resulted partly from the study design and partly due to the higher expectations for the new treatment (medical) under study. However, in both groups, majority of the women were satisfied and said they would use the same method again if they needed another abortion.

Legarth et al ¹⁶⁵ in their study, reported no difference in acceptability of the procedures post treatment despite high failure and complication rates.

In a qualitative study by Holmgren et al ¹³⁸, the author conducted semi structured interviews, two weeks following their treatments, 70-80% of women reported that, if another abortion were necessary, they would prefer the same method.

Interestingly, pre-treatment could possibly have an influence on the acceptability. Henshaw et al ¹⁵⁷ proved this theory of acceptability in their study. In their study, women who agreed to be allocated to either medical or surgical abortion were randomized to one of the methods, while women who had preference to either the medical or surgical method were assigned to the method of their choice. After the abortion, women who were allocated according to their preference, majority of them found medical or surgical abortions highly acceptable, with only 4% opting for a different method in the future. However, 22% of women allocated at random to medical abortion would choose a different method in the future. These results showed that both medical

and surgical abortions were highly acceptable to women who chose the methods. However, in women without a preference and who were allocated at random, the surgical method appeared to be more acceptable.

In another randomized study by Creinin et al ¹⁶⁶ women in the surgical abortion group preferred for the same method again than women in the medical abortion group. In an earlier study by the Creinin et al ¹³⁹, on surgical vs medical abortions most women thought that the medical abortion “took too long”, were dissatisfied with side effects of cramping, nausea, vomiting, diarrhea, or bleeding they experienced, felt that there were “too many appointments, felt that the medical abortions did not seem to work and found the process emotionally difficult to see the tissue pass. However majority of women who felt that medical treatments were too long, expressed that they would choose medical abortion over surgical if they were faced with the decision again. Similarly those women, who perceived the number of appointments as excessive, would still have chosen medical abortion again. Women who found the adverse physical effect experience “not worth it,” 50% of them would choose medical abortion and equally 50% would choose surgical if having an abortion in the future. These results were different in case of failed medical treatments, very few women would choose medical abortion again. Women who were disturbed by seeing the tissue pass also preferred to choose surgical abortion in the future.

Although medical abortion is considered to be associated with more stress, Urquhart et al ¹⁶³ found that 68% of women who underwent surgical abortion reported stress while waiting in the hospital for the operation. The other reasons for stress included the process of being wheeled down to theatre, waiting outside theatre and receiving the anaesthetic. Women following surgical abortions had concerns with focusing on the reality of what was happening, and fears of the emotional consequences.

In a later review on acceptability of medical abortion by Berer et al ¹⁶⁷, the authors concluded that in the studies comparing the acceptability of the two methods, most women were satisfied with the procedure they had chosen and most would choose it again and recommend it to others.

1.7.2.4 Characteristic of patients

In a 1991 study by Tang et al, the authors reported that single women found medical treatments more convenient by preserving their privacy as the treatments did not require an overnight stay and could resume their work as usual. These group of women also felt that surgery might have affected their future fertility. Whereas married women with children often chose surgery due to child care obligations and the extra clinic visits required for medical abortion. In the study by Urquhart et al ¹⁶⁴, the investigators reported that women were less positive towards medical abortion if they were younger, nulliparous, had a failure or problems with the procedure or saw the products of conception.

Other characteristics as age and level of education are parameters that are thought to influence women's choice. In the study by Clark et al ¹⁶⁸ more educated women preferred to avoid surgery. Similarly in a study in the US ¹⁶⁹, 75% of young adolescent girls who had a medical abortion found the procedure acceptable. In the study from Hong Kong ¹⁶⁰, younger and single women were found to more likely choose medical abortion, although in another study in Scotland ¹⁷⁰ did not show any difference in age or marital status between women who chose medical abortion vs surgical abortion.

Ho et al ¹⁷¹ in their review on acceptability of medical abortion suggested that higher preference for medical abortion in those with previous abortions could be biased by sampling, as they might have chosen medical abortion because of a previous unsatisfactory experience with surgical abortion. In order to avoid this bias Henshaw et al ¹⁵⁷ in their study evaluated a subgroup of women who have experienced both procedures. The authors in their study however reported that previous methods of abortions had no influence on preference for abortion method.

Of the women interviewed in the qualitative study by Simonds et al ¹⁷² about three-fourths had one or more previous abortions. The reasons given by women who had a stronger preference for medical treatments, were that women the procedure would be less painful; wanted to avoid anesthesia and/or the insertion of surgical instruments. Some women who had surgical abortions

previously even described their previous surgical experiences as traumatic and so preferred medical abortion. Interestingly in the qualitative study, the unpleasantness of previous abortions that women recalled were related more to the way women were treated by medical workers than with their physical experiences of abortion.

Often acceptability and the reasons for preference are personal and determined by the clinical effects of the treatments. However whether culture has any influence on women's choices can be only speculated from the studies conducted in various countries with different ethnic background. Data from multicenter studies have been reviewed to understand how women perceive and respond to the various methods of abortion among the different ethnic populations. In a multicentric study involving women in China, Cuba and India ¹⁷³, women were asked their opinion on the best and the worst features of medical abortion. Majority of women stated that advantages of medical abortion as: avoidance of surgery and general anesthesia, less pain, safety, ease of use and compatibility with everyday responsibilities. Bleeding was the factor most frequently identified as the worst feature of medical abortion at all sites. Preference for a pain free procedure was especially important among the Chinese women. In another study from Finland ¹⁷⁴, the best features cited by women were avoidance of intervention, avoidance of general anesthesia and perception of it being a more natural method, while the worst features were prolonged bleeding, pain and heavy bleeding. In another multicenter trial in the United States ¹⁷⁵, the three best features were avoidance of surgery, perception of it being more natural, less pain and cramping, while the three worst features included pain and cramping, waiting, uncertainty and fear of the unknown, and the side effects of nausea, vomiting and diarrhea. In Hong Kong ^{159,160}, women found the medical method convenient, safe and natural. Around 10% women found the regimen too time-consuming, side effects bothersome, painful and bleeding too long.

In Scotland, 69–77% women preferred to be treated in the sitting room after prostaglandin administration, indicating that they wished to be treated in a group ¹⁷⁰, 54% women did not wish their partners or friends to be present. In another study in the United States ¹⁷⁴, 30.6% women preferred to be by themselves, while 17.6% preferred to wait with other women undergoing the same procedure.

A study from the US ¹⁶⁸ reported that US Asian women were more than twice as likely as others to choose medical abortion because they believed it was safer. White women were twice as likely to select it because they considered it more natural. Nearly all groups found the method highly acceptable, with few differences in overall satisfaction, willingness to choose it again or recommend it to others.

1.7.2.5 Home Management

Experience with medical abortion is closely related to having a miscarriage which is interpreted as being less invasive, preserving bodily integrity, or feeling less vulnerable while seeing the health care professionals. These factors have largely been found to contribute towards positiveness towards the method.

Among the numerous earlier studies evaluating the various methods of medical abortion for their preference among women, a study by Thong et al ¹⁷⁰ in 1992 conducted in Scotland of 180 women, reported that 25% would have preferred to have the abortion at home, although the option was not yet available then. The rest 75% found the availability of nursing and medical support reassuring showing preference towards hospital treatment.

Later Schaff et al ⁸⁴ in their RCT of 2295 women on efficacy of vaginal misoprostol administered at 1, 2, or 3 days interval after mifepristone provided information on the safety and acceptability of home administration of misoprostol. 1% of patients preferred to use misoprostol in the clinic, 91% found home administration of misoprostol acceptable, and 3% found it unacceptable. The authors stated that most patients preferred the privacy of their homes eliminating the long time spent for medical abortion treatments. This also had additional advantage of reducing the costs of treatment by decreasing the number of clinic visits.

Akin et al ¹⁷⁷ reported that 75% women opted for home use and 25% opted for clinic use of the misoprostol. 91% of those who opted for clinic use thought it would be safer whereas 77% of those who preferred home use thought it would be more comfortable.

In more recent studies ^{26, 30, 84,117} where mifepristone was administered at the clinic, but the misoprostol was administered at home, 80–90% of women found the procedure acceptable. A similar percentage of these women would choose the same method again or would recommend the procedure to other women. These data showed that administration of misoprostol at home is also highly acceptable. A logistic regression analysis by Schaff et al ⁸⁴ showed that likelihood of users reporting the procedure as acceptable was based on their acceptability of pain, bleeding and waiting until the procedure was complete.

Home use and self-administration also seems to vary according to ethnicity and geographical locations. In a multicenter trial by the World Health Organization,⁷³ 32% preferred to have medical abortion at home (41% in Caucasians, 21% in the Chinese population and 34% in other Asian populations). Of those who preferred home use, women were found to be older than 30 years and had previously undergone abortions or had pregnancies. In another multicenter study in the United States, ¹⁷⁵ a many women in the United States preferred to have medical abortion at home (91.7% women felt comfortable taking mifepristone at home, while 65.2% felt comfortable taking misoprostol at home) whereas the Asian and Hispanic women were less likely to feel comfortable taking these drugs at home.

Another prospective study by Hajri et al ¹⁷⁸ exploring medical abortions in women in Tunisia, showed that women who chose home use perceived it to be easy, simple and fast. Misoprostol tablets were however given to women by the oral route. Women who chose home use reported that the preference for home use was attributed to confidentiality, ease and convenience, whereas women who chose clinic use expressed their concerns over safety and fear of complications as a preference for care by health care professionals at the clinic. In their study, most women reported that at least one other person, including mothers, partners, friends or other family

members were present when they were taking their treatments at home. 91.3% of the home users said they would choose to administer the misoprostol at home, however the study found that women whose treatments were successful were more likely to be satisfied than those than those with failures and reported less preference. Similarly, in a study of 1,601 women in eight sites in Vietnam, 87% of the women felt home administration of misoprostol was the preferred method.¹¹⁷ In a Swedish study by Fiala et al¹⁷⁹ of women undergoing early medical abortion at home at ≤ 49 days of gestation, women felt that home regimen was safe and 98% of women said they would use this method if they had a further abortion.

Although most of the evidence on home use comes from RCTs and observational studies there have been few qualitative studies that reported on home use of misoprostol. In one such study by Elul et al¹⁸⁰ conducting in depth interviews in 22 women to explore home use in women undergoing medical abortions showed that all women interviewed had opted to take misoprostol at home. Most of the women were reported to be very satisfied with their home-use experiences. The reasons were that they felt more in control of the process and found it more comfortable at home and not having to return to the clinic for misoprostol. Nearly all women expressed that they would prefer to face complications in the familiarity of their homes where they could cope better. The other pragmatic reasons were having family or friends present, not having to interact with strangers, being able to express oneself as needed, as well as feeling emotionally stronger and safer at home.

Berer et al¹⁶⁷ in their review on choice and acceptability of medical abortions discussed women's home vs clinic use. Based on the evidence from previous studies the authors suggested that women should be given an option for home use of misoprostol however consideration should also be given to those women who would not cope and preferred to stay in the clinic. The authors also quoted a study in England and Scotland¹⁸¹ where women who had a medical abortion in a hospital clinic were asked if they felt they could have coped at home with the bleeding and pain involved. 71% said that they would have been able to cope at home, 36% said they would have opted to use misoprostol at home, had the choice been available. In a French

study by Faucher et al ¹⁸² access to a 24-hour advice by phone for women aborting at home was suggested to greatly reduce anxiety.

1.7.2.6 Over the counter treatments

With medical abortions available worldwide, the safe availability of the medications becomes the responsibility of health care services. However, these medications can still be available without medical supervision posing increased risks to women. As reported by Berer et al ¹⁸³ in his paper in some settings where medical abortion is only available through private practitioners, or self-medication following over the counter purchase is common because abortion is legally restricted, it can be a challenge in these situations to provide safe abortion. There were no studies that looked into this aspect of health care provision.

1.7.2.7 Views on very early abortions

Gestational age and efficacy of the treatments has been extensively studied in the RCT's. Generally gestational age of ≥ 9 weeks were associated with higher failure rates with more associated effects as pain and bleeding, this was shown to be a predictor of dissatisfaction among women assigned to medical abortion in the study by Henhaw et al.¹⁵⁷ However in their study earlier gestational age did not seem to have any impact on acceptability among the women who chose their own method of abortion.

In many abortion providing services, ultrasound is commonly used to confirm gestation and identify abnormalities such as ectopic pregnancy. This practice had become a routine procedure when medical abortion was introduced up to 9 weeks of gestation.⁹⁹ Therefore guidelines for early pregnancy ultrasound have to be followed. As per the early pregnancy scanning guidelines ^{184, 185} an intrauterine gestational sac can be seen as early as 5 weeks by transabdominal scan, however in very early gestations or with sonogram limitations, transvaginal scan may be essential. The limitations are that it may not be possible to provide sonogram service worldwide, in such situations a variety of other alternative methods to confirm and date

pregnancy include patient history, physical examination and pregnancy tests. Ultrasound may then be indicated when other assessments are discordant.⁹⁹ In these situations where ultrasonography examination is not available, treatments have to be carried out with strict follow up to prevent complications associated with undiagnosed extra uterine pregnancies.

Although no earlier studies have established the impact of women on seeing the USS images, the literature search found few studies that allowed comparison to seeing an embryo or fetus whilst having medical treatments. In their study, Slade et al ¹⁸⁶ reported that 51% had strong negative feelings of upset, distressed, sadness, shocked/scared or disturbed on seeing the fetus during medical abortion. Strong negative feelings of guilt/shame or anger were also reported to be directed at themselves in 14% of women. 7% of women felt it made the event more real and questioned what they were doing. 10% of the women had actively tried to distance themselves using the pretext of perceiving the fetus as a picture and not as a baby. 10% of women had neutral feelings and 5% had positive feelings of relief.

In general, seeing the fetus, appears to be a difficult aspect of the medical abortion process which can be distressing.¹⁵⁷ Majority of the women who not seen any clearly definable tissue were relieved and felt that they have avoided a potentially traumatic aspect of the experience. Interesting, positive responses to seeing the fetus or disappointment at having missed, although relatively uncommon have known to be expressed by women in other studies.¹⁸⁶

There are very few studies that have looked at the efficacy of very early pregnancy abortions with the absence of gestational sac on ultrasound examination. Shaff et al in 2001¹⁸⁷ evaluated the administration of mifepristone followed by vaginal misoprostol in early pregnancy when no gestational sac is present on sonogram. This was a prospective pilot study of 30 women who were undergoing medical abortions with no gestational sac present on ultrasonography (till 40 days of amenorrhoea). A baseline hCG and follow up hCG test were carried out at follow up. The authors reported success rates of 93% with no evidence of ectopic pregnancies. There were higher reported cases of ongoing pregnancies in this study. Excessive bleeding with very early pregnancy were not reported in this pilot study. The authors concluded that as very early

abortions are effective and acceptable, there should be a high degree of suspicion of ectopic pregnancy in the absence of intrauterine gestational sac and if treatments are given then a strict follow up protocol with serum hCG would minimise the risk of ectopic pregnancy.

In 2000 a study conducted by WHO ⁷³, 1589 were recruited into a double-blind, randomised controlled trial to compare the efficacy of two different regimens at in women with ≤ 35 days of amenorrhoea. The study reported that complete abortion rate declined from 92.2% at the earliest gestational ages to 80.3% at the later gestations. The failure rates increased from 7.8% to 19.7%, with a likelihood of failing to abort 2.5 times higher if there was a delay by at four to five weeks compared to two weeks delay in initiation of treatments.

1.7.2.8 Psychological aspects

Howie et al ¹⁶² assessed psychological sequelae by a semantic differential rating scale designed to measure self-esteem, and reported consultations for psychiatric morbidity. There were no significant differences between the groups in semantic differential rating scores for self-esteem. Following abortion treatments the rate of women having consultation with family doctors or specialists for subsequent psychiatric morbidity were similar for medical abortion and vacuum aspiration, (15% and 19%, respectively).

Urquhart and Templeton ¹⁶³ compared the psychiatric morbidity before and after surgical and medical abortions by using a standardized questionnaire to screen for anxiety and depression, there was no significant difference found between the two groups. In another study in the UK by Phelps et al ¹⁶⁹ there was no differences in emotional responses in relation to the type of procedure or to the length of gestation. However those women who underwent medical procedures rated it as slightly more stressful and experienced more post abortion physical problems with as disruption to life. Seeing the fetus was associated with unwanted thoughts related to the experience. Berer et al ¹⁸⁸ in their review, concluded that the overall available data indicated that there is little difference in emotional responses between medical and surgical abortions.

1.7.2.9 Long term consequences of medical abortions

In a retrospective study by Kero et al ¹⁸⁹ looking at women's reasoning, reactions and emotions 4 months and 1 year after abortions, 62% reported no emotional distress at the 4-month or 1-year follow-up. At 1-year post-abortion follow up, 74% associated their decision to undergoing an abortion with feelings of relief or release, whereas 50% also expressed parallel painful feelings such as grief, emptiness and guilt. When the authors compared the women's feelings when facing abortion to their feelings related to the abortion at the 1-year follow-up, they found that the number who primarily reported only positive feelings pre-procedure had increased from 16% to 47% while the number who reported only negative (painful) feelings had decreased from 30% to 3%. Those who had both positive and painful feelings remained almost the same (54% and 50%, respectively) at the end of 1 year. The study also reported that positive experiences expressed by women were that of deeper self-knowledge and strengthened self-esteem. The other positive experiences were that of maternal feelings and the knowledge that they were fertile. Tolerance, improvement in their partner relationship or in contraceptive practice were other aspects reported by the study. Those who had mixed or bad experiences related them to the emotional or mental suffering, bad treatment received at the hospital and/or disturbed sexual life.

When Kero et al evaluated relationships, 69% still had a partner relationship with the person they had become pregnant with, 43% described their relationship as unchanged in quality, 45% felt it had improved, while 13% reported that the abortion had influenced it in a negative way.

With aspects of long term effects on employment, 48% reported changes concerning employment; where they either had started to work or worked to a greater extent than before the abortion.

Several studies have shown that post-procedure, relief was the dominant feeling in the immediate and short-term period with very low levels of severe negative responses.^{190,191,192,193,194,195} Very few studies have investigated the long-term emotional response post-abortion. One study by Smith et al ¹⁹⁶ in 1973, conducted that 94% of the women felt satisfied with their decision to have

an abortion and that negative psychological reactions to abortion were rare immediately afterwards and at 1–2 years follow-up. Another study by Schaff et al ¹⁹⁷ found no negative associations occurred with regard to self-esteem up to 8 years following abortion.

1.7.3 Overall summary of findings in the context of this study

Across the various studies, the specific reasons for selecting the medical method included naturalness, privacy, less invasiveness, desire to avoid surgery/anaesthesia, and control over the abortion process. The reasons most frequently mentioned for choosing the surgical procedure were time considerations (perceived as quick), easy and simple, and fewer visits to the hospital. However the reasons for whatever choice women made were based on safety, efficacy, pain avoidance, and convenience.

Both medical abortion and surgical treatments appear to be highly acceptable in women allocated according to preference. In women who did not have a strong preference between medical and surgical abortion, the side effect profile and patient acceptability was significantly better for surgical abortion compared to medical abortion. Women also tend to choose the same method again if they needed an abortion in the future or would recommend the same treatments that were successful for them to their friends.

Method failure was a major reason for dissatisfaction in the medical group. As one would expect, women for whom a method fails are more often dissatisfied. The need for counselling and education regarding medical and surgical abortion was emphasized in all articles as a means to facilitate informed choices and better preparation of women for the actual abortion experience.

Many women for whom medical abortion has failed, however, rated the method as acceptable. This lack of precision limits generalizability of treatments for a critically important health-care service.

This ambiguity that is not possible to address in an RCT will have to be explored by other research tools. A useful tool would be exploratory qualitative study to identify a setting-specific context for discussing abortion methods.

Newer methods as different time intervals and route of administration of medical methods have been tested for their efficacy in well-designed RCTs however disparity may result from unrealistic expectations about a new method or providers' lack of experience in identifying or counselling women likely to be unhappy with the characteristics of the method. As the method becomes better known, expectations may become more realistic. There is lack of qualitative studies on the use and acceptability of different routes and time intervals of medical abortions. This information will be useful to clinicians who are required to give practical advice to women applying to have an abortion.

New approaches to the delivery of the two-drug regimen have also been considered. Alternative methods to avoid repeat visits to the hospital have been explored. A feasible solution to this is home use. This option implies a radical change in empowerment for women. Also allowing them the possibility to take mifepristone at home would increase their privacy and personal integrity even more. Although women are aware of the failures of the treatments, it has not prevented women from undergoing medical abortions. This poses the questions are women conscious of the safety with undergoing abortions in the absence of medical supervision? And has women's awareness improved over years to take the responsibility of undergoing these treatments without medical supervision? The in-depth interviews in this study will explore the perception of home use of medical treatments.

There was no difference in emotional responses or incidences of psychiatric morbidity between women who underwent medical abortion and women who underwent surgical abortion. These studies however raise the possibility of bias in sampling for some of these studies as women had chosen method of abortion after an explanation of the procedure.

Abortions are carried out worldwide. Provision for ultrasound services to date the gestational age of pregnancy are not available in some of the low resourced countries. In these situations abortion treatments are based on clinical history. With very sensitive urine pregnancy tests available women can present for treatments as early as 50 days of amenorrhoea. Studies on the use of medical methods at very gestational age (≤ 50 days of amenorrhoea) have found the procedures equally acceptable, however may place women at risk of ectopic pregnancy. From a health care service perspective the questions would be do abortions still have to be legally monitored or be treated as a routine health provision at the primary care?

The qualitative interviews from this study will add to the evidence on the acceptability of medical abortions at very early gestations and whether over the counter treatments will show the same benefits as seen with over the counter morning after contraceptive pill.

PART 2

EVIDENCE ON EFFICACY OF VARIOUS TIME INTERVALS - SYSTEMATIC REVIEW AND META-ANALYSIS

2.1 Introduction

Mifepristone and the prostaglandin Misoprostol are known to act in synergy with the optimum sensitization of the myometrium occurring after an interval of 36–48 h. This was proven earlier studies on myometrial contractility in response to prostaglandins following mifepristone by Bygdeman and Swahn.¹² In another study by Ashok et al ¹⁹⁸ it was shown that the effect of mifepristone on cervical ripening, dilatation and softening is maximal at 48 to 72 h.

Although the combined synergistic action of mifepristone-misoprostol was found to continue up to a maximum of 72 hrs, the peak increase of its combined effect on the myometrium was noticed from 36 hrs onwards. Therefore a regimen with an interval of 36–48 h between mifepristone and misoprostol administration had been approved and widely recommended.

However, waiting for 2 days may be inconvenient for the women. In view of this, a study ⁷⁸ showed that the sensitisation of the myometrium by misoprostol was found to develop within 24 hrs of administration of mifepristone with further increase in the sensitization until 36–48 hr, but this later increase was not found to be statistically significant. Therefore research into shortening of the time intervals between the administration of mifepristone and misoprostol to intervals of 24 h and 6–8 h have been explored in several studies.^{84,199,200,201} Efficacy has been found to be high in all these studies, depending on the dose, route of administration and potency of the misoprostol used.

In support of shorter time intervals; pharmacokinetic studies ^{39,33,36,46,202} have demonstrated that after ingestion of mifepristone of dose of 50,200 and 600 mg was rapidly absorbed and reached a peak level after 1-2 h for demonstrable biochemical effect. Further studies on the bioavailability of misoprostol have shown that the effect of misoprostol is optimal after 3 h. The peak serum concentration of vaginally administered misoprostol occurred 1 h post insertion with significant serum levels even after 4 hrs, the levels then diminished slowly over time.⁶³

Based on the pharmacokinetics of combined mifepristone and misoprostol regimen the present systematic review of individual randomized controlled trials of mifepristone and misoprostol medical abortion regimens explored the effect of selected regimen variations with regards to various time intervals.

2.2 Methodology

2.2.1 Search and Selection

The population of interest in this systematic review were women who underwent early medical abortions with combined mifepristone and misoprostol regimen, the intervention was shorter time intervals between the administration of Mifepristone-Misoprostol < 24 hrs, the comparison was with the standard time intervals of ≥ 24 hrs, the outcome was efficacy, acceptability and side effects. Following electronic databases were searched: MEDLINE (1990 to December 2010), EMBASE (1990 to December 2010), Cochrane Central Register of Controlled Trials). The terms used included: (abortion OR pregnancy termination OR termination of pregnancy) AND (first trimester OR early) AND (mifepristone OR misoprostol OR RU 486). Language restrictions on publication data were not applied. Cross-references of the selected studies were checked to identify other studies. Relevant abstracts were selected and full text articles were studied. The searches were conducted independently by the librarian.

2.2.2 Study population and eligibility criteria

We included studies according to the following defined criteria:

1. Randomised controlled trials.
2. Women undergoing medical abortion at ≤ 63 days of gestation with singleton pregnancy.
3. Comparison of shorter time intervals as simultaneous or 6-8 hrs with standard time intervals of ≥ 24 hrs.
4. Primary outcomes were considered to be failure rates of the treatments for various intervals

Reviews were excluded from analysis for this review. Only trials and meta-analyses with a clear description of the methods of medical abortions used were included in the analysis. No publicly accessible protocol for this current systematic review is available.

2.2.3 Assessment of methodological quality and data extraction

The systematic review was in accordance with the PRISMA statement **Appendix 2.2.3.a**. Methodological quality of the RCTs was assessed by the Jadad criteria **Appendix 2.2.3.b**. A numerical score between zero and five was assigned as a rough measure of study reporting quality (zero being weakest and five being strongest). Blinding of participants and caregiver as well as blinding of the outcome assessment was not possible because of the type of intervention. Therefore, the maximum score that could be given to these studies was three.

The following data were extracted from the selected randomised controlled trials: publication year, inclusion, inclusion criteria, exclusion criteria, parity, gestational age, dose and route of misoprostol, randomisation procedure, description of cross-over, dropouts, withdrawals, power analysis, success rates, repeat doses of misoprostol, treatment to abortion interval, acceptability and side effects. No original or unpublished data were obtained from the investigators of the included studies.

2.2.4 Data analysis

Primary outcome measure was the effect of various time intervals on failure rates of medical abortion with single or repeated doses of misoprostol at different follow up periods. However, the follow up at 2 weeks was taken the end point for the systematic review. For each study, risk ratio and its 95% confidence interval were calculated for dichotomous variables. Subsequently, data of all studies were pooled using the Mantel–Haenszel method. Fixed effect models with 95% confidence intervals were used throughout with heterogeneity (χ^2) at a 5% significance level, though low power was accepted because few studies were available for meta-analyses. Random effects models were considered where there was evidence of heterogeneity and estimating the variation between studies was difficult with low numbers. The differences were

calculated so that positive differences indicated that the effect favoured treatment and negative differences that the effect favoured control or usual care. Publication bias was not assessed because of the small number of trials. Analysis was performed using Review Manager (RevMan) (Computer program, Version 5.0, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008).

2.3 Results

2.3.1 Selected studies

The search identified a total of 164 studies including 2 duplicates. Of the remaining 162, 98 studies were excluded after reviewing the abstracts. Abstracts of 66 studies that included mifepristone and /or misoprostol regimen were screened for combined Mifepristone-Misoprostol regimen ≤ 63 days of gestation. Of these 35 abstracts were excluded for reasons explained in **Figure 2.3.1a**. 31 abstracts were reviewed to include only those studies that used vaginal routes of misoprostol. The full text of the remaining 17 articles was examined in more detail. This resulted in the exclusion of another 7 articles.

Finally, 10 studies met our inclusion criterion: mifepristone in combination with a misoprostol - 8 randomised controlled trials and 2 systematic reviews - appeared to be appropriate for review and fulfilled the inclusion criteria. A total of 8 publications compared and provided detail on regimen variations. These studies of various regimens with sufficient data were included as individual studies in our analyses. Two of the recent systematic review ^{76,203} filled the criteria for inclusion for this review.

2.3.2 Methodological quality, Description of studies and Characteristics

Table 2.3.2.a describes the specific study regimens, results, sample size, overall outcomes, maximum gestational age, and quality-related study methods for the studies included. Two studies were equivalence trial and two were non-inferiority RCT's. In six RCTs women were randomised using a computer-generated random number list.

For the RCTs by Schaff et al in 2000⁸⁴ and Creinin et al in 2004²⁰⁴ randomisation was stratified according to the recruiting site and in a later study by Von Hertzen et al in 2009^{205,77} stratification was by site and gestational age. The study conducted by Schaff et al⁸⁴ did not report on the rate of withdrawals or cross-over.

Two RCT's compared women who received 200mg of misoprostol and 800 mcg of vaginal misoprostol at 6-8 hrs.^{204,206} One RCT²⁰⁷ included women who received lower dose regimens of vaginal misoprostol of 400 mcg at 6-8 hrs. Other RCT⁸⁴ included women with time intervals of 24, 48 and 72 hours and two RCT's^{204,209} included simultaneous administration of mifepristone and misoprostol. One RCT²⁰⁹ that compared simultaneous administration of mifepristone and misoprostol used oral doses of 400 mcg as the route of misoprostol.

In the eight selected studies, seven studies compared mifepristone-misoprostol (vaginal) regimens at various time intervals. The two studies that compared time intervals of 6-8 hrs treatments to standard treatments; a total of 735 versus 746 were recruited respectively. In the other two RCT's that compared same time treatments to 24 hrs treatment intervals a total number of 594 women were compared to 606 women in each group. RCT by Von Hertzen et al⁷⁷ compared 24hr intervals in 516 women to 48hrs intervals in 517 women.

A total of two studies had results for gestational age <49 days, one for 50–56 days, five for 63 days.

In the most recent Cochrane review⁷⁶ on medical methods for first trimester abortion, six trials were included for this comparison in the combined mifepristone-misoprostol regimen varying in time intervals. Three trials used different dose regimens as well as time intervals; the results were presented for each trial separately. These studies were included in our analysis. However the other three trials that used mifepristone at different doses with various time interval regimens with misoprostol were not included.

In another meta-analysis on flexible regimens for mifepristone and misoprostol time intervals by Wedisinghe et al²⁰³ five randomized controlled trials were compared for the efficacy of

mifepristone and misoprostol administration intervals between 0 (simultaneous) and 72 h in 5139 participants.

Table 2.3.2a also shows the quality related aspects for the trials included in the systematic review. These include methods used for pregnancy confirmation before the administration of treatments, type of administration of misoprostol, methods used for determining treatment outcomes, management of failed treatments and the follow up rates. Pregnancy confirmation and gestational dating were classified as ‘a’ if the last menstrual period and/or physical exam were used to determine the gestational age, ‘b’ for determining the gestational age by abdominal sonography or by vaginal sonography if there were limitations to accurately date the pregnancy by abdominal sonography ‘c’ if vaginal sonography was used to determine the gestational age for all participants in the trial. The type of administration of misoprostol was found to vary within the trials, therefore the various methods used to administer misoprostol were grouped into ‘a’- for self-administered of vaginal misoprostol, ‘b’- if the health care provider (nurse) administered the vaginal misoprostol and ‘c’- if either of the methods was used. The primary outcome was the measurement of complete abortion, this was categorised as ‘a’ if the method was undefined or if history and/or clinical exam was suggested as the method used to determine the primary outcome, ‘b’ if urinary b-hCG were used as definitions of completion and/or sonogram if doubt, ‘c’ if all participants had vaginal sonogram and/or strict serum b-hCG assessments. At the end of first follow up visit; nonviable pregnancies as a result of treatment failures were managed by using different methods. If surgical evacuation was the preferred method, this was categorised as ‘a’, ‘b’ for repeat doses of misoprostol and ‘c’ if expectant management was preferred. Follow-up rates were classified as ‘a’- < 95%, ‘b’ - 95–99%, ‘c’ - > 99% respectively.

2. 3.3 Effect of Time Interval

Table 2.3.3a provides main outcomes for medical abortion (successful, incomplete, and viable pregnancy) by regimen, repeat doses of misoprostol and at various follow up intervals. For the purpose of analysis shorter time intervals were considered if the time intervals between the administration of mifepristone and misoprostol was <24 hours (same day or 6-8 hours). Longer

time intervals included regimens when the time intervals was ≥ 24 hours (24 hrs or 36-48 hrs or 48 hrs)

2.3.3.1 24 hrs versus 36-48 hrs or more

Two studies compared the efficacy of 24 hrs intervals to longer time intervals of 36-48 hrs. Schaff et al ⁸⁴ found no significant difference in failure rates following home administration of misoprostol 800mcg vaginally on day 1, 2, or 3 days later, complete abortion rates were 98%, 98%, and 96% on days 1, 2, and 3, respectively ($\chi^2=4.80$; $P=.09$). The study also reported that the interval between mifepristone and misoprostol administration may be shortened to 24 hrs while maintaining efficacy. In the equivalence study by Von Hertzen et al ⁷⁷ of two intervals of administration 24 hrs versus 48 hrs, the rate of complete abortion was 93.5% for 24- hour interval and 91.7% for the 48-hour interval. Interaction between doses and interval to misoprostol administration was not significant ($P = 0.92$). **Figure 2.3.3.1a** shows the two studies with the relative risk for the estimated failures at 24 hrs versus 36-48 hrs. There was no difference between the two groups (RR 0.87, 95% CI 0.57, 1.32), $P = 0.50$) and little heterogeneity ($P = 0.31$, $I^2 = 1\%$).

2.3.3.2 < 24 hrs versus ≥ 24 hrs

Creinin et al ²⁰⁴ in a multicentre, prospective, randomized equivalence trial found no significant difference in the complete abortion rates measured at 2 weeks for the 6-8 hrs interval and 24hrs interval groups were 96% (95% CI, 94–97) and 98% (95% CI, 97–99), respectively.

In a later study by Guest et al in 2007 ²⁰⁶ that compared treatment intervals of 6-8 hrs to 36 hrs, the success rate of medical abortion of pregnancy with 200 mg oral mifepristone followed by 800 micrograms vaginal misoprostol was found to be higher (96%) with the 36-48 hour regimen compared with that of the 6-8 hour regimen (89%), relative risk = 0.92(95% CI 0.84–0.98). The 6-8 hour regimen was therefore found to be associated with a higher likelihood of requiring a surgical evacuation of uterus for retained products of conception and a nonviable gestation sac.

It was also found that 6-8 hrs intervals were more likely to result in a viable pregnancy requiring a suction abortion compared with the 36- to 48-hour regimen.

In a more recent study²⁰⁸ comparing the smaller doses of 400 mcg misoprostol with simultaneous administration of mifepristone and vaginal misoprostol it was found that the simultaneous administration was almost as equally effective as administration of the two medications 24 h apart. Complete abortion rates with the two dosing intervals, i.e., simultaneous versus 24 h interval were 95.00 and 97.50%, respectively.

Figure 2.3.3.1b shows the overall outcome of failure rates at various time intervals. In the two studies that reported on persistent non-viable pregnancies following treatment failures the relative risk was found to be five times more for shorter time intervals treatments as compared to standard treatment intervals RR 4.91 (CI 1.30-2.85). Although there was little heterogeneity indicated between the studies ($p=0.62$, $I^2=0\%$), the RR could be interpreted to be more RR 1.92 (CI 1.32, 2.78) in the shorter time intervals (< 24 hrs) compared to longer time intervals (≥ 24 hours).

The relative risk of RPOC due to failure of treatments at shorter time intervals was found to be 2.09 (CI 0.66-6.56) and for viable pregnancy the relative risk was found to be 1.48 (CI 0.44-5.00), however this was not statistically significant.

2.3.4 Effect of number of doses prostaglandin analogues

In the eight trials that were included in the systematic review, the time for the first follow up ranged from 24 hrs to 14 days. Most studies had administered repeat dose of misoprostol at the end of the first follow up. In only one study⁷⁷ repeated doses of misoprostol were not used and the follow up was at the end of 14 days. **Table 2.3.4.a** shows the effect of single and repeated doses on success rates of treatments at various time intervals.

Four randomized controlled trials **Figure 2.3.4 a** that were included in the pooled estimate for failures after single dose of 800 mcg of misoprostol showed that the RR of failures was 1.81(CI

1.34, 2.43) in the shorter time intervals. This was found to be statistically significant. There was no heterogeneity ($p=0.88$; $I^2=0\%$). The follow up was at 7 days following the single dose of misoprostol.

2.3.5 Effect of gestational age

Large trials using the mifepristone-misoprostol regimen found statistically significantly higher rates of complete abortion in women with gestation from 57 - 63 days as compared to those < 57 days.²³ For mifepristone- misoprostol regimens, the rates of incomplete abortion were 8% (50-56 days group) and 7% (57- 63 days group) compared with 5% (≤ 49 -days group). The largest increase was in failures with ongoing pregnancy, which increased from 1% in the ≤ 49 -days group to 9% in the 57- 63 days group ($P < 0.001$). Abdominal pain, nausea, vomiting, diarrhea, and vaginal bleeding were also found to be more with advancing gestational age. The authors concluded that mifepristone–misoprostol regimen was more effective in terminating pregnancies of ≤ 49 days.

Studies^{204,206,77} that analysed data for the success rates of complete abortion at various gestational ages, showed that the complete abortion rate did not vary significantly when the gestational age was ≤ 49 days. **Figure 2.3.5 a.**

2.3.6 Acceptability

The results of the acceptability questionnaire from the Schaff et al ⁸⁴ study showed that more than 90% of patients in each time interval group (day 1, 2 and 3) agreed or strongly agreed that the overall procedure was acceptable. Major differences were found in the acceptance of the waiting time to complete abortion with preference for shorter waiting time. Women who were assigned to take misoprostol 3 days after mifepristone were the least likely to report that the waiting involved in their regimen was acceptable; 86% in the day 1 group agreed or strongly agreed that the waiting time was acceptable compared with just 79% in the day 2 group and 76% in the day 3 group ($\chi^2=31.76$; $P=.001$). Logistic regression analysis of variables found to influence overall acceptability were acceptability of waiting (OR, 4.9; 95% CI, 3.28-7.28), pain

(OR, 10.0; 95% CI, 6.3- 15.93), and bleeding (OR, 4.9; 95% CI, 3.24-7.46). Younger women found the procedure more acceptable (OR, 0.96; 95% CI, 0.93-0.99).

Post treatment acceptability questionnaires results were identical between 6-8 hrs group and 24 hrs groups.²⁰⁴ In the 6-8 hrs group 95 % (95% CI, 92%-96%) would recommend this method of abortion to a friend, and 89 % (95% CI, 86%- 92%) would choose medical abortion using this regimen again if they were to have another abortion. Similarly in women who received their treatments 24 hr apart, the results were 95 % (95% CI, 93%- 97%) and 90 % (95% CI, 87%- 92%) respectively.

Patient acceptability for the overall acceptability, vaginal bleeding and adverse effects showed no statistically significant differences between the two groups in the study by Guest et al.²⁰⁶ However the differences were noted in the time taken to undertake the procedure and the severity of the abdominal cramps experienced. 97 % of women in the 6-hour regimen found the shorter time taken to undergo the abortion process to be more acceptable compared to 90% of women in 36- to 48-hour protocol (RR = 1.07, 95% CI 1.02–1.14). The experience of abdominal cramps was less acceptable to those participants in the 6-hour regimen (78%) compared with those in the 36- to 48-hour regimen (87%) (RR = 0.90, 95% CI 0.81–0.99). There was no preference between the participants in the two study groups as to whether they would choose to have the same abortion protocol for any future abortions or to their recommendation to a friend or relative having to undergo an abortion.

Despite the failures and adverse events, 97.5% women receiving treatments at the same time and 95% receiving treatments at 24 hrs (p = 0.56) reported that they were satisfied with the medical abortion and would use this method if needed in future.²⁰⁶

Figure 2.3.6 a shows that the overall acceptability was not found to be significant between the shorter and longer time intervals RR 0.99(CI 0.96-1.03, p=0.69). There was no statistically difference in the personal preference for the same treatment regimens abortions in the future RR 0.99(CI 0.96-1.03, p= 0.73). Similarly when participants in the trials were asked if they would

recommend the treatments regimens to a friend or relative, there was no statistical difference seen 1.00(0.97-1.02, p=0.82). There was no heterogeneity across the studies (p= 0.35, I2=0%)

2.3.7 Bleeding

Abdominal cramping and bleeding typically begin 3–4 h respectively after misoprostol insertion.
210, 23, 22,204

While evaluating the outcome of bleeding at various time intervals Schaff et al⁸⁴ found that 86% of patients started to bleed within 4 hours of using misoprostol. 12% started bleeding between 4 and 24 hours after inserting misoprostol, and the remaining 2% began bleeding more than 24 hours later or never bled at all. There were no differences among the different groups. Of the 1859 women who used misoprostol on their assigned day and had completed data on bleeding cessation the mean of the number of bleeding days was 17.

In the study between the two groups (6-8 hrs vs 24 hrs group) by Creinin et al²⁰⁴ cramping and bleeding began after a median of 2 hours (range, 0–87.5) and 3 hours (range, 0–72.5), respectively, after the first dose of misoprostol when women received misoprostol at 6-8 hrs after mifepristone. In those that received misoprostol after 24 hrs, cramping and bleeding began after a median of 1.5 hours (range, 0–35.75 hours) and 2 hours (range, 0–43.1 hours), respectively, after the first dose of misoprostol. These times were not significantly different. The total duration of bleeding and spotting was also not found to be different between groups (median of 7 and 5 days respectively in 6-8 hrs group, 7 and 6 days respectively in the 24 hr group).

The onset of both vaginal bleeding and abdominal cramps occurred significantly earlier with the 36- to 48-hour regimen compared with the 6-hour in the study by Guest et al. The time taken from the administration of vaginal misoprostol till the end of the vaginal bleeding and abdominal cramps was not found to be statistically significantly different between the two study groups.

Bleeding began after a median of 3.7 hours (range 0 to 74 hours) and 2.0 hours (range -23 to 24 hours), respectively (p<0.001) in the study by Creinin for same time administration of

misoprostol. The total number of days of bleeding after misoprostol insertion in the two groups were 7.90 ± 2.30 days (same time) versus 8.23 ± 2.14 days (24 hrs), ($p = 0.18$). 27.5% and 22.5% of women reported heavy bleeding ($p = 0.83$) in same time treatment and 24 hrs treatment intervals respectively.²⁰⁹ The bleeding was highest on day 1 with the same time treatment and day 2 when treatments were given at 24 hrs interval and then decreased steadily **Figure 2.3.7a**.

2.3.8 Pain

The results of the 2 logistic regression analyses by Schaff et al⁸⁴ found that women who had experienced one or more prior live births were more likely to find pain acceptable compared with women who had no pregnancies (OR 2.6, 95% CI 2.1-3.31). Women of earlier gestational age pregnancies were more likely to find pain acceptable compared to later gestational ages (OR 0.97, 95% CI, 0.95-0.98).

Creinin et al²⁰⁴ evaluated pre- and post-treatment VAS assessments. The median levels of pain reported on the post treatment questionnaires were 57 mm and 58 mm, respectively. The indicated level of pain was 2 mm lower than that anticipated on pre-treatment VAS assessment in both groups. The findings were similar for bleeding with a median post treatment severity of bleeding of 64 mm and 65 mm for the 2 groups, and the differences as compared with pre-treatment estimation of bleeding 5.5 mm and 2 mm lower, respectively.

In the study looking at simultaneous administration of mifepristone and misoprostol²⁰⁸ cramping began after a median of 2.5 hours (range 0-143) and 1.7 hours (range -24 to 115 hours) after misoprostol administration in the two groups compared ($p < 0.001$).

Almost all women were found to have abdominal pain²⁰⁹, however its overall incidence did not differ among the two groups. 7.5% of the women in same time treatment and 5% in 24 hrs group had episodes of severe abdominal pain needing analgesics. **Figure 2.3.7a**

2.3.9 Induction to abortion interval

Data on induction to abortion after misoprostol administration was reported in only two RCTs. In both studies^{209,77} no significant difference was observed in the time interval from misoprostol administration to expulsion of products between the two regimens. The induction–abortion interval was 6.50 ± 1.48 h in 24 hrs group and 5.95 ± 1.81 h in the same time group ($p = 0.13$).

2.3.10 Complications

Data on complications is very difficult to interpret because of the lack of standardized clinical protocols in the various studies and because of the subjective assessments of side effects overlapping with some of the pregnancy symptoms.

In the randomized, multicenter trial of 1080 women by Creinin et al²⁰⁴ evaluating time intervals at 6-8 hrs versus 24 hrs; the side effects of nausea, vomiting and heavy bleeding were significantly more common after misoprostol treatment for women in the 24-h group. Although a few of the side effects differed by gestational age or study site, regression analysis did not show any statistical difference of these effects.

The incidence of nausea, vomiting, diarrhoea, headaches, dizziness and sweating were not statistically significantly different between the 6-hour and 36- to 48-hour regimen in the study by Guest et al.²⁰⁶ However, the chills that were experienced by women as side effects found to be were significantly worse in the 6-hour regimen compared with the 36- to 48-hour regimen (RR = 2.03, 95% CI 1.09–3.77).

The pooled analysis of side effects from all the RCTs included **Figure 2.3.7a** show that the risk of side effects are lesser with longer time intervals compared to shorter time intervals RR 1.10(CI 1.06-1.15, $p < 0.00001$). The overall heterogeneity was ($p < 0.00001$, $I^2 = 71\%$)

Other important clinical factors such as serious complication of haemorrhage requiring blood transfusion and sepsis following infections have been poorly understood as they depend on

screening methods, antibiotic prophylaxis and on population characteristic to be reliably compared across studies.

2.3.11 Effect of Other Regimen Factors that Effect Efficacy

Several other regimen characteristics in studies with shorter time intervals were examined.

Route of prostaglandin analogue administration has been found to be a significant predictor of incomplete abortion for the Mifepristone-Misoprostol regimen. There was very little evidence on different routes of administration with shorter time interval regimens. There were only two studies ^{207,205} that compared oral and sublingual to vaginal routes of administration of misoprostol at shorter time intervals.

In the randomised controlled trial by Creinin et al ²⁰⁷ comparing oral administration of misoprostol 400 mcg at 6- 8 h or 48 h after mifepristone 600 mg, 50% women (95% CI, 35–65%) had a complete abortion within 24 h of the misoprostol dose in 6 to 8 h group, compared to 91% (95% CI, 82–99%) in 48 hr (RR 0.55, 95% CI 0.42–0.73). Thus, decreasing the time interval between mifepristone and oral misoprostol was not clinically beneficial with oral route of misoprostol.

In the most recent RCT (WHO study) by Von Hertzen et al in 2007 ²⁰⁵, complete abortion rates at 2-week follow-up were reported as 84% with the sublingual form of misoprostol administration and 85% for the vaginal group when misoprostol was given at 3-h intervals (0.4%, 95% CI –4.0 to 4.9, p=0.85 equivalence shown). The complete abortion rates were 78% in the sublingual, 83% in the vaginal when the 12-h interval groups (4.6%, –0.2 to 9.5, p=0.06, equivalence not shown). The study concluded that with 12-h intervals, vaginal route are recommended, whereas with 3-h intervals either route could be chosen.

2.3.12 Effect of Study Characteristics

Other quality-related study characteristics as gestational dating, type of administration, outcome measurements were analysed. Examining the influence of gestational dating was difficult because most of the studies used transvaginal sonography to confirm gestational age. In most studies that were conducted in the US, self-administration of misoprostol was routine. Although the studies evaluated the time lag in the self-administration of misoprostol, this was not found to have significant difference in the overall outcomes for efficacy or for the side effects. However, 3% of women found using misoprostol at home to be unacceptable Schaff et al.⁸⁴ The overall effect for the third quality-related study characteristic i.e. the outcome measurement was difficult to compare as most studies used transvaginal sonogram or strict serum b-hCG definitions (“c”), some used b-hCG lenient definitions and transvaginal sonogram if there is doubt (“b”), and none of the studies relied entirely on history or clinical examination (“a”). The success rates of medical treatments with the “c” method of follow up (TVS or serum b-hCG) was 98% (CI 92–100%) and those with the “b” method (b-hCG lenient definitions and transvaginal sonogram if there is doubt) was 97% (CI 95–99%).

There was a wide range of follow up period ranging from 15 days to 5 weeks for the end point of successful outcomes of the treatments; some women were managed as expectant management during this time.

Due to lack of variation within categories of gestational age the effect of previous abortions, parity and previous caesarean section that can affect the success rates could not be assessed.

2.4 Discussion

Meta-analysis for medical abortion based on time intervals of 24 hrs in comparison to ≥ 24 hours treatment intervals showed no significant difference in their efficacy. Therefore for the purpose of this RCT, 24 hours administration was considered as standard treatment. The evidence on other shorter time interval regimens of <24 hours such as same day or 6-8 hrs could not be established due to few comparative studies.

In another meta-analysis on flexible regimens for mifepristone and misoprostol time intervals by Wedisinghe et al ²¹⁰ the complete abortion rates were found to be between 90% and 98%. Although the meta-analysis of pooled data of all RCTs from the study showed no statistically significant difference in efficacy between the shorter and longer dosing intervals, the study reported a slightly lower success rates with administration intervals earlier than 8 h. The authors suggested a ‘flexible policy’ with fully informed consent and consideration of all circumstances in clinical practice. The meta-analysis on the overall failure rates at the various time intervals- same day, 6-8 hrs, 24 hrs and 36-48 hrs in this study favours longer time intervals. However the studies selected for comparison used various routes of misoprostol, repeated doses and different follow up duration. The results on overall failure rates therefore could not be used as evidence for recommending longer time intervals to shorter time intervals.

A further meta-analysis on the effect of number of prostaglandin analogue doses (one versus two or more) at the time of first follow up visit showed that multiple doses of misoprostol in the Mifepristone-Misoprostol regimen were found to have better outcomes than a single dose, with higher success and lower incomplete and viable pregnancy rates in different regimens, though the time of repeat doses varied from 24 hrs to 7 days depending on the time of the first follow up. The differences were however are marginally significant.

This RCT therefore aims to evaluate the efficacy of shorter time intervals of 6-8 hrs avoiding the bias of repeated doses of misoprostol with only vaginal use of misoprostol at 2 weeks follow up with in a pragmatic clinical setting avoiding repeated visits to the clinic.

Gestational age has been known to be a strong predictor of outcomes. The meta-analysis on the various time interval regimens at various gestational ages did not show any difference. In this RCT we have stratified randomisation based on gestational ages to understand if gestational age has an influence on efficacy.

Women using regimens using mifepristone at shorter time intervals (6-8 hrs) were found to find abdominal cramps less acceptable compared to standard time interval administration of

misoprostol. The spectrum of overall acceptability was however found to be the same in all the regimens.

2.5 Overall summary of findings

This systematic review shows that it is difficult to compare regimens across studies when they differ in multiple dimensions (e.g. choice of drugs, number of doses, timing of doses) as well as in subject characteristics. It can be even more challenging to compare the clinical outcomes including side effects due to the rarity of failures (viable pregnancy) with medical abortion treatments. For a treatment to be effective, many patient variables have to be considered, this systematic review has not been able to make firm conclusions on the predictors of efficacy. Relative cost-benefit analysis is uncertain as both regimens require multiple visits. Moreover in those regimens using two or more doses of misoprostol, although improves outcomes require additional visits to the clinics with a prolonged duration of follow up.

Follow-up is another concern, loss to follow-up rates were based on the assumptions that the treatments had worked based on the clinical information and case records. With practicing clinicians not being involved in the administration of misoprostol in most of the studies; the potential for poorer adherence to medication regimens may influence the efficacy in relation to the various time intervals.

These limitations, emphasize the value of well-designed randomized clinical trials directly comparing mifepristone/misoprostol with single dose administration of misoprostol and follow up at 2 weeks to minimise clinic visits. Such trials could eliminate most subject and methodological variation, and, if appropriately sized, could yield more certain conclusions about differences in low probability outcomes.

Despite the fact that < 24 hrs treatment regimen is not significantly less effective than \geq 24 hrs, the failure rates are however found to be higher with < 24 hrs treatment intervals on deeper analysis. This has not stopped health care providers from using < 24 hrs regimen as the general impression is that the shorter regimens are ‘user friendly’.

Therefore the aim was to investigate the < 24hrs time interval to add to the currently available evidence on the treatment effect of time intervals between 6-8 hrs and 24 hrs interval so that a more confident point estimate could be achieved by meta-analysis.

PART 3

CURRENT PRACTICE- OBSERVATIONAL STUDIES

Chapter 3.1

Retrospective audit on Early Medical Abortions at various time intervals

3.1.1 Introduction

At the abortion service clinics (Calthorpe clinic). It was noticed that there was growing awareness of shorter time intervals (6-8hrs) treatments among women referred for medical abortion treatments. This information on shorter treatment options for early medical abortions was mostly accessed from the internet. With this increasing preference for shorter time intervals by women, an audit was carried out to evaluate the potential efficacy of treatment with mifepristone 200 mg and misoprostol 800 mcg vaginally at 6-8 hrs interval for abortion \leq 63 days gestation. This observational study was also considered to have an additional benefit to assess the feasibility of carrying out a randomized controlled trial at the clinic (Calthorpe Clinic) providing abortion services.

3.1.2 Method

Data was collected over a 12 month study period April 2008 to March 2009. Women had early medical abortion treatments at the research centre (Calthorpe Clinic an independent abortion care provider for NHS patients). Majority of the women that were seen in the clinic were referred by their local general practitioners, some from the pregnancy advisory centers and few were self-referrals.

Women received information on the various methods of treatments such as medical and surgical treatments at their respective counselling sessions with general practitioners or counsellors. The appointments for their chosen methods were booked over the phone. Gestational age was estimated by ultrasound assessment during their clinic visit. Only those women with singleton pregnancies of gestational age \leq 63 days were considered as eligible for the purpose of this observational study. A history and physical examination, baseline hemoglobin, and blood type were performed routinely. Women were then seen by a doctor to discuss the various time

interval methods of i.e. 6-8 hrs, 24 hrs or 36-48 hrs. Consultation also included discussion on side effects and failure rates with various regimens. Written consent was subsequently obtained for the medical treatments as per consent guidelines for abortion treatments. The medications were then administered by the nursing staff at the clinic. During their first clinic visit mifepristone 200 mg was taken orally in the presence of a member of the nursing staff and subsequently at their second clinic visit misoprostol 800 mcg was administered vaginally at the preferred time interval. All participants were given a prescription of codeine phosphate 60 mg or paracetamol with dihydrocodeine (500 mg/5 mg) for analgesia. After receiving misoprostol women were treated as outpatient and allowed to go home along with written information. Women were also instructed to contact the clinic if there were any concerns about bleeding, pain or other side effects. If the patient's blood type was Rh-negative, they received Rh-immune globulin 250 iu intramuscularly.⁹⁹

Women were informed that they would be contacted by the nursing staff for a telephone follow up. To confirm if the treatments had worked, women were asked to perform a urine pregnancy test 2 weeks after receiving their treatments. Women were given further follow up appointments at the clinic if they felt that the treatments had not worked. A repeat ultrasound was then performed to confirm either an ongoing pregnancy or retained products of conception. The procedure was considered successful if there was no evidence of ongoing pregnancy or retained products of conception (RPOC). In those women where treatments had failed a repeat course of medical regimen or surgical treatment was offered. Data was collected retrospectively from case note review and the clinic database. This was then analysed on SPSS v 15.

3.1.3 Results

Table 3.1.3a shows the overall results of medical abortions during the study period. 4240 women underwent medical abortions between April 2008 and March 2009. Of these 36% (n=1525) women preferred to have their treatments at 6-8 hrs intervals and 64% (2715) women had preferred their treatments at ≥ 24 hrs intervals.

The overall failed treatments rate was 1% (n=42). The failure rates were 2.2% and 0.4% for 6-8hrs and ≥ 24 hrs treatment intervals respectively. The odds of a failed pregnancy was 6.65 (CI 95%, 3.17 to 13.93)

On further analyses of the failures among the different treatment intervals, in the 6-8 hrs group there were twenty four (73%) ongoing pregnancies and four (44%) in the ≥ 24 hrs group. Women with RPOC after treatments in 6-8 hrs were nine (27%) and five (56%) in the ≥ 24 hrs group respectively **Table 3.1.3b.**

3.1.4 Discussion

From this observational study, the overall failure rates for medical abortions were similar to a comparative review of medical and surgical methods for early abortion.^{211,99} Women preferred ≥ 24 hrs treatment compared to 6-8 hrs treatment in this study. However the reasons for preference for ≥ 24 hrs regimen were not explored in this study. The findings were in contrary to the belief that women preferred shorter time intervals.

Among the overall failures; 6-8 hrs treatments had higher failures compared to ≥ 24 hrs regimen. Therefore the odds of a woman having failed abortion in this observational was found to be approximately 7 times higher with 6-8 hours treatment compared to women having the usual standard treatment of 24 hours.

3.1.5 Conclusion

The conclusion drawn from this study have limitations to show that the actual efficacy of shorter time intervals, a larger randomised controlled study was therefore proposed to answer the question on whether shorter 6-8 hrs time intervals should be continued to be offered and remain an option to women without reducing the efficacy; if so what sort of information would be necessary to be given to the women to make informed decision. Considering the number of women undergoing early medical abortion, this observational study had formed a basis and provided the logistics of carrying out a randomised controlled trial.

Chapter 3.2

Current Practice- Retrospective Audit on telephone follow-up

3.2.1 Introduction

In the UK, according to the RCOG ⁹⁹ recommendation, for women who have their medical abortion treatments as in-patient, should be offered follow-up to exclude continuing pregnancy in whom successful abortion has not been confirmed at the time of the procedure. However for those women who are allowed to go home (out-patient) to complete the abortion process and where the outcome of the abortion is not confirmed clinically, currently there is no evidence to recommend a particular process for routine follow-up, service providers therefore should agree on a local protocol.⁹⁹ Alternatives that have been considered appropriate are for the women to be contacted by telephone post-procedure to assess bleeding and symptoms together with urine pregnancy test or serum hCG determination. Telephone follow up can provide a cheaper and convenient alternative method of follow up. In this study we have explored the effectiveness and responsiveness to telephone follow up for assessing confirmation of completeness of medical abortion.

3.2.2 Method

Women who had early medical abortion at the research centre (Calthorpe Clinic an independent abortion care provider for NHS patients) between the period of October 2008 and December 2008 were contacted by telephone as part of routine clinical practice following their treatments.

All women received counselling by health care professionals about what to expect following their early medical abortion treatments. This included information about bleeding, abdominal cramps and expulsion of pregnancy products. During counselling women's preferred choice of telephone follow up was explored i.e. for a clinic nurse to contact the woman or for the woman to contact the clinic herself. In those women who preferred not to be contacted over the telephone, home pregnancy test at 4 weeks was advised. These preferences were documented in

the notes as the patient's choice. For those women who preferred telephone method of follow up, their telephone numbers were confirmed.

Women who had shown preference for telephone follow up by the clinic nurses, were contacted by telephone within 2 weeks of their treatments of medical abortion. For women who did not respond to the initial telephone call, it was agreed to attempt to call them three times before classifying them as non-respondents.

During the telephone follow up, direct questions were used to know if the women felt that the treatments had "worked". Open ended questions to assess clinical symptoms of bleeding, pain and expulsion of the gestation sac were asked to evaluate subjective assessment of successful treatments. Additional information included open ended questions on their overall assessment and questions related to the after abortion care.

In those women where responses to questions were not adequate and raised the suspicion of continuing pregnancy, transvaginal ultrasonography was performed followed by surgical treatment. Surgical treatment was also offered to women who had positive pregnancy test 4 weeks after medical treatment.

For the purposes of analysis the overall efficacy and successful outcomes of complete abortion were considered if no further medical or surgical intervention was required beyond the initial dose of 800 mcg of vaginal misoprostol.

Data on the telephone follow up was obtained from the review of individual case records and analysed by SPSS v15.

3.2.3 Results

A total of 952 women underwent medical abortion between 1st October 2008 and 31st December 2008.

Of the 544 women whose notes were available for analysis, 289 women (53%) preferred to contact the clinic themselves for a telephone follow up, 151 women (28%) indicated that they would prefer a nurse to contact them regarding their follow up, and 104 (19%) did not prefer any form of telephone follow up.

In the group of women who had agreed to have telephone follow up by the nurse, 56 (37%) were approached by the health care professional's for the telephone follow up and in the other 95 (63%) there was no attempt of telephone follow up.

73% (41/56) responded to telephone follow up when approached by the clinic nurse. Among those who responded to the telephone confirmation, 88% responded to the first attempt of phone call and 12% to a second or more attempts of the phone call. The results of the follow up are represented in the flowchart (**Figure 3.2.3a**).

Subgroup analysis of the 15 failures of the early medical abortions during the period of the study, 8 women agreed to have telephone follow up by the clinic nurse, however of these only 4 women responded to the telephone follow up. All of the 4 women who responded and had telephone follow up within the 2 weeks of their treatments felt that the treatments had worked based on the symptoms of abdominal pain, bleeding and passing of pregnancy products. However, these women were diagnosed to have failed treatments by a pregnancy test done at 4 weeks after their treatments.

Therefore, of the 41 responders to the telephone follow up by the clinic 37/41 (90%) felt that the treatments “worked” and did not have any further treatments, and 4/41(10%) who felt that the treatments “worked”, underwent surgical treatments following a positive pregnancy test at the end of 4 weeks.

3.2.4 Discussion

In this study on preference for telephone confirmation for completeness of abortion following early medical abortions, only 28% preferred the clinic to contact the women following their

treatments for telephone follow up. Although the reasons for less preference for this form of telephone follow up where the nursing staff were to contact the women was not explored, it was speculated that the probable reasons could be issues related to confidentiality. Further qualitative studies will be needed to explore this aspect of women's preferences for follow up.

The overall response to telephone follow up when approached by the clinic was 73%. In this study 90% of women felt that the treatments had worked, and 10% who predicted that their treatments had worked based on their symptoms had further treatments for a positive pregnancy test at the end of 4 weeks. It is not clear if those women with successful treatments had confirmed negative pregnancy test at the end of 4 weeks. In a previous study by Rossi et al ¹¹⁹, the ability of the patient to predict medical abortion treatments outcome was found to have a high sensitivity 96.5% and low specificity 31.3% with a positive predictive value of 98.8% and negative predictive value of 13.5%.

Although subjective confirmation of completeness of abortion may be reassuring for women, more important is the significance of objective follow up in women undergoing medical abortion. Grossman et al ²¹² compared semi-quantitative urinary pregnancy test to serum β -hCG and showed that low sensitivity test correlated well with serum β -hCG measurements among women undergoing medical abortion. With the high sensitivity urine testing of detection threshold of 25-50 mIU/mL hCG and the low sensitivity urine testing with detection of 2000 mIU/mL hCG more than 60% of both the tests can be positive at 2 weeks.¹²⁸ Therefore the reasonable doubt of what should be the cut off level of urinary hCG and what should be the sensitivity level to exclude ongoing pregnancy has to be explored further. This could be best done by quantitative sequential testing to determine a discriminatory zone of urinary HCG within 2 weeks of medical abortion. With no current robust evidence on the quantitative correlation on serum HCG to urinary HCG, this aspect of quantitative urine hCG follow up before and after medical abortion treatments have to be evaluated in the setting of a larger randomised controlled trial as an alternative to serum HCG testing or ultrasonography. Once this discriminatory zone has been determined it would also be significant to assess the response to postal urine sample to test for quantitative urine hCG along with telephone follow up within two weeks of follow up.

3.2.5 Conclusion

As found in this study the limitation to telephone confirmation is the patient's acceptance. The potential of a telephone follow up to predict completion of the abortion process as an assessment tool by reducing further clinic visits and interventions may be useful, however there are limitations as it does not improve earlier diagnosis of failed treatments. Moreover as telephone confirmation is based on the subjective symptoms of pain and bleeding, detailed counselling of women is essential for telephone follow up to be reliable. A more reliable quantitative urine pregnancy test at 2 weeks to assess completion of the abortion process is a useful alternative to telephone follow up. These unproven protocols have to be tested in future studies for reliability and acceptability.

The conclusions drawn were that although telephone confirmation is considered as a cost effective method of follow up in women undergoing medical abortion, the patient's acceptance to telephone follow up is poor and there is also uncertainty about the accuracy of the completeness of abortion purely based on the symptoms. There are other issues that have to be considered such as staffing for a telephone follow up. These issues of telephone follow up and the use of semiquantitative urine hCG as alternative methods for home management of early medical abortions have to be explored in a randomised controlled trial setting.

PART 4

RATIONALE AND OBJECTIVES OF THE STUDY

Chapter 4.1

Rationale for Mixed Methodology

With changing trends in medical field, focus in current clinical practice is towards patient's preference and choices. This change has become more apparent in women's health more so with reproductive choices. One aspect of women's health that is controversial is the provision of abortion care. The core idea of the study was to address various aspects of early medical abortions taking into consideration women's perspective with emphasis on shorter time intervals of administration of the medications. The methodology that was found fit for this purpose was mixed methodology. Both aspects of the study-qualitative and quantitative were carried out under the **TIMES** study (**T**ime **I**ntervals for **M**edical **E**arly **A**bstion**S**).

This chapter discusses the rationale for choosing a mixed methodology for this research project.
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4.1.1 Meaning of Acceptability and Preferences

With an increasing awareness among both the general public and the medical profession for the need to incorporate patient's preferences into medical decision making, preferences influence decision making which in turn depend on acceptability of interventions.

In general, acceptability is a result of an interaction between the values a person holds, ²¹³ individual's perceptions of the attributes of particular products, and service delivery system rather than being strictly an inherent quality of a method. Perceptions are also influenced by the inherent qualities of an item and the available alternatives.¹⁵⁶ They may also be influenced by ethnicity, nationality, culture, class, education, personality and experience.

4.1.2 A Brief History of Mixed Methodology

From the 1950s until 1980s, there was growing interest in using more than one method in a study. It gained momentum in the 1950s with validation of psychological traits on data collected from quantitative studies by Campbell and Fiske.²¹⁴ Later in the 1970s and the 1980s, as mixed methods gained significance within the academic community, varying views from researchers^{215,216} provided the foundations for quantitative and qualitative research. However, the paradigm was whether or not qualitative and quantitative data could be combined. The consensus was to adopt pragmatism as the best philosophical foundation for mixed methods research²¹⁷ and to use different paradigms in mixed methods research but to honour each and be explicit about their use.²¹⁸

Various authors^{219,220,221,222} began discussing specific types of mixed methods designs, paying special attention to issues as validity and inferences. Additionally in 1999, the National Institutes of Health's (NIH) Office of Behavioural and Social Sciences Research published guidelines for qualitative and mixed methods research and included models for combined qualitative and quantitative approaches. The National Research Council (2002) discussed scientific research in education and suggested both a quantitative and a qualitative approach to scientific inquiry. The number of mixed methods studies reported in journal articles continued to increase as mixed methods research was being applied in more disciplines and fields of study.²²³ Mixed methods research has further gained popularity through international journals (Sage Publications started a new journal called the *Journal of Mixed Methods Research* in 2005) and conferences (The first international conference specifically devoted to mixed methods research was held in July, 2005, at Cambridge University)

4.1.3 Definition

Mixed methods research is formally defined as the class of research where the researcher mixes or combines quantitative and qualitative research techniques, methods, approaches, concepts or language into a single study.²¹⁹

In order to understand mixed methods study methodology, a brief description of both methods with its comparison is summarised in **Appendix 4.1.3a**. In quantitative research emphasis is on measurement when collecting and analysing data. Quantitative research generally follows a natural science model of the research process measurement to establish objective knowledge (that is, knowledge that exists independently of the views and values of the people involved). Generally it makes use of **deduction**, that is, research is carried out in relation to **hypotheses** drawn from theory.²¹⁹ Whereas qualitative research emphasises on meanings (words) rather than frequencies and distributions (numbers) when collecting and analysing data. Thus qualitative ‘measures’ are often binary in that they are interested in the presence or absence of phenomena, or they work implicitly with simple scales. Primarily qualitative research seeks to understand and interpret the meaning of situations or events from the perspectives of the people involved and as understood by them. It is generally **inductive** rather than deductive in its approach, that is, it generates theory from interpretation of the evidence, albeit against a theoretical background.

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4.1.4 Mixed methodology for the TIMES study

- 1. When one type of research (qualitative or quantitative) is not enough to address the research problem or answer the research questions.**

Studies on medical abortions so far have assessed acceptability in an objective way, most studies on medical abortions have asked women how satisfied they were with the medical abortion treatments. Some studies on acceptability have asked if they would choose the same treatment or recommend this to their friend, however studies did not include questionnaires to include whether the treatment option was convenient for their circumstances or to fit into their schedule for looking after the family. Qualitative studies although few in number have relied on interviews being conducted before and after abortion treatments. This technique may have several methodological pitfalls for example a user's thoughts recorded before and after use may be interfered by the method's attributes, allowing inferences about any changes that occur difficult to interpret.

2. Pragmatism—practicality; multiple view points; biased and unbiased; subjective and objective.

From the results of the clinical trials on newer methods of medical abortions, there can also be disparity in results when comparing two different interventions arising from unrealistic expectations about a new method or providers' lack of experience in identifying or counselling women likely to be unhappy with the characteristics of the method. Women for whom a method fails are more often expected to be dissatisfied, however within a quantitative study this may have a small impact on overall levels of dissatisfaction. Interestingly, women for whom new medical abortion has failed, may still rate the method as acceptable. In case of medical abortions although the primary outcome is the success of the treatments there can be other reasons for satisfaction or dissatisfaction.

Not only is the acceptability of any method of treatment influenced by the degree of satisfaction of its consumers, it also has important implications for health care planners. With this perspective, Schwartz and Lellouch ²²⁴ distinguished between "explanatory" and "pragmatic" objectives in clinical trials. In summary explanatory trials seek to enhance scientific knowledge by identifying the most efficacious treatment under ideal circumstances, but generalising from a rigidly controlled experiment to actual clinical practice may be difficult.^{225,226} Pragmatic trials seek to answer the clinically more relevant question, "Which treatment is most effective in normal clinical practice?", thus contributing to improved decision making.²²⁷

This concept of pragmatism seems to emerge predominantly in clinical practice for abortions, and for this reason a mixed methodology was found to be an ideal method to answer the many aspects of medical abortion treatments that suit women with the best available evidence.^{222,223,224} The recommendations from this study would also provide a basis for incorporating these aspects into health care provision for medical abortions.

Lewin et al ²²⁸ have explained use of mixed methods for complex health interventions. Complex healthcare interventions that involve social processes can be difficult to explore using quantitative methods alone, qualitative research can hence support the design of interventions

and improve understanding of the mechanisms that effect complex healthcare interventions. Increasing numbers of randomised trials of complex interventions are now thought to include qualitative components.²²⁸

To understand the working principles of mixed methodology, mixing quantitative and qualitative studies is described in the next section.

4.1.5 Mixing Quantitative and Qualitative studies

There are different ways of collecting and mixing data obtained from different studies in mixed methodology.²²³ For this study the approach has been convergent parallel design.²²³ In this method qualitative and quantitative strands are conducted separately yet concurrently and merged at the point of interpretation. In the process there is equal priority given to each strand. It also allows to form a more complete understanding of a topic, or to validate or corroborate quantitative scales. **Figure 4.1.5a** is the diagrammatic representation of the convergent parallel design. The strengths of the convergent mixed method design are that they are intuitive and efficient.²²³

This method was found to be best suited for this study as the researcher is able to collect data for both types of studies within one study group as both types of data have equal value for understanding the research problem. The two data sets would be analysed separately. Following this, the results of the two studies will be merged during interpretation.

However, the challenges can be that they would require substantial effort and expertise. Issues relating to the samples and sample sizes for each type of study can affect interpreting results. The most significant challenge is the difficulty in converging the two sets of different data and the problem of resolving discrepancy in results.²²³

Limitations from mixed methods can also arise if the qualitative studies are carried out before the trial so opportunities to understand better the effects of interventions and how they are experienced by recipients are not being fully utilised. If the qualitative studies had important

methodological shortcomings then their findings would poorly be integrated into those of the trial in which they were nested.²²⁸

Foot note: § References for this chapter are from 1950-1970, this is because the history and principles of mixed methodology dates back to this period. They have been mainly quoted in published books.

Chapter 4.2

Qualitative and Quantitative aspects of this study

4.2.1 Rationale for RCT for shorter time intervals

For abortions of up to 63 days gestation there is convincing evidence suggesting that mifepristone (200 mg) orally followed 1-3 days later by misoprostol 800 micrograms vaginally is safe and effective with 95-97.5% of women achieving complete abortion.^{99, 229, 71}

A Cochrane systematic review concluded that there was no difference in the failure rates of abortion when comparing day 3 versus day 2 and day 2 versus day 1.^{84,207} These studies also compared the side effects (nausea, vomiting, and diarrhoea) and found that there was no difference in occurrence of side effects between the 2 groups. Based on the available evidence on 24-hour vaginal misoprostol administration, it is clear that use of misoprostol at a 24-hour interval can be a standard regimen.

A pilot study on the same day (i.e. 6-8 hours) administration of mifepristone and vaginal misoprostol that showed a promising regimen of a shorter time interval for medical abortion up to 63 days gestation. The authors, however, suggested that further investigations were required.^{230,121} In two US based multicentric RCTs by Creinin et al more than 1000 women were evaluated for efficacy of flexible regimens. The authors concluded that shorter time intervals (6-8 hours) were as effective as the 24 hour regimen.^{207,208} Although the effect on efficacy was found to be more, additional doses of misoprostol were used during the study. A subsequent small RCT of 450 women has shown that administering misoprostol on the same day was less effective than using misoprostol at 36-48 hours after mifepristone.²⁰⁶

These studies, with conflicting evidence, have resulted in a large variation in clinical practice for administration of misoprostol at different time intervals for medical abortions.

A non-inferiority RCT to evaluate the effects of 800 ug of vaginal misoprostol administered 6-8 hours compared to that administered 24 hours following 200 mg of mifepristone in medical

abortions of ≤ 63 days gestation will add to the evidence on shorter time intervals. In this study the efficacy at the end of 2 weeks with no additional misoprostol administration or conservative management will be evaluated. It would also be important to patients and the NHS, as shorter time intervals of administration of misoprostol, if found effective and safe, will avoid unnecessary interventions, clinic visits and shorten the entire process of abortion.

4.2.2 Rationale for RCT to assess follow up

Follow up and evaluation for completeness of abortion has clearly become an important issue in the context of the current varied practice of different medical regimens of different time intervals.

Based on previous observational studies ¹¹⁹ the ability of the clinician and patient to predict pregnancy expulsion after using mifepristone and misoprostol for medical abortion up to 63 days gestation can be inaccurate in determining the expulsion of the gestational sac without ultrasonography or a physical examination. Other objective methods as measuring serum hCG ¹²⁹ and ultrasonography assessment ¹²⁰ before treatment and at follow-up are effective methods. However, the Cochrane review on follow up stated that it is not clear if the new regimens could be implemented where back-up facilities are not available and women are less likely to attend for the follow up. In our follow up we will be assessing the various follow up methods as clinical history, serum hCG and ultrasound scan in women treated with 6-8 hours and 24 hour treatment intervals and anticipate that the outcome data from both the study groups at various gestations will help clinicians to offer a reliable method for follow up in accordance to the patient's choice.

4.2.3 Rationale for Qualitative study

Qualitative studies in the past have focussed on the various experiences of abortions evaluating a wide range of issues and have compared women's experiences with medical versus surgical abortions.²³¹ As with earlier studies, most trials of new medical abortion regimens have assessed acceptability or satisfaction post treatment. In general, overall satisfaction has been reported as

high regardless of regimen.¹⁷¹ However, specific aspects of the medical abortion treatment such as women's preferences for various routes of administration have not been explored.

A narrative review of qualitative studies of women's experiences of abortions and their perspectives on surgical or medical methods by Lie et al ¹³⁷, identified 18 qualitative studies on women's experiences of abortion and concluded that qualitative data was inadequate and data often missing on factors affecting the choice of method of abortion.

Literature review on these aspects (Chapter 1.7) showed that there is little research available regarding women's perception on aspects of medical abortions such as; very early abortions; newer methods of medical abortions; experiences though the process. In this study, a qualitative study of women's preferences, beliefs and experiences with medical abortions will be explored. The evidence generated from such a study can add to the aspects of medical abortions from the women's perspective that can have clinical implications for better service provision as well as help us understand the process of decision making that in turn can have an effect on wellbeing of the women

There is also limited data in early pregnancies focussing on the ethical dilemma of psychological impact and preferences to medical abortion with an identifiable or unidentifiable fetal heart within the gestational sac. This study will also explore women's views on these issues.

Chapter 4.3

Objectives of the study

4.3.1 Objectives of the RCT

To evaluate the efficacy of shorter dose regimens with a time interval of 6-8 hours compared to 24 hours of misoprostol 800 micrograms administered vaginally following oral 200mg mifepristone in women for medical abortion up to 63 days of gestation.

The primary outcome would be to determine the proportion of complete abortions where no further medical or surgical intervention beyond the initial dose of vaginal misoprostol required.

The secondary outcome measures would be to evaluate the induction to abortion interval, adverse effects, pain, bleeding and acceptability of women towards the new regimen, and to determine the most reliable methods of assessing completeness of abortion following medical abortion.

4.3.2 Objectives of Qualitative study

The aim of the qualitative study will be:

- To explore the decision making process of women undergoing medical abortions while looking into:
 1. Views and Attitudes of women towards abortions
 2. Understanding the Process of Decision making
 3. Views and Attitudes of women towards various methods of abortions
- To explore the acceptability of medical abortions:
 1. Views of women on the newer methods of medical treatments
 2. Understanding women's views on Follow up
 3. Understanding women's expectation before and their Experience after treatments
 4. Understanding women's views on Home Use
 5. Understanding women's views on very early abortions

- The study also will explore the process of having medical abortions:
 1. Understanding how well women are informed
 2. Understanding the role of health care providers
 3. To know what kind of Support women have during abortions
 4. Understanding Perceptions of women about USS
 5. Understanding the emotional Experience of women with abortions
 6. Understanding women's views on preventive measures

PART 5
RANDOMISED CONTROLLED TRIAL

Chapter 5.1

Methodology

5.1.1 Study design

The study was designed as non-inferiority RCT to compare 6-8 hours (shorter time interval) medical abortion regimens to 24 hours administration of 800 mcg of vaginal misoprostol following 200mg oral mifepristone in women having medical abortion for ≤ 63 days of gestation.

According to DOH statistics on abortion (2010), 94% of abortions were funded by NHS; 60% took place at independent sector under NHS contract. This study was conducted at an Independent Abortion Care provider-the Calthorpe Clinic, Birmingham. The provider was approved Abortion and Contraceptive care provider for women being referred from Primary care general practitioners, Family Planning Clinics and Brooks Pregnancy Advisory Centre. The clinic was considered suitable for the study on medical abortions due to the following reasons: 1) the nature of the treatments and 2) for the logistic that these services were not provided by the NHS units 3) outpatient setting

Women were recruited when they attended the clinic. Healthy women requesting medical abortion with a single intrauterine pregnancy of ≤ 63 days of gestation, willingness to comply with the study and follow up within 2 weeks at the clinic were considered eligible for the study. Women eligible for the study were allocated to control (24 hours interval) or intervention group (6-8 hours interval) according to computerised randomisation codes. Once randomised participants were then administered 800 mcg of misoprostol by the vaginal route depending on the treatment arm they were randomised to. Women were also offered the option of self-administration under supervision.

Follow up visit to confirm complete abortion was arranged at 2 weeks ^{71, 232,233,106} by one or all of the following methods:

1. Telephone confirmation of bleeding / passing a gestational sac 48 hours following administration of misoprostol and up to 2 weeks.

2. Performing a semi-quantitative urinary β hCG pregnancy test pre and 2 weeks post treatments. Semi-quantitative urine β hCG measurements were performed by Veda lab urine hCG analyser. A cut off level of at least 20% fall from the initial β hCG was considered as completion of abortion ^{106,111}
3. Ultrasound scan to confirm complete abortion.

As observational study on follow up (**Chapter 3.2**) had shown poor follow up rates, all women had to preform urine pregnancy test at home at the end of 4 weeks to confirm complete abortion. (routine protocol followed in the clinic). Women were asked to report if they had a positive pregnancy test. This was considered while assessing success of the treatments for this study especially in those women who were lost for follow up.

Primary outcome measure was completeness of abortion at the end of 2 weeks.

Secondary outcomes were acceptability, pain, bleeding and severity of side effects measured at the end of 2 weeks during follow up.

Participants were asked about their acceptability and side effects by a questionnaire **Appendix 5.1.1a**. For the treatment adverse effects, following responses were considered to be clinically insignificant: (a) none at all; (b) present, but not worse than before taking the medication (c) present and worse than before, but not troublesome and not clinically significant with responses: (a) present, worse than before and troublesome, but with no requirement for additional treatment and (b) present, worse than before and severe enough to require additional treatment.

Patient acceptability was assessed by the time taken for the treatment, vaginal bleeding, abdominal cramps, treatment adverse effects and overall acceptability of treatment. Following responses were considered to indicate satisfactory acceptability: neither agree nor disagree, agree and strongly agree. Patient acceptability was unsatisfactory if responses were: strongly disagree and disagree.

In participants who failed to respond at 2 weeks, data collection was attempted by contacting participants over telephone or by postal questionnaire. For participants who did not have any follow up at the end of 2 weeks, effectiveness of the treatments was confirmed through case notes review. To avoid any further bias, all women were asked to report if the pregnancy test was to be positive on urine pregnancy test at the end of 4 weeks. In cases where medical abortion was unsuccessful at the 2 week follow up visit, either a repeat misoprostol dose or a surgical abortion was offered irrespective of the viability of the gestation, this was as part of the routine care and was not considered part of the research objective.

Flow hart describing the RCT and summary is shown in **Appendix 5.1.1b, Appendix 5.1.1c.**

5.1.2 Subject Population

Participants were recruited if they found to be eligible for the study based on the inclusion criteria **Appendix 5.1.2a** and exclusion criteria **Appendix 5.1.2b**

5.1.3 Sample size calculation

As this study was designed to be a non-inferiority study, the sample size was calculated based on the effectiveness of 6-8 hrs interval by the study by Creinin et al.²⁰⁴ Sample size of 600 per group with 1200 in total at 80% power, $p=0.05$ (one-sided test) assuming that 0-24 hrs works at 97%, 0-6-8 hr interval at 95%, but less than 92% would be unacceptable. Allowing for a 10% drop-out rate, 1300 patients would be required.

5.1.4 Subject Recruitment and Consent

Women were informed of the study at the referral centres through Participant information leaflet **Appendix 5.1.4a.** This was based on the standard information leaflets on medical abortions, changes were made accordingly for research purposes. Women were also provided information on the study at the time of booking appointments in order to make women aware of the possible arrangements that would be required for shorter time interval treatments. Participant information leaflets with the study details were provided for women if they missed the opportunity to be

aware of the study while waiting to be seen by the Health Care Professionals at the Calthorpe Clinic. Participants were seen by nursing staff to have their clinical history, transabdominal (TAS)/ transvaginal (TVS) ultrasound and for blood tests (routine procedure). Nursing staff trained in early pregnancy scans performed either TAS or TVS as appropriate to date the pregnancy. Following this women who had shown interest in the study and were suitable for medical abortions were seen by the researcher. The initial consultation by the researcher involved assessment for eligibility of the study. Willing participants were consented **Appendix 5.1.4b** to confirm their decision for randomisation into either of the treatment arm. Randomisation, appointments for the misoprostol treatment and for 2 weeks follow up was given by the researcher as per the allotted arm.

5.1.5 Randomisation

A computerised randomiser constructed by the statistician at University of Birmingham was used for randomisation. Opinions from the WHO expert on RCTs for abortions was considered in creating the randomiser. In order to ensure that participants were allotted equally into different gestational age groups, randomisation was stratified by the woman's age, parity, number of previous abortions and gestation using a minimisation procedure. Women were then randomised to receive 800 micrograms misoprostol administered vaginally at either 6-8 hours or 24 hours following oral 200mg mifepristone.

5.1.6 Data Collection

Baseline demographic data, as previous abortions, socioeconomic status and ethnicity were collected by the researcher and filled on the computer randomiser. Eligibility criteria was also cross checked on the computer randomiser before processing for randomisation. Those women who were randomised for the study had their urine hCG levels quantified by semi-quantitative method using the Veda lab urine hCG analyser. The initial urine hCG results were collected for pre-treatment to compare with the post treatment levels.

Contact details including telephone numbers along with preferred time to contact them were also collected for telephone follow up. All participants were attempted to be contacted by the nursing

staff by telephone to assess completeness of abortion. A telephone follow up questionnaire was filled in over the phone **Appendix 5.1.6a**.

At the 2 week follow up visit at the clinic, post treatment urine hCG and ultrasound (TAS) to confirm success of the treatments were performed. Complications and any unscheduled visits to hospitals were documented. Participants' acceptability and assessment of secondary outcomes **Appendix 5.1.1a** was also collected at the 2 week follow up. Secondary outcome questionnaires included: (i) duration and severity of vaginal bleeding; (ii) visual analogue scale to assess pain (iii) the severity of side effects.

Participants who consented for the interviews were interviewed during their 2 weeks follow up visit to the clinic.

5.1.7 Data Generation and analysis

Statistical tests were discussed with the statistical advisers to compare two independent samples - the intervention groups (6-8 hr time interval) and the control (24 hr time interval).

The data was entered into a database and analysed using SPSS v19.

Descriptive statistics was applied as appropriate according to the distribution of variables. Categorical data was reported as percent, and non-categorical data was reported as mean / median and interquartile range. The main analysis compared primary outcomes in the two arms of the randomized controlled trial. Mann–Whitney's *U*-test for ordinal or non-parametric continuous variables and χ^2 test or Fisher's Exact test, as appropriate, was used for independent nominal data. Statistical significance was defined as a p value <0.05 and 95% confidence intervals were appropriate. Ordinal data such as the treatment adverse effects and patient acceptability were analysed in two categories to generate relative effect sizes. Dichotomous variables were described using proportions. Where appropriate, relative effect sizes were quoted with difference between medians or relative risk (RR) with 95% confidence intervals. All data were analysed primarily on an intention-to-treat basis.

Socioeconomic status was based on the five-class version of self-coded NS-SEC **Appendix 5.1.7a**. and also graded based on the level of education as per the International Standard Classification of Education (ISCED) **Appendix 5.1.7b** for this study as many women were in the younger age groups.

5.1.8 Study monitoring

An interim analysis was intended to be carried out to assess complete abortion rate and side effects profile of the treatment regimens. As the numbers to recruit were many, an interim analysis was required to assess the feasibility and continuation of the study.

Setting up the study involved recruiting women from referral centres to the Calthorpe clinic. The awareness of the study at the practices was promoted by visit to the practices by the researcher. During the course of the study, it became clear that fewer women than expected were being recruited and as a result, further general practices were approached.

Based on the recruitment logistics it was decided that the initial analysis of the recruited 121 would be taken as pilot data for the feasibility of the study.

5.1.9 Ethical Considerations

Prior to commencement of the trial, a Clinical Trial Authorisation was obtained from the MHRA (Eudract number 2009-010277-21), favourable opinions were sought from the Research Ethics Committee and South Birmingham PCT (09/H1208/22). The study was funded, sponsored and covered for indemnity by the Calthorpe Clinic.

Chapter 5.2

Results of Quantitative study: Efficacy and follow up

5.2.1 Introduction and overview

This chapter describes recruitment and follow-up of study participants in detail. An overview of the numbers recruited and followed up as part of the study is provided in **Figure 5.2.2.a**.

5.2.2 Study Population

400 women were found to be eligible for recruitment during the study period from September 2009 to December 2010. 122 women consented to participate in the study, 61 women were allocated to 6-8 hour and 24 hour time interval groups.

Before randomisation, participants were counselled to ascertain their decision to proceed with treatments and to consent to recruitment. 3 participants in the 6-8 hour regimen group withdrew from the study as they preferred 24 hr intervals. This was considered as protocol violation. These participants were excluded from the data analysis. The final analysis was therefore performed on 58 women in 6-8 hour group and 61 women in 24-hour regimen group. Trial flow diagram is shown in **Figure 5.2.2.a**. All women received misoprostol within the allotted assigned time.

44/58 women in the 6-8 hrs group and 42/61 women in the 24 hr group had 2 weeks follow-up.

5.2.3 Results

5.2.3.1 Baseline characteristics

Baseline demographics of the two study groups are presented in **Table 5.2.3.1a**. The two groups were relatively balanced with regards to maternal age, previous parity/abortion histories and gestational age. Both groups were similar with respect to age (mean, 25 years; range, 17 to 44). $p=0.345$. The mean BMI was 25, range from 17-44. There was no difference in the parity between the two groups; 49% (para 0) and 14% (para 3 or more) **Figure 5.2.3.1a**. Gestational

age on the day of mifepristone administration ranged from 35 to 63 days **Figure 5.2.3.1b**. 40% \leq 42 days gestation. Gestational age was confirmed by ultrasonography in all the women. There was no significant difference between the two groups $p=0.745$ **Figure 5.2.4 b**.

41% of the study participants had undergone a previous induced abortion.

There was wide variation in the ethnic or racial distribution white (60 %); Asian (18%); Black African (16 %); mixed (5%).

84% of women who underwent medical abortion were single, 14% married and 1.7% divorced. 40% of women had GSCE/O level qualifications, 26% had a degree and 20 % were qualified up to A levels. 45% of women who had undergone medical abortion were employed, 33% unemployed, 16 % students and 7 % self-employed.

5.2.3.2 Efficacy

The success rates of different groups of treatments are shown in **Table 5.2.3.2a**. Efficacy of the treatment was assessed, as stated in the protocol, 2 weeks after treatment. Efficacy outcomes were analysed for 119 women (98%). 14 (24%) participants in the 6-8 hour group and 19 (31%) women in the 24 hour group failed to attend the 2 week follow-up ultrasound scan but their treatments were deemed to be successful as they did not have any further treatments.

In the 6-8hour regimen 98.2 % (57/58) had complete abortion without any further intervention and in the 24-hour regimen 98.3% (60/61) women had similar outcomes.

In those women who had follow up by transvaginal ultrasound; one women in the 6-8 hour regimen required repeat dose of mifepristone and misoprostol after 2 weeks for RPOC. In the 24-hour regimen, two women had up to two further ultrasound scans to confirm a complete abortion without the need for a surgical evacuation of uterus for RPOC **Table 5.2.3.2b**.

Numbers were too small to determine failures according to the gestational ages.

5.2.3.3 Secondary outcomes

Secondary outcomes included vaginal bleeding, pain, side effects and acceptability.

Table 5.2.3.3a shows analysis of amount of vaginal bleeding in the two treatment groups. There was no difference in the amount of bleeding experienced by women within the two different regimens. Similarly there was no difference on the subjective assessment of the amount of bleeding in relation to their normal period, passing clots or for the number of pads used.

Time intervals from the administration of vaginal misoprostol to the start and end of vaginal bleeding was found to be significant; 4 hrs in 6-8 hrs group, 3 hrs in the 24 hrs group for start of vaginal bleeding. For the duration of end of vaginal bleeding after administration of misoprostol; 10 hrs in the 6-8 hrs group and 14 hrs in the 24 hrs group.

Abdominal cramps are shown in **Table 5.2.3.3b**. There was no statistical difference between the two groups in the quantification of pain in relation to a period $p=0.17$. Experience of abdominal cramps was not found to be statistically different in the two groups (VAS score 6, 5, $p=0.12$). Pain began two hours after administration of misoprostol in both the treatment group. Duration of pain was however longer in the 6-8 hour regimen compared with those in the 24 hr regimen (12 versus 6, respectively). More women used NSAID based analgesia in both the groups. The comparison for side effects between the two groups is **Table 5.2.3.3c**.

There were no difference in the overall acceptability between the two groups 96% in the 6-8 hrs group and 97% in the 24 hr group, with the exception of the time taken to undertake the procedure. Women in the 6-8 hour regimen found shorter time taken to undergo the abortion process to be more acceptable than the 24 hour treatment regimen (100% versus 53% respectively) **Table 5.2.3.3d**.

There were differences between the two study groups as to whether they would choose to have the same abortion method in the future or recommend the same method to a friend or relative having to undergo an abortion. 85% in the 6-8 hrs group felt that they would recommend the same treatment and 69% in the 24 hr felt that they would recommend this method to others **Table 5.2.3.3e**.

22 had undergone previous medical abortion. There was no difference in the way women perceived the treatments they have had compared to their previous medical abortions **Table 5.2.3.3f**

5.2.3.4 Results on follow up

As shown in **Table 5.2.3.4a**, of the 109 women, 86 (72%) had confirmation of the outcome of the treatments by one or more of the proposed methods of follow up. There was a better follow up in the 6-8 hrs group compared to the 24 hr group (76% versus 69% respectively). Of the various methods of follow up urine hCG and USS had follow up rates of 54% and 50% respectively, compared to 44% with the telephone follow up.

Among the women who had telephone follow up, women were asked questions about pain and bleeding along with the duration of bleeding following passing of pregnancy products. They were also asked whether they have passed pregnancy products.

Five women in the 6-8 hrs group but none in the 24 hrs group felt that they had not passed the pregnancy products **Table 5.2.3.4b**

Quantitative analysis of urine hCG levels showed that the pre-treatment urine hCG levels ranged from as low as 168.35 up to the range 50000- 250000 mU/ml. Due to wide range of the levels of pre-treatment urine hCG and the few numbers for statistical analysis, relationship between gestational age and urine hCG levels was not possible. Similarly agreement between two diagnostic methods- urine hCG and ultrasound confirmation of completeness of abortion was not possible.

5.2.4 Assessment of non-participants

Among those who declined to participate in the randomized control study, 266 women were analysed for their reasons for preference for either of the time interval regimens. 179 women (67%) preferred 24 hrs time interval **Table 5.2.4a**.

Most women gave more than one reason for their preferences. **Table 5.2.4b** shows the reasons for preference for various time intervals. For the 6-8 hrs group, 25 % preferred shorter time intervals as they had to travel from long distances, the second reason given were work commitments (24%). 24% of women in the 24 hrs gave reasons as child care issues. Equally 24% women who preferred 24 hrs regimen said that the information provided by the clinic staff on success rates of the 24 hrs treatment intervals was a reason for them to prefer 24 hrs time interval. This was followed by work commitments (16%) and travel from long distances (11%) as the other reasons. Among the longer time intervals of 36-72 hrs , the reasons given by women were child care issues (44%), followed by other family issues/confidentiality (22%) and work commitments (22%).

Chapter 5.3

Discussion

This chapter discusses the findings in the context of this research study. It will also cover in detail the strengths and limitations of this study.

5.3.1 The results in context

The two groups were comparable in various demographic characteristics such as age, parity, gestational age and previous abortions. In this study younger women with a mean age of 25 years were found to have medical abortion treatments. Majority of women were single and very few women were married or in a stable relationship. In almost half of the women undergoing treatments for medical abortions, the current pregnancy was found to be the first one. A high order parity of three or more was common among those who had children previously. Interestingly about a half had a previous abortion. Although the spectrum of the socio economic status was wide spread among women taking part in the study, almost half were employed or self-employed and the rest were mainly unemployed or students.

5.3.1.1 Efficacy of shorter time intervals

Previous RCT studies ^{204,206} comparing 6-8 hr intervals to ≥ 24 hrs interval regimens have shown conflicting results on the efficacy of shorter time intervals. In this study the success rate were found to be similar in both the groups with the success rates of 98% with either of the medical abortion interval regimens. There was one case of retained products in the 6-8 hrs group and two in the 24 hrs group, however none required surgical treatment. The numbers recruited in this study are too small to recommend shorter time intervals for a larger population in an outpatient clinical setting.

The risk of failures has been found to be related to advanced gestational age ²⁷, high body mass index ²³⁴ and multiparity.²³⁵ Although gestational age, parity and previous abortions were

considered for stratification, the risk of failure in relation to gestational age and parity was difficult to assess due to small number of failures.

For secondary analysis as there were only 26 participants in the 6-8 hrs group and 27 in the 24 hrs group, statistical analysis was not undertaken as this would have led to spurious positive outcomes.

Generally in a clinical trial involving medications; the dose, its mode of action and bio-availability have an impact on the efficacy of treatments. **Chapter 1.4** addresses the clinical effects of mifepristone and misoprostol based on their pharmacokinetics. In this study the clinical effects of the mifepristone-misoprostol regimen were evaluated based on the start and end of vaginal bleeding and abdominal cramps following administration of vaginal misoprostol.

The onset of bleeding was at 4.0 ± 2.0 h and 3.00 ± 2.0 h after misoprostol insertion in 6-8 hrs group and 24 hrs group, respectively. These results were not different from the onset of bleeding following misoprostol as shown in previous studies.^{209,204} Bleeding and spotting duration was found to be less in the 6-8hrs group with a median of 10 days compared to 14 days in the 24 hrs group. These difference were not observed in other studies by Creinin et al ²⁰⁴ and Guest et al ²⁰⁹, this difference could be due to the small numbers of the study. There was no difference in the amount of bleeding in either group.

Pain is a common symptom following medical abortion treatments. These are usually described as menstrual cramps, but the severity can be subjective. The experience of abdominal cramps was not found to be statistically different in the two groups (VAS score 6, 5, $p= 0.12$). However during the telephone follow up that explored this aspect of subjective quantification, 77% in the 6-8 hrs group and 42% in the 24 hrs group, described their pain to be more severe than their periods.

Duration of pain is another way of assessing pain symptoms. Pain began two hours after administration of misoprostol in both the treatment groups. Duration of pain was however longer in the 6-8 hour regimen compared with those in the 24 hr regimen (12 versus 6,

respectively). Analgesics are routinely taken for pain. During the telephone follow up most women reported that they required NSAID based preparations for pain relief.

The reason for the more pain and longer duration of pain could be related to pharmacokinetics for example the uterine prostaglandin receptors may not have been adequately sensitised with 6-8 hrs interval. However this can only be proved by pharmacokinetic studies.

None of the participants were admitted for severe adverse effects or required blood transfusion in either of the groups.

The numbers were very few to perform statistical analysis on the side effects. Other larger studies demonstrated these effects in relation to gestational age. However this was not possible in this study.

There were no differences between the two groups in the overall acceptability of either of the treatment groups. 96% in 6-8 hrs group and 97% in 24 hrs group felt that the treatments were acceptable. In the study by Guest et al ²⁰⁶ the time taken to complete the procedure and severity of abdominal cramps were found to less acceptable to women in the 6-8 hrs group, this difference was not seen in the study by Creinin et al.²⁰⁴

Following treatments 85% in the 6-8 group and 69% in the 24 hrs group, would recommend the same method of abortion to a friend or relative. These findings were similar to the observations by other studies.²⁰⁴

The findings from this study raises questions about the understanding of combination pharmacokinetics of mifepristone and misoprostol for shorter time intervals. Evidence on the pharmacodynamics process of the mifepristone and misoprostol combination from earlier studies ^{35, 63, 92,93} suggest that it could be biologically plausible that their actions may overlap sufficiently in the first few hours after administration of shorter time intervals. This study as in previous clinical studies ^{91,204} suggests that some of these actions may be initiated earlier in the

pharmacodynamics cascade. The same pharmacokinetic mechanism could also explain the adverse effects surrounding shorter time intervals. A better understanding would however be possible through further research on the pharmacological dose testing of mifepristone and misoprostol levels within the setting of a clinical trial.

5.3.1.2 Follow up

The overall follow up rate was 72 % when all or either of the methods for follow up were considered.

A higher response rate for patient acceptability questionnaire (50%) and the Urine hCG measurements (54%) compared to telephone follow up (44%) suggests that a face to face follow up had a better response compared to telephone follow up. The overall response to follow up was higher in the 6-8 hrs group (76%) compared to the 24 hrs group (69%) respectively. This difference can be considered due to treatment bias, where follow up rates were better with women who had new treatments i.e. the 6-8 hrs, as women tend to be more anxious about their treatments in the intervention group (6-8 hrs) compared to the control group (24 hrs). The other possible reasons could have been the number of visits to the clinic.

In this RCT the telephone follow up rates were 44% which were slightly more than non-research based routine clinical setting telephone follow up rates of 38% as seen in the observational study on telephone follow up (**Chapter 3.2**). However, for this women's compliance is essential that can be improved significantly by providing adequate information. In order to address the issue of women compliance, this has been addressed in the qualitative study.

This study was underpowered to report on the predictability of urine hCG quantification for assessing outcomes of the treatments for medical abortion. The accurate measurements upto two decimal points were only possible when the absolute levels were below 1000 mU/ml. In the rest the pre-treatment urine hCG varied between 5000-10,000 mU/ml, 10,001-25,000 mU/ml, 25,001-50,000mU/ml and 50,001-250,000mU/ml. The measurements could have also been dependent on other variables. These variations in the urine hCG levels in relation to gestational

age raises concerns about the test's performance and suggests further research for ascertaining the cut off levels for semiquantitative urine hCG measurements at different gestational ages. It is also possible that it could be related to urine dilution due to fluid intake, using the first morning voided urine sample, which is generally the most concentrated may therefore provide a more standardised quantification. Because samples were obtained in this study whenever a woman presented for care, it was not possible to obtain first voided specimens. This aspect of urine hCG measurement will have to be evaluated in future studies.

This study did not explore the association between urine hCG and serum hCG as the study was proposed to be pragmatic. The measurement of serum hCG would involve an additional blood tests that would not be cost effective. Testing for the urine hCG pre and post treatment can be a useful office procedure. However its use where ultrasound confirmation and lesser invasive methods as urine pregnancy test are preferred is questionable. This is supported by the findings of Godfrey et al ¹²⁴, where the high rates of false-positive urine assay testing was found to lead to unnecessary testing and a false negative test would be harmful in cases of on-going pregnancies.

In abortion services that provide in-patient services, completeness of the abortion process is confirmed by visualisation of the expelled products of conception by the medical staff. However, in those centres where as outpatient services are provided, confirmation of success of medical abortion treatments can be challenging as it requires complete compliance of women. This period is also seen as window of opportunity to provide advice on the contraception and for counselling, more importantly to reduce the risk of infection and sepsis. Although our findings did not show the efficacy of urine hCG in predicting outcome of medical abortions, it supports that a level of less than 1000 mIU/ml can exclude a proportion of women from further testing, which may be significant for clinics with few resources or for women living far from clinics. Further research with larger studies on standardised sampling for semi –quantitative urine hCG are required.

Assessment of symptoms through telephone follow up is a feasible method before further testing. ¹¹⁹ This study was very small to report on the ability of woman to predict outcome. During the telephone follow up, 19% women felt that their treatments did not work in the 6-8 hrs group,

where as in the 24 hrs group all women reported that their treatment were successful in spite of one failure.

5.3.2 Strengths and limitations of the study

The key question to these findings is can the results be generalised showing a genuine reflection of the effectiveness of the shorter time intervals or was the treatment effect because of methodological problems that caused the study to miss a real treatment effect.

Although there are many challenges faced by a researcher in conducting a randomised controlled trial, few relevant to this study have been highlighted in the following sections.

5.3.2.1 Design and conduct of the trial

Evidence-based medicine (EBM) was introduced based on the facts that clinical practice is often poorly informed by the best available evidence, and that many widely used treatments are either completely untested, or tested and proven to be ineffective or even harmful. On the other hand, research performed to test new treatments has often been of poor quality, or has asked the wrong questions.^{236,237,238,239} The main tool to answer such problems has been a well-designed randomised controlled trial (RCT). Typically, patients in the randomised controlled studies are highly selected and so may differ from those seen in routine clinical practice in many respects, and do not tell us whether a treatment is effective in wider clinical practice. Despite having good internal validity they lack external validity to the extent that their usefulness in routine clinical practice is compromised.

A non-inferiority refers to a randomized clinical trial in which a new test treatment is compared with a standard active treatment rather than a placebo or untreated control group. A prior judgement is made, that for the new treatment to be of merit it only needs to be as good as the active control regarding appropriate outcome measure(s) of response.

Patients play an active part in the outcome of all treatments, Brewin et al ²⁴⁰ suggest that clinical trials in which they are required to sustain an effortful and demanding role and those in which they are likely to have strong preferences for one treatment need to be considered and conducted differently.

Potential sources of bias

The randomisation procedure was designed to provide a balanced sample of women in both control and intervention groups and employed a computerised sets of randomisation codes stratified to the gestational age. There was therefore no baseline imbalance in the numbers of women who were recruited into either treatment arm.

Ideally, randomised controlled trials should be "double-blind", with the treatment allocation concealed from both the subject and the person assessing the outcome. However blinding was not appropriate for this study as treatments had to be given at different time intervals, unlike other studies placebo treatments were not possible as this study did not assess the dose or the route of administration of misoprostol. Almost all studies on different time intervals of misoprostol administration have not concealed treatment allocations from subjects.

One question raised by this discussion on blinding is whether women who had certain preferences knowing they were allocated to the control group or the intervention group were influenced to express strong preference and acceptability for the treatments that they have had.

Blinding was also not possible for follow up ultrasound confirmation as the clinic notes had the details of the treatments. However in order to reduce the inter-observer bias ultrasound were performed by different sonographers.

As reported in this study, for those women who had follow up, there was better follow up response in the 6-8 hrs group compared to 24 hrs group, these differences between the follow-up of control and intervention women, were very unlikely to have affected the results of the few numbers assessed.

Sample size and recruitment

Recruitment to the trial proved to be a Herculean task taking longer than expected. Prior to commencing the RCT feasibility for recruiting large numbers from a single centre was assessed in a retrospective audit at the research centre (**Chapter 3.1**). The data obtained from the retrospective study appeared promising however the feasibility for continuation of the study was challenged when fewer numbers were being recruited. In the process, although the intended sample size was 1300, a small fraction of only 121 (9.3%) participants were recruited. As the aim of the study was to conduct a non-inferiority study of shorter time intervals comparing them to the standard treatments for comparative efficacy, an interim analysis was proposed to assess if the study showed any significant evidence on higher failure rates with shorter time intervals. This was particularly important to avoid higher failure rates in the experimental group as this study was being carried out in a clinical setting with home use (outpatient) i.e. with less supervision by health care professionals.

One of the reasons for delay and lesser number of women being recruited was that women already had preferences for their chosen treatments before randomisation. 266 women declined to participate in the randomized control study for their own reasons for preference for either of the time interval regimens. An alternative methodological approach such as a patient preference trial could perhaps address this particular issue. However the bias generated from this will have to be considered.

The recruitment was also affected by new information and change to the routine practice of providing shorter time intervals. Prior to the commencement of the study the information from the observational study was disseminated to the general practitioners and referral centres. This changed the practice and with new information of efficacy of shorter time intervals, women who were informed declined to participate in the study. This is reflected in the results of the assessment of non-participants, where majority preferred 24 hrs treatment following their consultation with the doctors at the general practice and the doctors at the clinic. What the general practitioners and the health care staff at the clinic failed to understand and explain to the women was the need for the conducting a well-designed randomised controlled study to continue providing same day treatments.

The total number of calendar days where recruitment was possible were considered as the “days of active recruitment”. In particular, recruitment had suffered due to constraints on the “days of active recruitment”. 388 women were seen on the “days of active recruitment”, however 266 women declined to participate in the study although they fulfilled the inclusion criteria.

It would have been ideal to have the clinic working on all the days in the week till 8pm so that more women could be counselled about the RCT and would be well within the 6-8hrs time interval for the second part of the treatments. Looking back perhaps conducting the study in a hospital setting with in-patient care could have avoided this barrier in recruiting adequate numbers.

The major setback was the non-availability of a research nurse to be on site at all times. This was mainly due to lack of funding to employ a research nurse for this study. As with any large RCT successful recruitment also depends on the understanding and following of the study protocol by the various health care professionals interacting with the participants. In this study for example - receptionists, nursing staff, clinic doctors, general practitioners and family planning services. This was overcome by regular visits of the researcher to the general practitioners clinics, family planning clinics and counselling services. There were meetings held within the clinic to provide updates and reminders of the study.

One alternative would have been to recruit through other hospital clinics and the general practices, but work load for the follow up ultrasound scan would still remain a challenge. Many of the difficulties encountered for follow up have been reported by others who have conducted randomised controlled trials in an outpatient setting. One of the other advantages of having a single centre is the avoidance of protocol violation while recruiting. This stresses the significance of appropriate counselling while consenting women into research and is therefore is one of the challenges of recruitment in randomized controlled trial.

As a result, the study was less powerful than planned. However this has not affected the study results.

Finally evidence-based in healthcare is based on the results of a range of studies. When studies on their own are small to achieve statistical significance, their inclusion in meta-analyses will be valuable to provide evidence. The result from this study can contribute to evidence as being part of a meta-analyses.

The lessons learnt from conducting this trial provides substantial information on the administrative setbacks that NHS will have to overcome, to provide women with medical abortions expressing strong preference for shorter time interval in a clinical setting providing home use (outpatient) in the future.

5.3.2.2 Intervention and Follow-up

The intervention tested in this study was based on the hypothesis that shorter time intervals (6-8hrs) treatments are as effective as standard treatments and can be an acceptable alternative to standard treatments. The time of administration of misoprostol was therefore seen as potential source of intervention bias. To minimise this, the appointment time for the administration of misoprostol was arranged by the researcher. The women were informed of their appointment times before leaving the clinic. For those women allotted to the 24 hrs group, appointments were given 24 hrs or after but before 36 hrs. All women in the intervention and the control group received their misoprostol within the specified time, there was no violation in the time of administration of misoprostol. In few women who had severe symptoms of morning sickness, antiemetic was administered prior to administration of oral mifepristone. In those cases where women vomited within thirty minutes of administering 200 mg of mifepristone, additional dose of mifepristone of 200mg was given orally. In the few numbers recruited, none of the participants required additional mifepristone.

The study also looked at the response of women for follow up following medical abortion treatments to find the most suitable follow up method in women treated as outpatient. The abortion follow up information from the general practitioners and the clinic notes were scrutinized for re-admission and complications related to abortions. All women with a

continuing pregnancy following the medical regimen were identified and had evacuation of products of conception.

Telephone follow up was arranged a week after the treatments, trained nursing staff at the clinic performed the telephone follow-up. A maximum of three attempts were made to contact the participants.

For this study, retained products of conception and failed treatments were confirmed by ultrasound assessment. A potential weakness in ultrasound assessment is that the clinicians performing the ultrasound examinations were not blinded to the urine assay results. In theory, the possibility of knowing the results of one test may have influence the interpretation of another test. However ultrasound examination of success of medical abortion treatments is simple and basic i.e presence or absence of the gestational sac. It is therefore highly unlikely that knowing the urine pregnancy test results could have influenced ultrasound interpretation.

PART 6

QUALITATIVE STUDY: IN-DEPTH INTERVIEWS

Chapter 6.1

Research methodology for Qualitative study

6.1.1 Introduction

This chapter explains the research methodology used for the qualitative part of the study. It will be covered under the following subheadings:

- Justification for qualitative methodology
- Justification for In-depth interviews
- Research procedures
- Data Analysis
- Ethical issues

6.1.2 Justification for Qualitative methodology

In order to seek information on women's attitudes, beliefs and perception towards various aspects of medical abortion, the techniques employed should be exploratory in nature. Exploratory research has been found to be most useful in situations where limited information is available and the researcher wishes to have the flexibility to explore future areas of research. Exploratory research has been defined as being typically qualitative.^{241,242} Therefore qualitative research approach has been chosen to explore those areas of medical abortion that cannot be interpreted through quantitative methods.

The first step in exploratory research is to analyse the existing studies in the subject area and then to transform potential issues into more defined problems to develop research objectives.²⁴¹

The chapter (**Chapter 1.7**) on literature review on beliefs, attitudes and perceptions of women towards medical abortions provides an analysis of the previous research into the area of women's attitudes, beliefs and perceptions about medical abortions; this in turn set the aims for the qualitative study (**Chapter 4.3**)

6.1.3 Justification for In-depth interviews

Qualitative research is often referred to as interpretive research as its intention is to build an understanding of an issue rather than prove a theory^{243,241,244,245} and involves a high level of researcher involvement and interpretation.^{246,247,248,249} The researcher is interested in the perspective and the beliefs of the respondents being interviewed and places emphasis on their words, with an aim of identifying patterns through observations, documentation and analysis.²⁵⁰ For this reason the method used for qualitative data collection was individual in-depth interviews.

In-depth interview allows the respondent to freely discuss feelings or beliefs about the subject of interest and provide a more detailed response.²⁵³ As this study aims to find out more about the use of newer medical abortion treatments (such as shorter time intervals, abortions at very early gestation, home use, over the counter use and issues related to follow up) from women's perspectives, in-depth interviews will provide an opportunity for women to express freely their beliefs, attitudes and acceptance.

The benefits of using in-depth interviews includes the opportunity to discuss particularly sensitive topics with participants.²⁵⁴ If the interviewee has views which are non-conforming, they are more likely to express them in an in-depth interview and often such data has depth and comprehensiveness.²⁵⁴ In this study through in-depth interviews women will be given the opportunity to express some of the sensitive issues surrounding medical abortions and their personal experience while undergoing treatments. In-depth interviews also provide the opportunity for building trust and rapport between the interviewer and interviewee which in turn improves the quality of the data.²⁵⁵

The researcher has greater control over the selection of the participants in in-depth interviews.^{255, 256} Interviewees are selected for their knowledge, experience and opinions on subject matter.²⁵⁶ For this study various ethnic groups were selected to explore the diversity and variations to cultural interpretation of abortions. The study also included women of different socio-economic groups, ages and parity. Participants also included women who had previously undergone abortions.

There are however limitations and challenges to using in-depth interviews. They are considered to be less cost effective in terms of time and resources. Analysis and interpretation of data can be highly subjective. Much of the success of the interview is dependent upon the experiences and the ability of the interviewer. Generalizations of the results are difficult to make because of the small samples size.²⁵⁴

6.1.4 Research Process

Summary of process for this qualitative research is described in the form of flow chart in **Appendix 6.1.4a** adopted from review article on data analysis in qualitative research.²⁵⁷

6.1.4.1 Developing the interview guide

The design of the interview guide **Appendix 6.1.4.1.a** was based on the theoretical framework approach.^{248,258} The questions were designed to encourage the flow of information and ensure that they were focused on the issues and topics relevant to the research question.²⁵⁹ Interview questions were also developed to relate to the situation of the participants and be sensitive to their needs and feelings.

The in-depth interview questions were designed to clarify and further investigate the concepts identified in the literature review **Chapter 1.7**. The interview guide consisted of open ended questions designed to gain the participant's views, experiences and opinions about medical abortions.²⁵⁴

The interview guide included a brief introduction to the research objectives followed by open ended questions to make the participant feel comfortable and to collect background data for further analysis. In order to cover all aspects of the research questions set out, topics that formed part of the interview guide were selected in a sequence such that the responses in context of the individual topic would act as a guide to follow up questions. In those topics that explored the feelings and attitudes of women, the questions were set from general to more specific questions so that participants had the opportunity to express their personal feelings freely. The questions

on their experience with the service and treatments were interspersed between questions related to reasons or motivational questions to allow women to reflect and express openly without emotional pressures and stress. The interview concluded with their views on follow up, feelings during recovery and views on prevention of abortions.

Probes were often required through the interview process. As illustrated by Rubin et al ²⁶⁰ probing questions can be of different kinds, for example clarification probes to obtain more clarity on expression, steering probes to bring interview back on track, evidence probes to aid in assessing the knowledge of the interviewee and elaboration probes to encourage the interviewee to expand more about the topic. Wherever necessary the above mentioned types of probes were used in the interviewing process of this study.

The questions were pretested on two medical students in the age group of 20-25 (who had not undergone medical abortions). The piloted topic guide provided the researcher with opportunity to revise questions where necessary and practice the interviewing approach, review the questions and consider feedback to develop a greater understanding of the process. Pretesting the topic guide allowed the researcher to divide the interview into broader sections, revising the topic guide to omit questions that were found to be unrelated to the topic and to modify the topic guide such that the flow of the interview progressed from generalised to personalised questioning.

6.1.4.2 Recruitment of interviewees

The sampling strategy for the in-depth interviews was purposive sampling which is considered appropriate in qualitative studies where the intention is not to demonstrate any statistical representativeness, but to represent salient population characteristics.^{247,261,262,244} The sample size was considered to be sufficiently adequate at a point when no new information was available based on the analysis of the interviews conducted, thus confirming data saturation for the purpose of this qualitative research.

The criteria for selecting the interviewees for the in-depth interviews were:

- Participants must fulfil the criteria to enter into the randomised controlled study (**Chapter 5.1.2**)
- Participants must have completed their treatment
- Participants should have had successful treatment at the end of 2 weeks
- A mix of different age groups, parity, ethnicity and socioeconomic groups. For determining the socioeconomic status based on employment the five-class version of self-coded NS-SEC **Appendix 5.1.7a** was used. As many women tend to fall in the younger age groups the socioeconomic status was also graded based on the level of education as per the International Standard Classification of Education (ISCED) **Appendix 5.1.7b** for this study. No age limit was specified, although a range of age was desirable within the sample in order that experiential variation between younger and older could be explored. Participants below the age of 18 years were not included (according to the inclusion criteria for the RCT). Women with and without children as well as those who had previous abortions were included in the study to obtain a wider range of behavioural changes, perceptions and feelings towards abortions. During the interview the participants were asked about their occupation and their ethnicity in an attempt to understand the different cultural views and the dynamics of decision making in different cultural and socioeconomic backgrounds.
- Participants should be able to speak English

Participants for the in-depth interview were selected randomly from the cohort of those taking part in the randomised controlled trial and would have completed their treatments so that they would be able to speak with some experience and their thoughts and beliefs could be of value to the study.

Appendix 5.1.4a provides a copy of the patient information letter and **Appendix 5.1.4b** a copy of the consent form.

6.1.4.3 Conduct of the interviews

In-depth interviewing relies upon the interviewer and interviewee developing trust and a dialogue.²⁵¹ DiCicco-Bloom et al²⁶³ suggested that personal interviews can take between 30 minutes to two hours to complete depending upon the person being interviewed and their interest in the subject matter. One researcher (S.M) carried out all the interviews. In-depth interview component of the study consisted of a series of seventeen face to face interviews that were about 30-40 minutes in length. Interviews were scheduled for all the women at their 2 week follow up visit to give them some time for reflection, to avoid additional visits to the clinic, thereby increasing the likelihood of completing the interviews. All interviews were conducted in the clinic, an environment familiar to the participants and after confirming that their treatments were successful. The researcher made an appointment for this interview on the day the women received their treatments. Information on the qualitative study was also given at the initial clinic appointment. Participant's name was not recorded, other identifiers such as names of the family members or particular staff were excluded. Participants could terminate the interview at any stage if psychologically distressed, in such as situation they were offered support for counselling services following their interviews.

6.1.4.5 Characteristics of the researcher

Researcher in the qualitative study plays an active role in the development of data and its meaning. Gender, cultural affinity, socio-demographic characteristics and experience of researcher are aspects of the researcher that can influence data collection and interpretation.²⁵⁴ The researcher for this study was a female of 37 years of age. A woman interviewing women of the same age group would have been the most ideal in order to develop a relationship that is required for the sensitive nature of this study.²⁵⁴

The basis for an interactive in –depth interview is the ability of the interviewer to establish a good rapport with the participant, this comes by establishing a good working relationship with different kinds of people.²⁵⁴ A good working relationship with others helps the researcher put the participant at ease and to develop trust. Key to this is the researcher demonstrating a real desire to understand perspective of the interviewee and to display confidence. Having a background in medical profession and relating to patient interaction in regular practice, the

researcher was able to demonstrate the above qualities. The researcher was also familiar with the medial abortion procedures, confidentiality, legal implications, service provision and ultrasonography.

In order to gain rich data from the interviews, the researcher used the following strategies: ²⁵⁴

- Active listening (both of what is being said and the unstated messages being sent) ^{264,265}
- Expressing interest and attention by displaying eye contact, and body language expressing attention but not approval.
- Employing interview skills of questioning (using open ended and closed questions in combination), paraphrasing (repeating back what was said to ensure validity) , establishing right or wrong answers
- Making the interviewee feel comfortable and at ease in the interview environment. ²⁵⁴
The researcher had anticipated in advance the sensitive nature of the topic and therefore a quiet room within the clinic environment was arranged. Reassurance about confidentiality at the outset of the interview, reiterating the consent of the participant and details of the counselling services.
- Observing non-verbal behaviour whilst expressing strong emotional response. Allowing the participant time to cope and if willing to continue the interview.
- Adopting strategies for addressing anxiety among participants by spending more time on the opening subjects, spending time on more descriptive topics and then moving on to emotions and feelings.

6.1.4.6 Data analysis

Data analysis for the in-depth interviews was performed in two stages.

Stage one was recording interviews and preparing the transcripts. Interviews were transcribed in their entirety by two independent medical secretaries.

Second stage involved constructing themes and coding these in order to retrieve information on specific ideas.²⁵⁴ Interim analysis of the analytical process ²⁶⁶ has the advantage of allowing the researcher to go back and refine questions, develop hypotheses, and pursue emerging avenues of

inquiry in further depth. Using this method emerging themes were identified from the coded data of the first three interview transcripts. The interviews were coded within a week of transcription by the researcher so that themes could be adjusted if required.

For coding of the transcripts, NVivo 9 computer software was used.

A framework approach was adopted for the purpose of analysis, the transcripts were analysed for their content. During the analysis of the interviews, theme relevant to the research question were identified within the in-depth interviews by listening to each of the recordings and rereading the transcripts. The codes was revised, deleted or added as the data collection and analysis progressed. Quotations were then selected to illustrate the coded themes.

All coded material was then tabulated in the matrix format. A summary of the main matrix can be shown in **Appendix 6.1.4.6a** with an example of the structure below in table below. Data in the form of text was entered into each matrix cell.

Patient Characteristics	Case 1	Case 2	Case 3	Case 4	Case 5
Theme 1					
Theme 2					
Theme 3					

Relevant data to each category was identified and examined using a process called constant comparison, ^{253,254} in which each item was checked or compared with the rest of the data to establish analytical categories.

6.1.5 Ethical considerations

The ethical issues that have been considered when undertaking this study were:

- Informed consent of the participants
- Voluntary participation without coercion or deception
- Confidentiality and anonymity
- Potential for harm
- Ethical issues specific to the study

Before any primary data was collected, ethical committee approval was obtained from South Birmingham PCT. Prior to their involvement, participants were advised about the nature of the research and an assurance was given that all data would be treated confidentially. Participants had the opportunity to cease involvement with the study at any time. There was no potential for harm as a result of being a participant for this study.

Chapter 6.2

Results of qualitative study

6.2.1 Participant's characteristics

Of the 121 women who participated in the RCT, seventeen women were selected based on inclusion criteria for in depth interviews. The demographic characteristics of the participants are given in **Table 6.2.1a**. The age group ranged from 18-36 years. Participants included women of different ethnic backgrounds- White British, Asian, Black Caribbean, Middle Eastern. Women of various socio-economic backgrounds were interviewed, these included women that were employed, self-employed, unemployed and students. Twelve women were single and others were either single but in a stable relationship or were married. The interviewee group included four women who underwent abortions previously (2- surgical, 2- medical). Nine women had children previously. As this study was to explore views on shorter time intervals, eight women were from the 6-8 hrs group and nine from the 24 hr group.

The themes and quotations that have emerged from this study have been presented in the relevant sections relating to the specific research question. Each quotation is followed by the participant's reference number. The illustrative quotes have been presented in the boxes under the sections addressing particular theme.

6.2.2 Attitudes towards abortions

The initial part of the interview was to understand some of the general aspects abortions such as beliefs, attitudes and perception about abortions.

6.2.2.1 General views of participants on abortions

Opinions of the participants on general views of abortion among the public were varied (**Box 6.2.2.1a**) In general, majority of the participants believed that the attitudes of people towards abortions were negative. Few participants felt that the general population would consider

abortions as an act of shame and cruelty. Some participants associated abortions to being perceived as a stigma or taboo. Equally participants also felt that abortions were acceptable in the society. This was attributed to open mindedness, being more tolerant and non-judgmental attitude among the general public.

Some participants felt that the views of the general population depended on the circumstances at the time the decision was being made such as-social, cultural, religious or financial.

Two participants quoted temporal trends in the attitudes towards abortion with more acceptance among the younger population compared to the older generation. With regards to parity two participants felt that having children could have a negative effect on the attitudes towards abortion. One participant believed that attitudes towards medical abortion were perceived to be more acceptable than surgical abortion.

A minority of participants were of the opinion that the concept of abortion is often not discussed and that there is an element of secrecy about abortions. One participant felt that there were misconceptions surrounding abortions. Conversely, another participant believed that women would not be against abortions as long as they are had the right to make their own decision.

Box 6.2.2.1a :General views of participants on abortions

I think a lot of people look down on it, can make you feel quite ashamed about things #8

I suppose it depends on the situation that you are in at the time doesn't it. I mean if you are in a stable situation then obviously a lot of people wouldn't agree with it. ,because you are killing off another life ain't you. But then again you shouldn't get yourself into the situation where you would need to have an abortion should you. #9

I think it varies a lot with those women who've already got children probably disagree with it more than those who haven't got children. Probably those that can't have children. . . probably disagree a lot with it because they'd probably think it was unfair that people are terminating, But I definitely think those with children will probably disagree more. #1

I think in today's kind of society it's their body really, to be quite honest; they can do what they want to do with that.

I can only speak for my age group which I think is a little bit more broadminded and a lot more kind of free in what they do. They tend to be all right. If I say to someone I've had an abortion they're not going to look at me like I'm strange or anything like that.

So they tend to be a bit more accepting of it than maybe the older generation #6

6.2.2.2 Personal views of participants on Abortions

Participants across the research sample believed quite strongly in and agreed with the concept of having abortion. They expressed a positive relationship between abortion and personal circumstances. The common circumstances were financial, unstable relationships, conditions at home, age, lifestyle, education. Other circumstances that were mentioned were family pressure, rape and for health problems such as disabilities in the baby (**Box 6.2.2.2a**)

Box 6.2.2.2a: Personal views of participants on Abortions

If you're stuck on your own with a baby or you was unfortunate to be raped or something, I think it's a very good option. But I think it's down to that individual and you've got to think it through and decide for yourself. I don't think anyone can tell you the answers to it to be fair. But I think it's a good option if you want it #8

I don't know just the whole experience of being pregnant, social and personal issues come into it a lot. Because depending on, like, your situation at the time, when you find out that you're pregnant. I probably horrible things say if somebody got raped maybe, depends if you are in like not a very good relationship. If obviously if you have cheated on someone and got pregnant. Its probably if you are not in a stable, if you are not stable at all like money wise or relationship wise. If there was a high risk of it being disabled. # 10

Some people get raped. In that issue, I think that should be there because that's not fair. Because children are meant to be made out of love. . . and commitment and family. It's not fair on the child. I suppose in that sense, especially when someone's been raped, they definitely need to have that because why should that child and that mother be left with that. Mother might look at that child in the future and think 'What the hell? Where have you come from?' And that's not fair, that's abuse really. Emotional abuse to both and I just don't agree with that. #2

It depends on the individual situation. I think, if you really want that child at that time, you always manage, you always financially do what you can. But I think it depends on your age, what situation you're in and your lifestyle but I think it's just one of those things; it can happen to anyone basically. #8

But when you start to realise the cost of childcare, if you are working full time then it might not be an option for everyone to have a baby financially. I think so but then again it depends on the woman, because I think that some women probably breeze through pregnancy, and even if they are not even planning to get pregnant, and they might find out they are pregnant and they might only be 24 and they might have poorly paid job and no prospects and be happy. So, really I just think it depends on the individual and how it affect you and you know how emotionally prepared you are. It doesn't necessarily correlate to your level of income, your normal mental health, or your age #14

If you cant financially fund the child then I don't think you should bring it up but obviously you get support off the government and stuff but yeah. I don't know. Its up to that person isn't it if they wanna bring it up with no money but, better not to. #15

I think age appears a bit factor as well and, job, education and your job, stable to bring a child up. You need to be able to look after yourself and look after someone else. It is everything money, house. You cant just expect everything to fall into place so I think those are yeah #16

Availability and choice of abortion was also thought to enhance a sense of independence, an attribute that was highlighted by most participants. There was a general perception among the participants that the decision to have an abortion was strongly associated with aspects related to upbringing of children (**Box 6.2.2.2b**)

Box 6.2.2.2b: Personal views of participants on Abortion

*But if abortion wasn't there, what would they do? They'd be stuck with a child they didn't want and that child would be stuck with somebody that didn't want them and that's unfair
I think everybody should be given their choice. Of course nobody wants to do it. . . . but if they're in that situation where they have to do it then I think that option should be there for them. #2*

*Being able to afford a baby and the time a baby takes is quite a big part. And. . . . I think that's mainly it.
. . . . Just being able to afford and giving them the time they need. #4*

*I don't think it's wrong. Yeah but, I think religion plays. . . . And then, also, their background as well.
'Cos like people say 'Well, don't have that. ' But then, what's the point of not having it?
if that's going to come between you bringing the child up then there's no point because that child's going to be born into care, anyways.*

I don't think a child should come into the world if you're not prepared as a parent. Because that child will, like, you know, going to the Government. It's not the Government's responsibility to look after the child; it's yours. #5

But justifiable, I think I don't know, everyone has their own opinion but I think it can be, depending on your situation because it could be, you are alone, you have nowhere to live, no job, no money, then you cant have a baby. You cant rely on the government now like there is nothing you can do. Cos I've got someone else I know who has had a number of abortions and she kept her baby but she found it so hard to live on her own and bring her baby up, its was really difficult, she went through a lot of hassle and I just done think people think about it that, they don't think its that hard. They just think oh its easy to have a baby and someone will help but its not. So, I know all these ideas are selfish but at the end of the day you gotta, you have to look after yourself as well, its not, it is about the child but its when you are ready to have the child, its not just oh I am pregnant I am gonna keep it that's it. #16

One participant felt that the earlier in the gestation an abortion is performed more acceptable would be the process (**Box 6.2.2.2c**)

Box 6.2.2.2c: Personal views of participants on Abortion

I think early abortions are different to. . . . if I was further gone than I was, I would have probably found it difficult to have had an abortion. But early stages, it's really not much different to taking a pill in the first place or a man wearing a condom. Yes, it's formed but it's not got feelings. It doesn't know it's a baby. I imagine it's because it's a child and its murder but no, I don't see it that way at all. #4

As the interviews were conducted after women had completed their treatments, opinions about medical abortions changed in few women (**Box 6.2.2.2d**)

Box 6.2.2.2d: Personal views of participants on Abortion

I thought of it as I agreed more with abortion than I didn't agree but now that it's actually happened to me it's changed my views a bit. So, I still agree with it, depending on your home circumstances and stuff, whether you can deal with it. until you've actually experienced it and had to deal with it yourself, you can't really say. #1

Well I wouldn't want to do this again, to be honest. I wouldn't say to someone 'Don't do it' but I personally don't want to do it again. Deal with it holistically. Not just rush to get over it. #6

I probably had a different opinion to this myself until I was actually put in this position. But, I just think that until you've been in that situation, you can't really comment. I think at the stage I was, it was an option and I took the best option that would suit me for my life at the moment. I think people, if they are in that situation, should just do what they want and not worry about what the media thinks or the general public thinks. #8

you don't think about it until it actually happens and then that is when you have to deal with it. And like I cant believe I have done it myself as well. Like I didn't ever think I would do it cos I thought no, you know, abortion that's a big thing. You should plan it properly but when it happens you just have to do it, you've got no choice. #12

I don't think it is something that you think will ever be applicable to you until you are in the position where you think about having an abortion. I can not until what happened to me I wouldn't have thought that financial reasons would come into it. #14

6.2.2.3 Views on cultural aspects of abortions

On interviewing women about their opinions on the religious and cultural aspects of abortions, majority of the participants were of the opinion that religion and culture in general had a significant influence on abortions. Both seemed to have a negative effect on abortion beliefs. Of these religion was found to be the main reason followed by cultural and ethnic background. (**Box 6.2.2.3a**)

However participants also expressed their own personal opinions on whether religion and culture should have an influence on abortions. Most felt that the issue of abortions should be free from religious and cultural pressures (**Box 6.2.2.3b**). One participant believed that religion and culture may have to be considered in the decision making process (**Box 6.2.2.3c**)

Box 6.2.2.3a: Views on cultural aspects of abortions

Some religions that don't agree with abortions it's against some religions. when I was at school watching videos on it and you can see people protesting against it, a lot of people protest against it. well some religions, they see it as if, you know, you produce a baby I just know most people are against it for religious reasons. I know that religious is the main one #1
#3
#5

Religion, culture, heritage and so forth.... - against abortions. Religious reasons are not going to be something that changes. I think so. If you grow up in a society where it's not even part of the law or the freedom, the women, then I think even those kind of situations are a lot more difficult obviously to see the individual. #6

I think that religious reasons are normally against abortion, would view it as taking a life. And culturally a lot of cultures are not, well because cultures that are not westernised are they are not even meant to have sex before marriage so culturally they are in a difficult position because their culture might be completely against abortion but then again they could be in a position where they couldn't possibly say that they are pregnant which might lead even to suicide or people running away. Yeah. #14

I think the family plays a major role because sometimes they wont agree with it obviously, especially Asian families, traditional ones, they wont agree with it at all and it's a lot of, but I've got friends that are and I've discussed it with them what they would do and a lot of them said no because of the religion but then if you follow the reasons sort of and you shouldn't have got pregnant if it was out of marriage, whether I don't know when you are married and stuff its different but a lot of my friends say they would keep it purely because of religion, its bad and things like but I just dont think #16

Box 6.2.2.3b: Views on cultural aspects of abortions

It's a shame for people that are pressurised into not, into abortion being a bad thing 'cos it's a baby at the end of the day #4

Not see them as part of the bigger picture", "I think in terms of that, the individual becomes less of an individual and more like a part of society and not a person", "decisions change depending on what society and culture ", "when you are in a situation when you don't really have a choice and you, well you do have a choice you either carry on or to have consider your actions #6

culturally they are in a difficult position because their culture might be completely against abortion but then again they could be in a position where they couldn't possibly say that they are pregnant which might lead even to suicide or people running away". " but I just dont think, you have to think about yourself as well because you cant just do it for religion", "There are loads of issues though, like, I don't think it is right doing it because its like there is, I don't know how to explain it, there's someone growing inside you, its not something, not something that you should do I suppose and that's a morale and ethical issue, its wrong really. But if you are just gonna keep it for that then it doesn't make sense, if that's your beliefs that just because its morally wrong I am gonna keep it, you are gonna have to want to keep it #14

Box 6.2.2.3c: Views on cultural aspects of abortions

I think it's important to just listen to the point of view of view of religion because you might learn something", "I don't have any guilt feeling about that because in my religion you are allowed to get the abortion up to 3 months because the soul hasn't entered the body, we believe, until the fourth month so I don't have that feeling", " But I think it's also important to at least to just listen and then weigh, you know, what's in your religion and what's good for you", " I think it does count, to what religion you are. You have to follow your religion", " But I think the morale issue is its unethical isn't it the way like it's a human life, its not really your choice to get rid of it to be honest and its religion as well that only God can take away like and give life, so you should appreciate it but I suppose you become selfish and think about yourself first"

#7

Most participants were not clear about the role of antiabortion activists, political and legal issues surrounding abortions and only three participants expressed their views (**Box 6.2.2.3.d**)

Box 6.2.2.3d: Views on cultural aspects of abortions

Some countries probably allow it but you have to be married and you have to have the consent of the partner or something

#7

what I like about here is that it is that the woman is completely free about this choice because it is her body so I hope it is like that in other countries as well because it is the woman's body and she is going to carry it

#7

I haven't heard the arguments really for people not to have abortions, why they're so strongly against them

#4

The only thing, with religion, I think, like the last time I left here there was Catholics outside and a priest and I did feel a bit sick

8

6.2.2.4 Men's views on abortion

During the interview process participants were interviewed on what women's views were on men's perceptions of abortions. Two participants felt that in general men would disagree with abortions. However majority of participants felt that the men's views on abortion in society would be circumstantial or based on relationships, some women felt that culture and ethnicity can be influential (**Box 6.2.2.4a**)

Box 6.2.2.4a: Men's views on abortion

<i>I think they just think it's wrong</i>	#5
<i>It was too early for us but like I think some men probably would be against it. I think it is 50:50 like I said before, some will and some wont. I haven't really thought about it really, what men would think.</i>	#12
<i>it depends on the situation, whether they were in a relationship, whether he wanted, whether he agreed with the abortion or whether he disagreed with the abortion.</i>	#3
<i>I think that depends on the individual as well. The situation that they are in at the time</i>	#13
<i>I don't know. I think they think it depends on what circumstances it is. I suppose.</i>	#15
<i>That's quite tricky I think. It depends on the man I think. If he is ready to settle down then I dont think he would want that, but if he is either studying or just not at the right time, right place in his life then he will a lot of I don't know.</i>	#16
<i>I think religion for boys as well especially plays a lot", family especially in the Asian community it plays a huge role with the boys but it just depends on the individual himself I think"</i>	#7
<i>I have got friends who agree and disagree with both. I have got one friend who would never do anything like that who just thinks it wrong to take a life. But I have got other friends who are like you need to be at the right stage in your life to be able to have a child. I think religion for boys as well especially plays a lot, family especially in the Asian community it plays a huge role with the boys but it just depends on the individual himself I think.</i>	#16

Participant's general opinion were that men were unaware, may go through the same emotions or even feel ashamed, may feel that they have financial obligation to pay for the treatments. Some women felt that men don't talk openly about abortions, but it can be emotionally difficult for them. Few women felt that men can also be less responsible as they bond less with the fetus, therefore have to be made aware of the various aspects of abortions. Some women said that the burden of the process falls on the women as there can be very little co-operation from men.

(Box 6.2.2.4b)

When participants were asked about their own partner's views, the responses were varied ranging from both acceptance to non-acceptance (**Box 6.2.2.4.c**)

Box 6.2.2.4b: Men's views on abortion

But I don't think men are as aware. I think all men think they have to pay for you to have an abortion. #4

at the end of the day, they're not bringing it. they can just hop and go whenever they feel like it. you're the one that's left with the child. #5

So, I think they do find it difficult. They may not talk about it but I think it does affect them. I think... I don't know. I have a feeling they might be a little bit ashamed because it's all their fault or something #6
#7

I don't think that their views are different; I think that their views are probably the same as a woman who has never thought she would have an abortion. I don't think you could possibly form a view until you have been in, you have walked in the shoes of a woman who has had an abortion. #14

The only thing I think is that it should be out there more of what you actually – a woman – has to go through 'cos I think man's got an easy life, to be fair, and I think that way, I think perhaps it should be out there more for men to realise their responsibilities towards things as well. But that's just. . . . it's a man's world, isn't it, unfortunately?' The thing I get from a lot of men, they're quite pig-headed, they think 'Oh, you can't get rid of my child but, to be fair, it isn't a child or a baby, you know, it's nothing until a certain amount of weeks', I think there should perhaps be more feedback for men to realise the different stages, it is just a cell or a fetus #8

"they are not the ones who have to go through it", "they are not the ones who have to bring up the child", "They just go to work and they have still got their life", "It's the women who have to like give up everything, give up their body and everything #10

Box 6.2.2.4.c: Men's views on abortion

my partner's white so he doesn't have to worry about the cultural ,first time, he didn't want me to, he don't want me to but we know that it's just not the right time #2

I know he found it very difficult to do, there was always the 'Why was you doing it in the first place?' kind of reasoning. He did find it very emotional, very difficult to kind of watch me go through, also the concept that he did have a child, there was a child involved #6

he was always been against it anyway I couldn't really speak to my partner because he didn't want me to do it #10

he has just been okay #11

he did say well that is ridiculous because if you know you are being unreasonable why are you doing it #14

he reckons that if we were like if we were a bit older and had better jobs, we probably would have kept it, it all depends on your circumstances I suppose #15

6.2.2.5 Personal views on repeat abortions

Most women expressed negative feelings about repeat abortions. The views did not seem to differ among women who had undergone abortions previously and those who had not **Box**

6.2.2.5a

Box 6.2.2.5a: Personal views on repeat abortions

You've got to be responsible and about your situation at the time and you can't just keep having abortion after abortion because I think that's wrong . #7

So, I don't think people should be allowed to have it all, because I know some people who have had it more than two or three times and I just think how can do you that to yourself, cos its not messy up you emotionally but physically inside as well when you wanna have children later, it affects you every time you have an abortion. #16

6.2.3 Process of decision making

6.2.3.1 Influence on decision making

Data analysis of the transcripts from the interviews showed that many participants considered the decision to have an abortion was a personal decision with very little involvement from others. Those participants who strongly felt that the decision should be made by an individual, felt that if advice from others was sought, the advice could be opinionated and biased (**Box 6.2.3.1a**) However few others found the process difficult and consulted their partners, friends or relatives.

Most women had expressed their views on the influence of men or a partner's opinion in the process of decision making. One participant disapproved of men's involvement in the process of decision making. However participants who were in a stable relationship felt that their partner's opinion was significant in the decision making (**Box 6.2.3.1b**).

Very few participants had involved their family in the decision making (**Box 6.2.3.1c**). Those who involved their family felt supported in their decision to have an abortion, however the decision was mostly personal

Box 6.2.3.1a: Influence on decision making

But obviously it's a decision that I've had to make for myself #2

*I don't think you should be influenced by nobody.
when you do talk to people you tend to get, like, their feelings about what they think. But, at the end
of the day, it shouldn't be their decision, it should be your decision.* #5

*I think it depends on the individual. I made my decision before I spoke to anyone. I think people
can be very opinionated. So, it could make you up and down with your decision all the while. So I
think you need to think about your head, know your own decision and then, if you want to listen to
people's opinions, you can.* #8

*If it's best for me then I gotta go ahead with it. I don't worry about anybody else. If they need to
make the decision, or they want my advice then I will speak to them about it, but if its my decision
and I have to make it, I am not gonna rely on somebody elses answers.* #9

my decision. I didn't talk to nobody. #11

Box 6.2.3.1c: Influence on decision making

*I don't know about the family, I guess I expect them to be...just to try to understand from the woman's
point of view, even if they were against it. Well, I didn't tell my family but my partner.* #7

*Everybody's different and obviously everybody's affected different by the situation but I think you've
just go to get on with it. Only told very close friends. I never told none of my family. So I didn't
obviously have to explain to my Mum or my Dad, you know, not that they'd judge me;* #8

*I didn't really speak to a lot of people about this to stop me feeling so negative in a sense. My Mum
really. That's the only people I spoke to. But my Mum says it was my decision to make so.* #9

*I spoke to my Mum more and then I found out that she had an abortion after me and she just, and I
found out a load of other women in my family had and like obviously it was just kept a secret. And
like she was in the same situation I think I was about 2 and it wasn't the right time and so that made
me think about it more.* #10

*My sisters helped me a lot cos they, they did the pros and cons like family and things like that and
how everyone would react.* #16

Box 6.2.3.1d: Influence on decision making

*I only spoke about it to one person and that was my friend who has had an abortion before. She was,
she is not a judgemental person and she didn't try to tell me not to do it, she didn't try to tell me to do it,
she did come round my house the day before I was due and said, she didn't tell me, she didn't give me
any advice either way. She just left it to me.* #14

I have a friend that she had been through a similar thing and she gave me her view on it as well. #13

my partner's always been understanding, of course, a bit like me, he don't want me to but we know that it's just not the right time; overall it was my decision. Whatever I would have decided, he would have stuck by me #2

I don't think the men should have a say. I think it's down to the woman. It's their body; it's them that have the after; it's theirs at the end of the day. I know there's a lot of great men out there that would probably take the child and do what they're meant to do but. . . you can never trust one. You couldn't rely on a man from at 7 weeks pregnant to say, 'Yes, that's it, I'll take care, I'll look after her. I'll pay for it and. . . ' you can't guarantee, it always comes back to the mum. A responsible mother anyway. #4

We spoke in length about this termination. No, he didn't have a choice. He really didn't have a choice. I was adamant. . . I didnt want to have children. So he didn't have a choice about what I did. #6

I never spoke to him about it. I mean, he had been in touch but I didn't want discuss it because I didn't want him to influence me 'cos I had made my decision. So I think it's down to that individual, to be fair. #8

Obviously I got my boyfriend I couldn't talk to him really. So I just, it was all in my head really, I didn't really speak to anyone. #10

Like we both agreed that we didn't want this. " I cant think of anyone else that would influence. #12

I feel like the man has to have a say. If you are in a relationship with somebody then your partner should have a say, well their opinion should be put across as well. We sat down and we discussed it. #13

Well I certainly haven't admitted to the fact that I have had an abortion to him. Because I wouldn't want to put him off putting me pregnant in the future, so that in itself is deceit.

I did speak to my partner about it a week or so before I came and said it is getting a bit too late for me to have an abortion, and he is like what are you talking about, what on earth would you want an abortion for. And he did kind of take it on board and he was saying well some people breeze though pregnancy. I said well unfortunately it has become apparent to me that I don't and I wont probably ever breeze through pregnancy so he goes, well it was difficult for me as well because I didn't know what to do or say, and I said well I would rather be in your shoes through the pregnancy than in mine and I suppose it is all about lessons learned in life isn't it, you cant change what has happened and the abortion is done now. #14

He knew. I think, definitely my partner because it was both of our decision really. He wasn't ready, I wasn't ready, we weren't, we weren't at the right time to have a child, frankly. #16

Oh no, he was fine telling me he didn't wanna keep it, but if I kept it he doesn't really bother. He

Only two participants had taken their friend's opinion (**Box 6.2.3.1d**). One participant felt that independent advice from health care professionals would be advisable.

6.2.3.2 Reasons involved in decision making

The most common reason that participants felt would make a women to decide to have an abortion was an unplanned pregnancy with the additional responsibilities of bringing up of a child. The second common reason to emerge was for financial reasons. Other reasons quoted among the participants were unstable relationships, for medical reasons, education, career, religion and sexual assault. Some women felt that age of the women could be a reason, where women of both extremes of age would be inclined to opt for an abortion (**Box 6.2.3.2a**)

6.2.3.3 Personal reasons of the participants for having an abortion

Similar reasons such as finance, not the right time, education, an unstable relationship and inability to raise a child in their current circumstances were quoted by participants for their own personal reasons for having to undergo an abortion (**Box 6.2.3.3.a**)

Box 6.2.3.2a: Reasons involved in decision making

I think social and personal issues come into it a lot. Because depending on, like, your situation at the time, when you find out that you're pregnant. . . Um. I think, like, treatment woman might already be on. #2

*bringing a child into the world because they might pass that onto their child.
Not being in a stable relationship. you'd had unprotected sex with somebody. the child would have a father, then that could be another reason for not wanting to bring a baby into the world.
I've mentioned other things like being too young, being in education still* #3

*Just not enough money, not enough room at home, Not enough time. Yeah, just to look after them.
Not in a good relationship. That's quite an important one. They're too young? Or they're too old.
Not got a very good home life. If you're not happy at home then there's no way a child's going to be happy.* #4

I don't know. Maybe they're not ready to have children. Or maybe they're not in a comfortable position to bring children up. Maybe they just don't want any children to be quite honest. Or they're not in a steady relationship. Or financially. The most is unplanned pregnancy. #6

I mean for other people, it could be financial. And I know there are many women like me, from all over the world. And so, for many other people, for financial reasons, I guess, as well. I'm not sure. I mean I just thought of an extra reason I didn't think about first that maybe some women would do it because of they are a career, because they don't want to be mothers. I'm not sure. I think it's relative. Everyone thinks that some reason has more priority than the other. #7

Because if you are not ready to have baby, then its no use having the baby and then you don't know what to do. #11

Sometimes there are a number of religious reasons or just like society in general. If it is was an unplanned pregnancy. something like it was a rape #13

An abortion, well I think if someone was very young then it might be well advised to have an abortion. Yes, teenagers. Perhaps in early 20s. If someone was raped .#14

Well just against it just the pain and well emotional stuff isn't it. Well for it is just so you don't have to bring up a child if you cant look after it or you just cant cope with them or too young or whatever. Yeah, sometimes your family as well how they would react to you being pregnant or bringing up a child at a young age or whatever. #15

Box 6.2.3.3.a: Reasons involved in decision making

I think social and personal issues come into it a lot. Because depending on, like, your situation at the time, when you find out that you're pregnant. . . I know, with me, it came into it a lot That was a big influence whether I kept the baby or not. So, yeah, I think, yeah. I think there was a lot going on at home with qualifying in 5 months, not having much money, still living at home. Because I knew a few weeks before I found out I'd taken litocaine [spelling?] which causes, like, serious birth defects so that was a kind of a big influence on me whether I kept the baby or not 'cos of not wanting anything to be wrong with it. So that was an issue for me so I suppose any treatment a woman might be on already, any health conditions. . . "

#1

at the moment, how my life is and what's going on, it's just not the best time. I want to go to work; I can't afford to have another child right now. It'd just be silly to do that. Even last time. Last time was just because I'd just had my daughter. And it was just not right that time either. It wouldn't have been fair for another new child because a new born child always takes most of your time, of course. I've already got a child and I can't afford it. Hence why I haven't this time round and I've had to have an abortion. I don't know. It was just best for my life at the moment, for my child's life and overall. Of course I'd like children again but I've got to weigh my pros and cons right about now. And, you know, my cons were looking heavier than my pros"

#2

my reason really was financial. I'm not financially stable at the moment. I wouldn't want to bring a child into the world if I couldn't provide for the child. Still living at home with my parents. Don't think it's the surroundings, you know, an environment. And with my situation I was like it was best that I didn't have a child at the moment"

#3

When mine were little, I was full-time and I did stay at home and it was great and I loved it and I'd love to be a full-time mum again but I couldn't possibly afford to do it now so how could I possibly afford to do it with a baby, with another one? it's the next 18 years of your life and you only get one life. And it's so important that that child gets everything it needs – it needs love, care, time, attention. And it's a lot of all. . . well, it's 24/7 for the first 5 years. And if you can't offer that, then you definitely shouldn't have a child"

#4

why would I want to be bringing another child into the world when I can't afford it; I can't mentally and physically maintain that child; I, personally, am not ready for another child until I've actually finished my degree and, like, am steady in a job. So I just went for the part that was, you know, the brighter future. But for me, it's more for social and cultural reasons because I'm not married so it's very shameful to be pregnant. For me, personally, it's just because of the cultural; the reason I did it was for the cultural one. That seemed the most important thing for me because it's like being bad if my parents know about it, otherwise I don't think it's important"

#5

at this time of my life I'm quite happy with my life the way it is and I don't want another child at the moment. I'd been with my ex-partner 10 years and we've unfortunately split up but I didn't want to bring another child into that situation. I just ain't ready for that. And if I'm going to have a child, I'm going to give them the best I can. Not scrimp and save or not be able to give the emotional, that love to that child because I think children are wonderful. I adore my daughter so I don't want her to suffer for my mistake"

#8

ut for me, it's more for social and cultural reasons because I'm not married so it's very shameful to be pregnant. For me, personally, it's just because of the cultural; the reason I did it was for the cultural one. That seemed the most important thing for me because it's like being bad if my parents know about it, otherwise I don't think it's important.

#7

I am a single parent already. I have just got back into work. I have just started a career. I am just about to move home. I am just not ready for another baby and it would be unfair to bring another baby into the world. I mean like me if I was to have another baby I would probably fall apart to be honest, it was about 6 - 7 months ago when I stopped taking depression tablets as well so I have just stopped suffering from depression, just started to get myself back on track. I found out I was pregnant and it threw me completely off the rails again, Well its for your whole life isn't it so you gotta think of your whole life ahead. Do you wanna be a single parent with 2 children, not in work, not doing anything, just simply living off other peoples money. Do you wanna do that or do you wanna make the right decision and go for your own personal career, your own personal choices. And that's the decision I had to make. I wrote like I sat there and I wrote down like all the reasons why I am not ready and the reasons why I would be ready. And the reasons why I am not ready kind of triple kind of tripled the reasons why I would be ready for another baby.

#9

Obviously with me I am pregnant again after 6 months, 5 or 6 months, so that reason as well. it just wasn't the right time for me, felt like I had been pregnant all last year. I didn't wanna go through it again, yet I wanted to spend time with her, bring her up before even thinking about having another baby. Even a few weeks ago I was even saying that I wouldn't want any more children, so. No, not again yet. - not physically and mentally prepared to bring up another child. Obviously me and my partner are still really young so, we're not really financially like stable so. It just wasn't the right time at all. Cos I did that early before just, I don't think it would be fair to bring up another baby yet.

#10

I think with me I couldn't have a baby now. I wouldn't know what to, I don't know I wouldn't be ready. I haven't got enough money to look after the baby how I would want to look after. So, to have a baby I think it would be selfish you know. Because I cant do the best that I can, whereas if I waited then hopefully I will be ready. Just I wasn't ready and my partner wasn't ready either. So, I don't think we would have coped; Physical really.

#11

I had to have this treatment cos I just felt I wasn't ready for it right now. Well, basically just got married recently and I think it is too soon. We didn't plan it. We want to get our own place first and you know financially want to be stable for a family so I don't think. I think it is too early stages for us and we just need to plan it now, But yeah in my case it was just too early. I was not physically ready for it or mentally not ready for it.

#12

I had depression; didn't plan to have any more children. And I felt like that if I did have, if I did continue, it wasn't this one, it wasn't planned; the depression could have got far worse if I had continued it. Knowing as well that it wasn't wasn't wanted, but in the situation that I am in and feeling how I feel now then if it is something that has to be done then you have to. I considered my options before deciding to go ahead with it. if I did carry on with the pregnancy would the baby be in a stable environment, but they are young babies, it takes a lot of stress out.

#13

I just feel too young. I couldn't financially provide cos I am only part time, I haven't been with my boyfriend that long really. I don't really wanna bring up a child yet. And my family as well. Cos last time my 2 sisters got pregnant at a young age and they wasn't very happy.

#15

But I think the reasons for sometimes you just cant, it doesn't work, for example I am studying and stuff I wouldn't be able to have it now, no way and, I cant even look after myself and I know the training, but I think like, yeah my biggest issue was my family probably. That's why.

#16

Because I have already got a little boy and it would hard having another one and his dad is not the greatest, he doesn't really help and I wouldn't be able to go to college and go to Uni and I am at college now. I aint got a job, like a proper job to look after it. I have got depression and that would not help with the depression, really. I think it would be worse. I got depression really bad after I had the baby so if I had another baby it would just come back worse.

#17

6.2.4 Attitudes towards various methods of abortions

6.2.4.1 General views on preference for abortion methods

General views expressed by women interviewed suggested that the choice of either medical or surgical treatments depended upon various factors. Reasons that were quoted in the interviews were mostly for personal reasons such as work commitments, children or time to travel. Other reasons were the number of follow up appointments, aspects of confidentiality and subjective issues such as individual pain threshold.

Surgical abortions were perceived to be less painful and less emotional, however surgical abortions were also thought to be more frowned upon by society (**Box 6.2.4.1a**)

One participant felt that if they were beyond the gestation age for being eligible for medical treatments, then she would prefer to continue with the pregnancy rather than undergoing surgical treatments. One participant felt that surgical methods may put women off abortions itself for its invasiveness. **Box 6.2.4.1a** suggests that invasiveness, future fertility, work commitments and emotional aspects were the reasons strongly against surgical methods in the quotes as expressed by the participants. Ease and convenience were the reason for women to favor surgical methods.

Participants felt that women tend to prefer medical methods to surgical methods for the fear of surgery and exposure involved with the surgical methods. Most women felt that medical methods were the easier option as it involves only taking tablets and has less psychological impact.

The most consistent views that were expressed among participants were that women should have all the options available and discussed (**Box 6.2.4.1b**).

Box 6.2.4.1a: Attitudes towards surgical methods

	Surgical methods- For	Surgical methods-Against
Gestational age		<p><i>But, then saying that, I could be contradicting myself if I was so far gone I'd probably would have had to have that procedure. I couldn't, I think that would be horrible. I would never want to do that. If that was the case then I just wouldn't bother; I'd just have the child because that's too much.</i></p> <p><i>That's not an emotional thing that you can just blank out. Giving birth is supposed to special. You can't give birth and not have anything – that would make you feel empty and I can't have that. #2</i></p>
Invasiveness		<p><i>It's invasive, It's not very pleasant, it'd be terrible. it'd probably put people off having abortions #4</i></p>
Anaesthesia	<p><i>I think the surgical is better if you don't want to feel any pain because you have the anaesthetic. #7</i></p>	<p><i>some people might be afraid to go under, like under a general anaesthetic #5</i></p> <p><i>Waking up. That's all I think about, not waking back up #13</i></p>
Work commitments		<p><i>with the surgical one, would you be able to, like, go to work, like, more or less the next day? I don't think so. But then with the medical one, I think you could. #5</i></p>
Future fertility		<p><i>But I certainly didn't want someone going into my stomach and messing about. And if I had a surgical all the complications that could happen there could put me in a position where I don't have children again. And that's not an option for me #6</i></p>
Fear and uncertainty of the Procedure	<p><i>I think the surgical one; they don't know what's happening. While with the surgical, it's just you're knocked out and then it's over and done with. #5</i></p> <p><i>I think that you know if are may be a bit further gone than I was then the surgical treatment would be more accurate in a sense of it</i></p>	<p><i>I think cos I thought of it and what its called 'surgical' that sounds scary. Yeah, is it like a vacuum sort of thing. its just frightened me a bit and I think I was still in like the gap where I could have the medical, only just I think. And it just sounds easy, cos you are at home and just frightened me a bit the surgical. #10</i></p>

	<p><i>working. Surgical treatment is more successful, so people would rather go for that to save having to go through it twice I think. Cos I actually thought about the surgical treatment # 9</i></p>	<p><i>So I was thinking oh I could that in one day but then I thought, that it feels like someone, you are in, like you are having something done to you, you are having like an operation basically. So I didn't want that. #11</i></p>
<p>Worry about Side effects</p>	<p><i>The only negative was that: for the surgical you bleed for one day, I think, and then it's over. Whereas the medical, I bled for about 7 days. So, do you know what I mean, it's stretched over a longer period of time but I think the actual thought of having the surgical is more intense. #3</i></p> <p><i>I think the fear of being on your own when they started bleeding or losing. . . I think it would frighten a lot of women 'cos it isn't a very nice experience. #8</i></p> <p><i>I was thinking that maybe I wouldn't bleed so much as I did. Obviously you bleed and may be it would have been easier just to do the surgical way I did think more, looking at it more convenient cos you wouldn't have to, maybe I am wrong but with the surgery, it would have just been taken away and you wouldn't have to like bleed #13</i></p> <p><i>Apparently you are meant to bleed less, it is supposed to be less painful, but I don't know why they would chose it.</i></p> <p><i>Or may be cos they are definitely knew its gone then cos if you have a tablet it might not work but the surgical one is definitely gone I suppose, they definitely know. #17</i></p>	<p><i>I just think that would be even worse, so I don't think I would attempt to do that. No I couldn't do that. Definitely, I think there would be a lot more pain there, that's why. I would be worried because I think there is a lot of side effects , it would hurt a lot #12</i></p>
<p>Emotional aspects</p>		<p><i>I don't know how a surgical abortion would happen but I assume you would have to take your trousers off and it would go, a kind of implement would go through your vagina. So, in a way you might have a instinct more to protect the baby because it is directly going, Even though I don't know whether that is true or not#14.</i></p>

<p>Ease and convenience of the procedure</p>	<p><i>a bit off-putting if you don't want to have the surgical. . . 've had to come back 3 times for the medical and the surgical would only be once, wouldn't it? So follow-up appointments would influence it as well. You only have to have a day off from your personal life for the surgical. I suppose if your family members don't know surgical is easier for that, whereas they'd probably notice more if you had to get away for 3 different times. #1</i></p> <p><i>Where some people would rather be in hospital, go home the next day and that's it. #8</i></p> <p><i>I mean cos I did think about having the surgical cos its just over and done with like that #10</i></p> <p><i>I think the surgical one oh I can do that in one day and it will just be finished, so cos it didn't say about the one day for the medical one at first. #11</i></p> <p><i>Cos that can be like knowing that the clock, that the abortion and things can do, it might affect you emotionally and knowing that, you know it is gonna come away from you and whereas with the surgical part of it, there is nothing there to come away, its already gone. I said if I did do it, even though I was scared if I did it the surgical way, I wouldn't have had to come back cos it would just have been over with #13</i></p>	
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Box 6.2.4.1b: Attitudes towards surgical methods

I didn't realise that there was a thing such as a medical abortion. So I think there's a lack of awareness of the ways in which you can have a termination. I think that possibly that needs to be shared more with the patients and stuff like that. So I was given the option. And I think that was good really because I wasn't even aware of the medical. I think an awareness of both of the methods, really, yeah, that's all I can really say. I think it was less stressful for me as a person and for other women to have that option first and then if that fails then go on #3

and they should make the decision for you. Surely, you know which is the best solution, the best way to go about it. How can someone who's not a doctor know the best? Do you really have that much of an option? Oh, I just presumed if you were under so many weeks, then you were lucky and you got to take tablets. But if you're over that, sorry, you've got to go in for the. . . #4

6.2.4.2 Influence on choice of type of abortion-surgical or medical

Most participants had said that their friends had an input in making a choice of method of abortions, this was mostly based on their friend's own experience. Few women also said that they had discussed and taken opinion from partners and family.

Equally participants made their own choice of the method of abortion. They felt that the decision was personal and spoke of physical aspects of the procedures such as pain that influenced their decision.

Other reasons that women based their decision were on the gestational age and the flexibility of the various treatments in relation to the gestational age. However, most women felt that adequate information was essential to make a decision (**Box 6.2.4.2a**).

Box 6.2.4.2a: Influence on choice of type of abortion-surgical or medical

My friend she had the surgical, not the same one as I had, but she said that everything, like she was trying to reassure me that in fact if it did come to that that everything would be okay. I think it is down to the individual. Because I mean you can talk to people and people can give you an opinion but you have got to make your decision from what people, from what you hear and from what you have read” #13

My friend said it was just like having to take the pill cos that was just like a normal period but because it might have been for her but she might not have been as far gone as me. She said take the pill, its like having a period and I, no I didn't discuss the options, no. #14

I discussed with my friends, not my sisters as much cos they didn't really know as much about it. But I discussed with my friends about the different types and they, they kind of were all for this one as well because of my situation at the time and how it fitted in” #16

*I decided myself to have the medical abortion. I spoke about it with other people but I made the decision to have a medical abortion. #3
But, I think, then not everyone's, like, the same because there's pain that you'll feel that I won't feel. It still goes back down to your decision. So in that sense I'd say, that's why I think the patient being able to choose is like really important. #5*

*But obviously when you get to a certain far in your pregnancy you don't have that choice.
#8*

6.2.4.3 Reasons for preferring Medical abortions

As the participants in the study group underwent medical abortions following counselling about both abortion methods, the participant's own personal reasons for choosing medical abortions were explored. The reasons quoted by women that influenced their decision to choose medical methods were: less invasive and intrusive; more in control; time, safety and convenience of the medical procedure; and emotional acceptability (**Box 6.2.4.1a**).

Women described having a medical abortion was more like a miscarriage or childbirth and less of “abortion” (**Box 6.2.4.3a**).

Participants felt that by choosing medical methods as their preferred method they would be more in control so that their routine work would not be affected, that they would be able to experience the procedure which would not have been possible if they were under anaesthesia for a surgical method and also felt that medical methods were emotionally more acceptable. One participant chose to have the medical method to experience the pain, rather than being oblivious to

procedure by choosing the surgical methods. Another participant felt that by choosing the surgical methods the fetus would be experiencing pain. One participant felt that by having medical treatments it would be easier to forgive herself (**Box 6.2.4.3b**).

Box 6.2.4.3a: Reasons for preferring Medical abortions

Personally, for me, I prefer to do it the way I did it. realistically what I'm doing is the same as if I was to have the operation! can't have someone else remove that from me and throw it away. I'd rather it be done myself, me do it, because it's my thing. I know it's weird 'cos it's the same thing really. But I just don't want somebody invading that and taking it away. I'd rather it just go, you know, just the way it does And then there's anticipation. You don't want to feel anticipation; you just want to know what's happening, like childbirth. #2

I think maybe, maybe also – this is a little bit funny – but maybe the medical abortion was a little bit milder, I think, because it's more like a miscarriage (it's like an induced miscarriage, isn't it?). I just have the feeling that just the surgery, like just getting the fetus out, was just a little bit painful for me to see that or go through that. So I preferred the medical, just like a miscarriage. #7

Box 6.2.4.3b: Reasons for preferring Medical abortions

the medical one, you know 'Cos I don't know what's going on and I just wanted a bit more control. And I think medical is like more, more. . . it's easier. You've got more control. You can still go about and do your daily stuff. #5

But I wanted to feel the pain, actually, I wanted to go through with it. Because that's why I tried to avoid the surgery because I didn't want to have an actual shape of a human. Because that's really scary, you know. I wanted to actually experience it myself #7

Cos again I looked on the internet and it was saying that the baby has got a brain and it can felt it and stuff and I felt that was a bit harsh. Pain wouldn't bother me. I would be alright with that, it was more about the baby, because it was gonna be painful for the baby. I don't know how to put it like, with the surgical one they are too like I don't know they are too far gone for the medical so they are more like a baby kind of thing. #17

I think the medical treatment is a lot easier to go through, the medical treatment is a lot easier to forgive yourself for. I thought I would try the medical first. Cos I thought it would suit me better. #9

Time and convenience were also other important reasons that women considered whilst making a choice about their abortion treatments (**Box 6.2.4.3c**).

Although most participants were aware of side effects such as pain as a major disadvantage of medical abortions, women chose medical methods over surgical methods for the fear of surgical

procedures (**Box 6.2.4.3d**).

Box 6.2.4.3c: Reasons for preferring Medical abortions

I just thought the treatment that I had would be easier than the rest cos it limits our time so it was convenient for me basically. Just because I didn't wanna have a surgical procedure because I drive and I didn't wanna have anaesthetic and things like that. #16

Privacy of my own house. Well, I suppose, if I had to go in hospital overnight, I'd have to get cover for my daughter and I'd probably have to explain to more people because obviously I'm single. So, perhaps for me, it was just easier to be at home and carry on as normal. To me, it just suited my needs. #8

I didn't wanna feel like I have been in hospital or something like that I just wanted to take the tablet and go home and be in my own area, be in my own environment, and just relax rather than have it done here and have to stay here for a few hours. #11

Box 6.2.4.3d: Reasons for preferring Medical abortions

think I just chose the medical cos I was frightened of the surgical more #1

I did read both of them and they both said pain, like obviously you will feel pain, but the pill one it said will feel like just heavy period pain and that was, I thought well its only for after the one pill, its not gonna happen hopefully after both pills, so. #11

Probably medical, because it is not as a painful I would imagine but I don't know. I thought the surgical one would probably be more painful with like being sucked out of you. #15

Other reasons were safety, effectiveness, medical methods being less traumatic and simpler; as well as confidentiality.

Although women considered surgical abortion in relation to the gestational age, women felt that they would choose surgical abortion as a second option if medical treatments failed (**Box 6.2.4.3e**).

Box 6.2.4.3e: Reasons for preferring Medical abortions

was allowed to have it because it was within the weeks that I could. I felt that if this didn't work I could always fall back onto the surgical. #1

I was 5 weeks, so I should have waited for the surgery but I didn't want to wait and I didn't want the baby to grow either so that's why I did the medical abortion. #7

6.2.4.4 Experience with previous abortion methods

Four participants had undergone abortions previously, two women had medical methods and two of them had surgical methods. All the four participants were in favour of the medical methods. (Box 6.2.4.4a).

Box 6.2.4.4: Experience with previous abortion methods

I'd just rather stick to the way I know I've had it. Once you know you've done it once, you know you can do it again.

from past experience to this one, like, past experience I was never given the choice. Nothing was, like, more or less really explained to me. I didn't even know what was happening. And then recovering after that, Because I've had the surgical one already and I don't like being put to sleep.

#5

6.2.5 Views on newer methods of medical abortions

6.2.5.1 Various routes

Currently vaginal route of misoprostol administration is the standard practice, this is based on previous RCTs showing equal efficacy with fewer side effects as compared to the oral route of administration. There is ongoing research on the use of oral misoprostol for its convenience and being less invasive. Views and perceptions of women undergoing medical abortions on vaginal and oral routes of misoprostol administration has been explored in these interviews. Most participants agreed that oral treatments would be the preferred method if given the choice. They described the oral route of administration of misoprostol as comfortable, less intrusive, less invasive and as an easier process. Some women felt that there was no exposure with the oral treatments, felt “in control” and as casual as taking any other tablets (Box 6.2.5.1a). One participant was of the opinion that oral treatments take longer to act.

Some women expressed the view that oral treatments would be ideal for younger women and for those in the early stages of pregnancy (Box 6.2.5.1b).

A small group of women found vaginal treatment acceptable and perceived this route of administration as “normal”. Some women expressed their experience of vaginal methods of treatments to a cervical smear tests and induction of labour experience (Box 6.2.5.1c).

Box 6.2.5.1a: Various routes

I think for some women not nice to expose yourself having pessaries. A more comfortable way of doing it. It's less invasive #1

The second part was more daunting because having tablets inserted is quite, you know, it's like a private area. So I think if it was taken orally, the second part, women would, in general feel more positive towards it and more comfortable with the procedure. I think a lot of women would come in and be ok with the first part of the procedure but then the second part they'd be a bit daunted by it. Like on the way back home I could feel pain straight away. So taking it orally, would it take longer to be effective to work its way down? Rather than it being inserted #3

I felt probably oral would be better but they told me that's not how they do it here. Oral just seems easier. You just do it yourself. It's less invasive. I had to except, yeah, that the second pill was oral rather than vaginal #7

If it is as effective, it would be easier because inserting the second tablet especially because I was surprised there wasn't an applicator for it. Inserting it and when they say get it as far up as you can, obviously you want to make it as effective as possible. It is very fiddly and you, well I was very shaken anyway, it was a very awkward, emotional time, very traumatic time to be dealing with stuff. So obviously to get it as easy as possible but then if you are taking it orally and it is going to take hours on hours to work then you have got to balance it suppose. #14

I think oral tablets would be better but wouldn't they take longer to take effect as well. I suppose it would be less degrading I would say. If you take the oral one. But I just think it is easier to get it over and done with. #15

Box 6.2.5.1b: Various routes

I think that in the early stages of pregnancy it would be easier for women to do the oral tablets. That's what I expected to be honest from my doctor. For people in earlier pregnancy. Because I suppose that it is easier to cope with rather than, because to be honest with you when I came to have my medical treatment I was quite embarrassed so I suppose like within the first 12 weeks of pregnancy, if you could get the oral treatment it would be less embarrassing in a sense so it would be lot easier for women to deal with. #9

I don't like, I mean didn't even like having the pessary and stuff. For girls that like don't really know what is expected then it would be better to have just the tablets. #10

Box 6.2.5.1c: Various routes

I didn't have a problem with it. it's not going to be a nice experience #1

When I actually had them inserted? Nothing. It was fine. It probably could be more acceptable but, to be fair, I can find a smear test more uncomfortable than what it was for me #8

Other aspects of vaginal treatments mentioned by the participants included that they found vaginal treatments more embarrassing than painful. There were also different views expressed on how women perceived the action of vaginal tablets to cause abortion (**Box 6.2.5.1d**).

Box 6.2.5.1d: Various routes

<i>That goes straight onto your cervix doesn't it and works straight away.</i>	#10
<i>I think it is like, it is close to where the actual, is it egg or, yeah it is and it is actually like touching it almost</i>	#12
<i>I don't know much about the oral tablet to be honest. I just know that the one that goes into the vagina, that opens it up doesn't it so that the tissues can fall out so I suppose that's a good one. It worked well I think.</i>	#15

Some women felt that there was not much difference between the two routes and the choice would depend on whether both the routes were effective and faster acting. Others felt that there should be a choice given to the patients about the various routes available for treatments.

6.2.5.2 Same day vs Longer time intervals

Women preferred same day treatments for reasons such as convenience and described the procedure to be quicker. Most women expressed the view that the longer the treatments are prolonged there could be more associated emotions and could have an effect on decision making (**Box 6.2.5.2a**).

Those women who had the same day treatments in the RCT and were interviewed had a very positive experience with the same day treatments (**Box 6.2.5.2b**).

In contrast although most women had a preference for same day treatment, women felt that in same day treatment there was less time to cope physically. Some of the disadvantages that were expressed by women for same day treatments were experiencing side effects during the night having received the second part of the treatment late in the evening (**Box 6.2.5.2c**).

Box 6.2.5.2a: Same day vs Longer time intervals

I prefer it that way. the process doesn't need to be prolonged. If it works within the same day, great. I don't think it should be that I'd have to come again and again. 'Cos it just makes it harder. You just want it done and dealt with. #2

the only worrying thing would be if they changed their mind, I suppose. But, obviously, I tried to get back the same day but I couldn't. . . I think it's more convenient to do the same day, if you could. Then it's over with and it's a lot quicker #8

I think the difficult, the most difficult part is coming back for the second treatment. It was a difficult period of time waiting for the next day to roll round knowing that I had half killed the baby really but it wasn't fully killed and then to come back here and then to have that tablet inserted. And then to go back and be in all that pain and being sick. #12

Box 6.2.5.2b: Same day vs Longer time intervals

Because you just get it done like within one day. And you can experience it all at once, whereas I think if it was like 2 days or 3 days then I think it would be more difficult because you have had the first one and you are thinking oh my God, the second one you know. It is good to just get it over and done with in one day. In my case that is what I did. I preferred it that way. I had same day. I thought it was better. Didn't want to come back the next day. You get worried about the pain or the bleeding so the sooner you do it Fevers. I went very cold and ended up on the sofa with a blanket. And I was fine the next day. #4

I think it is because I had mine on the same day. So, yeah, I think it is 'cos it's like, oh yeah it's going to be over and done with soon, rather than me thinking, 'Oh, I've got to go back in a couple of days time.' 'So, I think that's the downside. That people think, like, 'I don't really want to do this again' because then they've got more time to think about it. Some people just tend to forget their appointment. #5

I had read that I had it in the one day and that was relief cos I thought it was just finished then. But then you feel upset that you have just done it as well. because I just wanted to get it over with. I would always have the one day rather than coming back #11

No, it was easier to have it over and done with in one day, instead of all night thinking about it and having to go back the next day. It was easier to get it over and done with in the same day. That they can have it on the same day, cos a lot of the stories are saying you have to go back in a few days but no one really wrote that you could have it the same day. Cos that would help a lot of people get it over and done with in one day. And it would be a lot easier as well instead of having to come here and then go all the way back and then come again, it would be a lot easier. #17

Box 6.2.5.2c: Same day vs Longer time intervals

May be same day more convenient. ,if you had it the same day you might get it a bit later on and then you wouldn't wanna go through it in the night and wake up with like the clots or anything, so I mean, but then you worrying because you don't know what the second treatments gonna be like #10

Obviously I did mine in the same day. It was good in a way because it was, everything was done in one way. But then on the other hand, it was a lot in one day. I don't know whether that was reflected because it was done in one day or whether would it have been less pain if it had been done over 2 days? I don't know how it works, I'm not sure. No, not really. I mean I did have a bit of side effects but... Whereas if I'd gone home, I wouldn't have been able to sleep, you know. So in one way. . . it depends on the individual. I think if I'd been prepared to come back on the same day, I'd have been ok with it. But, you know, when I left here and then I went, I knew I had to come back here on the night, so it was like, anticipation.

Kind of knowing what I went through with the next day tablet, if I had to take it on the same day and it was worse, I think I'd opt for the next day, to be quite honest. Because I don't think my pain management could manage that, could cope with anything more severe than that. #6

Among the participants interviewed after a 24-hr interval the majority felt that prolonging the treatments was associated with more negative emotions, but also perceived these treatments positively as an opportunity to get more information (**Box 6.2.5.2d**).

Box 6.2.5.2d: Same day vs Longer time intervals

wouldn't say it was too bad having it the day after; it didn't make too much difference really. Just having to come back more times and remind yourself of what you're going through. #1

So if, in terms of the time period it would be better to have it on the same day but if it is not as effective then it must be absolutely traumatic to find out that the pill has not worked and then you have got to go through the whole thing again surgically. Something that you would want to avoid at all costs. So for the sake of a 24 hour period it is well worth taking the 24 hour period #14

I suppose coming back a second time you gain more information from the healthcare professionals. Some people wouldn't ring up and ask questions whereas if they did have to come a second time they'd be more likely to. Because I wanted that as well I am just thinking, I think it was better over the 2 days. Just so I could get myself used to it. In the one day I think it would be too fast and it would be too intense and you wont realise what you have just put your body through. But over the 2 day treatment you get time to think, you get time to talk to people and so I think it might be a bit prolonged but it would be worth it in the long run, like you get any other questions you might think about oh I will ask them tomorrow now. its just I think it is better to do 2 days definitely. #16

6.2.5.3 Home Management

Most women who were interviewed felt that they would have preferred to have the process in the familiar and known surroundings of their home in order to cope with pain and other symptoms. Most women also felt that they would have felt more comfortable self-administering the vaginal tablets at home which could avoid another visit to the clinic especially if travelling from long distances. Although most women felt home use was a better alternative, they also had two varying opinions. They felt that the effectiveness of home management depended on the users understanding of how the tablets work (**Box 6.2.5.3a**).

Box 6.2.5.3a: Home Management

Well, yes because then the lady can take it and do it in her own time rather than. I mean I suppose it depends on the person itself. If the person is pretty responsible person then knows that they are making the right decision and that has had consultation before hand then yeah I suppose taking them at home would be more comfortable rather than having to sit through appointments and appointments and see so many different people about your own problems, like if it is a responsible person sat there and had a proper conversation with the doctor and the doctor has decided that that's the right thing to do then it would be, I reckon it would be acceptable for a lady to do it at home, because it is more comfort for them.

Well, less embarrassing. You have got your own bed to go into as well. You have got like people at home to help you. I mean I don't know you are closer to support aren't you rather than being at a clinic. I think that everyone should see a doctor first. #9

I mean for some people it would be convenient if it was done properly without coming here because it is not everybody that could walk into a place and, every though everybody in here for the same reason, sometimes it is, I find it difficult walking into a place where there is people I don't know cos I find it difficult to talk to other people. #13

Majority of the women however found home use not acceptable. Few participants felt that the second visit to the clinic offers an opportunity to women for further information, advice and reassurance. The second visit has the potential to increase compliance among women.

Some women felt that women may not know how to insert the vaginal tablets, increasing their chances of failure. There were also concerns expressed that by home use, young women may misuse the treatments, it may also affect the decision making process, treatment could be incomplete leading to increased complications and some women may find it emotionally difficult. Only one participant said that she self-administered the vaginal tablets but in the clinic (**Box 6.2.5.3b**).

Box 6.2.5.3b: Home Management

I don't know, are they dangerous if people don't take them and give them to their friends? I know you only give one dose out but. . . if you had young kids and one didn't want to come so the friends went to the doctor to get the tablets and gave them to them. #4

if they have to take it home and do it then, like, a couple of hours later, they might change their mind; they don't want to do it again. And then that causes lots of complications then. On the other side, you've gotta thing about people who might change their mind a couple of hours after. #5

I don't think that is very sensible. You might have an instinct not to insert and then because you took the first one you could have a baby then with defects I think really it does need medical supervision in all honesty because you don't know what kind of frame of mind people are in. You don't know what IQ people have got, you don't know what people's home circumstances are like. I really think it is quite, the stuff that medical, close medical supervision. #14

6.2.5.4 Over the counter use

All the women interviewed had strong opinions that treatments for medical abortions should not be available as over the counter supply or in the pharmacy. They felt that younger women would be pressurised into using the treatments or similarly women may be forced by their partners, it would be an unsafe practice and potentially could be misused. Some women felt that having the tablets without restriction would be seen as an easier option instead of using contraception, in comparison to emergency contraception women felt having medical abortion treatments to be more serious. They strongly felt that women should see a doctor or health professional before undergoing the treatments to avoid taking the wrong doses. (Box 6.2.5.4a).

Box 6.2.5.4a: Over the counter use

I think it would be misused. I think anybody can get access to it even like younger kids as well and I think it could be misused, like people just take advantage of it, oh yes who needs contraception, we've got these tablets always we can buy them whenever we want. I don't think that is a good idea at all. I think if it is so easy to get they will just get it any time they want. #12

Just in case anything goes wrong, its like a girl could just go and get it on her own, not tell anyone, and then something could go wrong and nobody would know, so I don't think you could get a leaflet and with the tablets if you get them over the counter but I mean some girls probably wont even read it, at least when you come here you get all the information, you know what could happen, what could go wrong, just so you know and I just think it would be better to keep it in the clinic #10

No I wouldn't agree with that at all, cos I think you need the support that the staff give you as well, like the nurses and the doctors because they talk you through it. If you do it yourself it is a bit of paper you are gonna read but it doesn't tell you everything. At least if you have got any questions to ask you can ask them they will be answered in person. Whereas over the counter, I think it is too much of a serious procedure to be taken so lightly. #16

6.2.5.5 Perceptions of newer treatment regimens for medical abortions

Whilst expressing their expectations about the various new methods of medical abortion, majority felt that effectiveness of the new methods would be a priority, the second factor was the side effects such as pain. Other anxieties expressed were the cause of any harm to the woman or the fetus (**Box 6.2.5.5a**).

Participants felt that the treatments would be more acceptable if they had the same efficacy, worked faster and had been regulated (**Box 6.2.5.5b**).

Box 6.2.5.5a: Perceptions of newer treatment regimens for medical abortions

Would it be effective? So I think it would be the worry that would it be as effective as the other method of doing it. That would be the worry #3

So I think it could have a bigger effect in the long term. Did it work but it caused problems for the fetus if there was something wrong with the child if you had to carry on with the pregnancy. That's probably the only thing I'd worry about. Or if you had a side effect yourself. Because everybody's individual; we all take the same tablet and we could all be totally different from it. #8

Just the pain, the pain and the success rate. And whether you would have to go through it again. I think they would be my only 2 main #9

I think it's a good idea, if it's less painful. I'm not sure how that works, I'm not sure if it's more painful or less painful. If it's less painful, fair play. . . #6

Well, my main worry was, how, like, how painful it was going to be. That was my main worry. I didn't have any other worry #5

If I couldn't get pregnant again, definitely that would be a big one. That would be probably my most worrying one, if it damaged me, damaged me internally or something like, that would be my most scariest thought going through my head at the time. Or, if it affected my health in any other way in general really. That's what would bother me the most. But definitely not being able to have kids because then you think I had an abortion then I cant have kids. So that would affect you major I think. But yeah that's definitely my number one for that #16

Box 6.2.5.5b: Perceptions of newer treatment regimens for medical abortions

If it does the same thing then, yeah, I think it'll be more acceptable for an individual. I think it depends on the severity of the treatment. #6

I would rather something that is known to work rapid #10
Realistically, doctors wouldn't try something that was absolutely life-threatening and you were gonna die. #2

But if it had been carried out, you know, over time and research had found it was successful, then I wouldn't see any problem with it #3

And you need to carry on and as long as you're regulated #4

6.2.6 Views on very early abortions

6.2.6.1 Awareness about Ultrasonography

Most women were aware that ultrasound examination was for dating the pregnancy in order to offer the appropriate treatments, however a few women were uncertain about the purpose of having an ultrasound. They were not certain if the ultrasound was to confirm pregnancy or to administer the correct treatments. Few women felt that ultrasound examination was done as a baseline for after treatment follow up and another woman felt that it was to diagnose ectopic pregnancy. Most women were not aware of some aspects of ultrasound examination as the transvaginal examination or about ultrasound scan images. Most of the information that women had about the ultrasound examination was from the pregnancy advisors, clinic staff, internet and patient information leaflets (**Box 6.2.6.1a**).

Box 6.2.6.1a: Awareness about Ultrasonography

I had to have the other ultrasound (transvaginal) which I wasn't prepared for. So that kind of like shocked me a little but you just go along with it because it's just what you need to do. #3

I didn't know. I knew about the scan because I'd had it done before. I didn't know you could have a picture. I didn't know you could have a picture. Because last time I came, I wasn't able to get a picture. That's something that's changed. Is it just to get the accuracy of how many weeks it is?#6

I didn't know, Well I found that out when I got here. Is it to check to see if like. To check how far you was gone to see if it was the correct treatment. #9

My partner told me about it, but I just thought, nah. That's not true, you don't know. No, they told me themselves. #12

6.2.6.2 Determining Gestational Age on Ultrasound and its effect on women

There were varying opinions on being informed about the gestational age after an ultrasound examination. Participants felt that having an ultrasound examination and being informed about the gestational age of pregnancy was associated with indecisiveness, doubts about continuing with abortions and sometimes change in the preference for the treatments (**Box 6.2.6.2a**).

The immediate reaction among the participants to finding the gestational age of pregnancy at the ultrasound examination was that of shock or relief (**Box 6.2.6.2b**).

Box 6.2.6.2a. : Determining Gestational Age on Ultrasound and its effect on women

I think it is. It is definitely important to. I suppose, I don't, well for me it was important. I wanted to know how far I was and it just you wanna know, you wanna know whats going on inside you like. They cant just do the abortion and that's it. It doesn't make sense and you still want to link like they need to tell you how far you are, what they are gonna do and what, whats safe for them to do, and what they can and cannot do. I wish I did this and I wish I saw that, so I think they should, I think people should be told, definitely. Its important. #16

I think they should know unless they specifically say they don't want to know because it affects also what kind of treatment you pick. And also if she wants to know, she has a right to know. #7

they'd need to know that information and the age of the child 'cos that would influence whether they wanted to wait to have the surgical. #1

Because if I was too far gone, I probably wouldn't have had an abortion. So I think it is because that changes your decision. you don't want to be so so far gone where you can see the child 'cos obviously that's not nice. I think a woman does need to know #2

So, for me, it was very important to find out how many weeks I was; to be sure about it so that I could be. . . make an informed decision, to be quite honest. #6

Box 6.2.6.2b: Determining Gestational Age on Ultrasound and its effect on women

So, I was shocked that it was only 6 weeks. I was hoping it was 9 weeks and then I could have kept it. was quite clear from day one, even with the nurse in the health clinic, that if I was over 9 weeks I would not terminate the baby. #6

Happy that I wasn't more than 9 weeks. I could have the tablet. And that it was really small and you know. When I knew it was 5 weeks I was quite happy. Knowing that I'd got them few weeks, you know, have the tablet and stuff and know that I could get it over and done with. Cos last time I come here I was 9 weeks and 3 days, and it was like I had just missed it. #17

6.2.6.3 Views on Ultrasonography images

Most women were of the opinion that the ultrasound images should ideally not be shown to the women but could be offered as an option to respect women's wishes (**Box 6.2.6.3a**). One participant felt that the ultrasound pictures of the pregnancy should be offered to women as a remembrance of the pregnancy.

Box 6.2.6.3a: Views on Ultrasonography images

I don't think you should just show it direct because, in my opinion, I wouldn't want to see it. But then, on the other hand, some women may want to see it, for themselves, that that's inside them. So maybe give the option 'Would you like to see it?' Or maybe show them the scan photograph later, if not show them on the screen, show them later if they would like to see it. But not just automatically show them.

#3

I wanted to see the picture. I think that can confuse women generally; seeing the scan. But for me, I wanted to see the picture. I wanted to keep a souvenir because it's not something I'm going to forget so why try and forget it?

#6

I didn't really think about it. I've had a baby; the scan picture was amazing to me when I was wanting the child. So I think it would. Obviously it's down to that individual and their state of mind but I think it could have a big impact on that person.

#8

I think, even you cant really see anything, I didn't really see anything, its just the fact that its that picture, then everyone knows what that is and that scan picture, well its relating to you. I think unless the person asks to see it then they should see it, otherwise I don't think people need to see that. Sometimes it might be better not to see it.

#16

6.2.6.4 Views on very early abortions

Most participants related very early pregnancy to absence of the fetal heart (**Box 6.2.6.4a**). Those participants who had a preference for very early abortions expressed that having a very early abortion generated positive effects as making the process of abortion emotionally acceptable, less attachment or bonding, less painful, less complications, less guilt and easier. Some women felt that very early abortions would be ideal for younger women. One participant felt that by having a very early abortion she would not have to see the pregnancy whilst being expelled. Although some women were not certain if the treatments would work if given at very early gestation, they were willing to try them. In contrast there were some women who felt that they would wait till ultrasound confirmed an intrauterine pregnancy before having the treatments to minimise the risk of failures and avoid a surgical abortion if the treatments failed (**Box 6.2.6.4b**).

Box 6.2.6.4a: Views on very early abortions

Knowing it was there and developing well. Whereas if there wasn't a heartbeat it'd be different. . . you'd be less attached to it. For some women, once they knew there was a heartbeat in there they'd probably. . . forget about any of the problems at home and just want to keep it.

#1

Yes, to me it is. Yes. Well, I was under the impression that they don't get a heartbeat until 5 or 7 weeks and if they don't get a heartbeat then it's not living; it's only the same as an egg.

#4

Box 6.2.6.4b: Views on very early abortions

It makes you feel better. 'Cos there's nothing there to feel attached for or emotional for. It makes you feel less guilty, more at ease. Probably. But then I don't know 'cos, would it still work? Well, there's no harm in trying I suppose. suppose I'm contradicting myself in a sense 'cos yeah, you could do it but then, if it didn't work, that person would have to do it again and that's not fair. And then that prolongs the process. maybe it should be tried at that early stage. #2

I think it is more acceptable because obviously the fetus hasn't developed as much as it can, as much as it should be so you are stopping it before it can go any further, before it is actually like a baby, its not just a bunch of cells really, so I think it is good to get it early definitely. Especially if you find out later, I think you still have more of the attachment as well like I am this far now I don't wanna get rid of it cos it is a baby now and things like that. So, I think it is acceptable and I think it would be acceptable to have it early, definitely. #16

I don't know. I don't think 'more acceptable' because at the end of the day we know what we're doing. So I don't think it's like that. It's just not acceptable like when you think about it; it's more emotional, I think. Yeah, I think so. Yes, especially, because in my mind, I don't know how other people think, but in my mind, like maybe the soul hasn't entered the body and that's like the most important thing so if it's too small. So not seeing anything is much easier and more acceptable. Yes, I think so. Because, like, the medical is just 5 weeks so I think by the time you find out you're pregnant and book an appointment, I think you can wait until 5 weeks. #7

I am presuming like 2, 3 or 4 weeks may be it is less dangerous to have the tablet to go through. Yeah. I think it would be easier for them. Especially like young girls that get pregnant. I think it would be a lot easier for them #9

They've come in and there's nothing there and they prefer to have the treatment? No, I don't think so. I just think that's wasting resources. If there's nothing there, then what's the point of having the treatment? No, I'd wait. Well, yeah, like if they have seen a fetus, then yeah. But if they haven't seen it then I don't see why they should. #5

Maybe. I think, um. . . I would question that because if I can't see anything how do I know if I'm getting rid of anything? And then I might be putting myself through something for no reason at all. And that's my curiosity anyway. #6

If, not if there was nothing on the scan. Only if there was something on there I think that it might change my mind. Or it might make me, may be not change my mind but make me think like do I really want to do this. I would go ahead. #11

May be, I don't know, if the scan is done and they cant really see, may be leave it a couple of weeks and then come back. I don't know. To be sure that everythings ok. I know, well I would be worried if there was, if they couldn't see anything like couldn't they. I wouldn't want the treatment if they couldn't see what was there in the first place. The early scan pictures is just like a circle, you cant really see. That, obviously you know that, whats there but that that doesn't mean anything to us, so that's like, that wouldn't bother me. But if it was like further on in the pregnancy and I did see like a child developing there, I wouldn't be able to go ahead. #13

Yeah. Cos I had to have the surgical I decided to keep him. I was, I don't know. I couldn't get rid of him. I was like, he had a brain or whatever he had and he was like a little thing and I just, I didn't wanna get rid of him then. But this time they said there was nothing in like the sac so. There wasn't anything there really. Yeah. I was gonna do that but then I got told that if it doesn't work then I wouldn't be able to have the medical one again. So I didn't know what to do then cos I didn't want the surgical one. So I waited until they could see it. wait for 2 weeks - Yeah, just so I knew that its there. #17

Those women who had undergone very early abortions were satisfied with their decisions and found it less stressful rather than wait to confirm the presence of a fetus before having their treatments (**Box 6.2.6.4c**).

Box 6.2.6.4c: Views on very early abortions

it made it easier for myself.

#2

I would want it, I wanted it there and then that I couldn't really talk to anyone, especially my family members cos they are the most important. so I just wanted to get it done straight away. I just thought it would make life easier for myself, doing it now than later. But in my case I suppose they did find in there and so I was happy that I didn't have to wait. I don't think I would have dealt with it. I am glad I had it then cos I was going balmy in my head then just like cos I knew my situation and the stress and everything was just getting to me

#16

6.2.6.5 Views and Perceptions on complications of very early abortions

When women were asked what kind of complications they would anticipate in very early abortions and were given a hypothetical scenario of having an abortion after an ultrasound examination that showed an empty uterus, women felt that ectopic pregnancy would be a complication that they would avoid. Most participants however were not aware of the complications and would make a decision based on all the information. Some women would still take the risk and carry on with the very early abortion with no confirmed intrauterine pregnancy (**Box 6.2.6.5a**).

Box 6.2.6.5a: Views and Perceptions on complications of very early abortions

It probably would, yeah, 'cos ectopic pregnancy's not very nice, It's more traumatising than anything else. You just don't need that really, on top of all the decisions you have to make. . . that's not nice. #2

I don't know what the complications are. . . . of having a that early a termination so that would certainly be worrying to me. About that early a termination? I've not given myself any opportunity to make an informed choice to be quite honest. And I think. . . when you have all the facts you can make an informed decision. When you haven't got anything there to kind of draw everything together, so to speak; it's kind of. . . well, I'm doing it kind of blind sighted. That's how I feel about it anyway. #6

That would be very disappointing because it's hard enough to just take the decision to come here and go through it so to go through it again is terrible. Yeah. I don't know. #7

But what is the risk of that happening? What is the percentage? I think I'd probably take the risk if it ain't worked you're only going to have to do the same thing again. So at least you've experienced it to a degree. So I think if it's explained to that person, it's their individual choice, but I would have taken the risk. #8

Side effects is not really that important to me but treatments not working, that's important yeah cos I want it to work. #12

Yeah, I suppose in that sense, it is good to wait just in case cos they don't know what is going on but like they said they refer you to the hospital and stuff if it is an ectopic pregnancy. So, yeah I suppose it is good to just know that its there and you might just be given treatment for no reason or something like that, its not good for your body. #16

ectopic pregnancy would be a risk. - No, I never thought about that. #17

6.2.7. Views on follow up

6.2.7.1 Personal views on follow up

Majority of the participants felt that it was important to have a follow up. They felt that by having a follow up they were well supported. The women also preferred tests even if it involved another clinic visit. However women also indicated that follow up should be individualised based on women's choice. Few women were not aware of any follow up tests (**Box 6.2.7. 1a**).

Women felt that the follow up was the responsibility of service providers and ideally follow up should be at places where treatments are given. One participant questioned the provision for not providing follow up for all women undergoing medical abortions (**Box 6.2.7.1b**).

Box 6.2.7.1a: Personal views on follow up

<i>It's important to follow up medical and surgical because problems can occur in either case. Really important.</i>	#1
<i>It's nice to know that someone, like, does bother</i>	#2
<i>After I'd had the procedure done, and after the week, and I'd gone through the pain and everything... you do think 'Has this worked successfully?' I think maybe it could be offered and it's up to the patient, the individual patient, whether they take the opportunity.</i>	#3
<i>I think it depends on that individual, really, how she feels about it.</i>	#8

Box 6.2.7.1b: Personal views on follow up

<i>I just think that wherever you've had your treatment done, that's where you should have your follow-up. He (GP) was, like, 'Well, what happened then?' And I was, like, I had to tell him everything from scratch. So I just think where you had your treatment is the best place to have your follow-up, yeah. Than if you, like, go somewhere else then you've got to explain everything, where you had it done. And I think, in a sense, that also evokes a lot of emotion as well, It's like, I'm bringing the past up. Yeah. And here, you already know what it is.</i>	#5
<i>I think it's very important. I think women are running away from it. But if we, or if the medical profession, can have those kind of services available and encourage women to use it, I think they would use it. Rather than if there's no follow-up, a woman thinks she's on her own anyway</i>	#6

Most common reason for follow up that appeared in the interviews was reassurance. Other reasons that emerged were that follow up appointments were an opportunity for counselling, medical support and contraception advice. Phrases that were frequently used among the participants were: “peace of mind”, “carry on with their lives”, “having a closure”, “feel back to myself” (Box 6.2.7.1c).

Participants shared varying opinions about the follow up methods. Some women felt that a repeat ultrasound as follow up was the most reassuring, however participants were also satisfied with a semi quantitative urine hcg testing. Most women agreed to a telephone follow up as a means of continuity of care and was as an opportunity to discuss side effects. Women also preferred urine pregnancy test at home. Postal questionnaire was not seen as an adequate method of follow up (Box 6.2.7.1d).

Box 6.2.7.1c: Personal views on follow up

Reassuring. I think it's just a reassurance thing, to know it's all worked and it hasn't failed. you can try to get back to your normal life as soon as you can. I think for some women it'd be beneficial to, like, give them counselling contact numbers during the last visit. Even though. . . well, it's their choice if they go ahead with it or not #1

Well, to deal with any complications obviously. And then to make sure that the process has worked. Because you could have an individual still being pregnant at the end of it. And what would they then do? I don't know. What would they do then? Would they then go to their GP? Would they know? Would they even know? That's another question as well; would they even know? You know. There's all those questions to ponder, to be quite honest. Who would you go to, who would you speak to after you had that? It's a bit like being discharged from the hospital, at least you can go back to the ward if something happens. But if you're discharged from here with no follow-up, you're kind of at a loss as to where you go. #6

'Cos, I suppose, obviously I'm still bleeding and some people'll probably find that quite frightening 2 weeks after the event. And I think some people might not understand that there could have been. . . there could be a problem if you don't go back and be checked over. So I think perhaps it probably would be a good idea to bring them back into the clinic just to be checked over, to be fair, to make sure everything's as it should be. You don't want nothing going on that you don't know about. If you needed to actually take the coil or the Pill. if they needed just to be reassured in their own mind, mentally, what they'd done as well as emotionally. because see I knew that I, I knew that I had stopped bleeding and everything but I didn't, I still had the worry that there was still tissue inside really frightened me but then, so then I was gonna phone the clinic the next day like if I was still bleeding but it stopped. So I think it is important yeah, I am glad that I came today just cos its likes but like an end on it. So I know that its all over now, I know that I am okay. But coming back and having the scan done it makes me feel better because when I was having the scan done I was really scared in case there was anything left because then I knew I had to have the surgical but its like a big relief to come back and know that everything is okay.

Cos then you know, how effective it is and how it actually works and stuff cos once people leave here you don't know what happens then. At least you can sort of get a bit more information and know more about the tablet and how it works. No, I would still think you might be, like I didn't think it worked cos I never bled a lot. So, you wouldn't be sure that its gone and you are just panicking. I am running around playing with the baby and that and I am not having any pain I don't think it is working. I even rang up here to see if you know that's right or wrong #17

Box 6.2.7.1d: Personal views on follow up

because you had the scan after then it is like you definitely know its finished then but you don't have to go through anything again. because if anything went like, I didn't have any side effects but if someone did then I suppose and they wasn't sure whether to phone in or not if when they got phoned or they could tell the nurses then they could sort it out, so that's good and it puts your mind at ease. Cos you know that okay everything is okay now. Everything is happening how it should be. And if nothing worried the nurse then I suppose there is nothing to worry about . #11

if I had done the pregnancy test and it would have come back positive I would have been fretting. It is kind of reassuring, cos you are, obviously it shows whether everything has gone away and it is done. Everything has got done properly or whatever. Just a reassurance thing. #13

I didn't expect all that but that's really reassuring that yes, you know my pregnancy levels have gone down now. this is actually worked, so obviously you wanna know. so I think it is definitely reassuring #12

I just generally think its safer to go to the healthcare professional than doing anything myself like doing a pregnancy test myself, instead of coming to the follow up. I prefer to go to the follow up #16

I suppose it's nice to have a call-back. they may not know what to expect so I suppose that feedback call-back is better so that they can tell the doctor exactly what is going on and to them what might be normal, I suppose yeah, that's good, 'cos some people are just naive and won't think to ring. whereas some women wouldn't ring, they just want to leave it alone. Some people don't even want to do pregnancy tests after and what-not. when you rang earlier, I felt comforted #2

No, I don't think people would bother, I don't think I would bother doing that either because you know yourself whether you are pregnant and you could just get a urine stick yourself with a pregnancy. Not if they know their bodies and they know that they are not pregnant from how they feel #14

6.2.7.2 Timing of Follow up

Overall opinion among the participants on the time for follow up after their treatments was that 2 weeks was ideal for a follow up, this was because bleeding and pain could last for as long as this time. Other reason was avoidance of repeat visits (**Box 6.2.7.2a**).

6.2.7.3 Time taken to recover

When participants were asked how long it takes women to completely recover, the duration varied from week to one month based on individuals. Both the physical and emotional recovery varied from 2-3 days after the treatments to 4 weeks. The emotional effects were not related to the physical recovery (**Box 6.2.7.3a**).

Box 6.2.7.2a: Timing of Follow up

Probably 2 weeks after. I think 'cos most women bleed probably about a week on average so possibly 2 weeks, I think. You've got over the initial pain and bleeding. So that reassurance 2 weeks after that would be good #3

Surely that would take a week or ten days easily, wouldn't it? For you to be able to scan and say, 'Yes, it's worked'. it would be nice to know 3 or 4 days after #4

I don't know how long it takes. I really don't know. I kinda liked the time I had which was 2 weeks. Yeah, I kind of liked the time I had which was 2 weeks. I'm not saying that. . . because I don't necessarily feel my process is finished yet in terms of the bleeding stopping and everything going back to normal and so forth. . . but I think 2 weeks is about suitable to kind of say 'Ok. How are you?'. Or even to have a phone call. Because I had a phone call which was nice #6

I don't know. For me, I think it was 2 weeks because that's the time when... It depends, like, maybe it could be earlier but it depends how long you are bleeding. I think if it is a week it would be too early cos I was still bleeding really in the first week so you don't really know. You cant really. I don't know, I think a week is too soon. Cos in the 2 weeks I was bleeding then I started spotting a little bit but if they phoned me when I was a week I would have just said I was still bleeding. Whereas in 2 weeks I could have told them a little bit more. Three weeks, I don't know, three weeks I suppose you could let me know everything that happened but I think 2 weeks is enough

Rather than constantly coming back and forth, back and forth. It gives it enough for the process to happen #2

I know that they say you can take a pregnancy test 4 weeks after and not before, but up to that point I'd still be worrying. #3

It just takes a while so I think 2 weeks is alright, a good enough time to sort everything out and for the pain to disappear. #16

Well, if its earlier your levels still might be quite high aren't it. But if it later that will just make people worry longer, 2 weeks is about right #17

Box 6.2.7.3a: Time taken to recover

So I think it gives yourself your body to get to normal. I think 2 weeks is a personal. I think it all depends on the personal situation themselves. I mean within 4 days of the treatment I tell you the truth I was back on the golf course practicing. I mean I gave myself a few days rest before I went out there and went back to work

So, I just think it weighs you down emotionally and physically everything, it takes a while to get back to normal. Like I know I am getting there slowly but I still don't feel like myself. Physically I don't think I am still back to normal I could tell I was changing and like after the abortion it has still taken a while for me to feel like I am going to back normal. I have had the flu, I have had back ache I feel run down

Not soon, I don't think, especially not emotionally. It takes quite a while, I think, to get over it all. Emotionally, for me it was more difficult, as I said, before the abortion itself but just exactly when it happened, I was just... emotionally I got over it. Like all the thinking was before.

6.2.7.4 Long term implications

Long term effects of medical abortions were broadly linked to relationships, sexual intercourse, emotional squeal, subfertility and planning a family. Some women felt that in a sexual relationship they would be more cautious and use protection. Emotions were expressed as a long lasting effect questioning their decision. The effect was more in the presence of young children in the family. Some women felt that they coped better emotionally in comparison to their earlier experience with abortions. Although the emotional aspects were perceived as negative emotions, there were also positive emotions. Some women felt that the more abortions a women went through, the more the effect on fertility, however most women felt reassured that medical abortions caused less harm and were adequately researched for any long term effects. One participant felt that she would not divulge the information unless her daughter was in a similar situation (**Box 6.2.7.4a**).

Box 6.2.7.4a: Long term implications

Especially if you've got young children in your family, I suppose, you'd think about it more often then. I definitely think that, having sexual intercourse and that, you're definitely more. . . make sure you're more protected once you've been through this so it raises your awareness a lot really. makes you more responsible. #1

I think it is an eye opener to be more careful and think more about it if you are going to have a baby. To, you know, make the right decisions when I am getting into relationships rather than end up back here #9

I wouldn't wanna just tell anyone so you do worry about it affecting pregnancies like future pregnancies and that was, probably that was my main worry. I think that was the big major like concern, you think like what if I cant get pregnant again then, that's what you think about like and then like obviously I did get pregnant and had like a miscarriage and then I would blame it on this and see blame it on myself. I don't wanna get pregnant again and that's why I was taking my pill every day but obviously this happened. This has been like a really big shock like to my system and so I am really paranoid now about getting pregnant again #10

Long termly, you'd always kind of wonder what ifs, I think, you'll always wonder what if? So long termly, it's not something that's going to come out of your mind. It's always going to be with you to be quite honest. I mean, it wasn't a negative experience, it was a positive experience because I know, for me right now, I wouldn't be any good. So I can always kind of comfort myself in that term. Yeah, again, when you reflect upon it, you do think to yourself he or she would have been such and such right now or they'd be going to school right now and all sorts like that #6

I don't think I'd want to tell anyone about it, I mean I only kept it between my boyfriend and my Mum. So I wouldn't tell anyone, obviously you have to say when I get pregnant again I will have to say that I have had it done but I don't think I would tell anyone about it, may be like if in like 20 years and my daughter is in the same situation I can give her advice on it or my friend or whatever, but I wouldn't wanna tell that I know. Yeah, cos I have had an abortion before and I still think, I was like going on 16 so that was 4 years ago and I still think like, I don't know just some days you still think about it, so. I wouldn't wanna go through it again. But I said that the last time and it happened so just, you never know. I didn't really feel anything I just done it and but now I feel like bad for doing it. I was a bit scared thinking oh I didn't want to have an abortion at first. Cos I thought what if in the future when I want kids I cant but I looked on the internet cos, and it said that a lot of people still have children after abortions so, I think that was the most worrying thing really.

If the issue came up, if like it was a topic that was being discussed I would, I would mention it yeah. That depends on each individual. I think in a year's time I wouldn't, yeah it would still be there in my mind but it wouldn't be as bad as what its been #13

But you just do what you do at the time so I don't know whether it is acceptable or unacceptable is the right words to use. It might be regrettable but it is a very, you know, you cant guess what being pregnant is like. Psychologically I think that it is something what if you have an abortion I don't know about everyone but for me personally its has slightly changed me and I will always slightly different outlook and it will always be I suppose something that will pick in to my mind that the baby would have been one, or two, or three unfortunately its something I have got to learn to live with. Yeah I couldn't, I would never have an abortion again because I could see it now being pregnant through clear mind and then just know that a lot of the anxiety pregnancy causes you. And when you are not pregnant really there was no, there was nothing to be anxious about.

I think it will yeah, cos you are always gonna know what you have done and probably feel guilty about it, but I suppose if it is or the better you will feel good about it. Yeah, I would imagine so yeah. So if you have to go through it again or, which hopefully I don't. Yeah when you become pregnant again it will probably bring it all back and stuff. So yeah I think it has, it would have a long term effect, I think emotionally it has on the people I know. Like a lot of them are younger, they say that they probably wouldn't do it again, they are like, it was, they didn't think about the situation properly then and pros and cons and some days they say they would just keep it and make everything better, easier life, cos I think it affects you in so many ways, so many different ways in some people, like emotionally you can if you've got 2 people like my friends you

can tell that I have got a friend who has had about a year and a half and she is still, if she talks to anybody now she will still cry about it even then cos it still gets to her, so yeah.

Definitely because with the contraception idea, I wouldn't kind of the easy, that's one reason you use them just cos they are there, they are convenient, its easy but now that I have been through this, now I would seriously think if I had sex again with my partner, that I would get something secure, something that I can rely on #16

6.2.8 Expectations about medical abortion

6.2.8.1 Expectations from health care

Most women expressed views that patient-doctor or nurse-doctor relationship was important and significant. They felt that this was important to build trust in order to talk openly, feel secure, feel at ease and a way to communicate. The significance was this professional relationship was attached to emotional understanding, for seeking advice and for reassurance. One participant also expressed that the gender of the health professional as important to make the consultation non-judgmental (**Box 6.2.8.1a**). On questioning what women expected from the health care professionals, most participants said that the information should be efficient with provision of contact numbers, confidentiality, non-judgmental, support and help.

Box 6.2.8.1a: Expectations from health care

If you have got no communication with the people that are going to help you then you are going to have no communication with anybody. If you cant ask the right questions or get the answers that you need to know then you are gonna be completely in the dark and its probably gonna haunt you in a word. #9

Somebody you can talk to. You need to feel comfortable around them. You would be able to tell them if there was anything wrong or even if you think it is embarrassing or whatever, just be able to talk to them stuff so I think it plays a huge role because you need to be able to talk to them as well about the way you are feeling #16

Women also seemed to have different expectations about the service provision of medical abortions, few women expected that there would be only one clinic visit and were not prepared for multiple visits to the clinic. Women also preferred to have the services provided at their surgery, closer to their homes. One woman also expected to find younger women such as teenagers attending the abortion clinic (**Box 6.2.8.1b**).

Some participants had opinions on the referral process and felt that the referral process should be easier and quicker. Few women felt that the clinics should be a self-referral service rather than through their general practitioners and few participants also expressed that there should be more clinics to make the services easily accessible. Some women were satisfied with the referral system (**Box 6.2.8.1b**).

Box 6.2.8.1b: Expectations from health care

think it should be a very easy process. I had to wait 3 weeks to come and in the last couple of days I was finding it very hard 'cos you kind of get excited about having a baby and then you realise the reality is very different. I think it should be quicker. You should be able to have them quicker. yeah, if you need the support, you should have had that support before you got to this stage; surely this is the final stage? #4

I was under the impression that this was self-referral and not necessarily a GP referring you to the Clinic to have an abortion. So in terms of that I think it would be beneficial for an individual especially. . . I drive but for someone who doesn't drive it might be difficult to get all the way over here, for someone who doesn't maybe have the support that I had, it may be difficult to get someone to come with them all the way over here or something like that in terms of that. So, maybe, having something in closer proximity. Maybe distributing the clinics a little bit more evenly across, would probably be a good thing. #6

I think the woman that gave me the final treatment, she has got a difficult job and perhaps a doctor should be administering that rather than a nurse but I suppose like everything it comes down to cost and if you can't get any more funding you can't afford for a doctor to be doing everything. I think in an ideal world, I would think that all, if you came here and you just turn up from the street and you are here and they have obviously been trained to make it as easy as possible like you know, it is like a drive through service, which I can see the rationale for that #14

I think some women may think that they just come once and then it's just in one go. That's it. with the medical, it was...you had to come on two visits. You visit your doctor's first. So there's a lot more to it than just going to a clinic, having it done and that's it #3

I mean like if you have got to have it done in the clinic it might be ideal for a clinic closer to home. So I was just wondering why I had to go the long way about it to be honest. #9

Well, I was shocked when I first went upstairs because I thought it would be really all young girls and it wasn't, #10

I thought it was just a tablet that I would actually like you know swallow it. I didn't know the second tablets would have to be like the way they were. I just thought that's it but I don't know I expected it to be like this. #12

6.2.8.2 Views on consultation and approach of health care professionals

From their own experience of the service provision, most women had a positive experience. Staff were described as friendly, welcoming and supportive. Participants felt that they received adequate and discreet information, did not feel that they were coerced or judged, and that confidentiality was maintained. Most participants also felt that the service was provided by trained staff, was quick and well organized (**Box 6.2.8.2a**).

Most participants expressed the view that after consultation they were emotionally positive, less scared, felt at ease with their decisions, less embarrassed and less stressful.

Box 6.2.8.2a: Views on consultation and Approach of health care professionals

Definitely. I think when I came I wasn't made to feel even worse. In fact, the atmosphere was different; it was all very friendly, the nursing staff were very friendly. So in terms of that, the staff were very friendly and they made me feel at ease, They explained it thoroughly and so forth so that was good as well so at least, sort of, I didn't went in blind sighted to be quite honest; it was very well explained. The detail was explained; they kind of told me what to expect so there was that expectation

So, in terms of the staff and the. . . and way that they handled the confidentiality as well which I thought was good. It wasn't forced upon me; it wasn't like someone was saying 'Oh you should be ashamed of yourself' or something like that. So in terms of that I only had me to deal with; So that was helpful, #6

It was all explained to me well. I think it's good to know that you feel comfortable with someone that you can talk about different things. It was quite good to be able to talk about it openly. I thought I'd be looked down upon or sort of sneered at but there weren't none of that, you know. But it was totally the opposite and I did find everybody very helpful. I felt I could ask any questions so it was quite good really. I found everything quite nice and easy. Well, it helped me a lot, But it was good that I thought, 'Well, it does happen to a lot of people'. And it did actually take my embarrassment away a little bit which I thought was nice. #8

Yeah, I think it is very adequate, yeah. Just to have someone with you at all times, well not all times, but I think you need someone to talk to and help you with the pain and like doctors and stuff so that you can ring them for advice like I did. That was really good help cos the tablets worked that they advised me to have so. All the information on the booklets and stuff that was given as well was really good. You just read all that and it will tell you what to expect and everything so. Yeah, it was all really good. #15

I think the information what's put out there, what's given to you when you come here, it's enough to be fair. Because everything was explained to me at each stage so it was quite good really. #8

They know their information because I asked them lots of questions. I wanted to cover everything. I suppose because I know the danger and things myself. So because of studying them you tend to ask more because you know what can happen and what if this happens, so I was really glad that whatever I asked they knew, there wasn't something they would be like oh let me hold on and find out for you. They knew everything. They had leaflets for everything and they covered everything I could ask. Yeah.

I think in ... I think more information should be added because there is a lot on the physical side of what it will do you, like it will do this to your body, it will do, you will bleed for this long and it will take this long but there is not much like I just don't think people know really about the support out there if they go through this. #16

6.2.9. Experience with medical abortions

6.2.9.1 Source and adequacy of Information

Women seek information about treatments from various sources. Most of the participants had prior information from different sources before they were seen in the clinic. The most common source that participants mentioned was the internet (**Box 6.2.9.1a**).

Box 6.2.9.1a: Source and adequacy of Information

Well, they explained it to me but I also read, before I came here, about it on the internet. Yeah, more or less, I knew everything. I had to except, yeah, that the second pill was oral rather than vaginal. But at least it gives you an idea before you came here. Um, the methods and yeah, actually, on the internet I did also read that it should be 5 weeks before you are allowed to take them.

So I think the method and how far in your pregnancy, how it affects which treatment you have. And if there are any side effects but I don't think there are any. It was helpful that I read a women's blog about their experiences of abortion so that was helpful to me. Some of them were talking about their dilemma about whether they should have it or not. And even though I didn't really have a dilemma it was so... it did help me to approach the thing in my mind. Also the medical abortion, because they were saying that because it happens at home, so that it gives you... you have an active role and it gives you the time... Well, they were saying you can take the pill at home... But I did find that they were right, that I didn't want to do it the surgery way; I didn't want to just lie down and the doctor does that out of me. So I read that on the internet and it was true. #7

Off websites. I was like reading some leaflet as well. On the websites, not really. But the leaflets. . . that's where I got your number from as well, from the leaflet. So, I think, in the leaflet it was. But on the website, it was, like, they were like very contradicting. #5

We found it on the internet actually. #12

I did look it up on the internet as well. I found out most like with leaflets or looking it up on the internet before, I spent a lot of time on the internet looking what the risks were and things. Whether it was 100, well its not a 100% but what the percentage was of it being successful and things. #13

I looked on the internet but people just wrote stories like they bleed for weeks and weeks and weeks and they were in loads of pain and that, so that worried me. #17

Other sources that participants said women would get information were from the advisory clinics, family planning clinics and NHS direct (**Box 6.2.9.1b**). Some women relied on their doctors for information (**Box 6.2.9.1c**). One participant who had an abortion previously relied on her previous experience rather than looking for additional information on the internet.

Box 6.2.9.1b: Source and adequacy of Information

Advisory Clinic, one of the counsellors there, From the NHS website and Brook Advisory Clinic. I know a lot of younger people would probably be more likely to go to the Brook 'cos it's a younger person's clinic, older ones I'd probably say would tend to go for NHS Direct and things like that 'cos it's a more. . . it's a bigger organisation. #1

There's always the internet which has all the information in the world. But the fact that I could just go to my family planning clinic and say, 'Ok, I don't know where I am and I want to get some information about termination' and I was quickly referred that suggests to me that there's good quality information out there and that, there are services that know that you can have access to straight away. I went to the family planning clinic, think I just wanted that. . . rather than having that non face to face contact, I think it was good for me to have face to face contact so that I could see, analyse and decide. #6

I was given a lot of information about it all anyway. So I think the information's all there. When I went to the Lyng they talked to me about it and obviously when I came here. And I have got a couple of friends who have actually been in the same situation so it was quite good to talk to them about it. But in the job I do I've heard. . . obviously it's all women. . . so I've heard a lot of different stories. I've heard a lot of people have had abortions, how it affected them, different things. So you can pick up a lot of things from listening to other people. So I think listening and talking's a massive key. #8

I think if you go to the right places, like when I went to Brook and when I came here, they gave me a lot of information. Definitely. I think blogs are really good. #16

Box 6.2.9.1c: Source and adequacy of Information

So I was prepared when I came here and I knew what was going to happen really. Initially I spoke to my friend and then I went to my GP. A number of ways really, from like your doctor, your GP, your family really. Or like on the news. 'cos I know sometimes things come on the news or the newspapers, stuff like that, so some women might spot things from that. Or the internet, they might research into it themselves if they think they might be pregnant. #3

Presume the doctors or family planning clinics. Internet. I just went straight to my doctors. #9

I was there for quite a while seeing different doctors and nurses and they told me everything #10

got pregnant 7 years ago, the. . . what I had done was available then and I was going to have it done and I changed my mind, in that waiting period. I'm sure there's lots on there. I didn't look. I felt very confident with where I was coming and what you were going to do. I didn't feel I needed to check it out. #4

Participants preferred to have all the information about the procedure including the success rates and side effects. They also emphasized telephone helpline numbers for further advice (**Box 6.2.9.1d**).

Box 6.2.9.1d: Source and adequacy of Information

The different types of abortion. What exactly's going to happen. Like, numbers to ring again in case you've got any queries. Time. . . how long each ones going to take. Where you have to go. Just everything really. #1

Just like what each procedure contains, what's going to happen, after what, how long, just normal information that you need to know. when would I have the next one how long after would I bleed, the pains #2

what's going to happen to you and how long it's going to take and the after-effects, and that' about it. what you're doing to your body and how it's going to recover. #4

The pros and the cons. Definitely important. The length of time is important. If there's any follow up that's important too. And just having the awareness of what's going to happen to the contents. . . that's also important to me. #6

I think there was good enough information on there. I thing if you need further information you just ring the number, would be a lot easier. #12

Yeah. I mean like it was helpful as well, the fact that you've got that you can call up and if you have got a problem there is somebody there to talk to.

The risks like, infection and all that. Just what to expect. I mean I was still worried coming today just in case like, cos they said you might have to have your womb removed and it is a lot, because obviously you don't get told that when you are pregnant, you don't get told any of the worries. You just, you are happy but obviously you need to know with this. But that's it mainly all the risks and just what to expect then to have like somewhere there if you do need any sort of counselling or anything. #10

Yeah, information adequate in terms of everything. I am not sure to be honest. She gave me a leaflet of different types of abortions, different terminations and I went home and read and chose it myself, so I think it is just something that you have to think about on your own. I mean if you do need help then you know your doctor is there to discuss it with you. And you do go for a consultation as well don't you, like a counselling consultation first so if you have got any questions about anything you should talk to them. #9

Most women were satisfied with the information they got from health care providers. However few women felt that there was inadequate information especially about the different ways of having abortions, route of administration, about the tests and ultrasound. There also seemed to be different versions of the treatments on the internet (**Box 6.2.9.1e**).

Box 6.2.9.1e: Source and adequacy of Information

So I think there's a lack of awareness of the ways in which you can have a termination. I think that possibly that needs to be shared more with the patients and stuff like that. #3

I didn't really, I looked on the internet about what happens, but it just, it didn't really say anything about tests and scans. There was loads of American websites and that was telling you bad things and things like it told you what the, because I know I was like 6 weeks pregnant it told you what the baby's was doing at 6 weeks and that made you feel bad. And there was things like told you what happened after the surgical one, where the babies go. Things like that that put you off and that made me feel bad but then the proper websites were good, they let you know. #11

An interesting aspect of information sharing that emerged through the interviews was information sharing through blogs (**Box 6.2.9.1f**).

Box 6.2.9.1f: Source and adequacy of Information

I think it was BUPA that I looked at and I am sure it was NHS and they was good. About side effects, things like that and stories from other women, but not, of all ages I think they should have, like young and old, just things like that really. #11

They helped me and if people knew about them, cos I only found out by word of mouth, but if there is, I don't what it is like I suppose you went to clinics and they told you, you can visit blogs and they will help you. You don't think at the time, oh not really, but if you check it out, they are actually really good and I would recommend them to people. Because you don't feel you are alone, there are loads of people going through all these experiences and it is good to share them, especially if it makes you feel better, or if it helps in any way. If you share it then why not. Definitely. I think blogs are really good. #16

Well, yeah. I don't know if people write it to scare people or it is actually true what they are saying, like what people are saying or what their experience was but. Nah, mine was nothing like that. Well, write my story and say well I had no pain, I only bled for 5 days, not like 5 weeks like they are all saying. 5 days its like lighter than what I normally am. And I could get on with everything. Like you read stories on there and people are saying they couldn't get out of bed and that. And I was thinking well its not working, I am running around playing with the baby and that and I am not having any pain. #17

6.2.9.2 Emotional experience– Before, during and after

Most women expressed that they were apprehensive, scared and nervous about the treatments. Pain and bleeding appeared to be the most worrying aspects of the treatment. Some women were also concerned about the successful outcomes of the treatments (**Box 6.2.9.2a**).

Box 6.2.9.2a: Emotional experience– Before, during and after

it's quite scary. Just the procedure and pain. Not knowing whether it was going to be painful. Bleeding. Um. Just everything really. #1

I thought because I was just up for the worst I thought it was going to be, like, really painful. #5

I wasn't sure, I was very nervous. Because, even with this, I was too worried; they told me that there was like 4% chance that there would be some remains. And I was really scared about that because I didn't want to come back and do another thing. So I think the success rate is very, the most important thing. #7

I was worried. if you bleed for so many days, but that's what my impression was, that you would bleed for so long. - impression about medical treatment #13

I thought I was gonna bleed a lot and it was gonna be painful cos that's what I read like on the internet and that but. Then I heard as well that it might not work and then I was thinking it might not work. #17

In general, women were of the opinion that women would go through mixed emotions ranging from being “hard”, “scarred”, “depressive” and “worry”, however the intensity of these emotions would largely depend on the individual’s decision making. Some women felt that women tend to feel isolated and have thoughts about being judged by others (**Box 6.2.9.2b**).

Box 6.2.9.2b: Emotional experience– Before, during and after

Very emotional, really. Something growing inside of the woman so you have like this connection, kind of, with it and you're consciously thinking all the time. I think it must be hard for all women going through this. #3

I think a woman can feel isolated. Especially if you haven't spoken to anybody about it to gain any support and you're doing it by yourself. So in terms of that, yeah, a person can feel isolated. #6

Most women had undergone a certain degree of emotion during their treatments however those who were definitive about their decision had reflected back on the reasons for their decision to overcome the emotions feelings. Some women saw having had children as a distraction to cope with the emotional feelings and some felt more stressed after having a baby (**Box 6.2.9.2c**).

Women who were undergoing repeat abortions had the same feelings of guilt but did not appear to have changed their decision (**Box 6.2.9.2c**).

Box 6.2.9.2c: Emotional experience– Before, during and after

But once you get here, that's it. You're there, aren't you? You come here to have what you need to have done. But once you get to this stage, then, you've got to know for certain, by the time you've got here you've made that decision. #4

But for me, it was the right thing and, to be fair, I never really got upset or had a sad day about it. It was just a process for me. But, obviously, I knew what I wanted to do and there ain't no issues. So I think if you deal with something as quickly as possible, rather than leave it. But emotionally-wise I was fine, I just knew what I needed to do, you know. #8

a lot of negative things were running through my head but you just have to try and think for you; you have to put all that aside. You have to think what's best for you and for the baby really. #3

but yeah I think it was probably worse for me like cos I've just had my baby. Last time I felt really, obviously, I felt horrible. I felt 'Oh I can't believe I'm doing this; I shouldn't be doing this'. I felt guilty. #10 #2

There were mixed emotional feelings following ultrasonography, mainly due to the information given to women about the gestational ages of their pregnancies on ultrasonography. Those women that were shocked did not expect their gestational age to be as demonstrated by ultrasound, some were however reassured by the gestational age matching with their estimated gestation age by their first day of the last period (**Box 6.2.6.2b**).

Most women following their treatments were satisfied with their choice and felt that they had the option of choosing between surgical and medical treatments. There were mixed responses to the actual treatment effects in relation to pain and bleeding (**Box 6.2.9.2d**). Participants said that they would not want to have go this process again. There were negative emotions associated with post treatment experience (**Box 6.2.9.2e**).

Box 6.2.9.2d: Emotional experience– Before, during and after

But it wasn't really painful and I wasn't bed-bound. It was just. . . it was more like a normal period. But then when my pain started I thought, 'Oh, I can cope with this'. And I only like had one paracetamol through all that time and that was it. no, apart from the clotting. You know, is it supposed to last that long? The clots started and it was, like, really big clumps and it was scary. #5
The only thing I didn't like about the treatment was how long I had to wait for it. So it gave me more time to think about what I was doing. #9

It wasn't as bad as what I though it would be and it was just the bleeding really, I mean it would be better cos of that way cos you only bleed a little bit after don't you cos the bleeding was quite bad but it didn't stop me going out or anything. The medical it does drag on for quite a long time #10

Box 6.2.9.2e: Emotional experience– Before, during and after

Also, the experience was not pleasant. So, in terms of that, I wouldn't want to do it again. And also because of my religion as well. Then to all of a sudden, it stops. I mean I felt empty, empty the day after. #6

It wasn't a very nice experience. I mean it weren't a very nice lesson for me to learn. But it's a hard lesson learnt. It weren't very nice what I experienced, what was coming away from me, to be fair, which did make me feel a little bit sick. #8

Oh, it was difficult but in a way it was nice to be punished, you know. It was very painful but in a way ... #14

I would say it is a lot to put your body through definitely. I wouldn't do it again. Ever. But it is a lot emotionally and physically, everything, sorry.....its so much pressure to be able to go through this but I just don't think its worth the hassle, like putting yourself through it, Not just because of what it done to my body, because the physical stuff you can take, it will go but it's the emotional side of it that it affected everything in my life, my work, everything and you cant deal with that all the time. #16

During the recovery period, although morbidity was a concern for few, it was less intense. There was less sense of regret but feeling of emptiness, tearfulness and worry. Some women had also reflected on the fact that they had not experienced having an abortion as very distressing and that they had felt better than they had expected. Most women felt good about their abortion decision because it helped them maintain control over their lives.

The summary of the transitions in the women's emotions while undergoing abortions are shown in the **figure 6.2.9.2a**.

6.2.9.3 Support

Women placed importance on support from partners, family and friends and felt that it was essential to have support. The support seems to have come from single or multiple sources. Few women did not disclose to anyone or only disclosed to friends and partners but not their family (**Box 6.2.9.3a**).

Box 6.2.9.3a: Support

with the support from my, well not my family, my close family and my boyfriend, it was really beneficial for me to have that support there. I could talk to them about it, to take your mind off, I found that was really good for me. #3

I mean I stayed at my Mum's. My Mum looked after me a bit #10

Yeah, because I had her support in a way I had support. I don't really have family support, there is only like my friend and my partner. #13

I discussed it with her and she has tried don't beat yourself up about it, she goes you know, don't beat yourself up about it, you don't have to look at it as a baby, it is just something a pregnancy that you stopped. #14

its not easy, you need help if you are going through this because I think a lot of people think they can deal with it on their own. May be they can, may be I am just an emotional person, I probably am but I just feel like there should be like extra help for people, they should have like extra information like if you are definitely gonna go through this, this is what is gonna happen, the way you will be feeling, you might be feeling like this, you might be feeling like that. I think that would be quite good. #15

Support is really important. my friends I know that I couldn't have managed without my friends because they pulled me through really, yeah took my mind off it and they kept me going, checked up on me and stuff. My friend dropped me at home. I was in bed for the whole day since I got home, cos I got pain a few hours after, about 2 - 3 hours and I stayed in bed just with soup and a hot water bottle. So I was looked after alright. Everyone was checking up on me, even although my parents didn't know what was wrong, they knew I was ill or something, so they kept checking up on me and stuff but my sisters were there, my friends came round and so. It was alright. #16

Partner's support was mentioned by women who were in a relationship and they rated this positively. Only one women felt that she was not well supported during the process (**Box 6.2.9.3b**).

Box 6.2.9.3b: Support

He was well, he could have supported more really but. I don't know. I done everything on my own really. He was just at home, he was just there. But it feels a bit like I just done it on my own really #11

Yeah, he was very supportive. Yeah. He come with me to all of the places I had to go for it and stuff. My boyfriend was very supportive, like when I was crying all the time he just said I will stay with you all the time while you are like this and then he rang the clinic for me and tried to ask what I needed to take for the pain and stuff. #15

6.2.10 Opinions on prevention of abortions

6.2.10.1 Views on increasing abortion rates

Some participants believed that there was adequate awareness through sex education, however felt there was a wider spectrum of factors that could have contributed to the increase in abortion rates. The easy accessibility of abortion treatments was seen as a reason for not following long term contraception. Abortion itself was quoted as a means of contraception in those who had unprotected sexual intercourse (**Box 6.2.10.1a**).

Box 6.2.10. 1a: Views on increasing abortion rates

Maybe getting an abortion is just such a common thing to do when you fall pregnant that you don't worry too much about falling pregnant in the first place 'cos you know you can get an abortion. I don't know how we prevent it any more than it already is. when I was in my last years of school, there was loads of sex education. I know about all the different methods of contraception that are out there. What more are people meant to do? I don't know. There's got to be a total new way of. . . What the government's doing to treat pregnancies, unwanted pregnancies, isn't working. I don't know. What do we do? If you were 100% sure of what you wanted to do. What else can you do? There really isn't a lot until society changes its ways. #4

I mean when I came up there were some people who were all happy and things but they were gonna go through with it and I was thinking they obviously just using it as contraception like, they think oh I'll have unprotected sex I can just have abortion if I get pregnant. I think that's really wrong. I think it is hard really to like let people know cos obviously you do get sex education at school but you don't really pay any attention until you get a bit older. I don't know what way you can get round it really. I suppose they think that they won't get pregnant cos they are a bit older, but I mean I think people do need to be more careful. #10

I don't know, probably increasing. I am not, I really don't know. I suppose they should be on contraception really shouldn't they but then if they don't want that and if they don't want to take it, or they don't take it properly I am not too sure. I think everybody knows about contraception don't they. But then I don't think you could educate anyone on how that is. I think it is just something you have to go through yourself. And I am quite sure that some women do it and couldn't really aren't really particularly bothered. You know. And do view it, very, you know, very matter of factly. So I don't know really. #14

Well from them stories that I read it probably puts people off so it will make people more careful. But then if people read like what I say, then probably more people wont be careful thinking it wont hurt just to have a tablet that's it. So yeah, I don't know. Cos they could just have a medical abortion, a tablet and then they go that's it. They haven't gotta, I don't know, but the surgical thing probably puts people off don't it. It put me off. I don't know that's probably why they just think it is the easier option. #17

Three women associated failures of contraception especially with the morning after pill as a reason for increasing abortions (**Box 6.2.10.1b**).

Box 6.2.10.1b: Views on increasing abortion rates

I think that there are. . . there's going to be a number of factors why people have abortions in the first place. And if we can kind of solve the reasons before it gets to the stage of abortion. . . and maybe if someone was on a contraception and it failed and maybe looking at why the contraception failed to ensure that they didn't get to the stage of where they were pregnant in terms of that or I know that there's a lot of information out there about contraception already so people are educated in that. we have a lot of missed informed individuals, I think when the emergency after tablet went ahead and became available at the pharmacies it kind of encouraged that to be honest. Because a lot of children now use that as contraception. Not really in terms of abortions. Not really. I think women just need to be wise about these issues. #6

Sometimes it is accidental like my case, used emergency contraception and it didn't work. But then not everybody is in that situation, a lot of people just do it and regret it later. #13

it should be going down with all contraception and everything really. Because I had the morning after pill and we used protection and it still happened so, may be that happened to all them people as well. Because then if you use contraception you don't have to use the morning after pill. Then the morning after pill might not work obviously like what happened to me. And then you wouldn't have to have an abortion. I don't think it will ever stop #11

For some women culture and religion played an important role in the acceptability and awareness of different methods of contraception (**Box 6.2.10.1c**).

Box 6.2.10.1c: Views on increasing abortion rates

So again, families, culture, religion play a big part in that as well. So it is hard. #5

Like, still, if you want to buy them from the super... from the pharmacy someone might give you a look if you look too young or something, like a dirty look. they have the morning after pill, isn't it? So it's also very helpful, like if you knew you made a mistake and you can take it the next day. And I don't know about that in my country. That's why it's much more widely available here, different forms of it. #7

I don't think that well. I think. Asian community contraception. I think they find it harder to get contraception because I don't know they just like thinking oh my God if someone is gonna see me what is gonna happen and stuff. I know it is like that in our community. So I think it is harder for people to like access that contraception. #12

Some women felt that increasing rates of abortions reflected the changing lifestyle within society. Few women felt that perhaps more unstable relationships could be a reason for rise in rates of abortions (**Box 6.2.10.1d**).

Box 6.2.10.1d: Views on increasing abortion rates

Maybe it's becoming easier? I don't know. I mean there's more contraception but it's not that; that's not the issue. Maybe just the lifestyle. Maybe just women don't want babies any more. Yeah. #7

I don't really think it is really. It is not advertised a lot of stuff like that is it. So if like you go to the clinic then they will talk to you about it and stuff. I don't know. Its quite 50:50 thing, depends whether you put the effort in to find out stuff #15

And I think that there needs to be. . . I don't know. . . maybe we need to be a lot more patient in relationships and then we won't have the need to have abortions. So maybe if we do a little bit more planning than the spur of the moment things then. . . I'm not saying that that's everybody but. . . you know. #6

I think it is because of society in general and also the fact that years ago people were in relationships and now its like everybody is. I don't know if its like TV and things like that that have influenced people and they are just sleeping around with everybody. #13

6.2.10.2 Methods to reduce abortions

Towards the end of the interview participants were asked about their views on methods to prevent abortions to reduce the rising numbers of abortions. Providing contraceptive advice was mentioned by the majority of participants, this included long term contraception, giving information about the right kind of contraception and easy accessibility (**Box 6.2.10.2a**).

Other means of providing information on abortions and contraception mentioned by some participants were through media, information leaflets and in magazines (**Box 6.2.10.2b**).

Box 6.2.10.1a: Methods to reduce abortions

I suppose. . . inviting women to come to contraceptive. . . you know, like at your doctor's when they have sexual health clinics, inviting women to attend and to be put onto contraception if they're in active relationships. Even if it's accidental, they're going to be at less risk of becoming pregnant. #1

And the importance of like contraception. By stressing the importance of using additional contraception. I know that condoms don't. . . people just think 'Oh yeah, I'll use that'. They don't always, you know, work effectively. I think stressing the importance of using long term contraception. #3

I don't even think you can, like, it is so hard to like. . . when you talk about contraception it's so hard to reach people 'cos then you've got again religious reasons, like, why people can't turn out. So you can't even get in touch with them at home to say 'Do you want the pill or do you want. . . ' #5

I don't know. I would have said that more education on contraception. Um, I think people do have that information because... every clinic they tell you to ask for contraception and they tell you the different things. So I think the information is there, I don't know how else...

And contraception you can buy, pills and condoms but, um, first of all they're not free like here and they're not widely available.

They could make it much more accessible to young people if they provided like the NHS provides it for young people for free; that could help. But they don't do that. #7

To be on the right kind of contraception. I didn't get any like advice, just I mean I don't think I ever had from the doctors really they just say oh this is like, if you are younger then you are more likely to get pregnant and, you know you don't really get told it by the doctors and I think they should. But I think, like on the right contraception #10

I think that more people should just be aware about contraception. But I think it is so important to make it easier for people to get it. #12

Box 6.2.10.1b: Methods to reduce abortions

the media's a big thing. A lot of people'll watch tele and that would probably be the major one. I think the media would be the main one for that. 'Cos if they don't have jobs, they don't go to school, they'd be more likely to be sat at home watching tele. So the media, like, adverts and stuff would probably get their attention more. like leaflets and stuff through the post, to people's houses but then, it depends what kind of family. . . if something like that comes through your letterbox would you read it or would you put it in the bin? Depending on what kind of family you've got. #1

Stick it on the news. Put it in the magazines. #2

maybe more on the television, like through adverts. A lot of people watch television. Or on the radio. . . like when you're driving about in the car it catches your attention. I know there are some adverts out there but maybe there could be more. Just to prepare people. #3

I don't know, just advertise more what help is out there. May be on TV commercial advertise like you know, this is what help is out there if you need it. So you know people feel yes there is help out there. #12

I don't know. I would say leaflets through your door and stuff like that would help. Cos I don't think I have ever really received anything like that. Sometimes it is on the TV like little advertisements. There is a lot of TV programmes about it as well. Well its just normally, normally just about teenage pregnancies and stuff. Yeah, just posters in places. And sometimes you see them on bus stops. When I drive past I notice them. And on the radio there is quite a lot of them as well. Yeah. #15

Few participants felt that the Health Services have a role in reducing the abortions by giving advice mainly for younger women through their general practitioners and advisory clinics (**Box 6.2.10.2c**).

One participant mentioned that legalizing abortions could have an effect on reducing abortion rates. Another participant suggested that by limiting the number of abortions one could perhaps bring down the increasing rates of abortions (**Box 6.2.10.2d**).

Box 6.2.10.1c: Methods to reduce abortions

GPs it depends how often you go into visit your GP for other problems. I mean, I know that I'm more likely to go to somewhere like the Brook Advisory Clinic for sexual health advice than I am to my GP ' #1

I know like there's leaflets offered at your doctor's surgery, that's always good 'cos you can just pop in, pick those up, local clinics, doctor's surgery. #3

Box 6.2.10.1d: Methods to reduce abortions

Just make it legal. #2

I think it's really hard, it should come down because, I mean, years ago you didn't have the morning after pill and different things, you didn't have the Pill. I don't know how you could physically get out there and bring it down. It's just, obviously, the more information out there about what happens and perhaps more sex education in school and put it out there as much as you can. I think that's the only way you can bring it down. And perhaps limit the number of abortions you have, individually. Because, like I say, I have been known to hear that women use it as a precaution which is wrong. Perhaps limit the abortions you can have. #8

Chapter 6.3

Discussion

6.3.1 Results in context

This chapter discusses the findings of the in depth interviews. For the purpose of discussing the qualitative aspects of this study this section has been broadly divided into decision making, acceptability and the process involved in medical abortion. The themes generated from the interviews and their association with each other are shown in **figure 6.3.1a**. Decision making was dependent on the attitudes towards abortion, the process of decision making and the attitudes towards various methods of abortions. Acceptability for this study was discussed under the acceptance of newer methods of medical abortions, views on follow up and acceptability of abortions at very early gestations. This study showed that there was a close interaction with interdependence between decision making, acceptability and the process of having a medical abortion. A summary of process of having a medical abortion has been shown in **figure 6.3.1.3a**.

6.3.1.1 Decision making

In a suggested model for the decision-making process for abortions by Holmberg et al ²⁶⁷ three concepts were suggested. These concepts were reactions, impacts factors and tools for the process. Reactions included feelings, apprehensions, and moral conflicts. Impact factors were thought to be quality of relationship and psychosocial factors. Tools for the process included communication, secrecy/confidentiality, and organized support. In this study the decision making process was found to be influenced by the attitudes towards abortion, the decision to have an abortion and the attitudes towards various abortions methods. These aspects have been discussed in this section.

6.3.1.1.1 Attitudes towards abortions

Attitudes towards abortion by the general population have typically been explored through surveys such as the 2006 Ipsos MORI survey²⁶⁸ in the UK and the 2000 National Election Studies in US²⁶⁹ however there is inadequate data on how women undergoing abortion procedures perceive public attitudes towards abortions. Earlier studies have indicated that public attitudes can have a negative impact on the expectations and reactions in women who choose to have an abortion.^{270,271}

In a previous Swedish study by Kero et al¹⁸⁹, women gave “adapted” (most acceptable) answers about their reactions, this was because women felt that there were expectations from others or society. Participants in this study had mixed responses about the attitudes of the public towards abortion in general. Most participants felt that society still viewed abortions with a negative perspective associating them with an act of shame and a social stigma. However participants also believed that abortions have become more acceptable. In the public survey by the Ipsos MORI in 2006²⁶⁸ 63% respondents agreed and 18% disagreed with a women’s decision to have an abortion. The survey also evaluated the response among different age groups, a difference in agreement was noted among the older respondents over 55 years of age, where they were less likely to agree with the legal provision of abortion. Similar attitudes towards abortion among the general public were expressed by participants in our qualitative study with more acceptance among the younger population compared to the older generation.

Participants in our qualitative study felt that the views of the general population depended on the circumstances at the time the decision was being made such as-social, cultural, religious or financial. The common circumstances were financial, unstable relationships, conditions at home, age, lifestyle, education. The other circumstances that were mentioned were family pressure, rape and for health problems as disabilities in the baby. In the Ipsos MORI survey²⁶⁸ respondents were more likely to approve of abortion where there was evidence that the child would be born with serious physical disabilities or serious learning difficulties and were least likely to approve in circumstances when the woman does not wish to have a child.

Culture has also been found to play a role in the decision process in some of the previous studies.^{144,147,145,146} Participants from our study were of the opinion that religion and culture in general has a significant influence on abortions. They felt that culture and religion had a negative effect on abortion beliefs. Of these religion was found to be the main reason followed by cultural and ethnic background. However most of the participants felt that the issue of abortions should be free from religious and cultural pressures.

On exploring men's attitudes towards abortions the majority of participants in this study felt that men's views on abortion in society would be circumstantial or based on relationships, some women felt that culture and ethnicity could be influential. When participants were asked about their own partner's views, the responses were varied ranging from both acceptance to non-acceptance. Some participants felt that men don't talk openly about abortions and can find dealing with such a situation emotional. A few women felt that men can also be less responsible as they bond less with the fetus, therefore have to be made aware of the various aspects of abortions.

There is very little evidence on the characteristics of the partner that could be a factor for deciding on abortions. A study among teenage women by Zavodny et al²⁷² showed a positive association between the partner's education and the likelihood of abortion, where it was found the priority was to establish their careers, and to plan their family when the time was right, the authors felt that in this socioeconomic group, abortions were found to be more acceptable among the partner's as well. On the other hand, for young women with no plans for a career requiring an education, having a child was a way of gaining a social identity. Their data also suggested similar changes in the trends in some economically developed countries where there is growing aging population starting their family at a later time compared to those in the economically less developed countries. Our study did not explore the characteristics of the partners in this study towards abortions.

In the Ipsos survey²⁶⁸ on the Legal availability of abortion for all who want it showed that 59% adults agree that abortion should be made legally available to all who want it, 27% disagreed and 14% were either neutral or have no opinion. Most participants were not clear about the role of

antiabortion activists, political and legal issues surrounding abortions however the availability and the choice to have abortion was also thought to enhance a sense of independence.

6.3.1.1.2 Process of decision making

Most women in this study had made their decision to have an abortion before approaching the health care professionals. This suggests that who women talk to before having an abortion is important in shaping their decisions. Most women had consulted their partners, friends or relatives in the decision-making process. These findings were similar to those found in the study by Fielding et al ¹⁴⁴ on the involvement of friends and family in the decision making process. However women in our study also felt strongly that although women took advice from others, the decision to have an abortion was their own.

Earlier studies have shown how a partner's attitudes and support greatly influenced the decision to continue or interrupt the pregnancy.^{273,274,275,276} The results of this qualitative study are consistent with the literature. In our study partner's opinions were found to be of significance in the process of decision making especially for those in stable relationships.

Previous studies both qualitative ¹⁸⁹ and prospective trials ¹³⁹ have shown that the most common reasons for women to have abortions were unplanned pregnancy, financial constraints, studies, work and existing children. In this qualitative study women gave similar reasons for having abortions, in a few instances more than one reason influenced their decision to have an abortion.

The impact of some of these reasons and factors related to a woman's abortion decision vary according to the different phases of the life cycle of women. For the younger women in our study the decision to have an abortion was mainly influenced by their wish to continue their studies or to start work. In contrast the reasons for abortions for older women were for previously having children and being in unstable relationship. A multivariate analysis by Sihvo et al ¹⁵⁴ confirmed similar findings that factors influencing the decision to have an abortion in unintended pregnancy varied by age. Marital status was also found to be an important factor for

making decisions to undergo abortion and single parenthood was not found to be a desirable option, as earlier studies have shown.^{277,278,279}

Sociocultural influence on the decision making process is complex and geographical. In this study few woman quoted cultural background or religion as a reason to influence the decision to have an abortion. It is therefore difficult to draw definitive opinions based on this. A comparative qualitative study among the developing countries where culture and religion have influence on women's choice could help to bring new evidence on the social norms of childbearing decisions.

6.3.1.1.3 Surgical vs Medical abortion

Evidence from previous studies show that when women were given a choice between surgical or medical methods, women appeared to prefer medical methods.^{156,158,160,161} The most common reasons cited for choosing the medical method were greater privacy and autonomy, less invasiveness and greater naturalness than surgery. The commonly mentioned drawbacks included pain experienced, duration of bleeding, number of visits, and the waiting time to know if the treatment has been successful. In this qualitative study, participants had similar opinions and reasons towards preferences for medical abortions.

For many women, the avoidance of a surgical procedure and of anaesthesia were the central reasons to avoid surgical methods. On the other hand, women did not want to experience the abortion at all, surgical method was opted for in spite of anesthesia associated complications.¹⁶⁷ This difference in opinion on the fear of anesthesia was also seen in the views expressed by participants in this study.

From the interviews in this study it is clear that women place importance on intrusiveness, safety, time factor and emotional aspects for their preference to medical methods. In the study by Simmonds et al¹⁷² an important reason as to why women preferred medical abortion was that it was seen to be more “natural”, whereas surgical abortions were felt to be more medicalised leaving less option to allow women to experience all the events of the process itself. Participants from this study also preferred medical abortions in order to feel more in control and

to be as natural as possible. As in some of the other qualitative studies ¹⁷², women in this study equated the fetus to a “baby”, such as the “baby would experience pain” and felt that they could not come to terms with a surgical method of abortion that was perceived to be more harmful.

In our qualitative study the preference for medical abortions was influenced by participants’ characteristics such as parity, employment status and marital status. Parous women felt more emotional attachment to their pregnancies, however confidentiality, time, failure with the treatments, invasiveness and privacy were some of the other reasons for their preference for medical abortions. For nulliparous women time and convenience, fertility and invasiveness were some of the reasons for choosing medical abortions. It was found through the interviews that women who were employed and not in a relationship felt time and confidentiality as reasons for choosing medical methods. There were no major differences in the reasons for preferring medical abortions among the different age groups, ethnicity or level of education.

In general most participants preferred to be given adequate information on both methods to make informed choices.

6.3.1.2 Acceptability

The most important factor for patients’ preference is the acceptability of the treatments. Acceptability is the result of an interaction of the values a person holds, the individual's perceptions of the attributes of particular products and the service delivery system the consumer encounters.²¹³ An individual may consider a method desirable, preferable or acceptable if the method’s attributes correspond to a consumer's values. Characteristics that may influence both values and perceptions include ethnicity, nationality, culture, class, education, personality and experience. Perceptions are also influenced by the inherent qualities of an item and the available alternatives.¹⁵⁶

Previous research on abortions have identified attributes that can affect acceptability, these include efficacy, safety, side effects and pain, ease or convenience, gentleness and non-invasiveness, privacy, autonomy and affordability. However research on acceptability for

medical abortions is difficult to generalise because of rapid changes to the medical abortion regimens over the last decade. These changes to the regimens include shorter time intervals, different routes of administration, gestational age limits for administration and various doses of mifepristone and/or misoprostol. Also there is varied practice on the administration of misoprostol that can range from self-administration and home use to clinic staff involvement and hospital admissions. These differences have had an impact on the perception and acceptability of the medical methods of abortions. Within the comparative studies assessment of various medical abortion regimens against an alternative is not consistent and varies from study to study.

This disparity in acceptability for various regimens of medical abortions confuses patients thereby making it not possible to provide a uniform regimen in all units within the NHS. It is in this context that this qualitative study discusses the perceptions of women towards varying alternative regimens in this section.

6.3.1.2.1 Views on Newer treatments for Medical Abortion

There is ongoing research on the efficacy of alternative routes of administration of misoprostol (the second part of the medical abortion treatment).^{280, 281, 85,282,283} Alternative routes to vaginal administration include oral, sublingual or buccal administration. Most of these studies are RCTs or comparative studies assessing efficacy in terms of success rates and side effects. There are no qualitative studies on the acceptability of various routes of administration of misoprostol. Most participants found the vaginal route of administration to be uncomfortable and intrusive, however were willing to accept this route if there was no other choice available. Participants felt that the oral route made the abortion procedure easier, however women also felt that if the procedures were made easier, more women would continue to undergo abortions. Some women expressed that oral treatments would be ideal for younger women and for those in the early stages of pregnancy.

In the RCT conducted in this study the overall acceptability in the 6-8hrs and 24- hr group was 96% and 97% respectively. 85% of the women who had received the 6-8 hrs treatment said that

they would recommend the 6-8 hrs method of medical abortion to a friend or relative, whereas only 69% of women who had the 24-hr treatment would recommend a similar regimen.

The in depth interviews support the overall preference for shorter time interval treatments as a more convenient and quicker procedure. However the pain and bleeding could be intense to cope with at night. The waiting period between the first and second medications can pose some difficulties for some women generating negative emotions and influencing the process of decision making. On the other hand women felt that the longer duration between the treatments allows opportunity to ask questions and cope better.

In this study, women felt that having the procedures at home was less stressful in an environment surrounded by friends, family or partner. The other reason expressed by women as a preference for home use was to avoid repeated visits to the abortion clinics.

However, insertion of the misoprostol vaginally may be a possible barrier to compliance depending on the patient's level of comfort with inserting the medication. Most women felt anxious about home use and felt that if not done properly can lead to more complications. There were also concerns about the lack of support if self-administered. Interestingly, women saw self-administration as encouraging more abortions.

Most women agreed that medical abortion treatments should be medically advised and supervised to avoid misuse, for the procedure to be carried out safely and to prevent the use of such medications as an alternative to contraception.

When asked about their perceptions about any new treatments for medical abortions participants placed a high value on newer methods that were less traumatic, less dangerous, more effective and less risky for future fertility. The possibility of failure was regarded as an important factor to influence the preferences for a particular method, along with avoidance of physical effects such as pain.

6.3.1.2.2 Views on very early abortions

The main finding from the interview data on the views on the ultrasonogram as a test before medical abortions was that participants had prior information about the ultrasound examination, however were not entirely aware of the other aspects of ultrasound examination such as TVS (transvaginal) scan, imaging and the information about the gestational age. Most women suggested that a fully informed choice on the ultrasound examination and its findings have to be given to the patient before the examination.

As there is very little evidence on the perceptions of women on ultrasound examinations whilst undergoing medical abortions the only comparison can be made with studies that evaluated the visualisation of seeing the fetus being passed following medical abortion treatments. Simmond et al ¹⁷² conducted individual interviews with users and focus groups interviews with health care professionals who were involved in the clinical trials involving surgical and medical abortions. As reported by the health care professionals, women's reactions to seeing embryos were varied and unpredictable. In women who already had some guilt around abortion or were just unsure of their decision, their feelings of guilt were magnified because it gave them more time to think. The feelings expressed by participants in our study were that of shock, indecisiveness and sense of relief following an ultrasound examination. Women perceived the presence of a fetus or heart beat at ultrasound examination as traumatic with a feeling of guilt.

As suggested by Brietbart et al ²⁸⁴ a patient curious about what the products of conception will look like, may benefit from seeing a sonogram or a photograph of a typical early embryo to alleviate negative feelings by describing the USS images as an embryo and being offered an option to see the image. Some of the positive views expressed by the women in this study concur with the findings by Holmgren et al ²⁸⁵ where some of women in their study said that by seeing the fetus at the time of expulsion of products made the abortion more real to them. However, other women did not like to see the fetus for the same reason.

Women who present for a medical abortion with a very early pregnancy and no gestational sac visible on the sonogram are a dilemma for clinicians. According to the study by Schaff et al ¹⁸⁷, the advantages of offering very early medical abortion are reducing the anxiety of waiting when a woman knows she wants an abortion however to identify an ectopic pregnancy in an asymptomatic women, monitoring by serial ultrasound and hCG levels are necessary. This will require additional visits to the clinic. In addition, commercially available sensitive pregnancy tests particularly pose a risk for women wanting to have abortion treatments at a very early gestation specifically in those women who had emergency contraception. The limitations of urine pregnancy tests and ultrasound examinations to diagnose an extra uterine pregnancy at very early gestation therefore lead to unpredictable complications.

Data from the interviews shows that there are varying opinion on whether participants would continue with abortion treatments when no gestational sac was seen on ultrasound. In those participants who agreed to have very early abortions, the probable reason was the ability to cope emotionally in the absence of fetus. Equally participants also preferred to avoid any adverse complications and would have liked to be informed about the success rates and complications if they decided to carry on with very early abortions. Participants with a past history of childbirth or abortion were more likely to have the procedures only after confirmation of a gestational sac on ultrasound.

6.3.1.2.3 Views on follow up

In a review on counselling for medical abortion by Brietbart et al in 2000 ²⁸⁴ the authors suggested that when women return to the clinic for follow up; they felt supported and comforted when they saw the same practitioner. During follow-up the women had an opportunity to ask and answer questions and receive information. In the author's opinion by providing information and exploring the patient's concerns, the clinician can assess highly stressed patients and encourage them to regain a sense of control. The review suggested that by having a follow up it allowed women to gain a feeling of self-confidence about how they handled this challenging event in their lives and also to explore contraceptive options.

Participants interviewed in this study supported the idea of follow up following medical abortion treatments. Most women felt that 2 weeks following treatments was the optimum time for follow up as both physically and emotionally women tend to recover and feel normal by then. The duration to recover did not appear to vary with participants characteristics such as gestation age, previous pregnancies or previous abortions. Although participants felt strongly about follow up, the services where the woman has her follow up should be a women's choice as follow up could generate negative feelings.

Most women felt that the ideal place for follow up was at the clinic or service provider for continuity of care. The various reasons women felt that follow up was essential was for counselling, discussing side effects and for contraceptive advice. Of the various methods of follow up, the most reassuring method for follow up preferred by women was ultrasonography, followed by telephone follow up.

The analysis of the in depth interviews in this study confirms the findings by Kero et al ¹⁸⁹ that emotional feelings can be both negative and positive depending on the individual. The emotions could be more associated with previous child birth, abortions or presence of young children in the family. There was a universal opinion about contraception and avoiding an abortion in the future along with appropriate planning for a future pregnancy. The emotional aspects of post abortion have been discussed later in this chapter.

6.3.1.3 Process of having a medical abortion

There are different phases that a woman has to go through during the process of having a medical abortion as shown in **figure 6.3.1.3a**. Direct interaction with a health care professional is the first phase, during this phase women tend to have various expectations from the health care professionals and service providers. These have been discussed in the first part of this section. The second phase is the process of information gathering where women seek information about their treatments from various sources. Access and adequacy of this information has been discussed in the later part of this section. The most important aspect of the process is the emotional experience before, during and following abortions which has been considered as the third phase of the medical abortion process. Integrated within this phase is the support that women get during the process.

6.3.1.3.1 Expectations about medical abortion

Most women felt that counselling was very important, they expected the health professionals to support their decision and be non-judgmental. For those women who did not tell friends and family about the pregnancy, it provided their only opportunity to discuss the decision to have an abortion.

The referrals process to the abortion services was from various sources as their GP, FPC, Brook clinic or as self-referrals. Many women were keen to have the procedure done quickly and some commented about unnecessary delays during the referral process. Participants felt that these unnecessary delays could lead to significant distress and could make the decision-making process difficult, making them think again about their decision and so causing further mental anguish.

Overall most participants were satisfied with the counselling and felt that their decisions were respected. Participants felt that they received supportive listening which helped them with the decision-making process. Participants found the information provided adequate and felt more reassured with the opportunity to approach health care professionals via phone consultation if needed.

The experience of care is likely to influence emotional adaptation following medical abortions, ¹⁸⁶ participants in our study had felt that they had positive experiences from using the services.

6.3.1.3.2 Experience with medical abortions

6.3.1.3.2.1 Access and Adequacy of information

There are a number of sources for obtaining information on abortion, most participants preferred to see a health professional before undergoing treatment. With the widespread use of the internet, participants' views on adequacy of information on websites was mixed. Very few participants relied entirely on the information over the internet to make an informed decision.

However few participants found sharing of personal experiences through blogs as useful. Participants felt that there seemed to be disparity in the information more so with medical abortions due to the various regimens and advancing research. It often becomes difficult to address these issues in clinical practice. This qualitative study has not explored the difficulties faced by health professionals in addressing the information provided by the internet.

As abortions are associated with confidentiality very few participants discussed the treatments with friends or family.

6.3.1.3.2.2 Experience with medical abortions – Before, during and after

As shown in various randomized controlled trials, medical abortions are perceived to more unacceptable to women due to its effects of pain and bleeding. Qualitative data from this study suggests that are women are apprehensive about their treatments- pain and bleeding being the main aspects. However participants in the present study preferred to have medical abortions as they found the effects of pain and bleeding manageable, even at home. Whether side effects of pain and bleeding are better managed at home or in the clinic has not been explored in this study.

Expectations and the experience following medical abortions are not only related to physical, but also to emotional effects. In general, several participants in this study expressed ambivalence towards abortion and distress about terminating the pregnancy but at the same time women also expressed relief about making the decision to undergo abortion and saw this as an act of taking responsibility. In spite of ambivalent feelings most were settled in their decision to have the abortion, and declared that in the end the decision to have an abortion was their own.

Although most participants in the present study did not experience abortion as traumatic, the participants' responses to abortion were complex, a mix of both positive and negative emotions. In this study the overall transition of the emotions during the 2 weeks study period were from negative feelings (before) to more mixed feelings (during and after). There was not much difference of opinion between women who had undergone abortions before and those who had not with regards to their post procedure experience. However, they expressed that they would

not put themselves through another abortion procedure and that this was an experience as a “life’s lesson”.

As shown in previous studies by Kero et al ²⁸⁶ and Holmgren ¹⁹⁵, although most also experienced painful feelings while having an abortion, women thought of abortion as a possible solution to an unwanted pregnancy and only few had experienced any conflict of conscience when facing the abortion. Participants who had made a decision before coming to the clinic seemed to have coped better even following ultrasound examination which they considered as the most stressful time during the process. Similarly other ways of coping with stress as mentioned by some participants was resuming work and having other children as distractors. Those women who did not experience any distress post-abortion had also stated from the start that they did not want to give birth since they gave priority to other factors such as their work, studies and already existing children.

6.3.1.3.2.3 Support

Participants in their interviews expressed that support of any form and from any person close to them was important while going through their treatments. Although there are very few studies looking at the impact of partners’ support on the emotional outcome, it is clear that for those in a stable relationship partners’ support was perceived positively. It is however not clear if partners also seek this kind of support from others.

6. 3.2 Summary of findings

The decision to continue or end a pregnancy is multifactorial and usually women tend to have more than one reason for ending a pregnancy. The nature and interaction of the different factors influencing the decision to continue or o end a pregnancy however remains limited.

The main reason for an abortion decision appears to be for women to choose to have a planned family i.e. having children with the right partner and at the right time, and to limit the number of children. Whether there is a generation effect that influences women’s decision on abortion is difficult to ascertain, however views of women in current times seem to differ less from the

1970's when abortion became legal. There appears to be some variation with regards to abortion views at different age groups, younger women consider financial stability and completion of education as a priority to starting a family, whereas older women give importance to stable relationships and supporting other children. These attitudes towards abortions may however have an influence in the dynamics of the change in the society and motherhood. Within a society decision can also be influenced by religion and culture with some cultures allowing independence to women and others being more restricted. Forty years following the Abortion Act, attitudes towards abortion in general remain to be associated with negative views.

Despite the various changes to the regimens and protocols, some characteristics remain intrinsic to medical abortion. When compared to surgical abortion, medical abortion have slightly lower efficacy, take longer from initiation to completion and makes the women more aware of bleeding and pain along with the awareness of expulsion of products of conception. Many of these intrinsic characteristics of medical methods depend on service delivery choices. These include additional doctor visits, avoidance of admission to the hospital/ anaesthetic and women having more control during the process.

Research based on interviews with women who have used medical abortion have studied women's perceptions and their long term effects. These studies have shown that acceptability alone is not the determining factor for various regimens, another significant factor is the decision making process. The decision making process can be complex depending on multiple factors as social and personal beliefs, circumstantial, support system and information provision. Although it is the women's choice of making a decision to have an abortion, her partner may play a role in the decision-making process, particularly when the woman is undecided. Further research in the form of qualitative interviews may be needed to identify partner's experience and support during a woman's abortion experience.

There is an increasing awareness among both the general public and the medical profession for the need to incorporate patients' preferences into medical decision making. Most women attending an abortion clinic would have already been through a decision-making process and chosen a preferred abortion method. However, no assumptions can be made about the certainty

of a woman's decision and therefore input from health care providers offers an opportunity to further explore the thoughts and feelings about the decision. Whether the abortion decision had been taken as a matter of course and/or was the only alternative can have an impact on the acceptance of the decision made and in turn on the long term effects. It is therefore important that proper counseling and adequate information have a major role in medical abortion because the patient is a more active participant in the abortion process.

Along with other emotions women seeking abortion frequently experience uncertainty about what to expect. Health care professionals must be sensitive to the different stages of decision-making that individual women have reached and must be able to identify those who may require additional support and counselling. Health care providers' role is also to help put a woman at ease and communicate with a warm personality. Of significance is the sensitivity that has to be shown during the consultation of an ultrasound as women go through negative feeling while having an ultrasound. Most women who had gone through an abortion felt positively about future pregnancy but wished not to be in a similar situation in the future.

PART 7

RECOMMENDATIONS AND CONCLUSIONS

Chapter 7.1

Discussion

The results from this study suggest that shorter time intervals (6-8 hrs) can be offered to women as an alternative to standard time intervals. The shorter time intervals were found to be more acceptable as a more convenient and quicker procedure. However, the results from this RCT should be interpreted with caution due to the small number of patients recruited into the trial. The study does not recommend quantification of urine hCG as an effective method of follow up, however telephone follow up could be a more cost effective and feasible method in well informed women.

In this study the meta-analysis on the efficacy of various time intervals was conducted up until the point of commencement of the RCT i.e. till 2010. This is because the evidence from the meta-analysis was deemed to be sufficient to carry out the RCT. As suggested by the Cochrane review on the medical abortions for first trimester there are limitations to the generalisability of their results as almost all trials were conducted in settings with good access to emergency services. Similarly the meta-analysis from this study also identified difficulty in comparing regimens across the RCT's due to variations in the dose regimens and subject characteristics for the shorter time intervals.

The efficacy of shorter time interval (6-8 hrs) medical abortion treatments was 98%, similar to the standard time interval (24 hr). This was comparable to the results of the study from Crienin et al ²⁰⁴, however as this was a small study, the results of the shorter time intervals cannot be recommended to all women undergoing medical abortions. Similarly the significance of minimising risk of failures in relation to the gestational age and parity could not be demonstrated due to small number of failures. In secondary analysis of side effects, the duration of bleeding with the shorter time intervals (6-8 hrs) was less compared to the standard time intervals (24 hrs), this difference was not observed in other RCT's. ^{204,206} The duration of pain was found to be longer with the shorter time intervals (6-8 hrs), but the use of analgesics was not found to be statistically significant between the two groups. The possible reason for this could be related to

the pharmacokinetics of the two medications (mifepristone and misoprostol). As this study did not include the measurement of bioavailability of these medications it would be difficult to entirely prove these differences based on pharmacokinetics alone. There was no overall difference in the acceptability of the different treatments, these findings were comparable to the RCT by Creinin et al ²⁰⁴, however differed from the acceptability expressed by women in the study by Guest et al. ²⁰⁶

The results of the RCT itself have been underpowered by the number of participants recruited for the study. Although the study was set out to be conducted as non-inferiority study this was not feasible due to various factors as highlighted in the discussion section of RCT of this thesis. The evidence from this well conducted RCT can however contribute to the existing evidence as being part of a meta-analysis on efficacy of shorter intervals of medical abortions. The design of the RCT had additional value in contributing to providing medical abortion treatments as home use or outpatient treatments. The RCT on its own has therefore provided information on the feasibility of home use there by avoiding repeat visits to the hospital. The cost effectiveness of this method of regimen however has not been explored in this study.

Larger RCT's will be needed to assess success rates and side effects of shorter time intervals with regimens in which repeat treatments are not used will help to determine if shorter time intervals can be offered to all women.

The follow up response was better for those women in the intervention group (6-8 hrs). The study was not able to demonstrate the predictability of urine hCG quantification in assessing outcomes of medical abortion treatments due to lack of accountability of variables that could influence the cut off levels. In other studies where serum hCG and USS was used to assess outcomes, this study did not include these parameters as the study aimed to be pragmatic and avoid repeat attendance to the hospital.

Telephone follow up has been found to be a feasible method of assessment of outcome before further invasive testing.¹¹⁹ In this study there was inadequate data to recommend this method of follow up unless women were well motivated.

A robust systematic review on the various follow up methods will be able to answer the question of the most cost effective and feasible method of follow up in the low resourced countries offering home use.

The qualitative study has explored various aspects of medical abortion treatments. As there are very few qualitative studies to compare findings, this limits the generalisability of the results of the qualitative study. Qualitative study involving other ethnic groups without language barriers may generalise evidence to population worldwide.

The mixed methodology adopted in the conduct of the study has been unique as being the only study to be conducted on medical abortions for shorter time intervals. The recommendations as described in the next chapter will add value to the development of protocols and guidelines for provision of abortion care.

As home use has been found to be acceptable, the option to provide them within the primary care as is the well women's clinic or the sexual health clinics can cut down the waiting times for women to have their treatments.

In this study additional misoprostol doses were not administered and use of telephone follow up could provide additional advantage of reducing the bed occupancy.

Protocols and guidelines will have to be set for follow up along with training staff in providing these treatments as outpatient services.

Chapter 7.2

Recommendations

This chapter focuses on bringing the findings of both the RCT and the in-depth interviews together to make recommendations. As statistics and comparative results do not provide the motivation behind certain preferences and behaviours, the aim is to provide depth to the facts and figures. The aim is also to provide ideas for future directions in regards to improving health care services and interventions.

The findings of this study have implications for practice which go beyond the specific research questions asked. In particular, they point to ways medical abortion service can be made more effective and individualised.

Through the process of analysis of both the quantitative and qualitative data an attempt has been made to identify aspects of medical abortions research that could form the basis for further research.

Implications for clinical practice and recommendations have been discussed below.

Shorter time intervals

Recommendation 1: The results from the RCT in this study do not confirm the universal use of shorter time intervals of medical abortion treatments for all women but can be provided as an alternative tailored to individual choice depending on the patient's compliance.

In this RCT of 121 women the success rates were similar for 6-8 hr or the 24hr time interval regimen. The success rates were 98% with either of the medical abortion interval regimens. The numbers were few for secondary outcomes on pain and bleeding, however the overall patient satisfaction for either of the treatments were not found to be different.

The data from the preferences of the non-randomised women in this study showed preferences for varied time intervals as 24 hr or 36-48 hrs for their own personal reasons. These preferences were further explored in the qualitative study. The findings from the in depth interviews supported the overall preference for shorter time interval treatments as a more convenient and quicker procedure. However the pain and bleeding experienced with the shorter time intervals were found to be too intense to cope with at night, this is because of the onset of symptoms 2-4 hrs after administration of misoprostol. The waiting period between the first and second medications was also found to pose some difficulties for some women generating negative emotions and influencing the process of decision making. On the other hand women felt that the longer duration between the treatments would provide them the opportunity to ask questions and cope better.

In the present work, the use of flexible time intervals has been shown to be effective in medical abortions at gestations less than 9 weeks. Furthermore, women would be able to time the use of misoprostol in relation to the mifepristone based on their particular needs.

Home Management

Recommendation 2: Home use has a potential in carefully selected women, but before offering women the choice of home use and self-administration clinicians should assess women's understanding of the procedure.

There is no legal restriction on where the abortion process should actually take place, however in the UK according to the DH (Department of Health England) Abortion Act, both mifepristone and misoprostol are given within premises licensed for abortion.⁹⁹ Several studies from many countries have confirmed that home use of misoprostol is safe, acceptable and effective up to 63 days of gestation.^{117, 175, 178, 179,180}

This research was conducted in an outpatient clinical setting where women were discharged following misoprostol administration. The overall success rates of the treatments was not affected by home use as shown in previous studies on home use.²⁰⁸ Based on the findings from

in-depth interviews, women felt that having the procedures at home was less stressful in an environment surrounded by friends, family or partner. The other reason expressed by women as a preference for home use was to avoid repeated visits to the abortion clinics.

However, insertion of the misoprostol vaginally may be a possible barrier to compliance depending on the patient's level of comfort with inserting the medication. Most women felt anxious about home use and felt that if not done properly can lead to more complications. There were also concerns about the lack of support if self-administered. Interestingly, women saw self-administration as encouraging more abortions. Most women agreed that medical abortion treatments should be medically advised and supervised to avoid misuse, for the procedure to be carried out safely and to prevent the use of such medications as an alternative to contraception.

It may therefore be considered safe and acceptable for women to complete the abortion at home following misoprostol. If this were to be available as a choice for women, then adequate support and robust follow-up arrangements for these women should be considered as part of service provision.

Follow up

Recommendation 3: Services that provide home management or in women who choose to go home immediately after misoprostol administration, a reliable method for excluding continuing pregnancy is important.

Recommendation 4: Local follow-up protocol should be based on the gestational age and individualised to the women's choice.

Recommendation 5: Women found follow up at 2 weeks following their treatments ideal. The current evidence suggests that fall in serum hCG/ urine hCG at 2 weeks is reliable irrespective of gestational age.

Recommendation 6: The follow up method should be cost effective and avoid repeat clinic visits. The use of clinical assessment and women assessment in the form of telephone follow up may seem as an alternative in well-motivated women with appropriate counselling.

According to the RCOG guideline on abortion care 2011, there is no medical need for routine follow-up after surgical abortion or after medical abortion if successful abortion has been confirmed at the time of the procedure. The rationale behind this is that continuing pregnancy after medical abortion is uncommon, 0.5–1% after mifepristone–misoprostol regimens^{23, 211} and products of conception are identified by an experienced health professional at the time of medical abortion in those having inpatient treatments. In contrast an ideal follow up method in an outpatient setting (home use) can be a challenge.

The overall follow up rate among the women taking part in the RCT study was 72%, with one or all of the follow up methods. The follow up methods that were evaluated in this study were return of questionnaires, telephone follow up, semi-quantitative urine hCG or ultrasound scan. The return of questionnaires, telephone follow up having a urine hCG test or USS would arguably dependent on the logistics of any RCT study, however the response can also be interpreted as acceptability of women to have a follow up. The overall low uptake of follow up suggests that services that provide shorter time interval treatments will have to rely on women's motivation to be committed to follow up and most will need support as well as adequate information.

The response to follow up was high if the follow up involved investigations, 54% had Urine hCG and 50% had USS examination. Because of this, to integrate shorter time intervals of medical abortion treatments into outpatient service will have to be balanced with the effectiveness of follow up and the pragmatic issues of providing clinic time for ultrasound services.

Only 44% responded to telephone follow up. Although telephone support is relatively easy to provide, the findings suggest it is unlikely to be effective unless used by those who are more motivated. Where resources are limited, telephone follow up may be considered as an alternative

to ultrasound assessment as women's account of their symptoms following medical abortion treatments are an adequate indicator for completeness of the abortion process.

Participants interviewed in this study supported the idea of follow up after medical abortion treatments. This strong preference could have been influenced by the fact that the participants were part of the RCT, that all participants were treated as outpatient and that all of them had follow up. There was no differences in the preferences expressed in the interviews compared to that reflected by the figures for follow up in the RCT, the most reassuring method for follow up preferred by the participants was ultrasonography, followed by telephone follow up.

Most women felt that 2 weeks following treatments was the optimum time for follow up as both physically and emotionally women tend to recover and feel normal by then. The duration to recover did not appear to vary with participants characteristics such as gestation age, previous pregnancies or previous abortions. Although participants felt strongly about follow up, the services where the woman has her follow up should be a women's choice as follow up could generate negative feelings. Whether a follow up at 2 weeks should be a routine practice for home use for those treated in an NHS hospital or an abortion health care provider can only be explored by a further research. An earlier and rapid method of confirmation of these treatments therefore warrants further investigation.

Most women felt that the ideal place for follow up was at the clinic or service provider for continuity of care. The various reasons women felt that follow up was essential was for counselling, discuss side effects and for contraceptive advice.

Very early abortions

Recommendation 7: Women having very early abortions i.e. when ultrasound has not confirmed an intrauterine pregnancy require appropriate counselling and information on the risks of ectopic pregnancy to make informed decision if they wish to continue with the treatments.

Recommendation 8: Ultrasound if provided as a routine pretreatment test should be delivered with appropriate information on TVS scanning and imaging in a sensitive setting.

With increasingly available sensitive urine pregnancy tests providing an estimated gestational age with claims of accuracy, there are more referrals for very early abortions i.e less than 5 weeks. Failed emergency contraception poses a challenge to adequately date a pregnancy. Moreover ultrasound facilities are not available in all abortion service providers, this makes dating a pregnancy a challenge. Therefore medical abortion treatments for very early pregnancy has the implications of administering medical abortion treatments for women whose pregnancies have not been confirmed to be intrauterine predisposing them to risk of ectopic pregnancies.

The findings from this RCT were underpowered the by small sample size to draw any conclusions based on gestational age. Data from the interviews shows that there are varying opinions on whether participants would continue with abortion treatments when no gestational sac was seen on ultrasound. In those participants who agreed to have very early abortions, the probable reason was the ability to cope emotionally in the absence of fetus. Equally participants also preferred to avoid any adverse complications and would have liked to be informed about the success rates and complications if they decided to carry on with very early abortions. Participants with a past history of childbirth or abortion were more likely to have the procedures only after confirmation of a gestational sac on ultrasound.

The main finding from the interview data on the views on ultrasonogram as a test before medical abortions was that participants had prior information about the ultrasound examination, however were not entirely aware of the other aspects of ultrasound examination such as TVS (transvaginal) scan, imaging and the information about the gestational age. They suggested that a fully informed choice on the ultrasound examination and its findings have to be given to the women before the examination.

Service provision

Recommendation 8: Abortion Services should have robust referral systems that facilitate access without delay.

Recommendation 9: Information provided on all methods of abortion treatments should be objective, up-to-date and evidence based. Written information should be include information on complications and sequelae of abortion.

Recommendation 10: Women should receive counselling and decision-making support about their options.

Recommendation 11: Adequate information on contraception including long-acting methods should be provided by abortion care services.

Many women were keen to have the procedure done quickly and some commented about unnecessary delays during the referral process. Participants felt that these unnecessary delays could lead to significant distress and could make the decision-making process difficult, making them think again about their decision and so causing further emotional distress.

The option for self-referral has not been studied in this study. This study also does not shed light on the experiences of women who gave up trying to access NHS help and probably referred themselves privately, which could be a focus for further study.

Although this study was conducted in an area with an ethnically diverse population this study did not explore the barriers that women from different cultural backgrounds could face accessing abortion services.

The experience of care is likely to influence emotional adaptation following medical abortions, participants in this study had felt that they had positive experiences from using the services. Participants received supportive listening which helped them with the decision-making process.

Participants found the information provided adequate and felt more reassured with the opportunity to approach health care professionals via phone consultation if needed.

When women were asked about their perceptions about any new treatments for medical abortions participants placed a high value on newer methods that were less traumatic, less dangerous, more effective and less risky for future fertility. The possibility of failure was regarded as an important factor to influence the preferences for a particular method, along with avoidance of physical effects such as pain. These aspects should therefore be incorporated into information giving.

While information outlining the process of medical abortions was available from various sources it was clear that this was inadequate. Women felt the need to see a health care professionals for more reliable information and valued expertise. These perspectives from women need to be taken into account in considering how best to provide abortion care.

This study indicates the need for continued input following discharge to ensure provision of sufficient and appropriate information and to enable patients to develop realistic expectations about pain and bleeding duration.

There appears to be a significant role of the partner in the decision making process. Further studies to investigate ways of engaging more effectively with men in the society and their views would be valuable to provide support to women.

Findings of qualitative data from this study suggests that the use of contraception is inadequate despite adequate awareness about contraception and sex education. This possibly could be a contributing factor for abortions. The emphasis was more on the promotion of long term contraceptive methods. While the first step suggested by the women in this study was to recognise that there is a problem, there also appears to be a sense of despair that nothing can be done to improve the situation. As mentioned by women in their quotes there could be barriers to access information within certain cultural backgrounds and age groups. Further research would be useful to know how well services meet the needs of different groups and to learn about the cultural processes affecting contraception uptake in different ethnic groups.

Secondly women in this study suggested use of other means such as media for disseminating information. Limiting the number of abortions and legalising abortions were also suggested as a means of decreasing abortion rates. Media however is outside the health service and largely in private ownership, few studies have considered how to engage with the media, and how to best get positive messages across on television, radio, newspapers or magazines. This could be a potential area for further qualitative work on the use of media for adoption of health promotion messages.

Chapter 7.2

Conclusion

Having a choice in medical treatments appear to be associated with higher satisfaction rates. Flexibility in medical abortion treatments would therefore make the treatments more convenient and acceptable for women. Given a choice between shorter time interval and longer time intervals of medical abortion methods, women appeared to prefer time intervals that best suited their circumstances. In the groups studied, satisfaction with either treatments was high. Women who report higher levels of satisfaction are more willing to use the method again or to recommend it to others. Paradoxically preferences among the non-randomised women differed with more references for longer time intervals. This disparity may result from unrealistic expectations about a new method or provider's lack of experience in identifying or counselling women. As the newer methods become better known, expectations may become more realistic.

Generally women for whom a treatment method fails are often more dissatisfied. Nevertheless, the small failure rate associated with shorter time intervals can have only a small impact on overall levels of dissatisfaction. Many women with shorter time intervals found side effects as unpleasant experience however still rated the method as acceptable. Prolonged bleeding and multiple visits are associated with less positive attitudes toward newer medical abortion. The relationship between the effects of treatments to the amount of vaginal bleeding and pain are predominantly subjective.

Acceptance to newer regimens are based on their success and to determine this an ideal method of outpatient follow up method will be required. A combination of pregnancy testing at home and questions about pregnancy symptoms/signs through telephone follow up could be used to screen for continuing pregnancy after medical abortion and to identify those women who require a clinic follow-up.

The preference and acceptability for the treatments can also be influenced by previous experience and more importantly depend on the attitudes of women towards abortions. In

particular how much counselling women receive before their treatments and their interaction with health care professionals are an important factors in their acceptance.

New approaches to the delivery of the two-drug medical abortion regimens might increase both accessibility and acceptability of medical abortion, allowing women to have the treatments at home and complete the procedure in the vicinity of their familiar environment.

When evidence on use of the newer methods of medical abortions becomes available through further research, it will be important to monitor and adapt service delivery for its availability and safe use.

Figures

Figure 2.3.1.a Flow diagram to summarise the stages of systematic review

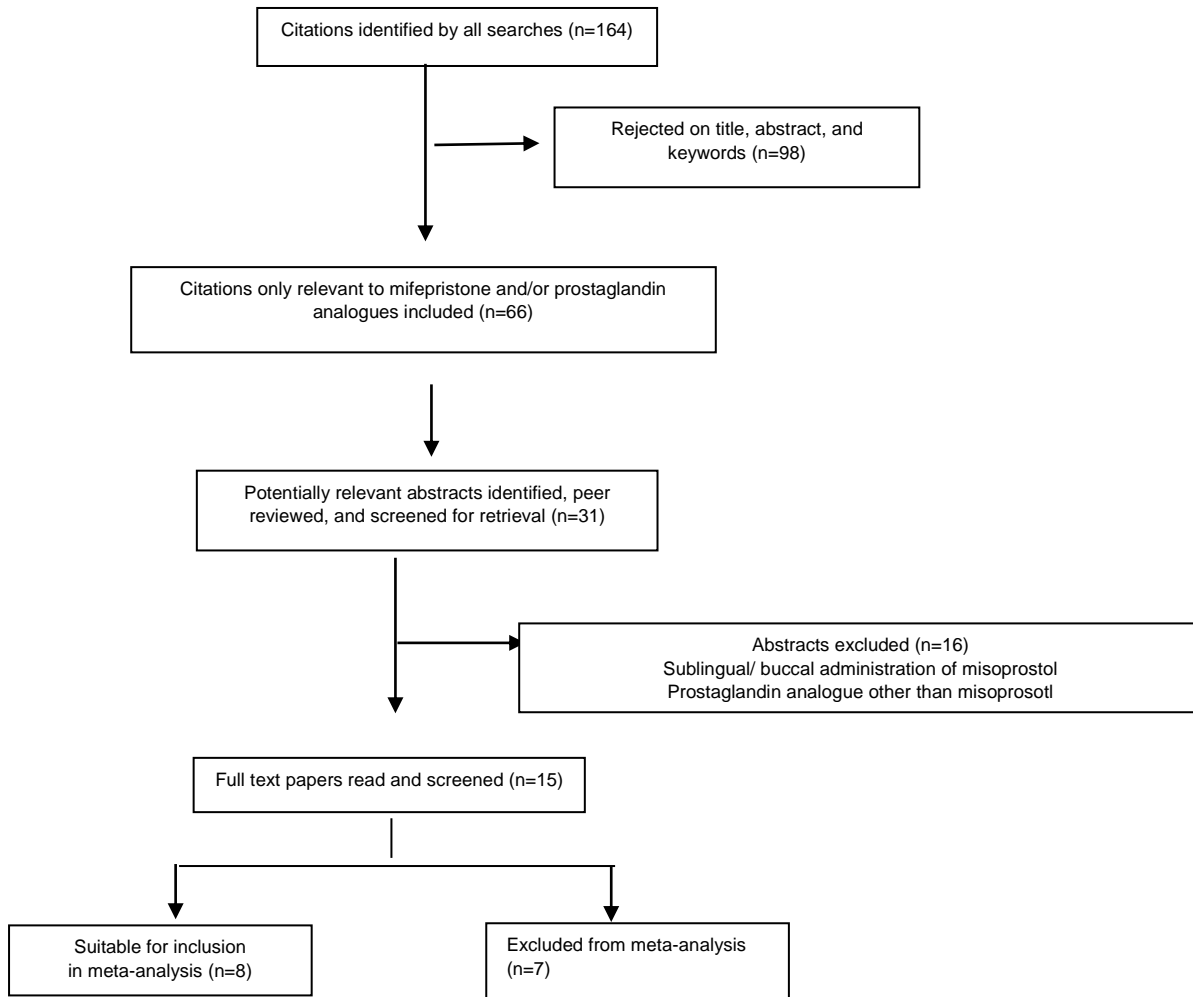


Figure 2.3.3.1a: Forest plot of comparison: 24hrs vs 36-48 hrs, analysis of failure rates at 2weeks

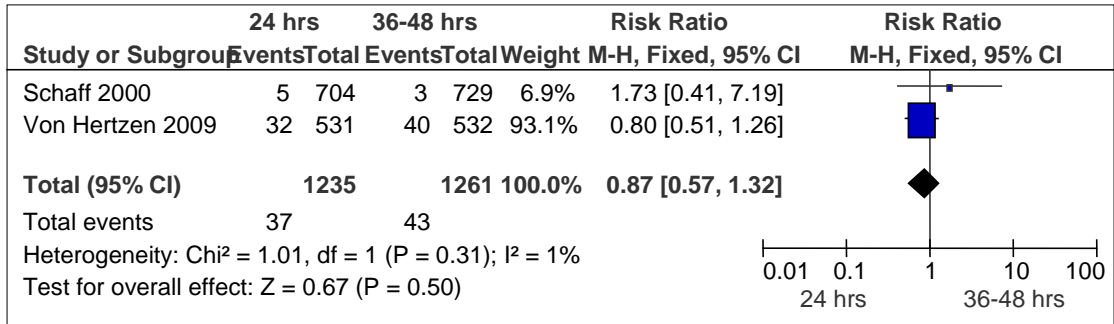


Figure 2.3.3.1b: Forest plot of comparison: Shorter time intervals vs Longer time intervals, outcome: Overall failure rates.

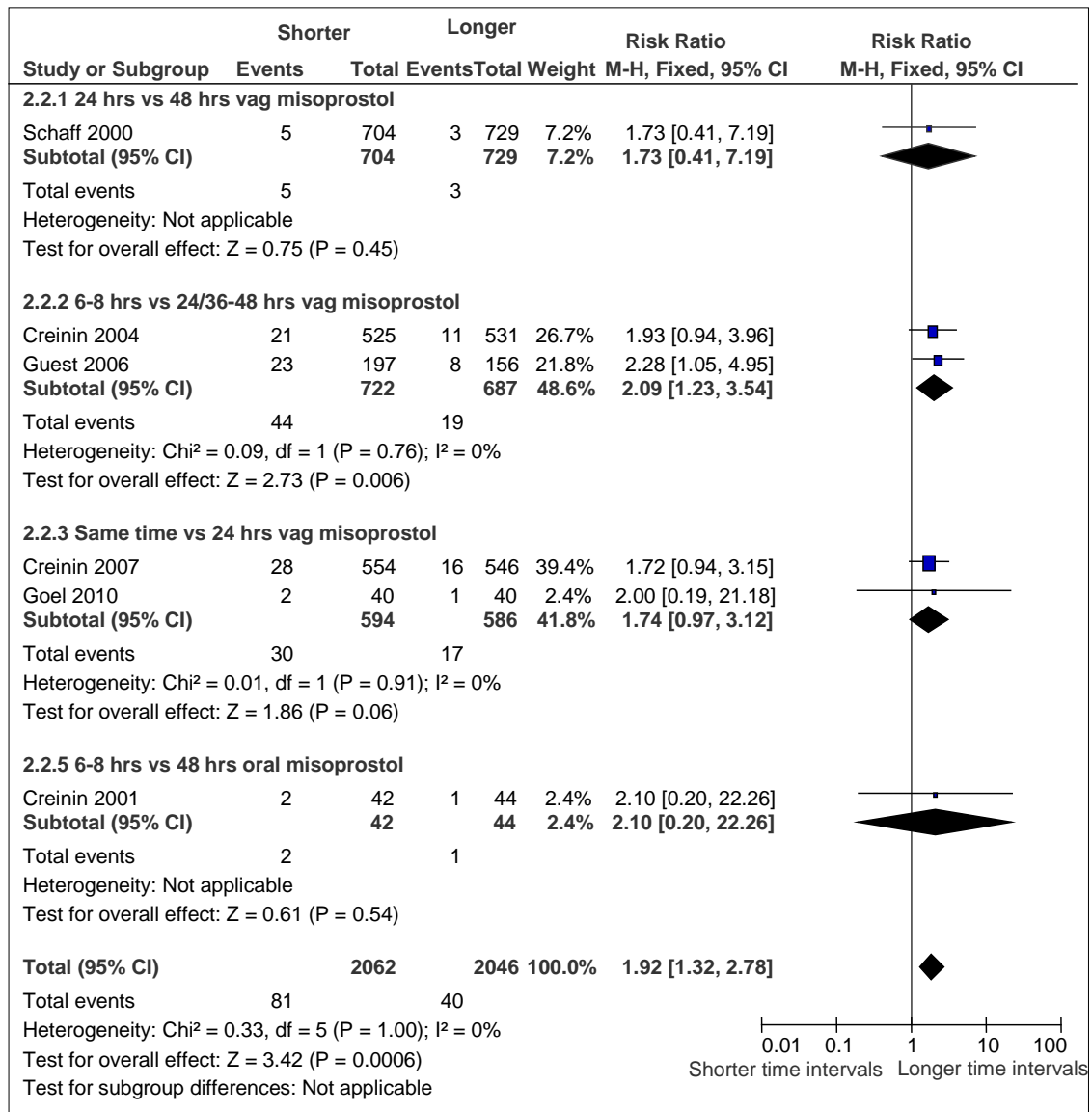


Figure 2.3.4a: Forest plot of comparison: Shorter time intervals vs Longer time intervals, outcome: Failure rates after single dose of misoprostol.

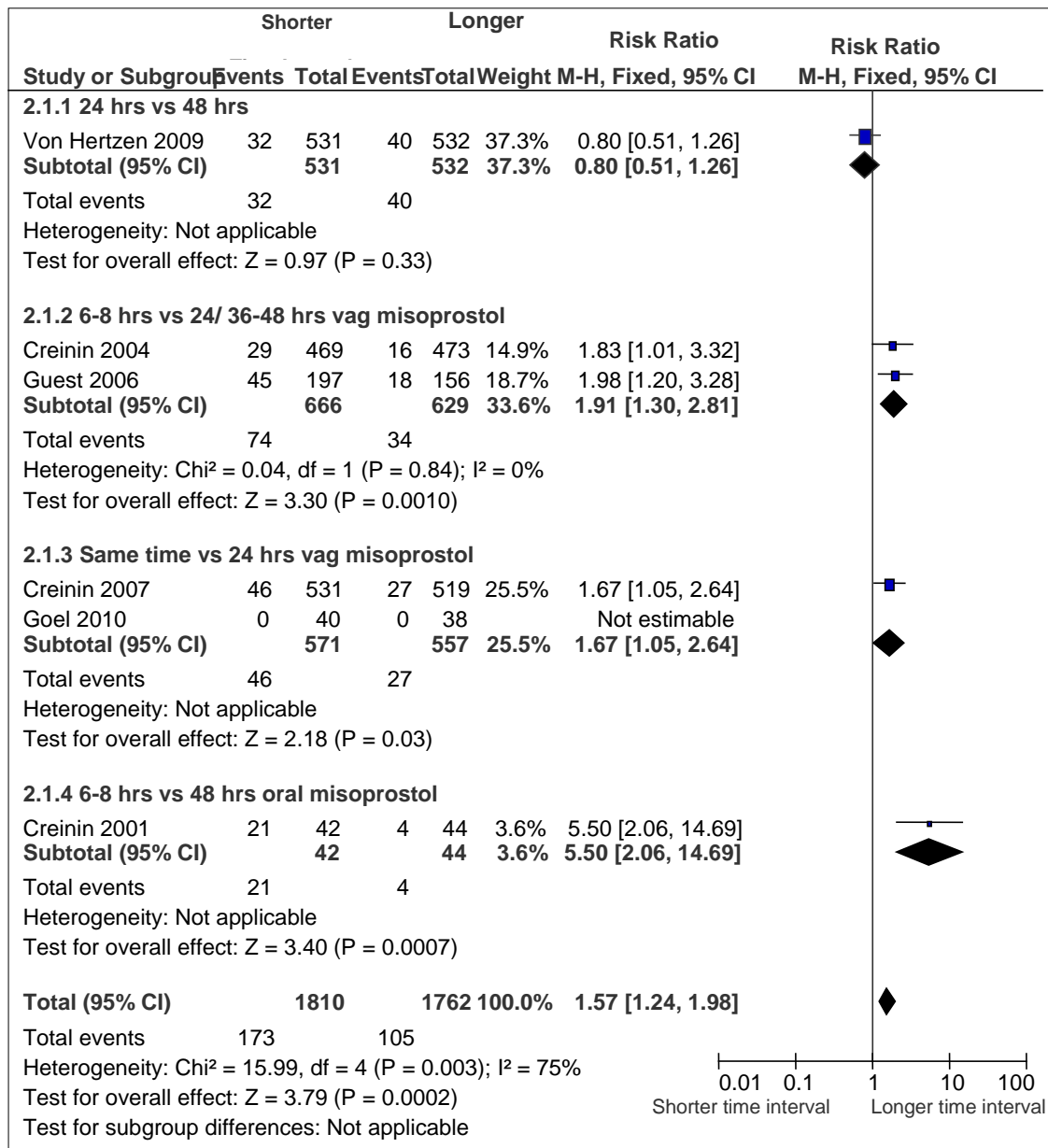


Figure 2.3.5a: Studies comparing the efficacy of shorter time intervals to gestational ages

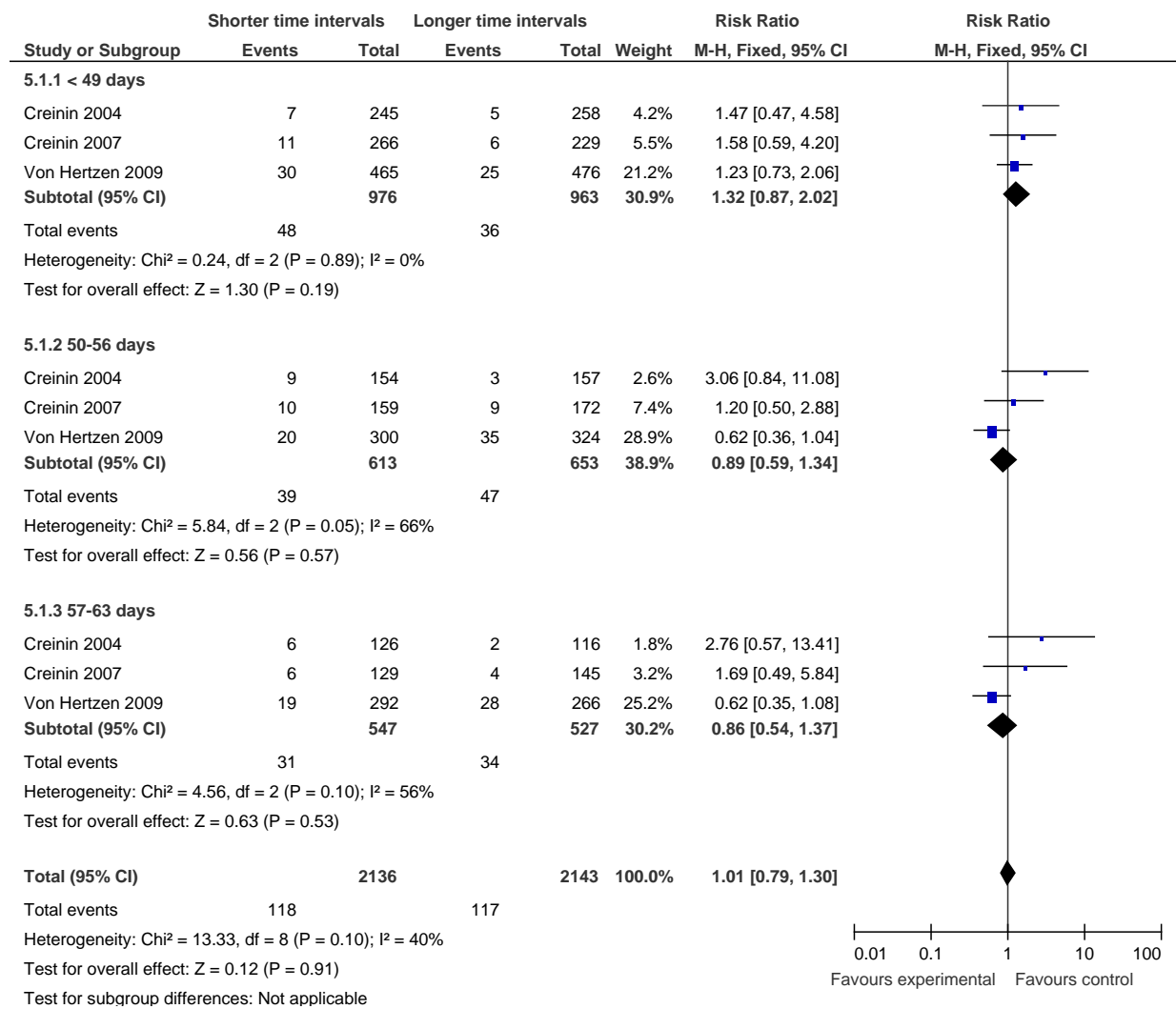


Figure 2.3.6.a: Acceptability of shorter time interval

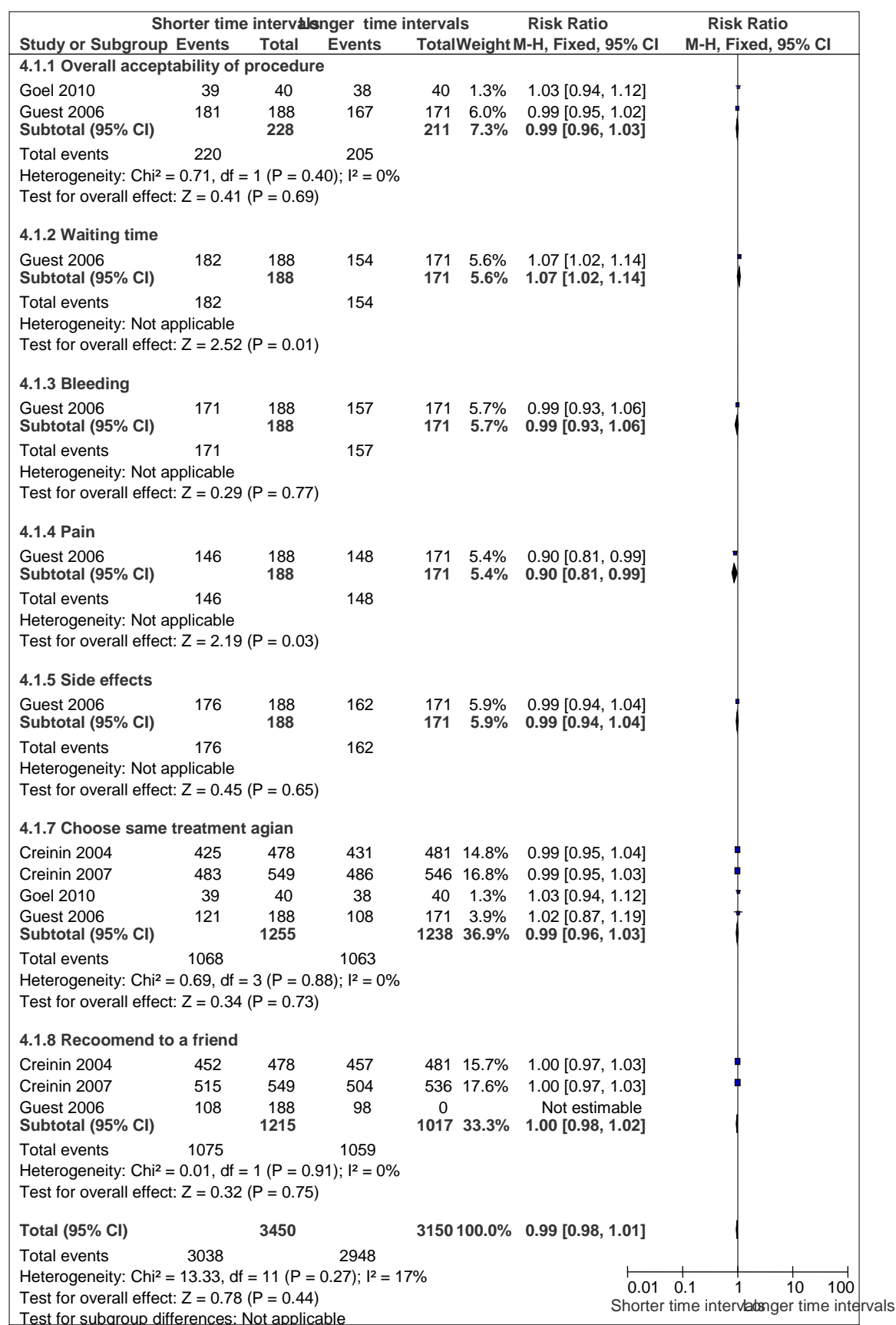


Figure 2.3.7a: Comparisons of side effects for time intervals < 24 hrs and ≥ 24 hrs

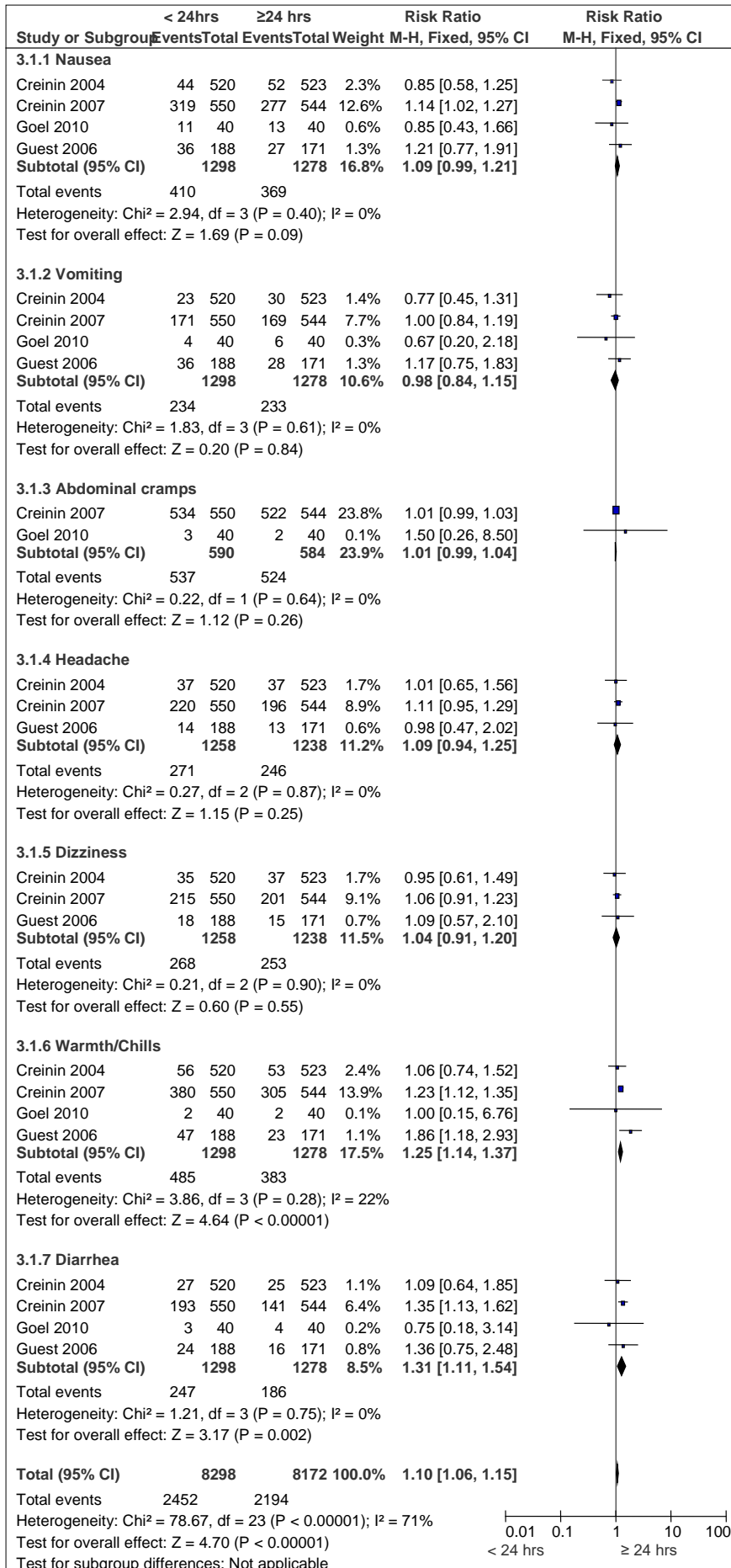


Figure 3.2.3a: Flowchart for telephone follow up

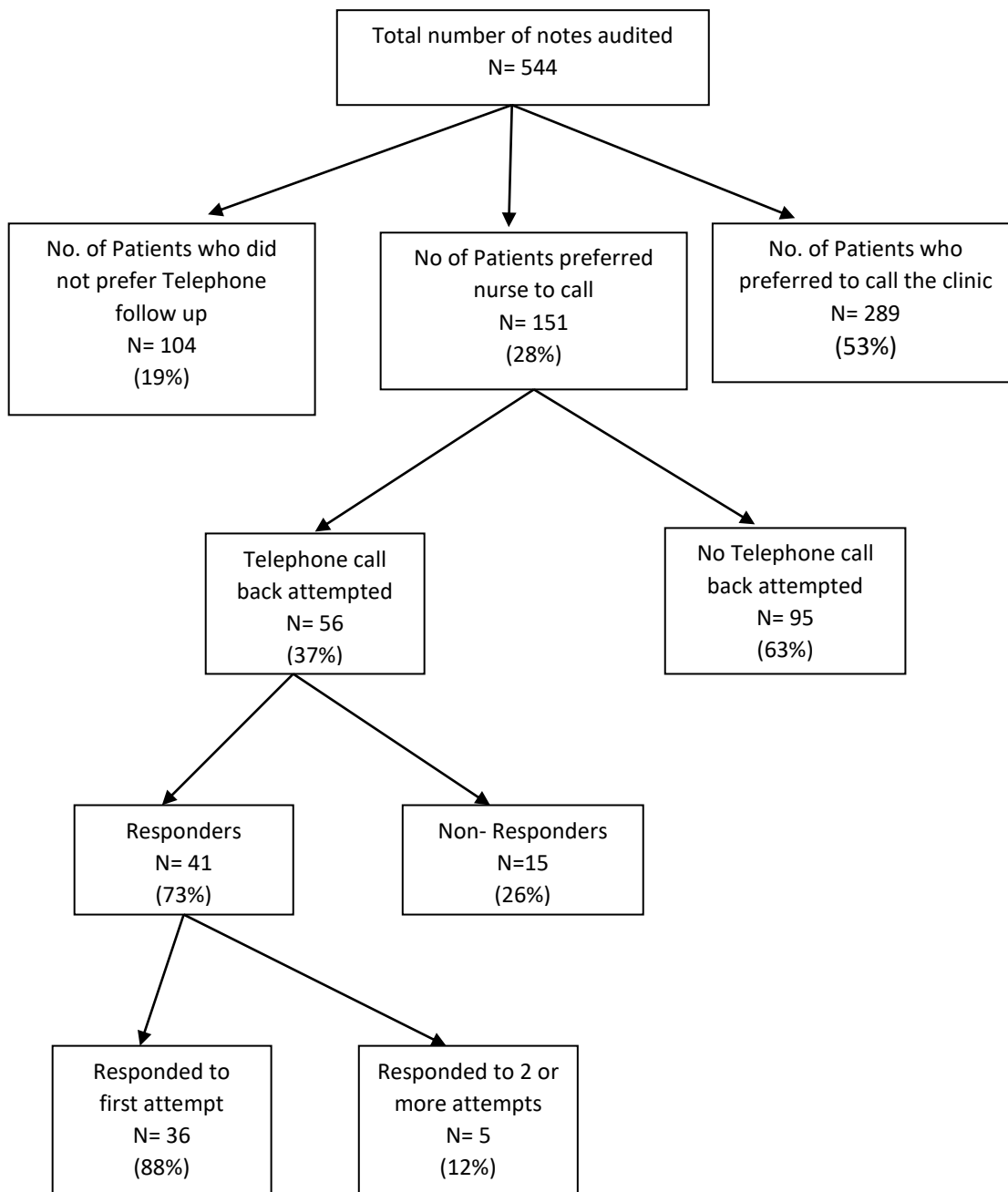


Figure 4.1.5a: Convergent Parallel Design (adopted from Three Ways of Mixing Quantitative and Qualitative Data Handbook of mixed methods in social & behavioral research. Creswell J)

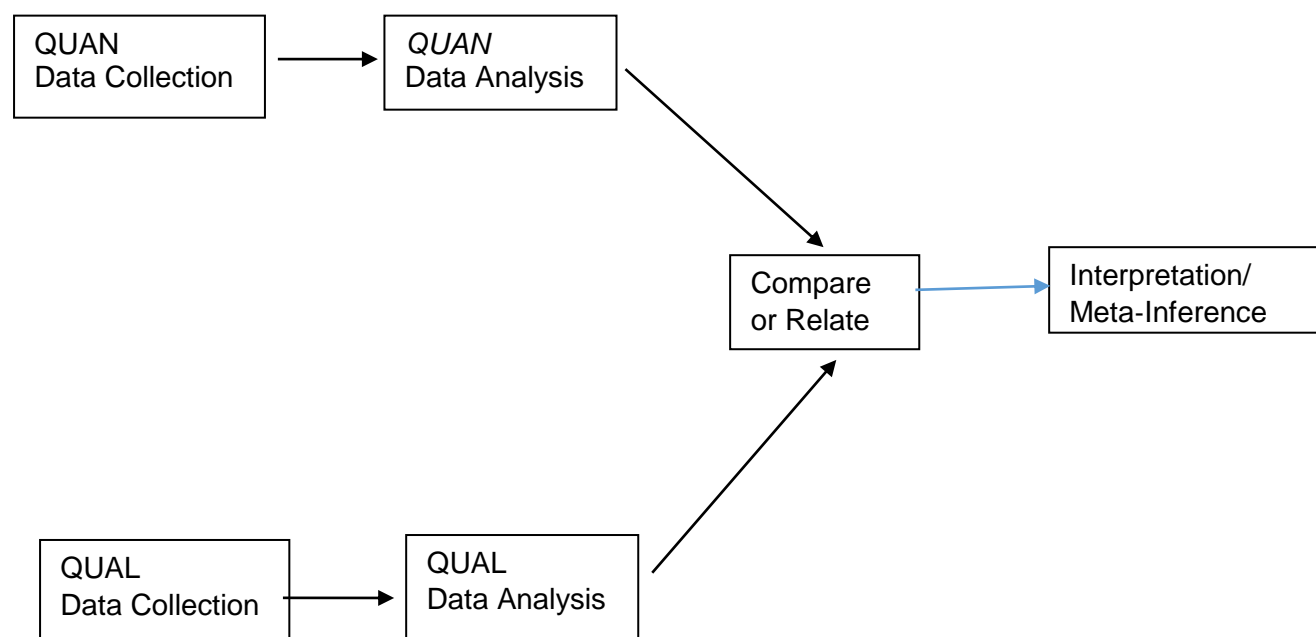


Figure 5.2.2a: Study design and numbers recruited

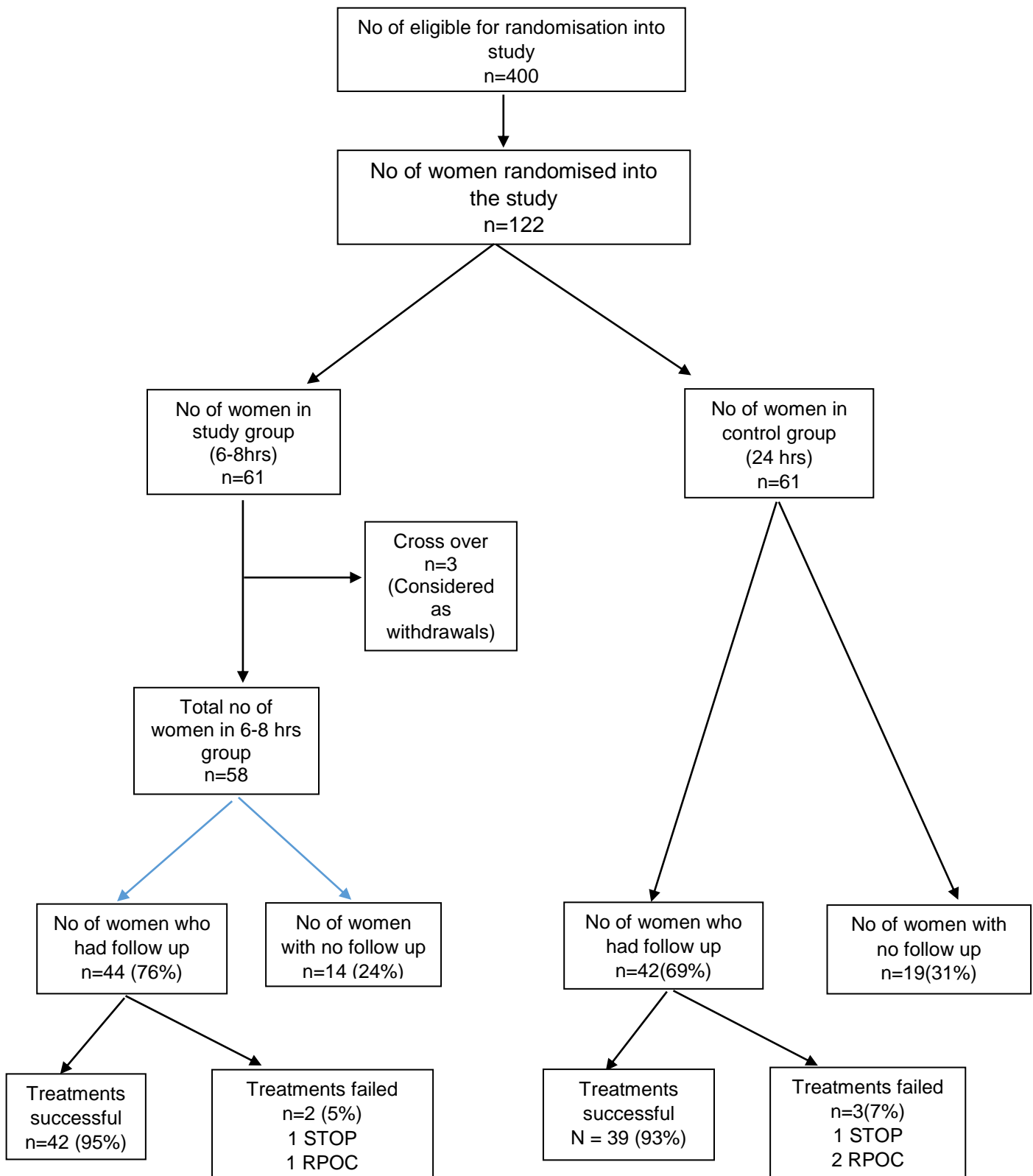


Figure 5.2.3.1a. Distribution of parity among the two study groups

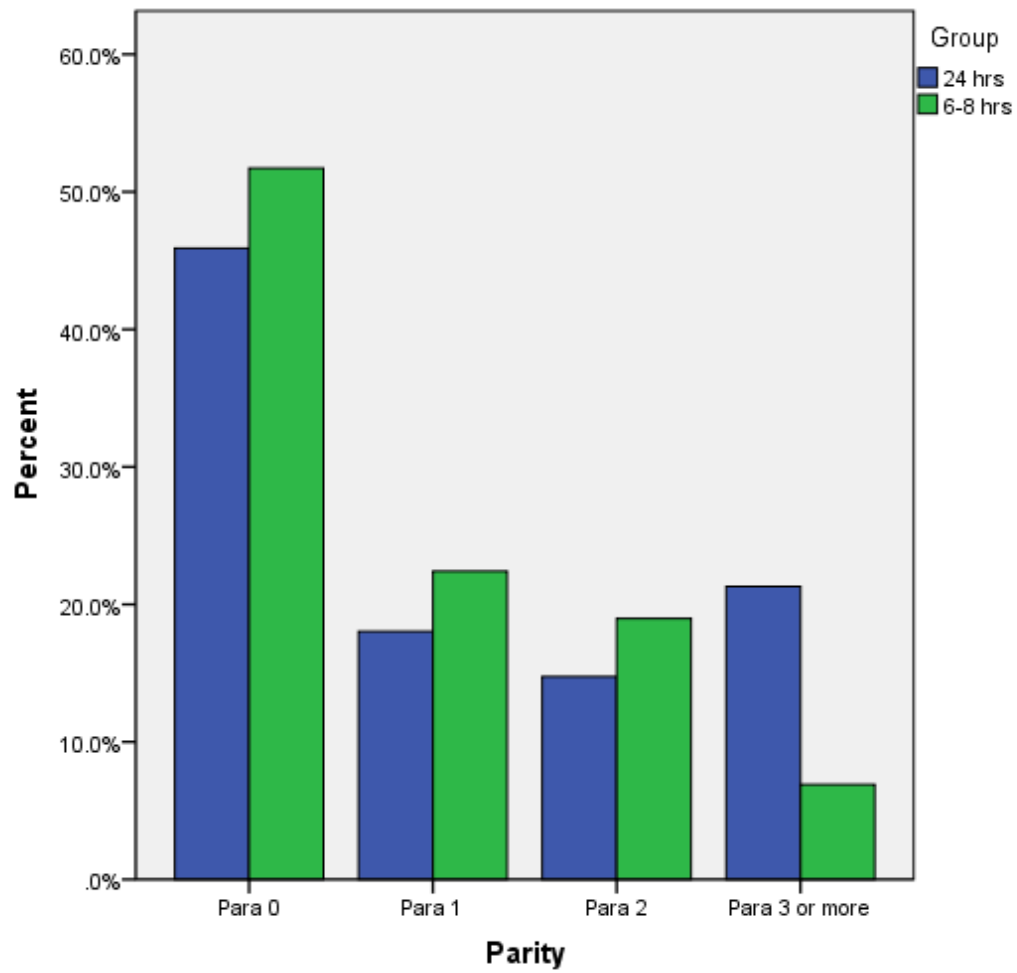


Figure 5.2.3.1b. Distribution of gestational age among the two randomized groups

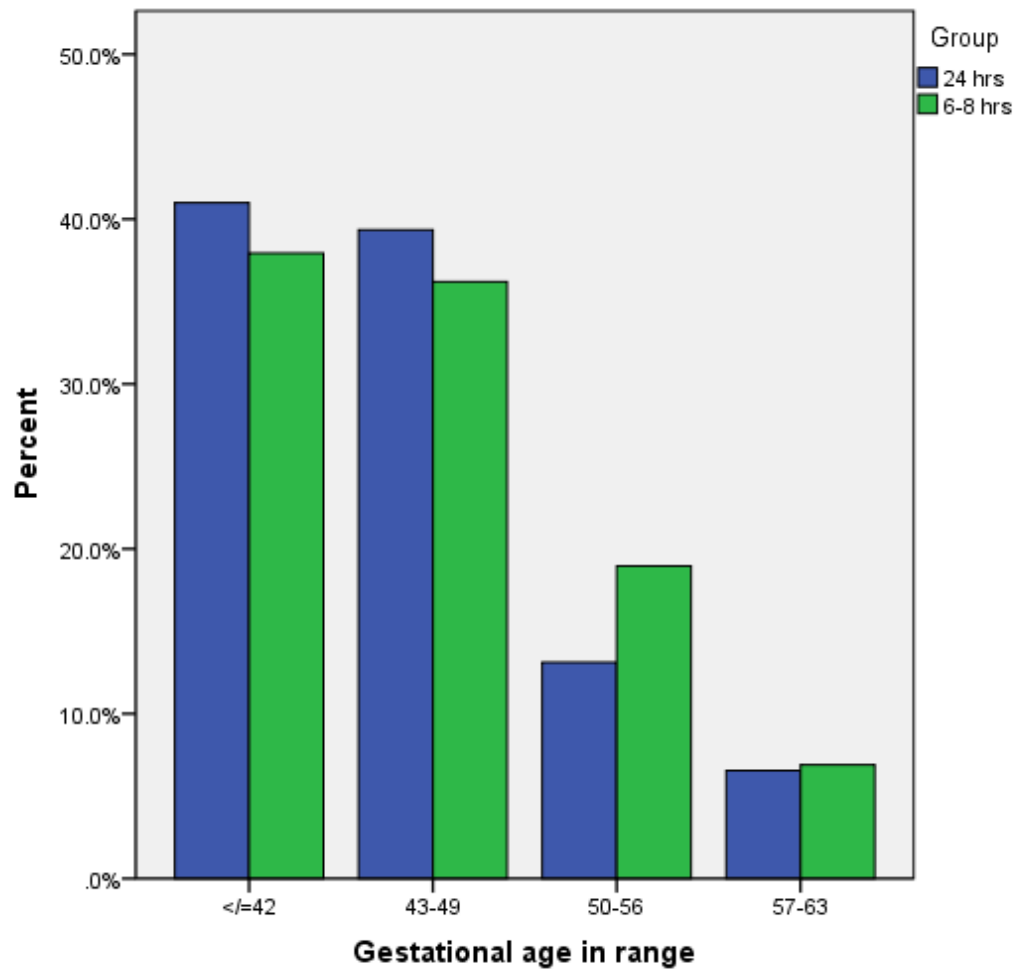


Figure 6.2.9.2a The transitions in the women’s emotions while undergoing abortions

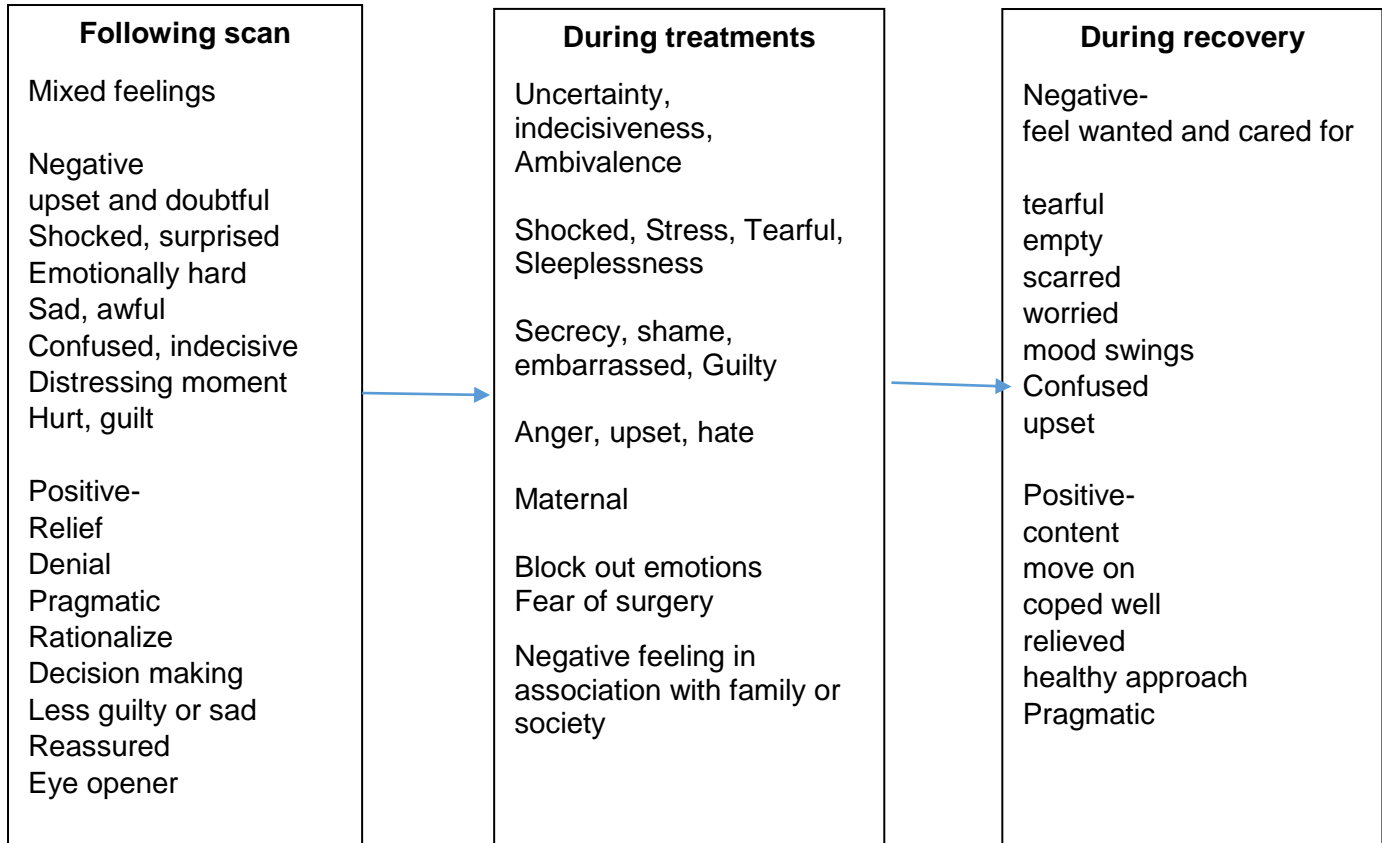


Figure 6.3.1a: Thematic mapping- Summary of themes and subthemes

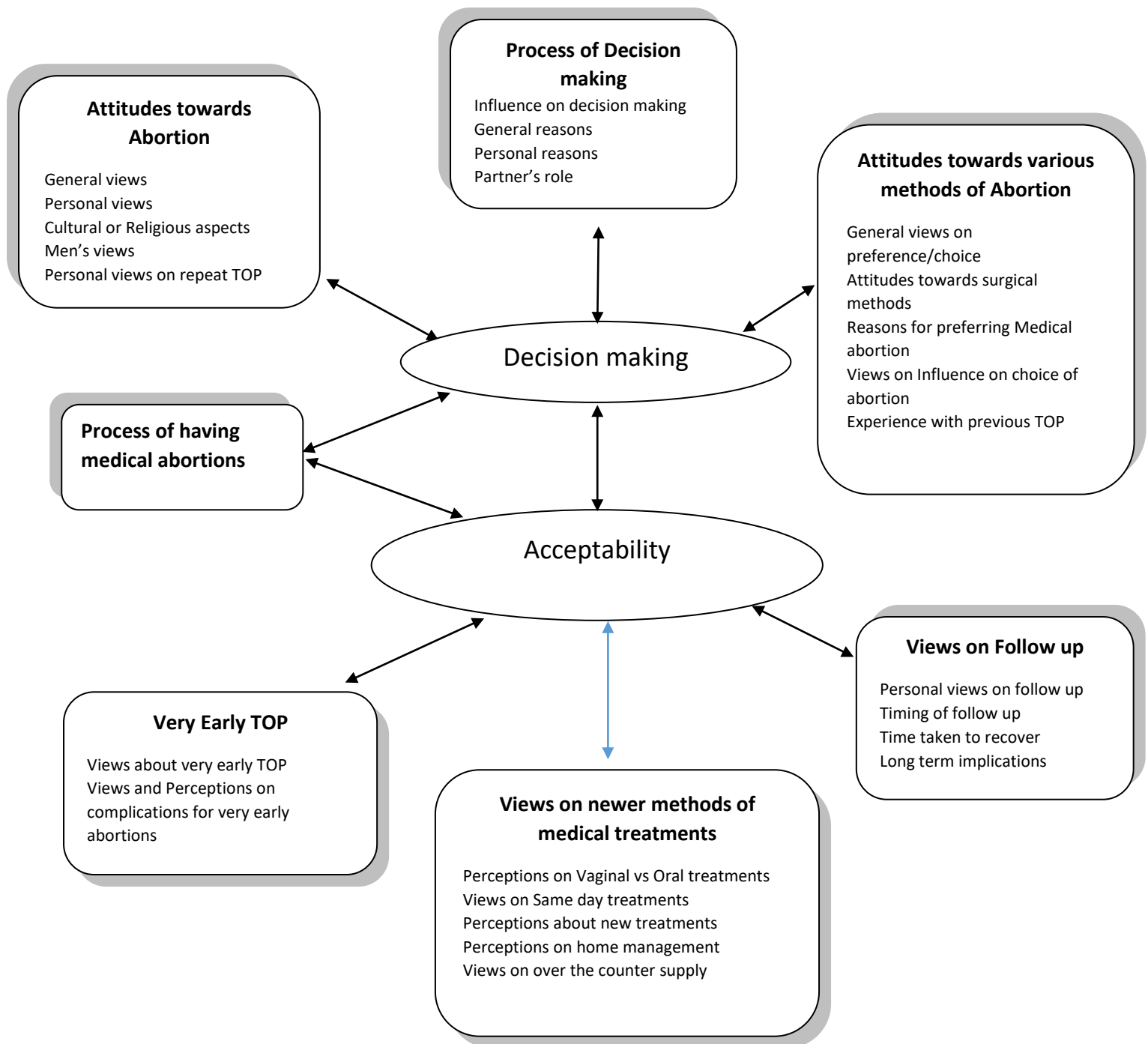
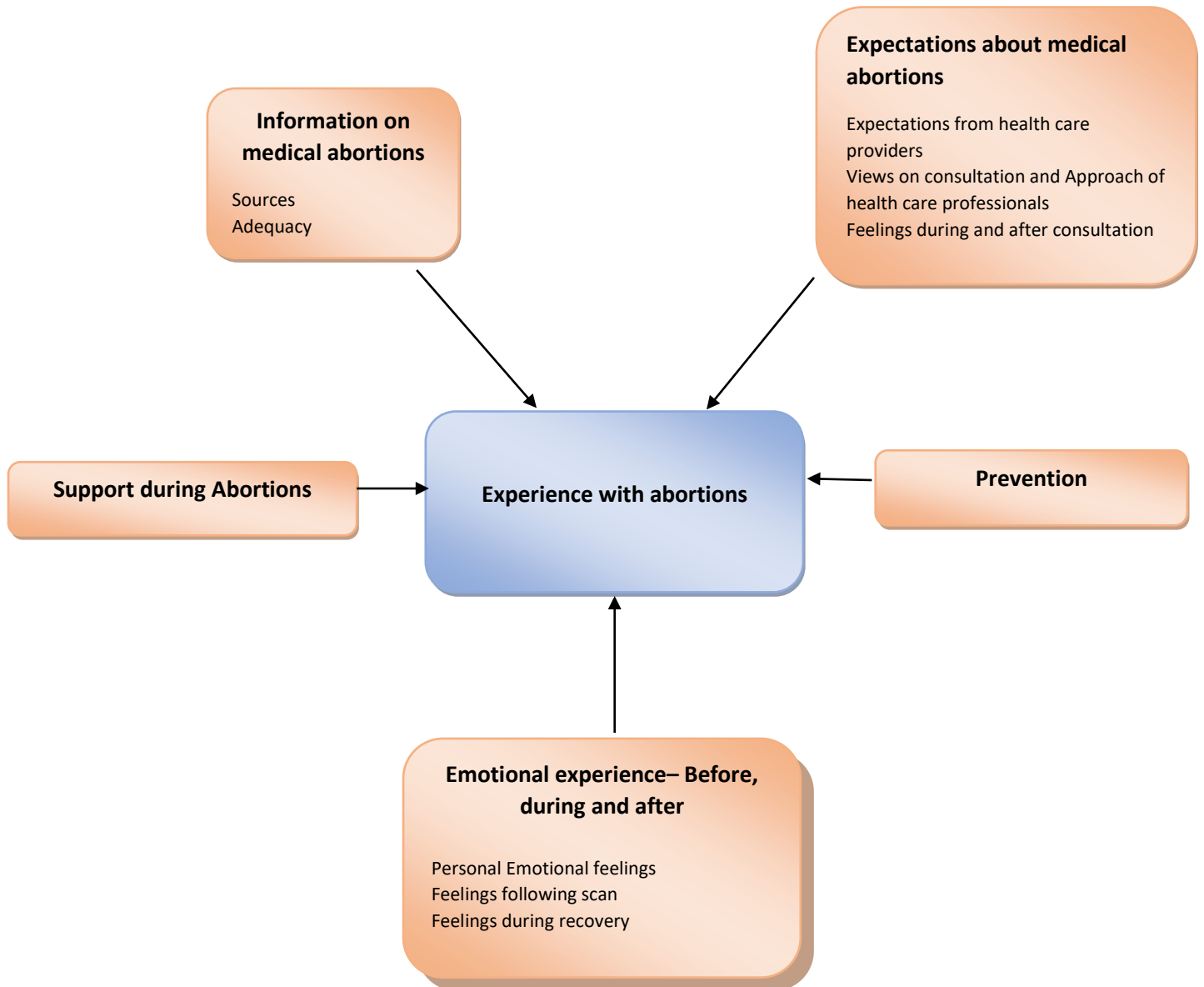


Figure 6.3.1.3a: The Process of having Medical Abortion



Tables

Table 1.6.3a: Literature Review of follow up methods following medical abortions

Authors	Location	Subjects and study design	Follow-up Intervention	Day of follow up	Outcomes	Findings
2001 Pymar	USA	40 ≤ 49 days Mifepristone (200 mg) + Misoprostol(800 mcg vag) -6–8 h -prospective	Clinician's assessment transvaginal USS	24 h after Misoprostol	Clinician had a diagnostic sensitivity of 95%, specificity of 67%, positive predictive value of 95% and negative predictive value of 33%	-very small -only reported the clinician's assessment - negative predictive value not assessed The negative predictive value was difficult to assess, as only four women did not expel the pregnancy.
2004 Rossi	multicentre study USA	931 ≤ 63 days - 6–8 h vs. 24 h - Misoprostol self-administered - Prospective	Women's Clinician's Vaginal USS	6–8 days after Mifepristone	-Vaginal USS confirmed expulsion in 915 [98.3%, 95% confidence interval(CI): 97.2–99.0] - Overall, sensitivity, specificity and positive and negative predictive values for clinicians were 98.1%, 50.0%, 99.1% and 32.0%, respectively. -values for subjects were 96.5%, 31.3%, 98.8% and 13.5%, respectively. - Predictions of clinicians and subjects had moderate correlation (k= 0.33) for total predictions and moderate correlation (k= 0.39) for accurate predictions. - Predictions were found to more similar when no expulsion occurred (k= 0.62) than when the sac was expelled (k= 0.23).	No differences were noted between study groups. - Neither the clinicians' nor the subjects' ability to predict expulsion varied by gestational age. - The subject's ability to correctly assess expulsion was not significantly related to prior history of a prior medical or surgical abortion - The amount of pain a subject experienced, as judged by VAS scores, was not correlated with whether or not she predicted if expulsion occurred - Amount of bleeding, as judged by VAS scores, was also not correlated.
2007 Parashker	-Norway -January and 2002 December, 2002	1255 women -misoprostol(800 mcg) vaginally -48 hours later	USS serum hCG clinical	(day 1) s-hCG (this hCG level being referred to as 1. hCG)	- The endometrial thickness ranged from 2 to 31 mm. Five women (5/235: 2.1%) required surgical intervention after Day 25, ultrasound examination performed in this group showed an endometrial thickness of 12–31 mm. A	-s-hCG drops after successful medical abortion with mifepristone and misoprostol. - combining clinical examination with a determination of

			assessment	- visual inspection by members of the nursing staff at 4-6 hrs after miso -day 25 and day 35 after mif Clinical, ultrasound examinations and determination of s-hCG	gestational sac was not seen in any of them. -The s-hCG levels prior to treatment ranged from 3970 IU/L to 199,360 IU/L, with a median value of 63,850 IU/L . -The decrease in hCG levels exceeded 99% in 99% of the women. -The values of 2.hCG varied from less than 3 IU/L to 597 IU/L, with a median value of 11 IU/L	s-hCG levels to evaluate the completeness of the process is recommended -ultrasonography should be carried out only when indicated. -More information is needed to correctly time the post-abortion hCG
2007 Godfrey	multicenter, US April 2002 and June 2003	1080 mifepristone + misoprostol(800mcg) vaginally -6–8 vs 24 h -randomized controlled trial - a repeat dose of misoprostol at first follow up with gestational sac on USS	transvaginal USS two urine pregnancy assays: an LS test (2000 mIU/mL hCG)an HS test(25 mIU/mL hCG)	follow-up 7 days ,14 days after mifepristone	-In the first week 14.8% of the LS tests and 7.9% of the HS tests correctly predicted the medical abortion outcome. - None of the LS tests and only 2 (0.2%) of the HS tests were falsely negative; however, 85.2% of the LS tests and 91.8% of the HS tests were falsely positive. - In the second week 39.1% of the LS tests and 33.8% of the HS tests correctly predicted the medical abortion outcome. Only 1 (0.2%) of the LS tests and 2 (0.3%) of the HS were falsely negative; however, 60.8% of the LS tests and 65.8% of the HS tests were falsely positive.	- When comparing urine assays, the best test to determine expulsion of the gestational sac is the LS test 1 week following medical abortion (lowest LR for a negative test). -Only specificity differed significantly between the first and second week and between the urine assays (p=.001); otherwise, the assays did not differ significantly.
2007 Grossman	private clinic in Mexico City -March to May 2005	-99 -≤ 8 weeks - 50 participants were undergoing (or had completed) a spontaneous or induced abortion, -1 participant had an ectopic pregnancy.	-semi-quantitative urine pregnancy test -whole blood sample	Day 1	- The sensitivity and specificity of the urine pregnancy test to determine whether an individual had a serum β-hCG value N1000 IU/L were 88.6% (95% CI 74.6–95.7%) and 71.7% (95% CI 57.4–82.8%), respectively - Forty-four of 97 samples had serum β-hCG results above 1000 IU/L. Of these, the urine test result corresponded to the serum result in 39 cases (true positives) but failed to detect five cases in which the serum β-hCG level was N1000 IU/L (false negatives).	The results of the semi-quantitative urine pregnancy test correlated reasonably well with serum β-hCG measurements among women in early pregnancy, approximating the a priori estimate for sensitivity but failing to meet the estimate for specificity.
2001 Walker	University of Rochester	-29 ≤ 45 days -Mif(200 mg) orally+ Mis orally or vaginally	Vag USS Serum hCG levels	-Vag USS 7 days after Miso - serum hCG levels on Day 1, 3, 4, 5–7, 8, and	-One participant had a surgical completion at 2 weeks for possible retained products of conception due to persistent bleeding, although her sonogram was	- serum hCG levels are an alternative approach to sonography for monitoring a medical abortion - prior to using misoprostol and

		-Day 1 vs Day 3 -self-administered		14–15.	<p>unremarkable and her hCG levels had fallen by 78% by Day 4 and 98% by Day 8.</p> <p>-10 participants who had repeat hCG levels prior to or on the day of using misoprostol, the mean hCG levels increased from baseline by 19%.</p> <p>- Day 4, the mean percent decrease in hCG levels was 60% (SD 22) with the lowest decrease being 13%.</p> <p>- Day , the mean percent decrease in hCG levels was 84% (SD 6), and all had at least a 76% decrease.</p> <p>-Day 8 values, the mean percent decrease was 94% (SD 6).</p> <p>- By Day 15, all participants had a >99% decrease in their serum hCG levels.</p>	<p>expulsion of the pregnancy, the hCG continues its rise.</p> <p>-After expulsion of the pregnancy, the hCG levels fall precipitously.</p> <p>- the hCG levels dropped by a mean of 60% within 24 h after taking misoprostol.</p> <p>-2 weeks after misoprostol, hCG values dropped to _1% of the value of Day 1.</p> <p>- a drop in hCG of >50% by 24 h and by >99% by 14 days was found to be consistent with a complete medical abortion</p>
2002 Honkanen	WHO multicentre trial	-34 women - ≤ 63 days - Mif (200mg) + Miso oral/vaginal+oral/v aginal (800 mcg) - 35-48 hrs	Ultrasonograp hy -serum hCG -serum pogesterone	- serum hcg and progesterone on day 0, Day 2,3 hrs after miso, day 3, day 14 -2 weeks - 6 weeks	<p>- concentrations of hcg increase after Mif until day 2</p> <p>- decline in hCG at 3 h, $18.8 \pm 2.0\%$ ($P \leq 0.001$)</p> <p>- Day 3 hCH levels had fallen by $70.5 \pm 8.8\%$ ($p \leq 0.001$) from the peak.</p> <p>- Correlation between the peak hCG and the time for abortion was weak and not statistically significant</p> <p>- percentage decline in serum hCG levels correlated with the time taken to abort</p> <p>- By day 15 the serum concentration of hCG had declined by $99.4 \pm 1.0\%$.</p> <p>- Concentration of progesterone continued to increase after administration of Mif until day 2.</p> <p>- 3 hrs later after miso, progesterone levels declined to $31.8 \pm 10.8\%$ ($p < 0.001$). On day 2 progesterone concentrations had fallen by $61.3 \pm 16.3\%$.</p> <p>- Serum levels of mife decreased by $47.6 \pm 20.2\%$ from day 2 to day 3.</p> <p>- A weak negative correlation was found between serum Mif and time taken to abort.</p> <p>- No Correaltions when the peak levels of Mif</p>	<p>- trend in the change of hCG and progesterone was similar in all the treatment groups</p> <p>- serum hCG followed the clinical course of MTOP.</p> <p>- serum hCG concentrations continued to increase up to Day 2.</p> <p>- following administration of misoprostol th elevels of hCG declined rapidly, a decrease of $70.5 \pm 8.8\%$ was evident in 24 h.</p> <p>- Initial miso dose starts a cascade leading to fall in hCG.</p> <p>- hCG declined by $99.4 \pm 1.0\%$ by 14 days following Mif.</p> <p>- further doses of Miso offered no benefit</p>

					measured on day 2 with the decline in serum hCG or progesterone from Day 0 to Day 2.	
2003 Fiala	- Austria - 26 April and 10 November 1999	-217 women \leq 49 days - Mif (600 mg) 48 h later Miso (400 mg) orally once or twice.	vaginal ultrasound -serum hCG	ultrasound examination and hCG testing day 6–18	hCG levels dropped to a mean of 3% (S.D. 3) of the value before treatment, ranging from 1 to 44% of the initial value in the cases of successful abortion - women with a continuing pregnancy had elevated hCG levels, 159% on day 10 and 7900% on day 8, respectively - Endometrium at follow-up measured 10 mm (mean, S.D. 4) in cases of successful abortion, ranging from 1 to 24mm - content of the uterine cavity was inhomogeneous in some cases, making interpretation difficult -Complete abortion could not be verified at first follow-up (performed on days 7–12) by ultrasound alone in 17 of these cases (10.2%) due to the in homogeneous picture.	When 20% of the initial hCG value was used as cut-off, a positive predictive value for successful expulsion of 0.995 was obtained - If the reduction of the hCG level is less than 80%, the negative predictive value is 0.5 and further evaluation using ultrasound examination and repeated hCG measurements are needed to confirm the outcome of treatment
2004 Rorbye	SACopenhagen University Hospital -August 1999 to May 2001	-871	-transvaginal ultrasonography - Serum b-hCG was measured initially and on day 15 (day 14±16)	-transvaginal ultrasonography was day 14±16 - Serum b-hCG was measured initially and on day 15 (day 14±16)	- The absolute as well as the relative values of b-hCG 1±2 weeks after the abortion were significantly higher in the late failure group than in the success group with a wide range within each group and a great overlap of values between the two groups - The median endometrial thickness measured by ultrasonography on day 15 was greater in the late failure than in the success group: 16 mm (13±18) versus 10 mm (7±13) (lower and upper quartiles, $P < 0.0001$)	-Absolute and relative b-hCG as well as endometrial thickness were poor predictors of late failure after medical abortion due to low positive predictive values in the range of 0.10±0.69.

Table 1.7.2.3a: Studies assessing acceptability of surgical vs medical abortion Pretreatment

Study	Comparison	Place	Type of study	No. of participants	Preference and Reasons for medical abortions	Preference and Reasons for surgical abortion
Rosén 1984	medical (home vs hospital) vs vacuum aspiration	Sweden	RCT	53	74% strongly preferred medical methods naturalness of the method, the privacy during treatment, partner support available at home	58% preferred surgical abortion
Hill 1990	Medical only			100	64% of the women offered the method agreed to try it instead of the routine surgical abortion	the length and the required follow-up, and about half stated that they would prefer to be asleep during the procedure
Tang 1991	Medical vs vacuum aspiration	Hong Kong	Non RCT	42	58% selected medical abortion Less trauma to the body (38%), that it was more natural (22%), or that the woman perceived that her physician preferred the medical method (13%). fears about aspects of surgery—pain (11%), general anesthesia (5%) and hospitalization (9%)	45%, Almost two-thirds of study participants who were repeat abortion patients chose to use surgery a second time rather than switching to medical abortion Worries about efficacy or side effects (28%), the length of the abortion procedure (18%), or a desire to get the abortion over quickly (16%)
Urquhart 1991	Medical vs vacuum aspiration	Scotland	Psychological assessment Questionnaires	91	36/ 54 Before abortion over 60% in both groups had high scores (compatible with psychiatric morbidity)	37
Legarth 1991	Medical vs vacuum aspiration	Denmark	RCT	50		

Holmgren 1992	Medical vs vacuum aspiration	Sweden	interview	128		
Bachelot 1992	Medical vs vacuum aspiration	France	Prospective survey	488	62 % requested medical treatment More women in the RU (44%) gave their reason as "having other priorities". This distribution was also found in women over 30 years of age as well as those who already had at least one child. Whatever the method they chose, it was because it seemed less traumatic (62%), less dangerous (29%), safer for future pregnancies (23%), or it had the lowest failure rate (16%). The RU group was more concerned by the risk of trauma and the risk of endangering future pregnancies	32% opted surgical treatment
Tang 1993	Medical vs vacuum aspiration	Hong kong	Non RCT	114	69% chose medical abortion fear of surgery (81%), fear of general anaesthesia as (11%), fewer traumas (21%), convenience for work (41%)	31% chose vacuum aspiration quick and convenient 82%, frequent visits were avoided (69%), side effect of drug (11%)
Henshaw 1993	Medical vs vacuum aspiration	UK	Partially randomized RCT	99	20% women had a preference for medical abortion afraid of surgery or anaesthesia (59%) felt medical abortion was more natural (21%) believed surgery was too fast (21%)	26% for vacuum aspiration medical method was too slow(40%) side effects of drug 29%
Creinin 1996	medical	US	open-ended questionnaire study	300	avoid some aspect of the surgery (48.4%).(64%) gave a specific reason, including pain/"scraping"/noise of the suction (34.7%), and the emotional stress associated with a surgical abortion (19.4%). Ten women had complications with a prior surgical abortion, and wished to avoid another surgical procedure. Interestingly, eight women specifically cited "avoiding protesters" as a reason to avoid a surgical	

					abortion	
Winikoff 1997	mifepristone- misoprostol versus surgical abortion	Multicentr e China, Cuba, and India		1373		
1998 Slade	Medical vs vacuum aspiration	UK	Preferences rated on 5 point scale Hospital Anxiety and Depression Scale (HAD) and measures of wellbeing through the Positive and Negative Affect Scale (PANAS) Post treatment Impact of Event Scale (IES)12 and the Satisfaction with Care Scale	275	fear of surgery easy and less painful 8%, maintains privacy 6%. avoid anaesthesia (61%), simplicity and naturalness method (32%)	avoid awareness and involvement in the abortion process (49%), pain related (10%)
Creinin 2000	methotrexate and misoprostol or surgical abortion under local anesthesia using manual vacuum aspiration	US		50		
Jensen 2000	mifepristone and	US	prospective, serially enrolled, cohort	326		

	misoprostol vs suction curettage		analysis			
Harvey 2001	Medical vs vacuum aspiration	US	self-administered questionnaires.	304	Medical abortion patients gave four attributes significantly greater importance than did surgical abortion patients: The procedure does not involve surgery, it takes place in the privacy of home, it does not involve surgical instruments and it is like a natural miscarriage.	Surgical abortion patients gave significantly greater importance than medical abortion patients did to 10 attributes: The procedure is over with quickly ; it does not have side effects such as nausea, headache and diarrhea ; it does not cause heavy bleeding ; the patient does not see blood ; the procedure does not cause cramping; it does not lead to bleeding for longer than seven days; it is a technique that has been used for a long time; it takes only a few visits; a doctor or nurse is present; and the patient knows where and when the abortion is taking place
2001 Lee	surgical evacuation or medical evacuation with misoprostol	US	prospective, randomized controlled trial psychologic well-being, level of depression, fatigue symptoms, psychiatric morbidity, social functioning, client satisfaction, and acceptance	218		
2005 Ashok	Medical vs vacuum aspiration	Scotland	partially-randomized patient	368	72% preferred the medical method	28% preferred vacuum aspiration

			preference			
2004 Hajri	Medical only	Tunisia			32.2% felt that medical abortion would not require surgery, enabled them to avoid hospitalization (32.2%), the need for anesthesia (28.5%) and was generally perceived as posing fewer risks (26.0%) than surgical abortion.	
1999 Ngoc	Medical vs vacuum aspiration	Vietnam	Prospective comparative study	393	avoid pain (50%) surgery or anaesthesia (43.4%) safe (40%) less traumatic (30%)	simple and faster (68%), more effective (64%), convenient (26%), involved fewer visits to the hospital (28%)
2005 Akin	Medical vs vacuum aspiration	Turkey	Prospective comparative study	409	Easy (31%) or involved less pain (22%) or that they were afraid of the surgical procedure (21%). The disadvantages of medical abortions were having to wait for the abortion to happen (41%) and that it was a new method (39%)	It took a short time and was safe. Fear was the most common disadvantage of surgical abortion expected, followed by concern about pain.
2007 Saha	Medical vs vacuum aspiration	Nepal	interviews	100	23% patient opted for medical abortion. fear of surgery easy and less painful 8% maintains privacy 6%.	74% of the patients opted for surgical abortion surgical abortion is complete, repeated visits are avoided, quick would be with service provider and feel safe, lack of expectancy side effect of medical treatment, twin pregnancy , easy , fear of pain.

Table 1.7.2.3 b: Post treatment preference

Study	Post treatment experience with medical abortion	Post treatment experience with surgical abortion
Rosen	<p>75% preference to same method</p> <p>16% would recommend and prefer other methods</p>	<p>68% preference to surgical method</p> <p>31% said they preferred medical abortion</p> <p>Positive features reported: quick, simple procedure with no pain</p>
Hill	<p>88% would use the method again, 9% surgical methods and 3% unsure Of the six women who said they would not use the method again, two were dissatisfied because the method had failed, and four considered it too painful.</p> <p>All 18 patients who had previously had a surgical abortion preferred medical abortion. the length and the required follow-up, and about half stated that they would prefer to be asleep during the procedure</p>	
<i>Tang</i>	<p>96%) would recommend it to friends</p> <p>91% would use it again</p> <p>Positive features: "natural" or like menstrual regulation (39%)</p> <p>Negative features: disliked the prolonged bleeding (11%) and the inconvenience of having to make the seven visits required in the study (9%)</p>	all women were satisfied
Tang	<p>85%, including four of 12 women for whom the method failed preferred same method.</p> <p>70% who had previous surgical abortion preferred medical abortion.</p> <p>Negative features reported: procedure took too long (11%), too much bleeding (10%).</p>	Positive features: 82% reported surgical abortion was quick and convenient, frequent visits were avoided (69%), side effect of drug (11%).
Bancelot	A wide majority of women very satisfied (59%) or fairly satisfied (32%), a slightly	

	greater number of women trying the drug-induced method (12%) who were slightly, fairly or completely unsatisfied. These figures were low, was due to unsuccessful treatments and where side effects occurred	
<i>Urquhart and Templeton</i>	75% would prefer same method again Reasons: aware of what was happening, felt more in control and needed no anesthesia, and considered medical abortion more natural and discreet.	94% would prefer same method again
<i>Legarth</i>	Negative features: more pain and prolonged bleeding	
<i>Holmgren</i>	87% evaluated the experience positively. Reported more pain and heavier blood loss. 40% were relieved not to have needed a surgical procedure	88% who had had an early vacuum aspiration, 72% who had had a later dilatation and vacuum aspiration—evaluated the experience positively
<i>Henshaw</i>	95% would choose the same method	90% would choose the same method
<i>Creinin 1996</i>	1.1% with a prior surgical abortion would choose medical abortion 57.6% who required a surgical procedure to complete the abortions would choose medical abortion	
<i>Winikoff 1997</i>	Women were satisfied with either method, but more preferred medical abortion	
<i>1998 Slade</i>	93% were able to specify the most stressful aspect with medical abortion, physical (pain and bleeding) and emotional experience of the process were most frequently cited (27%), followed by actually seeing the foetus (20%)	68% of the surgical group specified stress
<i>2000 Creinin</i>	63% (95% CI 43, 82%) of women randomized to a medical abortion would choose that option in the future.	92% (95% CI 81, 100%) stated they would choose a surgical for a next abortion
<i>2000 Jensen</i>	Subjects undergoing medical abortions reported significantly greater satisfaction than those undergoing surgical abortions (mean rank, 121 vs 149; $P < .01$) but were no more likely to recommend the method they had just experienced to a friend (97% vs 93.3%). If a future abortion was required, however, 41.7% of subjects undergoing surgical abortions indicated they would opt for a medical abortion, whereas only 8.6% of subjects receiving medical abortions would choose a surgical abortion ($P < .001$).	Surgical subjects who experienced more anxiety than expected during the abortion were more likely to choose a medical procedure for a subsequent abortion ($P < .01$)

	Failure of the abortion decreased satisfaction in the medical group and increased the likelihood of choosing a surgical abortion for a subsequent procedure (P <.001).	
2001 Harvey	48% very satisfied, 33% satisfied. 82% would recommend the method to a friend. 89% would have same abortion method in the future	43% very satisfied, 39% satisfied. 78% would recommend the method a friend. 93% would select the same abortion method
2001 Lee	Significantly more participants who experienced successful evacuation of the uterus with the misoprostol protocol would choose the same mode of treatment if they were able to choose again. medical treatment failed to evacuate the uterus and subsequent surgical evacuation was required are significantly less satisfied with the treatment.	
2002 Ashok	70% would opt for the same method in future	79% would opt for the same method in future
2005 Akin	87% were either very satisfied or satisfied 92% would choose the same method again. 93% would recommend this method to others. Best features: no surgery involved (62%), easy (30%) and at home during the abortion 25%). worst features: bleeding (30%), pain (20%) and waiting for the abortion to happen (10%)	79% satisfied or very satisfied. 71% would choose the same again 71% would recommend this method to others. Best features :quick(70%), the result was certain (30%) and there was little pain (20%). worst features :pain (65%), psychological burden of anxiety(22%) and feeling uncomfortable in the lithotomy position on the examination table (16%)

Table 2.3.2.a: Study characteristics of trials evaluated in systematic review

Year (citation)	Mifepristone dose (mg),	Misoprostol dose (mcg), route, number of doses*,	Maximum gestational age (days)	Interval (hours)	Number of women	Duration of follow up	Quality related methods**
Schaff 2000	200 mg	800 mcg, vag, 1+ after 1/7 days	56 days	24 48 72	704 729 654	1-7 days, 8-15 days	c,c,b,c,b
Creinin 2001	600mg	400 mcg, oral, 1+ 400 mcg oral in 6-8 hrs group after 24 hrs	49 days	6-8 48	42 44	24 hrs, 14- 20 days	c,a,c,b,-
Creinin 2004	200mg	800mcg,vag,1+ after 7 days	63 days	6-8 23-24	525 531	7 days, 14 days	c,a,c,b,b
Guest 2006	200 mg	800mcg, vag, 1 after 7 days	63 days	6-8 36-48	210 215	7 days, 5 weeks	c,b,a/c,a/b,a
Creinin 2007	200 mg	800 mcg, vag, 1+	63 days	Same time 24 hr	554 546	7 days, 5 weeks	c,a,c,b,b
Von Hertzen 2007	200 mg	800 mcg vag 3+ 800 mcg Sublingual 3+	63 days	3hr 12 hr	516 517	24 hrs, 2 weeks	a,c,b,a,c
Von Hertzen 2009	200mg	800 mcg vag,	63 days	24 hr 48 hr	531 532	2 weeks, 6 weeks	c,b,a/b,c,c
Goel 2010	200 mg	400 mcg, vag, 1+ 400 mcg after 24 hrs	49 days	Same time 24 hr	40 40	24 hrs, 2 weeks	c,b,c,a,c

* For number of doses of misoprostol, 1 - one only, 1 + one or more additional doses if no abortion initially, and 2 - 2 exactly.

‡“Opt out” means a woman requested surgical abortion after the medical abortion was initiated, for a variety of reasons including discomfort, unwillingness to wait, and unspecified.

**Quality-related methods:

- Pregnancy confirmation and gestational dating (a - LMP and/or physical exam, b - abdominal or vaginal sonography if doubt, c - vaginal sonography every time);
- Type of administration of misoprostol(a- self administered, b- health care provider, c-either),
- Outcome measurement (a - undefined or history and/or clinical exam, b - b-hCG with lenient definitions of completion and/or sonogram if doubt, c - universal vaginal sonogram and/or strict serum b-hCG definitions).
- Management of nonviable pregnancies at first visit: a-surgical evacuation-repeat misoprostol, c-expectant management
- Follow-up to definitive determination of outcome (a-< 95%, b - 95–99%, c - > 99%)

Table 2.3.3.a Outcome measure for RCT

Study	Regimen	Time intervals	No. of women	Time of first follow-up	Failure rates After first dose n/N	Repeat dose of miso	Time of second follow up	Failure rates After repeat doses n/N	RPOC	Persistent non-viable pregnancy n/N	Viable pregnancy n/N	Overall failures
Schaff 2000	200 mg + 800 mcg vag	24	704	1-7 days	75/2087	yes	8-15 days	5/704		0/704	5/704	5/704
		48	729					3/729		0/729	3/729	3/729
		72	654					12/654		4/654	8/654	12/654
Creinin 2001	600mg + 400 mcg oral	6-8	42	24 hrs after miso	21/42	Yes only in 6-8 hrs group	14 days	2/42				2/42
		48	44					4/44				1/44
Creinin * 2004	200 mg + 800 mcg vag	6-8	502	7 days	29/469	yes	14 days	4/409		2/409	2/409	21/525
		24	519					16/473		1/418	0/418	1/418
Guest** 2006	200 mg + 800 mcg vag	6-8	210	7 days	45/197	yes	14 days	23/197	8/197	10/197	5/197	23/197
		36-48	215					18/156		8/156	3/156	2/156
Creinin 2007	200 mg + 800 mcg vag	Same time	554	7 days	46/531	yes	14 days			7/?	4/?	28/554
		24 hrs	546							27/519	4/?	1/?
Von Herten 2007	200 mg + 800mcg vag/SL	3hr	516	24 hrs		yes	14 days	79/516	27/516	17/516	20/516	79/516
		12 hr	517					87/517		21/517	26/517	25/517

Von Herten 2009	200mg + 800 mcg vag	24 hr 48 hr	531 532	14 days	32/531 40/532	no	42 days				4/531 4/532	
Goel 2010	200mg + 400 mcg vag	Same time 24 hrs	40 38	24 hrs	0/40 0/38	yes	14 days	2/40 1/40	2/40 1/40			2/40 1/40

* The overall efficacy was noted for 502(6-8) and 519(24 hrs) at the end of 3 weeks, number of women that had follow up at first visit were 469 (6-8 hrs) and 473(24 hrs group). Number of women that had follow up at second visit were 409(6-8 hrs) and 418 (24 hrs)

** Total number of patients that had follow up by intention to treat were 210 (6-8 hrs) and 215(36-48 hrs) at the end of 5 weeks. Total number of women who had confirmed follow up at the first visit by USS were 197 (6-8 hrs) and 156 (36-48 hrs group)

Table 2.3.4a: Effect of repeated doses of misoprostol

Study	Regimen	Time intervals	No. of women	Time of first follow-up	Success rates following first dose	Success rate after repeat doses of misoprostol	Overall success rates	Follow up period
Schaff 2000	200 mg + 800 mcg vag	24	704	1-7 days		98%	98%	15 days
		48	729		98%	98%		
		72	654		96%	96%		
Creinin 2001	600mg + 400 mcg oral	6-8	42	24 hrs after miso	50%	95%	95%	15 days
		48	44		91%	98%	98%	
Creinin * 2004	200 mg + 800 mcg vag	6-8	502	7 days	94%	95%	96%	5 weeks
		24	519		97%	96%	98%	
Guest** 2006	200 mg + 800 mcg vag	6-8	210	7 days	79%	89%	89%	5 weeks
		36-48	215		92%	96%	96%	
Creinin 2007	200 mg + 800 mcg vag	Same time	554	7 days	91%	95%	95%	5 weeks
		24 hrs	546		94%	97%	97%	
Von Herten 2007	200 mg + 800mcg vag/SL	3hr	516	24 hrs		85%	85%	15 days
		12 hr	517		83%	83%		
Von Herten	200 mg + 800	24 hr	531	14days	94%			6 weeks

2009	mcg vag	48 hr	532		93%			
Goel 2010	200mg + 400 mcg vag	Same time 24 hrs	40 38	24 hrs	100% 100%	95% 98%	95% 98%	15 days

Table 3.1.3 a: Overall success rates of women undergoing medical abortions during the Audit period

Treatment Intervals	Failed treatments	Successful treatments
6-8 hrs N= 1525 (36%)	33 (2.2%)	1492 (97.8%)
≥ 24 hrs N= 2715 (64%)	9 (0.4%)	2706 (99.6%)
Total number of procedures N= 4240	42 (1%)	4198 (99%)

Table 3.1.3 b: Failures with 6-8 hrs and ≥24 hrs time interval regimens

Number of failed treatments	Ongoing pregnancy	RPOC
6-8 hrs n=33	24(73%)	9(27%)
≥24 hrs n=9	4(44%)	5(56%)

Table 5.2.3.1a Demographic and Baseline Clinical Characteristics by treatment groups

	6-8 hrs N(% within group)	24 hrs N(% within group)
Age	Total N=58	Total N=61
<18	1(1.7%)	1 (1.6%)
18-25	33 (56.9%)	30 (49.2%)
26-35	19(32.8%)	22 (36.1%)
>36	5 (8.6%)	8 (13.1%)
Maternal age (years) Mean(SD)	25.43(6.247)	26.52(6.342)
Ethnicity	Total N=57	Total N= 61
Asian-Indian	7(12.3%)	2(3.3%)
Asian-other	5(8.8%)	7(11.5%)
Asian-Middle east	0	1(1.6%)
White British	30(52.6%)	40(65.6%)
Mixed	0	6(9.8%)
Black Caribbean	8(14.0%)	3(4.9%)
Black African	6(10.5%)	2(3.3%)
White-other	1(1.8%)	0
Marital status	Total= 58	Total =60
Married	8(13.8%)	9(15.0%)
Single	49(84.5%)	50(83.3%)
Divorced	1(1.7%)	1 (1.7%)
Education	Total=51	Total=55
No Formal Education	2(3.9%)	6(10.9%)
GCSE/O Levels	15(29.4%)	27(49.1%)
A Levels	12(23.5%)	10(18.2%)
Post Sec Certificate	3(5.9%)	0
Degree	17(33.3%)	10(18.2%)
Masters Degree	2(3.9%)	2(3.6%)
Employment status	Total= 57	Total=59
Student	10(17.5%)	8(13.6%)
Unemployed	14(24.6%)	24(40.7%)

Employed	28(49.1%)	24(40.7%)
Self Employed	5(8.8%)	3(5.1%)
BMI	Total =58	Total=59
≤ 19	9(15.5%)	5(8.5%)
20-24	24(41.4%)	26(44.1%)
25-29	15(25.9%)	21(35.6%)
30-34	4(6.9%)	5(8.5%)
35-39	3(5.2%)	2(3.4%)
≥ 40	3(5.2%)	0
Parity	Total= 58	Total=61
Para 0	30(51.7%)	28(45.9%)
Para 1	13(22.4%)	11(18.0%)
Para 2	11(19.0%)	9(14.8%)
Para 3 or more	4(6.9%)	13(21.3%)
Previous Abortion	Total=58	Total=61
No Previous Abortion	37(63.8%)	33(54.1%)
Medical Abortion	8(13.8%)	12(19.7%)
Surgical Abortion	8(13.8%)	15(24.6%)
Both	5(8.6%)	1(1.6%)
Gestational age	Total=58	Total=61
≤42	22(37.9%)	25(41.0%)
43-49	21(36.2%)	24(39.3%)
50-56	11(19.0%)	8(13.1%)
57-63	4(6.9%)	4(6.6%)
Mean gestational age(days) (SD)	45.8(6.991)	45.3(6.388)

Table 5.2.3.2a: Efficacy of 6-8 hrs vs 24 hrs treatment regimens

	6-8 hrs (n=58)	24 hrs (n=61)	P value
Treatments successful	57 (98.2%)	60 (98.3%)	P=1.00(f)
Failed required surgical treatment	1 (1.8%)	1 (1.7%)	

(f) fisher exact test
Number (%)

Table 5.2.3.2b Outcomes following transvaginal ultrasound and telephone follow up

	6-8 hrs (n=44)	24 hrs (n=42)
Treatments successful	42 (95.5%)	39 (93%)
Failed required surgical treatment	1 (2.3%)	1 (2.4%)
RPOC	1 (2.2%)	2 (4.6%)

Table 5.2.3.3a: Secondary outcome- Vaginal Bleeding

Assessment of vaginal bleeding	6-8 hrs	24 hrs
No of women who had bleeding following treatment	25/26	27/27
No. Of women who felt that the bleeding was similar to a period	10/26	11/28
No of women who reported bleeding in comparison to periods		
Less	1/23(4%)	0/22
Slightly More	11/23(48%)	12/22(55%)
severe	11/23(48%)	10/22(45%)
No of women who had clots	25/26	24/25
No of women who reported the size of clots		
Small	3/25(12%)	2/27(7%)
Medium	5/25(20%)	3/27(11%)
Large	17/25(68%)	22/27(82%)
No of pads used in an hr	2 (2-3), n=26	2(2-3), n=26
No. of women who had heavy bleeding pads 'wringing wet'	18/26	19/27
Start of vaginal bleeding (hours) after	4.0 (2,6), n=25	3.00(1,4), n=27

Misoprostol administration		
End of vaginal bleeding (days) Misoprostol after administration of misoprostol	10(7,14), n=25	14(9,15), n=27

Data are represented as median (interquartile range), n= data collected in each group

Table 5.2.3.3b: Secondary outcome- Pain

Assessment of pain	6-8 hrs	24 hrs
No of women who had abdominal pain following treatment	25/26	22/27
No. of women who felt that the pain was similar to a period	14/26	9/27
No of women who reported pain in comparison to periods		
Less	2/22(9%)	3/24(12%)
Slightly More	3/22(14%)	11/24(46%)
Severe	17/22(77%)	10/24(42%)
VAS score median	6,n=25	5 , n=27
End of abdominal cramps (hours) from Misoprostol administration	12 (8-22), n=25	6 (4-10), n=27
Overall duration of pain		
< 6 hrs	8/20 (40%)	11/25(44%)
6-12 hrs	7/20 (35%)	9/25(36%)
>12hrs	5/20(25%)	5/25(20%)
No of women who used analgesia	23/26	22/27

Type of pain relief used		
Paracetamol	5/23(22%)	5/22(23%)
NSAID based	13/23(57%)	11/22(50%)
Opiate based	4/23(17%)	5/22(23%)
More than one	1/23(4%)	1/22(4%)

Table 5.2.3.3c: Comparison of Side effects

Adverse effect	6-8 hour regimen	24 hr regimen
Nausea	0(n=24)	4(n=29)
Vomiting	1 (n=24)	4(n=28)
Diarrhoea	0(n=24)	0(n=27)
Chills	2(n=25)	3(n=28)
Headache	0(n=25)	4(n=26)
Dizziness	0(n=25)	5(n=28)

Table 5.2.3.3d: Acceptability

	6-8 hour regimen	24-hour regimen
Acceptable time taken for treatment	26/26 (100%)	16/30 (53%)
Acceptable vaginal bleeding	22/26 (85%)	25/31(81%)
Acceptable abdominal cramps	17/26(65%)	19/30 (63%)
Acceptable adverse effects	9/23 (39%)	13/29(45%)
Overall acceptability of treatment	25/26(96%)	29/30 (97%)

Table 5.2.3.3e: Recommend this method of abortion to a friend or relative

	6-8 hrs (n=27)	24 hrs(n= 32)
Yes	23/27 (85%)	22/32(69%)
No	4/27(15%)	10/32(31%)

Table 5.2.3.3f: Experience with the current form of treatment to previous methods of medical abortions

	6-8 hrs (n=11)	24 hrs (n=11)
Better	7	6
Worse	2	3
No difference	2	2

Table 5.2.3.4a: Follow-up rates

	6-8 hrs	24 hrs	Overall
Telephone follow up	25/58(48%)	27/61(51%)	52/119(44%)
Urine hCG F/U	30/58(52%)	34/61(56%)	64/119(54%)
USS F/U	29/58(50%)	31/61(51%)	60/119(50%)
Questionnaires	26/58(45%)	31/61(51%)	57/119(48%)
Overall follow up	44/58(76%)	42/61(69%)	86/119(72%)

Table 5.2.3.4b: Confirmation of complete abortion by telephone follow up

	6-8 hrs	24 hrs
Yes	21/26	26/26
No	5/26	0/26

Table 5.2.4a: Personal Preferences for various time interval treatment regimens in the non-randomized women undergoing medical abortions during the study period

	6-8 hrs n= 75 (28%)	24 hrs n= 179 (67%)	36-72 hrs n=12 (5%)
No. of women giving one reason	55 (73%)	129(72%)	9 (75%)
No. of women giving more than one reason	20(27%)	50(28%)	3(25%)

Table 5.2.4b: Reasons for their preferences

	6-8 hrs n= 75	24 hrs n= 179	36-72 hrs n=12
Child care issues	10 (18%)	31 (24%)	4 (44%)
GP/FP advice	-	8 (6%)	-
Friends Advice	-	1 (1%)	-
Information from the CC	5 (9%)	31 (24%)	-
Other family issues/ confidentiality	6 (11%)	11 (9%)	2 (22%)
Travel from long distances	14 (25%)	14 (11%)	1 (11%)
Work commitments	13 (24%)	20 (16%)	2 (22%)
Other reasons	7 (13%)	13 (10%)	-

Table 6.2.1a: Demographic characteristics of participants for Qualitative study

Interviewee	Age	Ethnicity	Employment status	Marital status	Level of education	Previous abortion	Previous children	Group randomised
#1	22	White British	Student	single	A levels	no	no	24hrs
#2	24	Asian-Indian	unemployed	Single with partner	GCSE/O levels	1x medical	1x	24hrs
#3	22	White British	unemployed	single	degree	no	no	6-8hrs
#4	27	White British	Self-employed	Single with partner	GCSE/O levels	no	2x	6-8hrs
#5	26	Black Caribbean	employed	single	degree	1x surgical	1x	6-8hrs
#6	28	Black Caribbean	employed	Single with partner	degree	1x medical	1x	24hrs
#7	27	Middle east	student	single	Master's degree	no	no	24hrs
#8	36	White British	Self employed	single	A levels	no	1x	6-8hrs
#9	24	White British	employed	single	GCSE/O levels	no	1x	24hrs

#10	20	White British	unemployed	single	GCSE/O levels	no	1x	24hrs
#11	20	Black Caribbean	employed	single	degree	1x surgical	no	6-8hrs
#12	23	Asian-Indian	employed	married	GCSE/O levels	no	no	6-8hrs
#13	30	White British	student	divorced	A levels	no	2x	24hrs
#14	36	White British	employed	single	masters	no	no	24hrs
#15	20	White British	unemployed	single	A levels	no	no	6-8hrs
#16	23	Asian	employed	single	degree	no	no	24hrs
#17	18	White British	student	single	degree	no	1x	6-8hrs

Appendices

Appendix 1.5.1a Dosage and regimens for medical abortions adopted from the Royal College of Obstetricians and Gynaecologists (RCOG) National Clinical Guidelines 2011

Box 1. Dosage and regimens for medical abortion from 4–24 weeks of pregnancy

- **Between 4 and 9 weeks of pregnancy:**

200mg mifepristone orally followed 36–48 hours later¹ by 800mcg misoprostol vaginally. The misoprostol may be administered by a clinician or self-administered by the woman at home.² At 7–9 weeks, if abortion has not occurred four hours after administration of misoprostol, a second dose of misoprostol 400mcg may be administered vaginally or orally (depending upon preference and amount of bleeding).^{2,7}

An alternative regimen for 4–7 weeks of pregnancy:

200mg mifepristone followed 36–48 hours later by 400mcg misoprostol orally.^{8*}

Misoprostol alone: 800mcg vaginally, followed 3–6 hours later by a second dose of 800mcg misoprostol inserted vaginally. If abortion has not taken place after the second dose, a third dose of 800mcg can be inserted vaginally 3–6 hours later.^{9†}

- **Between 9 and 13 weeks of pregnancy:**

200mg mifepristone orally followed 36–48 hours later by 800mcg misoprostol vaginally. A maximum of four further doses of 400mcg misoprostol each may be administered at three-hourly intervals, vaginally or orally (depending on the amount of bleeding).² The woman is kept under observation in the clinic until she aborts.

- **Between 13 and 24 weeks of pregnancy:**

200mg mifepristone orally, followed 36–48 hours later by 800mcg misoprostol vaginally, then 400mcg misoprostol orally, three-hourly, to a maximum of four oral doses.² The woman is kept under observation in the clinic until she aborts.

In all cases, a follow-up visit should be carried out two weeks after misoprostol use to check that the abortion is complete and there are no complications.

Notes

*This regimen is approved in several countries and is also listed in the WHO Safe Abortion Guidance. However, 800mcg vaginal misoprostol after mifepristone causes a higher rate of complete abortion with fewer gastro-intestinal side effects up to nine weeks of pregnancy. On the other hand, some women may prefer to take misoprostol orally, knowing the complete abortion rate may be slightly lower.

†A meeting of experts convened in June 2003 proposed a misoprostol-alone regimen for up to nine weeks of pregnancy of 800mcg misoprostol, repeated after 24 hours.¹⁰ The above regimen is proposed instead because in a study comparing the two regimens (2005), women said that waiting for 24 hours to insert the repeat dose was too long and caused too much anxiety.⁹

Appendix 1.5.2a Contraindications to medical treatments

Prior to initiating the medical abortion treatments, contraindications for their use include ^{98,100}

- _ Confirmed or suspected ectopic pregnancy
- _ Allergy to mifepristone or misoprostol
- _ Bleeding disorders
- _ Severe asthma not controlled by therapy
- _ Chronic adrenal failure
- _ Acute porphyria
- _ More than one uterine scar (for abortions at 13–20 weeks)
- _ Long-term use of corticosteroids.

Appendix 1.5.2 b Conditions that are not contraindications ^{96, 97, 98}

- _ IUD in place in the uterus, should be removed prior to use of medical abortion.
- _ Mild to moderate anaemia (haemoglobin levels between 9 and 12 gm/dl) can use medical abortion safely, but iron pills might be advisable.
- _ Sexually transmitted disease or reproductive tract infection should be treated immediately. It is not necessary to wait for such treatment to be completed before having a medical abortion.
- _ There is some evidence that mifepristone and misoprostol are excreted into breast milk. Any effects of misoprostol on infants are not known. As misoprostol levels decline rapidly, it has been recommended that misoprostol be taken immediately after a feed and the next feed given after four hours in case of oral administration and somewhat later after vaginal administration. ^{102,103}

Appendix 1.6.4a Comparing ultrasound and hCG measurement to verify the effectiveness of the treatment Adopted from Fiala 2003

Advantages	Disadvantages
Ultrasound Usually done before starting the treatment Easy to perform Immediate result Great relief for the woman when there is no foetal structure visible	No reliable result in very early pregnancy Sometimes difficult to interpret at follow-up Vaginal ultrasound necessary
hCG Always a definite result Easy to perform	Not possible to exclude a gestational age <49 days LMP Some time needed to obtain the result

Appendix 2.2.3a PRISMA Checklist of items to include when reporting a systematic review or meta-analysis.

Section/Topic	#	Checklist Item	Reported on Page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

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Appendix 2.2.3b The Jadad Score

A Method for assessing the quality of controlled clinical trials

Basic Jadad Score is assessed based on the answer to the following 5 questions.

The maximum score is 5.

Question	Yes	No
1. Was the study described as random?	1	0
2. Was the randomization scheme described and appropriate?	1	0
3. Was the study described as double-blind?	1	0
4. Was the method of double blinding appropriate? (Were both the patient and the assessor appropriately blinded?)	1	0
5. Was there a description of dropouts and withdrawals?	1	0

Quality Assessment Based on Jadad Score

Range of Score	Quality
0–2	Low
3–5	High

Appendix 4.1.3a Basic differences between quantitative and qualitative research concepts created from the text from Research design: Qualitative and quantitative approaches. Cresswell JW (1994).

	quantitative	qualitative
Role of theory	Deductive approach, testing of theory	Inductive approach, generation of theory
Theory of knowledge (epistemology)	Follows a natural science model, particularly positivism	Interpretative
View of social reality	Social reality as something objective and measurable	Social reality as something constructed by people

Appendix 5.1.1c Summary of methodology used for the RCT

Setting:	<i>Recruitment in the Calthorpe clinic</i>
Inclusion criteria:	<i>Women who are 18 years and older</i> <i>Eligible for legal abortion</i> <i>Duration of pregnancy not more than 63 days</i> <i>Singleton pregnancy</i> <i>Agree to be able to be contacted by telephone (i.e. mobile telephone)</i> <i>English speaking</i> <i>No stated preference for treatment</i>
Randomisation:	<i>computerised randomisation</i>
Intervention:	<i>6-8 hrs interval and 24 hrs or more interval</i>
Follow up:	<i>Telephone follow up at 1 week</i> <i>Patient acceptability Questionnaires at 2 weeks</i> <i>Urine hCG measurement at 2 weeks</i>
Outcome measures:	<i>Success treatments requiring no further surgery</i> <i>Pain, bleeding and other side effects</i> <i>Patient satisfaction</i>

Appendix 5.1.2 a: Inclusion Criteria

- Ability to give informed written consent
- Women who are 18 years and older
- Requesting abortion and eligible for legal abortion
- Duration of pregnancy not more than 63 days (counted from the first day of the last menstrual period) in a normal 28-day cycle or verified by ultrasound.
- The pregnancy is single and intrauterine (single sac)
- Agree to be able to be contacted by telephone (i.e. mobile telephone)
- Women with limited understanding of English have been included only in the quantitative study where interpreters were available
- Willing and consent to participate after the study has been explained
- No stated preference for treatment

Appendix 5.1.2 b: Exclusion Criteria

- Any indication of serious past or present ill health were considered a contraindication for recruitment to the study
- Suspicion of any pathology of pregnancy (e.g. molar, nonviable pregnancy, threatened abortion)
- Current participation in a drug related trial
- Non-English speaking women for the qualitative study
- Women under the age of 18 years
- Stated preference for treatment

Appendix 5.1.7a The five-class version of self-coded NS-SEC

Class	Label
1	Managerial and professional occupations
2	Intermediate occupations
3	Small employers and own account workers
4	Lower supervisory and technical occupations
5	Semi-routine and routine occupations

Appendix 5.1.7b ISCED defined levels of education

Level	Description
Level 0	Pre-Primary Education
Level 1	Primary Education or First Stage of Basic Education
Level 2	Lower Secondary or Second Stage of Basic Education
Level 3	(Upper) Secondary Education
Level 4	Post-Secondary Non-Tertiary Education
Level 5	First Stage of Tertiary Education (Not leading directly to an advanced research qualification)
Level 6	Second Stage of Tertiary Education (Leading to an advanced research qualification)

Appendix 6.1.4.1.a Interview guide used for the qualitative study

Introduction

Beliefs and Attitudes towards abortions

- In general, what does a man or woman in the street think about abortions? (For, against, social, political, religious, financial)
- How important do you think these beliefs are while deciding for an abortion?
- What are your personal views? Why?
- Why do you feel this way?

Attitudes towards different methods of abortion

- How important do you think it is to be given options on the different methods of abortions? Why do you think so?
- What do you think influences a woman's choice in considering the different methods of abortion?
- Are there any other reasons that you think would have influenced your decision
- Why do you think some women choose surgical over medical or medical over surgical methods?
- What made you choose medical methods?
- Some women feel that there should be other ways of medical abortions instead of vaginal pessary. Do you feel that there should have been other forms/ ways that medical abortion medications can be given?
- Why do you feel that way?
- In some parts of the countries, medications can be given for home use? What do you think of home use? Why?
- Generally, the two lots of tablets for the medical abortions are given 2-3 days apart, but increasingly more women request for treatments on the same day? What are your views on the use of medical abortion medications offered at shorter time intervals?
- If this is something that you want some time, what do you think you would be most worried about these new treatments?

Experiences with medical abortion

- When you came to the clinic, were you aware that you would be having tests such as USS (yes/ No)
- Did you understand why they were doing the USS?
- How did you feel when you were told about the gestational age of pregnancy? Did you expect to feel this way?
- Why do you think it is important or not important to know the gestational age?
- How do you think women in general would feel if the scan images were shown to women ?
- What do you think would be the emotional reaction to seeing a fetus on the USS?
- We say that early medical abortions are between 5-9 weeks, but sometimes very early abortions are offered even before this?
- Do you think that very early abortions of less than 5 weeks ie when no fetus is seen on USS would change the feelings of the women who might be going through the abortion process

Significance of follow up

- You mentioned that to know if abortion has been complete or not is very important Do you feel that there should be a follow up visit?
- After having an abortion, how important do you think it is for a woman to know that the treatments have been successful?
- How soon do you think a woman would like to know?
- How long do you think it would take to for a woman to recover fully?

Expectations

- What do you think are the expectations of a woman before having an abortion?
- People talk a lot about the doctor-patient/ nurse- patient relationship? Do you see that as being relevant here?
- What effect did this have on you? (Explore negative and positive)
- What would you like to see/ expect to get from health care professional?

Awareness

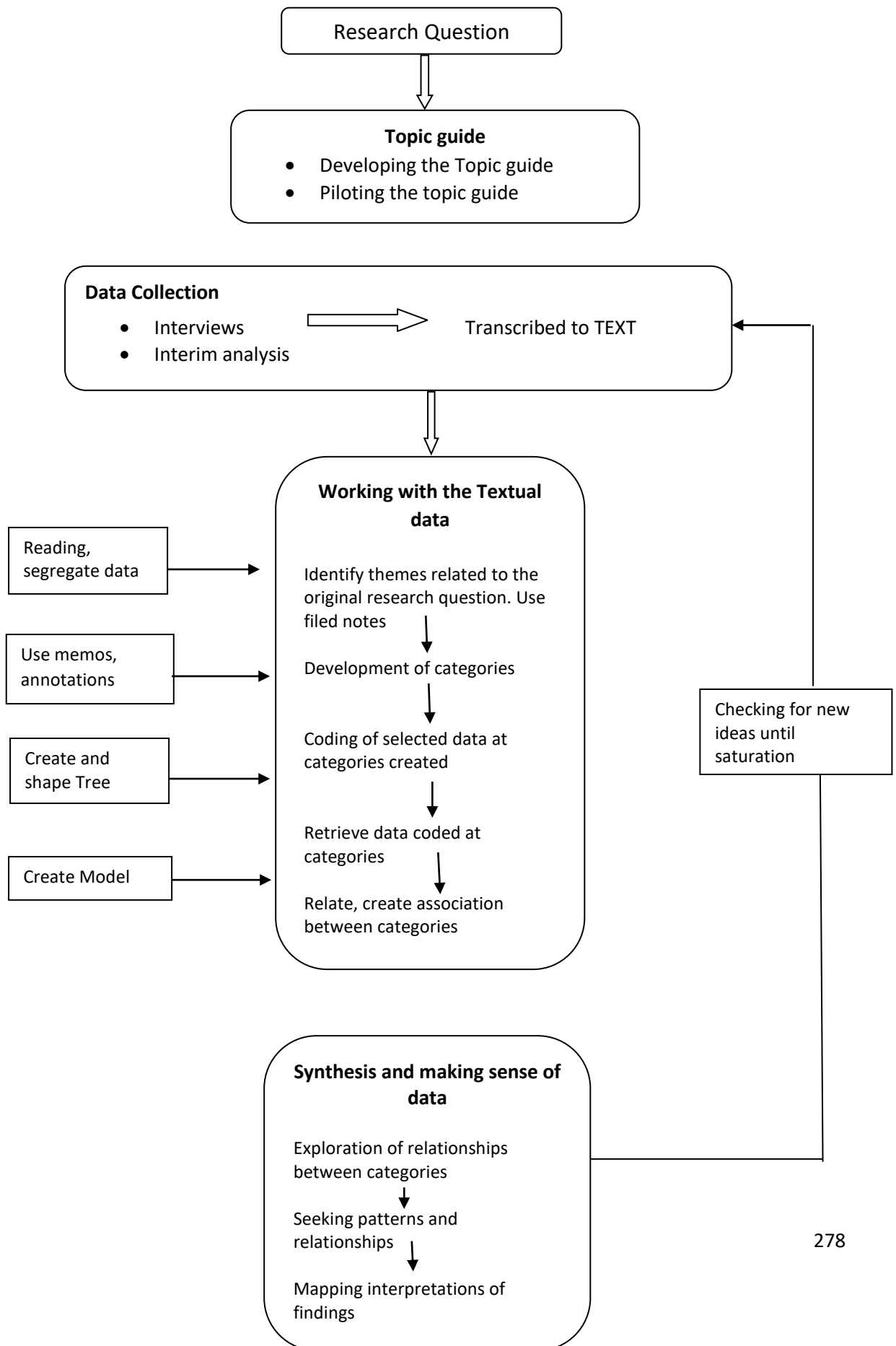
- Where do you think women go to get information on abortion?
- Where did you get your information from?

- Do you feel that the information was adequate?
- What sort of information do you think is important?

Prevention and recommendations

- Over the last few years, the rates of abortions have been increasing, what are your thoughts on the increasing rates of abortions?
- How do you think we can prevent more abortions?
- What sort of recommendations would you suggest?
- How do you think services can be improved?

Appendix 6.1.4a Process of qualitative study (adopted from review article on data analysis of qualitative research Data analysis in qualitative research: a brief guide to using nvivo. Wong L.. 2008



Appendix 6.1.4.6a Summary of the main matrix for the themes

Patients Characteristics	Case 1	Case 2	Case 3	Case 4
Participants Age				
Ethnicity				
Employment status				
marital status				
Level of Education				
Previous abortion				
Previous children				
Group of treatment				
Theme1: Attitudes towards abortions				
Subtheme1.1 : General views on participants on abortions				
Subtheme1.2 : Personal views of participants on abortions				
Subtheme 1.3: Views on cultural aspects of abortions				
Subtheme 1.4: Men's views on abortions				
Subtheme 1.5: Personal views on repeat abortions				
Theme2: Process of Decision making				
Subtheme 2.1: Influence on decision making				
Subtheme 2.2: Reasons involved in decision making				
Subtheme 2.3: Personal reasons of the participants for having an abortion				
Theme 3: Attitudes towards various methods of abortions				
Subtheme 3.1: General views on preference for abortion methods				
Subtheme 3.2: Views on influence on choice of type of abortions-surgical or medical				
Subtheme 3.3:Reasons for preferring Medical abortions				
Subtheme 3.5: Experience with previous abortion methods				
Theme 4 : Views on newer methods of medical abortions				
Subtheme 4.1 :Various routes				
Subtheme 4.2: same day vs longer time intervals				

Subtheme 4.3: Home management				
Subtheme 4.4: Over the counter use				
Subtheme 4.5: Perceptions of newer treatment regimens for medical abortions				
Theme 5: Views on very early abortions				
Subtheme 5.1: Awareness about USS				
Subtheme 5.2: Determining GA on USS and its effect on women				
Subtheme 5.3: Views on Ultrasonography images				
Subtheme 5.4: Views about very early abortions				
Subtheme 5.5: Views and Perceptions on complications for very early abortions				
Theme 6 Views on follow up				
Subtheme 6.1: Personal views on follow up				
Subtheme 6.2: Timing of Follow up				
Subtheme 6.3: Time taken to recover completely				
Subtheme 6.4: long term implications				
Theme 7 Expectations about medical abortions				
Subtheme 7.1 Expectations from health care				
Subtheme 7.2: Views on consultation and Approach of health care professionals				
Theme 8 Experience with medical abortions				
Subtheme 8.1 Source and adequacy of Information				
Subtheme 8.2 Emotional experience– Before, during and after				
Subtheme 8.3 Support				
Theme 9 Opinions on prevention of abortions				
Subtheme 9.1 Views on increasing abortion rates				
Subtheme 9.2 Methods to reduce abortions				



We would be most grateful if you could complete this questionnaire after your treatment to find out your views about your acceptability of the treatment.

Please read through the instructions at the beginning of each section carefully. The questionnaires are simple to complete. All you need to do is tick the appropriate box that best describes or mention in 1-2 lines how you feel.

There are no right or wrong answers. We are just interested your opinions about the treatments. Try not to dwell too long on any question and choose the answer that comes closest to how you have been feeling generally.

It is important to get complete information so please answer all the questions even if some may seem repetitive or less relevant.

If you have any queries about completing this questionnaire do not hesitate to contact:

Calthorpe Clinic: 0121 455 7585

Please return the completed questionnaire to:

Calthorpe Clinic, 4 Arthur Road, Edgbaston, Birmingham B15 2UL

or use the self addressed envelope provided.

Thank you for your participation in this study.

The information collected in this questionnaire will remain strictly confidential.

Please complete your address below

Postcode _____

For trial purposes only

Trial No.

Patient initials

Date received

Date entered



Patient Acceptability Questionnaire

Pain

1. How many hours after administration of vaginal misoprostol did you start to feel abdominal cramps?

2. Please place a mark (X) on the line below to indicate how much pain you have experienced during the whole process

|-----|

No pain **Worst imaginable pain**

3. How many hours after taking misoprostol were you pain free?

Bleeding

During the 2 weeks following the procedure:

4. When did you start to experience bleeding after having misoprostol?

5. For how many days did you experience bleeding?
PLEASE indicate in number of **days**

6. If you experienced any of the following side effects while undergoing medical abortion, please tick a box for each side effect.

	None at all	Present but not troublesome, no additional treatment needed	Present and troublesome, severe enough requiring additional treatment	Present and troublesome, even after additional treatment	Present and worse than before requiring additional treatment
Nausea					
Vomiting					
Diarrhoea					
Chills/Shivering					
Headache					
Dizziness					

Others please state:

7. Please tick a box for each question to indicate your experiences during the procedure

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Were abdominal cramps tolerable during the procedure?					
Was the amount of vaginal bleeding acceptable?					
If you have had side-effects, were they worrisome?					
Were you satisfied with the time taken for the treatment to complete?					
Were you happy with the overall treatment?					

8. Would you recommend this method of abortion to a friend or relative approaching you for your advice? Yes No

9. This question is for women who have had previous medical abortions. How would you rate your experience with the current form of treatment to previous methods of medical abortion?

Better Worse No difference

10. Can you please tell us why you chose to complete this questionnaire in the paper form?

Web facilities unavailable

Easier to complete on paper

No reason

Other

11. Please can you enclose your early morning first urine sample in the container provided along with this questionnaire in the self addressed envelope.

IMPORTANT: Please write down the date and time the sample was collected.

Date _____ Time _____

Have you consulted your doctor or been to any hospital since your abortion? No Yes
(If yes, please give details)

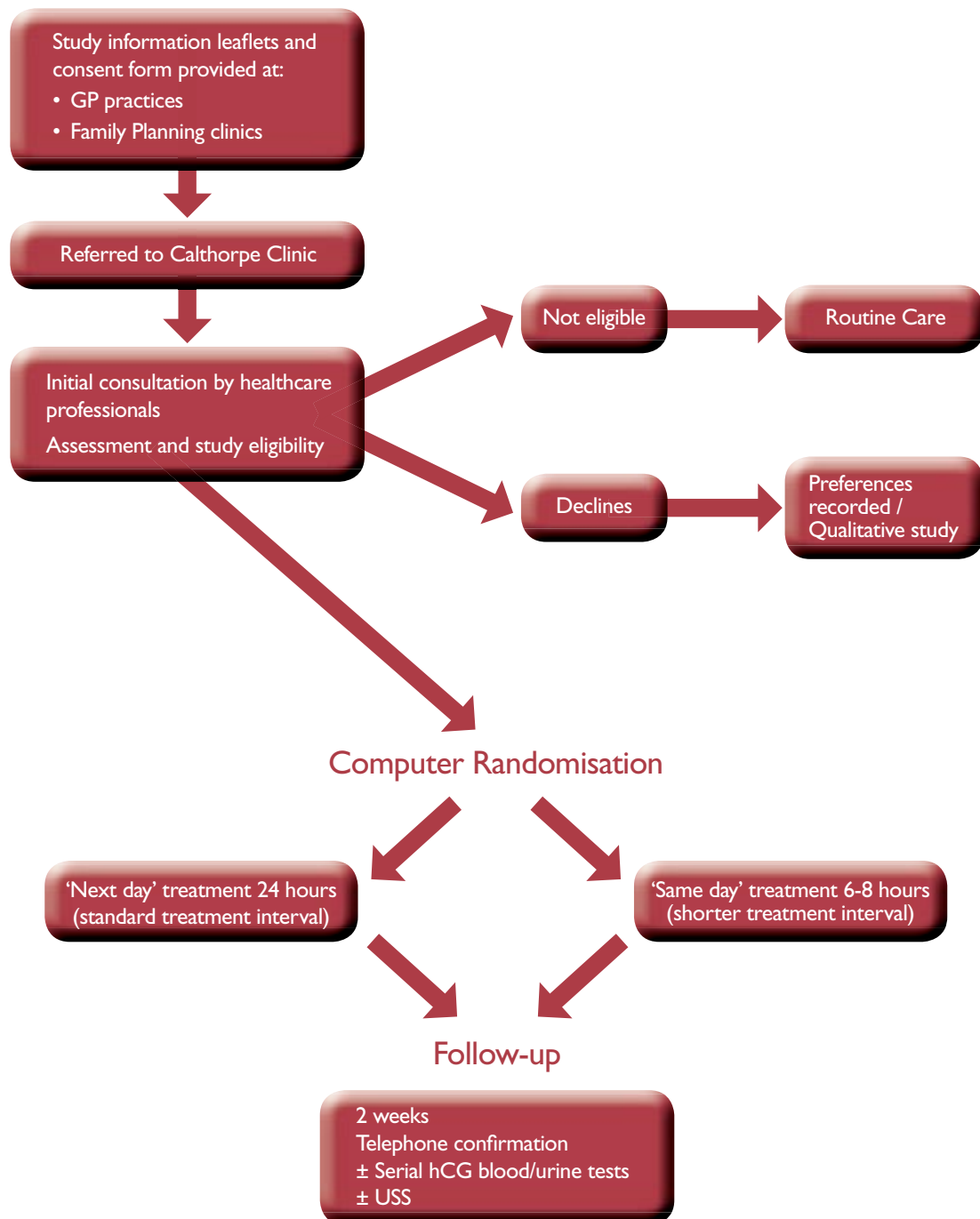


Trial Schema

Eligibility

- Any woman above the age of 18 years requesting a medical abortion
- Less than 9 weeks of pregnancy

Randomisation



Participant Information Sheet

Invitation to participate in the TIMES study

We would like to invite you to take part in a research study.

Before you decide whether to take part, it is important that you understand why the research is being done and what is involved. Please take your time to read this information carefully. If there is anything that is not clear, or you would like more information, please ask your GP or the doctor / nurse at the Calthorpe Clinic for advice.

PART I:

What is the purpose of the study?

In pregnancies before nine weeks of gestation, medical abortions are a safe alternative to surgical abortion. A medical abortion involves the use of two different kinds of medication given in two stages. The current standard interval between the first and the second medication is usually 24 hours (next day). However, there have been new developments indicating that medication given at an interval of 6-8 hours (same day) may have the same effect as that given over a 24 hour interval.

The TIMES study aims to establish whether the shorter 'same day' time interval of 6-8 hours is as effective and an acceptable method of abortion compared to the standard 'next day' 24 hours in women undergoing early medical abortion.

The study also aims to explore women's choices in early medical abortions. We hope that individuals sharing their experiences will provide us with valuable information in understanding the reasons why women prefer certain treatment options for medical abortion over others. A subgroup of women will be invited to take part in this qualitative study.

Why am I being invited to take part?

You have been invited to take part because you have chosen a medical abortion after discussing all the available treatment options for early abortions.

Do I have to take part?

No. If you do not wish to take part, doctors and nurses in the family planning clinics, your GP or members of the staff at the Calthorpe Clinic will not hold this against you. Your decision will not affect the standard of care you will receive.

Taking part is completely voluntary; it is your decision. If you wish to be part of the study, we will go through everything with you so that you understand what is required and what will happen. Please keep this leaflet so you can refer to it at any time. We will then ask you to sign a consent form to show that you have agreed to take part.

You can withdraw from the study at any time, without giving a reason. This will not affect the standard of medical care you receive in any way.

What would taking part in the study involve?

As for any women undergoing abortion, the options of medical or surgical abortion will be discussed by your GP, doctors or the nurses at the Calthorpe Clinic.

You will have an assessment that involves a finger-prick blood test or urine sample test and an ultrasound scan. This is routine for all women undergoing abortions.

The study will be explained to you in detail at the time of consultation and you will have an opportunity to discuss the study with the doctors or nurses.

You will be put into one of two different treatment groups; the 'same day' (6-8 hours) or 'next day' (24 hours) group. To make sure that the groups are equally divided, your placement will be by chance (random). This means that the doctor cannot choose which women will receive which treatment interval; this will make the results at the end of the study more reliable.

If you take part, you will be given the first treatment, a mifepristone tablet which is taken by mouth. This is followed by the second tablet, misoprostol, which is inserted into the vagina either 6-8 hours later or 24 hours later depending on the treatment you have been allotted. The Clinic nurse can do this for you or you can insert the misoprostol yourself.

After taking the tablet, we ask that you stay in the Clinic for up to half an hour so that we can check that you are all right; of course, you can stay longer if you wish. Before you leave the Clinic, you will be given your next appointment time and who to contact if you have any queries or problems.

What should I expect after the treatments?

The abortion process usually begins within four to five hours after the second tablet and the process is completed within one to two days. Miscarriage may occur in rare cases before the second tablet. It is also rare but bleeding can continue for more than 2 weeks. Occasionally women may bleed or have abdominal cramps on their way home after treatment. This is considered normal as the misoprostol causes the womb to contract, but the pain relief (60 mg of codeine orally) that will be given to you at the Clinic before you go home should help with the abdominal cramps.

If the bleeding is very heavy or the pain is unacceptable to you, you should contact the Clinic immediately and speak to a nurse. You can call at any time; there is an on-call nurse available at all times (contact numbers are at the end of this information sheet). If you wish you can always go to the A & E Unit at your local hospital.

How will I know if the abortion process is complete?

This is an important part of the treatment.

To know if the abortion process is complete and the treatment is effective a Clinic nurse will contact you by telephone 2-5 days after receiving the second medication. You may also be asked to return to the Clinic for a follow-up ultrasound scan and/or one or more urine/blood tests if needed.

If I am part of the study, what will I have to do after the treatments?

You will be asked to complete and return an acceptability questionnaire 2 weeks after your treatment (using a self addressed envelope which will be provided). In your pack, we will include a small container in which we would like you to send an early morning mid-stream sample of your urine. This is to test if your abortion is complete. A phone call, email or text message will be sent to remind you to complete the questionnaire. You can choose between a paper, web-based or text message-based questionnaire. The web-based questionnaire will be accessible only from the Calthorpe Clinic website and will be password protected.

To understand women's choices and preferences for abortion, we are asking a smaller group of women to take part in this additional qualitative study. If you agree, a researcher may visit you at home or at the Calthorpe Clinic to interview you at a date and time that suits you. The interview may last up to one hour. You will be asked to talk about your experiences of medical abortion, its effects and the treatments you received. To help us collect this information, the interviews will be recorded but only with your consent. Before each interview begins we will check again that you consent to the interview being recorded on a tape.

What are the drugs used in this study and how do they differ from the standard treatment options?

The two medications that are used are - mifepristone and misoprostol. The use of both these medications for medical abortion is a standard treatment method as per the RCOG guideline (Royal College of Obstetricians and Gynaecologists). The same medications will be used in this study.

The first medication, mifepristone, is taken by mouth and this will begin the changes in preparation for the process of abortion. The second medication, misoprostol, is given as a vaginal pessary after 6-8 hours or 24 hours to complete the process of abortion. The time interval for receiving the misoprostol at 6-8 hours or the 24 hours and its effectiveness in causing abortion is the only difference that this study is looking into.

What are the side effects and contraindications with the medications?

The abortion medications have been used safely for a long time and have few side effects.

The commonly reported side effects with mifepristone and misoprostol include; nausea, vomiting, abdominal cramps and shivering. These side effects can be present with either the 'same day' treatment or the 'next day' treatment. We are not sure if the 'same day' treatment causes more pain and/or bleeding and therefore it is an important part of our evaluation in this study.

Remember you can contact the Calthorpe Clinic at any point while you are undergoing the procedure. Contact telephone numbers are provided at the end of the leaflet. A nurse is present on call 24 hours a day, 7 days a week to answer any queries after the treatments.

What are the alternatives for diagnosis or treatment?

Routine treatment options for abortion less than 9 weeks are medical or surgical methods. If you do not decide to take part, you could opt for surgical treatment either under general or local anaesthesia.

What are the possible disadvantages and risks of taking part?

If you take part, the medical abortion treatments that you will receive in this study are standard, well-established treatments. The only difference would be in assessing whether the shorter time interval 'same day' is as effective as the currently established 24 hour time interval 'next day'.

There is a possibility that the 'same day' 6-8 hours treatment could cause more pain/or bleeding and possibly not be as successful in completing the abortion as the 'next day' 24 hour regimen. We will be able to assess these factors in detail in this study.

If your medical treatment fails to complete the abortion process, we will offer you the options of repeat medical treatment (the same treatment you have already had) or a surgical treatment. These are the routine options we offer all women in cases of unsuccessful treatments. These options will be provided at the Calthorpe Clinic. The surgical or the medical treatment will not incur any additional charges.

Are there any benefits for me from taking part in the study?

You will be helping us to understand if shorter time 'same day' treatments for medical abortions can be equally effective and acceptable to women requesting medical abortion in the future.

For the qualitative part of the study, we hope that the information you give us about your experiences with medical abortion treatments will help us to understand women's preferences and choices in decision-making.

What happens when the research study stops?

No further treatment will be needed after we have confirmed that the abortion process is complete.

The information and summary of the results of the study will be made available to you through the Calthorpe Clinic website.

What if there is a problem?

If you have any complaints about the way you have been dealt with during the study or if you feel any possible harm has occurred, we will address this immediately. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal guidance and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decisions.

PART 2:

What if relevant new information becomes available?

Sometimes we get new information about the treatments being studied. If this happens, your research doctor will talk to you and discuss whether you should continue in the study or whether you should withdraw.

If you decide not to carry on, your research doctor will make sure arrangements for your care will continue uninterrupted. If you decide to continue in the study the doctor may ask you to sign an updated consent form.

If the study is stopped for any other reason, we will tell you and arrange for your continuing care.

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time without giving a reason. Your treatment for abortion will not be affected in any way.

The data that was collected before this will be used only for research purposes of data analysis and will be made anonymous.

You are also free to withdraw from the interviews and further data collection for qualitative study, even if you have already taken part in the study that involves the medications. If you decide to withdraw from this part of the study we will destroy both your contact details and any recordings of your interviews.

What if there is a problem?

If you have any concerns about the study or about how you have been treated by the research team, please contact the Chief Investigator. Details are provided at the end of this leaflet. If you are still unhappy you can make a formal complaint through the Calthorpe complaints procedure. Details of this can be obtained from the Calthorpe Clinic Manager.

Will information about me be kept confidential?

Yes. All information collected in the study will remain strictly confidential in the same way as your other medical records. If you agree to take part, the basic information about you and the procedure will be put into a computer and analysed by researchers involved in the study. The questionnaires will only contain your initials and will be identified by using a code number. Interview tapes and printed copies of interview manuscripts will not have your name on them. In accordance to the 1998 Data Protection Act, all information will be held securely and in strict confidence at the Calthorpe Clinic. No named information about you will be published in any publications or presentations. Information held at the Calthorpe Clinic and records maintained by the Office of National Statistics may be used to keep in touch with participants during follow up of their health status. Occasionally inspections of clinical trial data are undertaken to monitor the standards of the trial; for example, to see if all participants have given consent to take part. Apart from this, only the study organisers will have access to the data. All have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Will my GP be informed about my participation in the study?

Abortion services do not have to inform your GP that you have asked for an abortion. We will only do so if you specifically ask us to inform your GP about the abortion treatment and/or taking part in the study.

What will happen to the results of the research study?

Our intention is to publish and present the results in various medical journals and conferences. You will not be identified in any of the reports, publications or presentations.

Who is funding and organising the research?

This study is being organised by the University of Birmingham and the Calthorpe Clinic. It is being funded and sponsored by the Calthorpe Clinic.

Who has reviewed the study?

All research in the Calthorpe Clinic has been looked at by an independent group of people called the Research Ethics Committee West Midlands (REC) to protect your safety, rights, wellbeing and dignity.

Do you have any other questions?

If you have any questions about the study, now or later, feel free to ask the nurse or doctor. Their names and telephone numbers are given below. You do not have to decide whether you wish to take part straight away. If you would prefer to delay your decision, perhaps to discuss with friends or relatives, then you can take this information home and make an appointment to come back later.

Contact details:

Clinic Manager: Carolyn Phillips
Telephone: 0121 455 7585

Gynaecologist: Prof Janesh Gupta
Telephone number: 0121 607 4751

Researcher: Dr. Sheethal Madari
Telephone: 0787 6436677

Out of hours, call the Clinic number (0121 455 7585)
and you will be directed to the on-call nurse

Patient consent form (Please INITIAL each box if you agree with the statement)

I confirm that I have read and understand the information sheet (dated 9/06/09, version 2.1) for the above study and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I understand what is involved in the TIMES study and agree to participate. I hope to complete the study, but I understand that I am free to withdraw at any time without necessarily giving a reason. If I do withdraw, I can continue to expect the highest standard of care from the health care professionals and gynaecologist.

I understand that the study researchers may contact me by telephone, email or text message to remind me to complete the questionnaire or to ask me the questions over the telephone or web-based and that I will be requested to fill in the follow-up questionnaire.

I understand that the information held by the NHS and records maintained by the Office of National Statistics may be used to keep in touch with me and follow up my health status.

I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that sections of any of my medical notes may be looked at by responsible individuals from the Calthorpe Clinic and the University of Birmingham or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

I agree to a researcher contacting me by telephone or email to arrange interviews about the study related to women's views on medical abortion.

I agree to give permission for the interviews to be tape-recorded.

I agree for my general practitioner (GP) / Family Planning practitioner to be informed of my participation in this study.

Name of the Patient

Date

Signature

Person taking consent / designation

Date

Signature



PATIENT
LABEL HERE

Telephone Confirmation for Medical Abortion

Patient Initials

Trial Number

Gestational age

Time interval allocation:

6 - 8 hours

24 hours

How are you?

Did you have bleeding?

yes

no

Was the bleeding similar to a normal period?

yes

no

If no

less

more

severe

Did you notice any clots?

yes

no

How big were the clots?

small (5p)

medium (10p)

large (50p)

How many pads did you have to use in an hour?

number

Were the pads "wringing wet"?

yes

no

Do you think you have passed pregnancy products?

yes

no

How many hours after passing the pregnancy products did you stop bleeding?

hours

Did you have abdominal cramps?

yes

no

Were the abdominal cramps similar your normal period?

yes

no

If no, were they...

less

more

severe

How long did the pain last for?

less than 6 hrs

6 - 12 hrs

more than 12 hrs

Did you have to use any pain killers?

yes

no

What type did you use?

NSAIDS based
(eg Ibuprofen, Voltarol)

Opiate based
(eg Codeine, Tramadol)

Both



Do you prefer to have the nurse phone you to confirm that the abortion is complete?

Or

Would you have preferred to complete this online yourself?

Or

Don't know

(Please tick the appropriate response)

Have you consulted your doctor or been to any hospital since your abortion? no yes

(If yes, please give details)

Do you have any questions you would like to ask me?



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