Decision making and abortion methods

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Declaration:

I confirm that the work is my own and that where appropriate, reference has been made to the work of others.

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ABSTRACT.

Introduction: This thesis investigates abortion service providers' adequacy to facilitate women's choices to have either a medical or surgical abortion. Both the medical and surgical methods of abortion are effective procedures to terminate unwanted pregnancies in early gestation. Provided there is no medical contraindication, women can make the choice about which method of abortion to have. The role of health professionals is to provide complete and accurate information that encourages women to make informed choices between treatment options. This thesis describes three studies which a) assess the adequacy of written information to support choices about abortion methods across service providers in England and Wales, b) describe the quality of verbal information provided by health professionals to women choosing to have an abortion type in routine consultations, and c) evaluate a leaflet designed to facilitate women's choices to have either a medical or surgical abortion.

Methods: Two studies employ a cross-sectional survey design with qualitative and quantitative methods, the third a randomised controlled trial. The samples include: service provider's leaflets from across England and Wales (n=44); the content of doctors' consultations in a regional abortion service in Leeds (n=23); women undertaking abortions for unwanted pregnancies in a regional abortion service in Leeds (n=313). Measures assess the accuracy and quality of information provided, and the degree to which the leaflet facilitated women's decisions about abortion method.

Results: The analysis of written and verbal information routinely provided by abortion service providers found that the procedures on having the abortion types were adequately described. However, information about the risks and benefits of each method were described less accurately and/or consistently. The findings from the trial indicate that a leaflet can enable women to make more informed decisions without increasing anxiety but does not impact on the type of abortion method chosen.

Conclusions: Most information about types of abortion method routinely provided by abortion service providers is not sufficient to enable women to make informed choices. However, services can meet policy objectives on informed patient decision making with minimal resource implications as the decision aid leaflet enabled women to evaluate more information about the risks and benefits of the abortion methods in accord with their own beliefs.

Publications from thesis

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Abbreviations.

CDSR	- Cochrane Database of Systematic Reviews
CINHAL	- Cumulative Index to Nursing and Allied Health Literature
DARE	- Database of Abstracts of Reviews of Effects
DoH	- Department of Health
D&C	- dilatation and curettage
MANOVA.	- multifactorial analysis of variance
MTOP	- Medical termination of pregnancy
MVA	- Manual Vacuum Aspiration
RCOG	- Royal College of Obstetricians and Gynaecologists
SMOG	- Simple Measure Of Gobbledygook
SPSS	- Statistical Package for the Social Sciences
STAI	- State-trait anxiety inventory
STOP	- Surgical termination of pregnancy
WHO	- World Health Organisation

Chapter 1 – Introduction

This chapter provides an overview of the issues associated with women's choices to have either a medical or surgical abortion. It will begin with an overview of the current NHS policy of abortion services, followed by evidence of the effectiveness of each abortion method, an outline of some issues in facilitating women in relation to informed decision making on abortion methods, and finally a discussion of the empirical evidence of women's decision making about abortion methods.

A literature search was performed to identify all literature that either evaluated surgical and medical abortion method or aspects of decision making for abortion method. Searches were performed on the following electronic databases: Medline (from 1966), Embase (from 1980), PsycINFO (from 1985), Cumulative Index to Nursing and Allied Health Literature (CINHAL) (from 1982), Cochrane Database of Systematic Reviews (CDSR), and Database of Abstracts of Reviews of Effects (DARE). The search terms comprised 'surgical abortion' OR 'medical abortion' OR 'abortion method' OR 'termination of pregnancy' OR 'decision making' OR 'informed choice' OR 'decision aid'. The specific search strategies were varied according to the search engine. The titles and abstracts were downloaded and scanned for suitability, excluding those that had no relevance. Complete copies of the remaining articles were obtained and selected for suitability. All the papers selected as suitable had their bibliographies reviewed to identify any further papers of relevance to the review.

1.1 Current policy

Abortions are provided in NHS hospitals and private clinics approved by the Department of Health (DoH). The current legislation in England and Wales enables abortion services to be carried out in these premises legally and in a regulated manner (RCOG, 2000). This legislation is based on the Abortion Act 1967, and was amended in 1990 by the Human Fertilisation and Embryology Act (Abortion Act, 1967; Human Fertilisation and Embryology Act, 1990). This legislation allows a pregnancy to be terminated up to 24 weeks, when continuation of the pregnancy would involve greater risk than if the pregnancy were terminated, or involve injury to the physical or mental health of the pregnant woman or any existing children of her family.

Many policies have been introduced within the NHS to ensure that medical services are performed to the highest standard possible (Department of Health, 2000). One of the aims of these policies is to enable patients to be fully involved in decisions about their care (General Medical Council, 1998; Department of Health, 2000). Offering choice is seen as a means of improving the patient and user experience by empowering them to make shared and sustainable decisions with the professionals. There is a consensus that making an informed decision requires the patient to be offered complete and accurate information that they may evaluate in accordance with their values before taking steps to act upon it (Bekker, 2003; Charles et al, 1999). The Royal College of Obstetricians and Gynaecologists (RCOG) refer to this framework of informed decision making when setting up guidelines on the organisation of abortion services (RCOG, 2000; RCOG, 2004). The guidelines recommend that services

should have local strategies in place for providing appropriate information to women on the choices available within the abortion service. Verbal advice must be supported by accurate, well-presented, impartial printed information that the women considering abortion can understand and which they may take away and read before the procedure (RCOG, 2000; RCOG, 2004). In addition, the guidelines state that professionals should possess accurate knowledge about the procedures, possible complications and sequelae of abortion (Department of Health, 2000; RCOG, 2000; RCOG, 2004). The professional should give patients information in a way that they can understand, and should respect the rights of the patients to be fully involved in decisions about their care (RCOG, 2000; RCOG, 2004).

1.2 Type of abortion methods

There are two main types of abortion method. The most established method in industrialised countries is surgical abortion. The medical method of abortion was developed in the 1990's. Both medical and surgical methods of abortion are effective procedures to terminate pregnancies of up to nine weeks gestation (RCOG, 2000). The uptake of the two abortion methods varies between countries; 20% of abortions in England, 30% of those in France and 60% in Scotland are carried out medically (Gupta, 1998; Thong et al,1992). The RCOG has recommended that each service provider in the UK should be able to provide at least one method of abortion for the relevant gestation. Ideally, a choice between abortion methods should be offered if possible (RCOG, 2000; RCOG, 2004). The following provides a brief description of both surgical and medical abortion.

1.2.1 Surgical abortion

Surgical abortion methods currently available are vacuum aspiration with or without dilatation and curettage (D&C) (Say et al, 2005). Vacuum aspiration is the evacuation of conception products using a vacuum source, either an electric pump or a hand-held plastic syringe (Manual Vacuum Aspiration, MVA). A cannula attached to the vacuum source is passed into the uterine cavity and the product of conception is evacuated. Vacuum aspiration is often performed as an outpatient or day-case procedure and can be performed under general or local anaesthesia.

D&C is still used routinely in many countries. It has been replaced by vacuum aspiration in most industrialised countries (Kulczycki et al, 1996). The product of conception is removed with a sharp metal curette following dilatation of the cervix. Softening of the cervix using prostaglandin before dilatation may be useful in order to reduce the incidence of cervical or uterine injuries and incomplete evacuation of the uterus (World Health Organisation (WHO) Scientific Group, 1997). D&C is usually performed under general anaesthesia although sometimes it can be carried out under local anaesthesia (Kulczycki et al, 1996). The complication rate of D&C is 2.3 times higher than with vacuum aspiration (Grimes & Cates, 1979).

The risks associated with surgical abortion are infections with an incidence of up to 10% (Sonne-Holm et al, 1981; Krohn, 1981; Westrom et al, 1981; Heisterberg & Petersen, 1985; Heisterberg & Gnarpe, 1988; Darj et al, 1987), cervical laceration up to 1% (Schulz et al, 1983), incomplete evacuation up to 0.23% (Kaunitz et al, 1985), uterine perforation up to 0.4% (Andolsek et al, 1977; Lindell & Flam, 1995; Hakim-

Ellahi et al,1990; Grimes, 1979; King et al, 1980; Hodgson & Protmann, 1974), haemorrhage up to 0.5% (Abortion statistics, 2000) and complication due to anaesthesia (MacKay et al, 1985; Grimes et al, 1979). Failed abortion was found in 2.3 per 1000 surgical abortions in a cohort of 33,090 women (Kaunitz et al, 1985). Risks can vary with the skills of the practitioner, gestational age, age and parity of the woman. The lowest major complication rate is when the procedure is performed at 49 to 56 days of amenorrhoea. Serious complications are more frequent in parous women and with increasing age (WHO Scientific Group, 1997). However, there is little empirical evidence to suggest that safe procedures are associated with long term morbidity such as future infertility (Daling et al, 1981; Daling et al 1985; Tzonou et al, 1993), miscarriages (Berkowitz, 1981; Dalaker et al, 1979; Maritius et al, 1998; Meirik et al, 1982) and low birth weight in subsequent pregnancies (WHO Division of Reproductive Health, 1998). Guidelines recommend conventional suction abortion as an appropriate method at gestation 7 – 15 weeks; surgical abortion may be an appropriate method at gestation of less than seven weeks, providing a rigorous published protocol is used (RCOG, 2000).

1.2.2 Medical abortion

Medical abortion methods involve the use of either prostaglandins or mifepristone alone, or a combination such as mifepristone with prostaglandins or methotrexate with prostaglandins. Prostaglandins (e.g. Gemeprost, metenoprost, misprostol) have a softening effect on the cervix, facilitate dilatation and can induce uterine contractions. Gemeprost and metenoprost given vaginally have been shown to terminate

pregnancies up to 49 days of amenorrhoea. These are less widely used because they require small doses at intervals of 3-6 hours i.e. it is a slow process (WHO Scientific Group, 1997). Misoprostol is a prostaglandin E1 analogue registered for the prevention of gastric ulcer related to the use of nonsteroidal anti inflammatory drugs. Misoprostol is more widely used as it is stable at room temperature, which makes it easier for transport, and it is less expensive than other preparations. Mifepristone is an antiprogestin and blocks progesterone receptors. This results in the breakdown of maternal capillaries in the deciduas, the synthesis of prostaglandins by the epithelium of the decidual gland and inhibition of prostaglandin dehydrogenase (WHO Scientific Group, 1997). Pregnancy support is inhibited and increased prostaglandin release induces uterine contractions. Mifepristone increases the sensitivity of the uterus to prostaglandins by a factor of five. This effect develops over 24 - 48 hours and this is the rationale for giving prostaglandins vaginally 36 - 48 hours after the administration of mifepristone. Mifepristone alone, with divided doses up to a total of 1600 mg given over a period of 4 - 7 days, was found to be successful in inducing abortion in 60 - 65% of cases for pregnancies up to 56 days of amenorrhoea (WHO Scientific Group, 1997). However in countries where there are problems with distribution of mifepristone, a regime involving misoprostol alone or in combination with methotrexate has been used. Methotrexate is a folic acid antagonist which inhibits purine and pyrimidine synthesis, thus halting cell division (Grimes, 1997). This combination is more effective when misoprostol is administered 7 days after methotrexate, as compared to 3 days, leading to a complete abortion rate of 98% (Creinin & Park, 1995).

The rate of failed abortion with continuation of pregnancy is around 2.3 per 1000 (Ashok et al, 1998). Both methotrexate and misoprostol may lead to foetal anomalies if the pregnancy persists (Grimes, 1997). Side effects of medical methods are moderate to heavy bleeding of less than 1% (Baird et al, 1995; El-Refaey & Templeton, 1995), pain, nausea and vomiting varying from 12 to 44% (Baird et al, 1995; El-Refaey & Templeton, 1995) and diarrhoea from 7 to 39% (Baird et al, 1995; Sang et al, 1994). The severity of the side effects of medical methods varies due to the protocols and gestational age involved (Henshaw et al, 1994).

1.3 Effectiveness of abortion method

The most frequent measures of effectiveness used to evaluate the different abortion methods are the success and morbidity rates of the procedures (Jensen et al, 1999; Child et al, 2001; Henshaw et al, 1993; Henshaw et al, 1994; Virgo et al, 1999; Wiebe, 1997; Winikoff et al, 1997; Bachelot et al, 1992; Cabezas, 1998). All studies have found that medical abortion has a higher failure rate, from 3% to 18% compared to between 0.5% and 6% for surgical abortion (see section 1.2). The failure rate for medical abortion increases as gestation increases but remains constant for surgical abortion (Cabezas, 1998; Child et al, 2001; Henshaw et al, 1993; Jensen et al, 1999; Winikoff et al, 1997). The reported level of pain, nausea, vomiting and diarrhoea in women having medical abortion is also higher than those having surgical abortion (Cabezas, 1998; Henshaw et al, 1994; Jensen et al, 1999; Slade et al, 1998; Winikoff et al, 1997). Women having medical abortion are more likely to have side effects during the follow-up intervals such as abdomino-pelvic pain, vaginal bleeding

(Child et al, 2001; Henshaw et al, 1994; Jenson et al, 1999) and more disruption in daily activities (Slade et al, 1998). Although visible blood loss reported by women tends to be higher for those having medical abortion, this is not related to differences in blood count levels (Cabezas, 1998; Henshaw et al, 1994; Jenson et al, 1999; Slade et al, 1998; Winikoff et al, 1997). Women having medical abortion were found to require more rest and sleep after being discharged from the hospital (Bachelot et al, 1992). On the other hand, a requirement for antibiotics by women who had surgical abortions is higher than for medical procedures (Henshaw et al, 1994), while surgical abortion is associated with the additional risk of anaesthesia but with local anaesthesia having a lower risk than general anaesthesia (MacKay et al, 1985). No difference in anxiety or depressive symptoms have been detected in women prior to and after either abortion method (Slade et al, 1998). Economic evaluations suggest medical abortion is more cost effective than the surgical abortion (Henshaw et al, 1994; Penney et al, 1995).

A few studies have assessed the effectiveness of methods in terms of women's satisfaction of their abortion experiences. Acceptability of both methods is high (Bachelot et al, 1992; Henshaw et al, 1993; Harvey et al, 2001; Jenson et al, 2000; Winikoff et al, 1997). Women having the medical procedure had greater overall satisfaction (Cabezas, 1998; Jensen et al, 2000; Winikoff et al, 1997). However, those with the highest level of dissatisfaction were also those who had had a medical abortion (Bachelot et al, 1992; Winikoff et al, 1997). Most women would recommend the method they had to a friend (Jenson et al, 2000). When asked what

method they would choose again, some studies reported most women would choose the same method again (Cabezas, 1998; Harvey et al, 2001; Wiebe, 1997; Winikoff et al, 1997), but others found about a third of women who had received a medical abortion would change to the surgical method (Slade et al, 1998), and over a third of the women would change from the surgical to the medical method (Jenson et al, 2000). One explanation for these contradictory findings is that satisfaction is highly dependant on how it is assessed (Robson, 2002). Some studies assessed satisfaction on a three point scale (Cabezas, 1998; Winikoff et al, 1997), while others assessed using a five point scale (Bachelot et al, 1992; Jenson et al, 2000). The different wording used by each scale such as "somewhat dissatisfied", "fairly dissatisfied" can influence the answer of the respondent. The different number of points and the wording used in each scale may be representative for the corresponding study being described, but the results cannot be generalised to all the studies on satisfaction of abortion methods since they are not comparable.

A few studies have looked at the association between the abortion experience, psychological outcome, anxiety and service satisfaction (Bachelot et al, 1992; Henshaw et al, 1993; Wiebe, 1997). The experience of more bleeding than expected and the failure of procedure in the medical group were related to a reduction in satisfaction (Jenson et al, 2000). Within the medical group, 56% who had seen the foetus were significantly more likely to be experiencing intrusive thoughts about their abortion than those who had not (Slade et al, 1998). One study showed that women having a medical abortion were more likely to ask to see what they had expelled,

which may suggest a desire to control the situation (Bachelot et al, 1992). The experience of discomfort or anxiety in relation to abortion, tended to be less than expected in both medical and surgical groups (Jensen et al, 2000). Women in the medical group both expected and experienced heavier and longer bleeding than did the surgical group (Jensen et al, 2000; Harvey et al, 2001). The mean experience for bleeding length exceeded the expectation for both groups in one study (Jensen et al, 2000) but not in the other (Harvey et al, 2001).

1.4 Decision making on abortion methods

Comparison between medical and surgical abortion methods has been made in many studies (see 1.3) but most of the comparisons have evaluated methods in terms of effectiveness and satisfaction (See 1.3). Few have studied women's decision making about options and / or whether women are making informed decisions when choosing between the two abortion methods. The following summarises the evidence describing women's decision making about abortion methods.

1.4.1 Models of healthcare communication about decisions

Decision making in the context of the interaction between patients and professionals has been divided into three models: the paternalistic model, the informed model and the shared model (Charles et al, 1999). In the paternalistic model, the patient passively accepts the doctor's choice of treatment. The patient assumes that the doctor will make the best treatment decision for her. This decision is made without considering the patient's personal values or her involvement in the decision making

process. There is no sharing of information within the decision making steps in this model (Charles et al, 1999). In the informed model, the doctor communicates information to the patient on all relevant treatment options. The amount and type of information communicated should at least include the minimum amount of information with sufficient pros and cons of each option for the patient to make a decision between options. The patient then makes her own decision reflecting her own preference. The doctor's treatment preferences do not enter into the decision making process. The information exchanged is one way i.e. from doctor to patient (Charles et al, 1999). In the shared model, there is interaction between the doctor and patient. They share all stages of the decision making process simultaneously. There is a two-way exchange of information. Both doctor and patient explicitly discuss their treatment preferences and then both agree on the decision to implement (Charles et al, 1999). In everyday practice, many clinical decision making interactions reflect a mixture of the three models (Charles et al, 1999). In early gestation, both abortion methods are proven to be effective. With the absence of any medical indication, the choice of abortion method is value led, i.e. it depends on the woman's preferences. The informed model of decision making is the most suitable model for this healthcare communication because the decision depends on the women's values and not medical expertise (Bekker, 2003). To enable women to make an informed choice the professional must provide good information. The woman must be encouraged to engage actively with this information in order to make an effective choice and to ensure that it is an informed one (Bekker, 2003). A decision is informed if it is based on an evaluation of information relevant to the alternatives and their consequences, an

accurate evaluation of the likelihood and desirability of these consequences in accordance with the woman's benefits; and a 'trade-off' between these evaluations is made (Bekker, 2003).

A key role for health professionals to enable informed decision making and to provide adequate information. Information aids that are well constructed help people to understand their condition and general health management (O'Connor & Edwards, 2001). Provision of good information has been shown to reduce the stress associated with undergoing procedures, i.e. to prepare patients (Johnston & Volgele, 1993). However, to help people making decisions, decision aids are required.

Previous studies on information provision have been found to be inadequate in many aspects of medical care (Davis & Fallowfield, 1991; Deeny & McCrea, 1991; Ewing, 1989; Hayward, 1975). No systematic evaluation of information provision on abortion methods has been performed to assess whether or not current practice has met appropriate criteria. From prior evidence in the area of information provision and guidance on informed decision making, adequate information should include: a description of the procedure for each abortion method; an explanation of the risks and side effects of each option; information on the benefits, and guidance on aftercare. In addition, the information should be written in plain English with high readability and in a well presented manner (Coulter et al, 1998; Duman & Farrell, 2000; Ley & Llewelyn, 1995). Decision aids have been developed to help people focus on a deliberate choice between two or more treatment options (Bekker, 2003; O'Connor &

Edwards, 2001). Decision aids tend to restructure the content of the decision information to make it easier for patients to process. Decision aids tend to have some kind of a visual representation of the problem, alternatives, benefits, risks and consequences of all decision options. In addition, the aids encourage patients to explicitly discuss their values or attitudes towards the decision options and consequences (Bekker, 2003; O'Connor et al, 1999). The aim of decision aids is to create realistic expectations of the consequences of the decision and to clarify values (Bekker, 2003; O'Connor et al, 1999). Evidence indicates that patients provided with a decision aid, in a range of health contexts discuss more of the decision relevant information, perceive themselves to be more involved in the decision process, are more satisfied with their choices, tend to have greater knowledge about the decision options, and appraise the decision information more realistically (Bekker et al. 2004; O'Connor & Edwards, 2001).

1.4.2 Decision making on abortion methods

There is little literature assessing women's decision making about choosing between abortion methods. Most studies on women's decision making on abortion methods explain differences in choices by demographics (Bachelot et al, 1992; Cabezas, 1998; Harvey et al, 2001; Henshaw et al, 1994; Jensen et al, 1999; Wiebe, 1997). In brief, women who have achieved higher educational qualifications, have a higher occupational class and are in a stable relationship tend to choose medical abortion (Bachelot et al, 1992; Cabezas, 1998; Henshaw et al, 1994); women who are younger and live further away from the clinic tend to choose surgical abortion (Bachelot et al,

1992; Henshaw et al, 1993; Henshaw et al, 1994; Slade et al, 1998; Tang, 1991; Wiebe, 1997). However, no single contributing factor in demography has been reliably associated with preference for choice. Also, these types of analyses do not provide insights into why these differences occur and whether these choices were informed.

In keeping with the model of informed decision making, women should consider the risks and benefits of both methods before making a choice. Few studies have examined the reasoning prior to decision making, most have focused on describing women's reasons for their choice in retrospect (Bachelot et al, 1992; Harvey et al, 2001; Henshaw et al, 1994; Tang, 1991; Wiebe, 1997). In summary, their findings indicate that the most common reason for choosing medical abortion was to avoid an aspect of surgery such as anaesthetic. Others perceived the medical abortion as a simpler, more natural and less invasive method with less risk to future fertility (Bachelot et al, 1992; Harvey et al, 2001; Henshaw et al, 1993; Slade et al, 1998; Tang, 1991; Wiebe, 1997). In contrast, for those that chose the surgical method, the most common reason was to avoid awareness and involvement in the process of abortion. Other reasons included avoidance of pain and emotional impact, perceived efficacy and fewer visits than the medical method (Bachelot et al, 1992; Henshaw et al, 1993; Slade et al, 1998; Tang, 1991; Wiebe, 1997).

As their reasons for their choice were assessed retrospectively, it is possible that they do not accurately reflect the reasoning process. For example, recall bias can occur

which relates to women's selective memory in recalling past events and experiences. Secondly, the women may experience "cognitive dissonance" when they hold two thoughts that are psychologically inconsistent (i.e. when a woman has contradictory thoughts on the chosen abortion method, she may alter her reason to reduce the dissonance). In addition, how question are asked may impede our understanding of women's reasoning. For example, when women were simply asked for their reasons for their choice, their responses tended to include only the most important one, rather than all the reasons such as the advantage and disadvantage of each method being considered in their decision. One of the studies asked participants to rate the importance of 21 characteristics in their choice between the two methods (Harvey et al, 2001). This method is more likely to explore different factors which women have evaluated when deciding on an abortion method. On the other hand, this study, like the other studies mentioned, asked participants' reasons for their choice after their initial decisions were made, thus reducing the reliability of the responses generated (Robson, 2002).

In order to make an informed decision, woman would need to be offered a choice prior to the decision making process and be able to choose according to their preferences. Two studies have confirmed that most women like being offered a choice on abortion methods (Henshaw et al, 1993; Slade et al, 1998). However, about one third of the women having the medical method, and over two thirds of the women having the surgical method, felt they played no part in the decision about method (Slade et al, 1998). Some women had erroneous views about the choices between methods,

perceiving that they were too late to have a medical abortion, or that one method was better at this gestation despite both methods being equally available, and some believing one method was available more quickly than the other (Slade et al, 1998). Further, some women were not even aware of having a choice between abortion methods or were not aware why they had experienced a particular method (Slade et al, 1998). A further study assessed knowledge of medical abortion as a hypothetical option; where women were provided with a brief written description of the method with the questionnaire. Results suggested women were confused about this 'new' method and some had mistaken it as a type of contraception (Virgo et al, 1999). Although the option of medical abortion was hypothetical, this study demonstrated that the information provided was not well understood, and that the women were unable to utilise the information in order to make an informed judgement. Finally, one study looked at non-pregnant women in the awareness of medical abortion. More than one-third of the participants had never heard of the procedure and the majority expressed confusion about the method (Harvey et al, 1995). These studies suggest that information about medical abortion is unclear to women. Further, a large number of women seem unaware that they had a choice between methods, suggesting it is unlikely that they are in a position to make an informed choice between methods.

As discussed earlier, there is evidence of discrepancies between expectation and experience of the abortion. For example, women having medical abortion experience more vaginal bleeding than expected (Jenson et al, 2000), the length of bleeding is more than expected for both methods (Jenson et al, 2000), and abortion related anxiety

and discomfort has been less than expected in both methods (Jenson et al, 2000). The discrepancies between expectation and experience in abortion can possibly be explained by inadequate information provided to the women prior to their decision. It is thought that decision aids can help to reduce the gap between expectation and experience (Bekker, 2003). Therefore, improving information provision on abortion methods may reduce these discrepancies and improve women's experience of the service and decision making about this treatment choice.

1.4.3 Critique on methods used for studies investigating women's decision making between medical and surgical abortion

The few studies performed on decision making on abortion methods were carried out under different circumstances and methods. The following section discusses the variation between each study and how these issues affect the generalisation, validity and reliability of their findings.

The regime of medical abortion offered varied between studies. Due to the unavailability of mifepristone in the US, two studies used methotrexate given by injections in clinics, followed by misoprostol given vaginally at home or in clinic four to eight days after the initial injection (Harvey et al, 2001; Wiebe, 1997). In other countries where mifepristone was available, 200mg to 600mg of mifepristone was given in the hospital or clinic followed by prostaglandin after 48 hours. The use of prostaglandin also differs between studies, some may have used gemeprost (Henshaw et al, 1994), while other used misoprostol (Cabezas, 1998; Winikoff et al, 1997) or sulprostone (Bachelot et al, 1992). The dosage being used also differs between

studies. The route of administering the treatment can vary from oral, intramuscular to per vagina. Depending on the regime used, the second visit to administer prostaglandin and the duration for observation in the clinic varies (Bachelot et al, 1992; Cabezas, 1998). Variation in regime used in each study can be a confounding factor when assessing the women's choice of abortion method. For example, a woman may choose the medical method because the second treatment can be given at home, but may not choose the same method if the second treatment has to be compulsorily given in the clinic requiring a second visit. On the other hand, another woman may choose the surgical method because she does not wish to have the first treatment which has to be given by injection (using the methrotexate regime), but she may choose the medical treatment if the first treatment can be given orally (using the mifepristone regime). Hence, the outcome between these studies cannot be generalised due to the presence of different confounding factors caused by different regimes used. Variation in the regime also occurred with the surgical method when the procedure on offer can be performed under local anaesthetic or general anaesthetic.

Availability of the medical treatment varied within the general population for each study varied. One study offered the medical treatment as a new treatment within a clinical trial (Harvey et al, 2001). Results from the sample have limited generalisability. It is possible that users of a new technology may differ from those who choose a method after it has become more established and familiarised (Harvey et al, 2001). Two other studies offered medical treatment as a less well established treatment despite being generally available (Bachelot et al, 1992; Henshaw et al,

1993). Participants from these studies can still be influenced by the novelty of the new treatment. Only one study offered the medical treatment as an established and routine method (Slade et al, 1998), the results of which are more likely to be applicable to current practice, as the use of medical treatment is no longer a new or unusual option. Few reliable conclusions can be drawn about women's reasoning from these studies. The recruitment of participants in each study occurred at different stages of the consultation and / or treatment. In one study, the women were recruited on their visit for the abortion procedure before the treatment was being performed (Slade et al, 1998), while another study recruited women at their first visit after their decision was made (Harvey et al, 2001). In two other studies, the women were recruited before they made their choice on abortion method (Bachelot et al, 1992; Harvey et al, 2001; Henshaw et al, 1993). Finally, one study recruited some of the participants before they were offered a choice on abortion method, while some of the participants were recruited after they had made a decision on the abortion method (Wiebe, 1997). Selection bias within the sample is more likely to have occurred if the women were only recruited after they had made the decision on the abortion method, and their results will be less reliable compared to those who were recruited before the decision was made (Robson, 2002; Sackett, 1978). Hence, when participants were recruited at different times within the same study, the results obtained would be the least reliable due to selection bias within the same population studied.

Two of the studies have multiple aims (Harvey et al, 2001; Henshaw et al, 1993; Henshaw et al, 1994); the efficacy of the treatment, acceptability of the treatment and

decision making about the treatment. These studies were less able to focus on the decision making process when choosing an abortion method. These multiple aims mean that decision making concerns were not well generalised, so the results could not be meaningful. Most of the studies have noted that follow-up was less well attended with the surgical group compared to the medical group (Bachelot et al, 1992; Harvey et al, 2001; Slade et al, 1998; Wiebe, 1997). The discrepancies in the response rate between the two groups may mean that one group is being less well represented and possibly reduced the reliability of the final result.

As discussed in the previous section, most of the studies have only enquired about women's reasons for their choice of abortion method. In most cases, only one reason was given for their choice but none have taken into account all the reasons they had evaluated during decision making (Bachelot et al, 1992; Slade et al, 1998; Wiebe, 1997). These studies have assessed part of the decision making process but have not provided a complete picture of the process. In most instances, there is no evidence to indicate whether the decisions made were informed or not. Further, all the participants involved were given verbal and written information on recruitment details of the study (Bachelot et al, 1992; Harvey et al, 2001; Henshaw et al, 1993; Slade et al, 1998; Wiebe, 1997). As no explicit description of the materials was given, it is unclear whether or not this information was useful in informing decision making.

1.5 Thesis aim

This thesis is concerned with facilitating women's decision making about surgical and medical abortion; and in particular, the role of the health professional in providing adequate information. The aim of this thesis is to develop written information that will facilitate women's decision making about treatment choices for abortion methods.

1.5.1 Research objectives

1. To describe the quality of written information currently available for abortion methods (See Chapter 2).

2. To describe the quality of verbal information currently available for abortion during a routine consultation (See Chapter 3).

3. To develop a leaflet to facilitate women's choices about abortion methods (See Chapter 4).

4. To evaluate the effectiveness of the leaflet to facilitate decision making in terms of choice made, decisional conflict, effect and reasoning (See Chapter 4).

Chapter 2 - Provision of written information about abortion methods

2.1 Introduction

Health policy in the UK has emphasized the importance of adequate information provision to patients with regard to all treatments (General Medical Council, 1998; Department of Health, 2000). Patients have a right to be given a clear explanation of any treatment proposed, including any risks and alternatives, before they decide whether to agree to the treatment (Department of Health, 1991). In addition, the NHS Plan suggests that patients should be more involved in looking after their own health (Department of Health, 2000). In the context of abortion, The Royal College of Obstetricians and Gynaecologists (RCOG) recommends that women should be provided with information on choices available within the service. Verbal advice must be supported by accurate, impartial printed information which the woman considering abortion can understand and may take away and read before the procedure to facilitate involvement in decision making (RCOG, 2000).

Evidence has shown that patients do not feel that they have been adequately informed about their healthcare (Ley, 1988). Patients have frequently complained about the lack of information given to them about their care (Davis & Fallowfield, 1991; Deeny & McCrea, 1991; Ewing, 1989; Hayward, 1975). Printed educational material is frequently provided to meet the needs of patients for good information that can be taken away (Meade & Smith, 1991; Merritt et al., 1993). Provision of written

information can ensure the delivery of complete information that may act as a memory prompt. Evidence has shown that patients given written information prior to discharge suffer less pain, less anxiety and go home earlier than other patients (Ley, 1988). Studies of psychological preparation for medical procedures demonstrate that provision of information for enhancing the patient's ability to tolerate the uncertainties can reduce the stressfulness of the experience. It has generally been found that patients given written information are more likely to express satisfaction with the patient / health professional relationship (Dixon, 1995; Hawkey & Hawkey, 1989). However, the information produced needs to be good quality. In general, written information has been found to be defective in content and difficult to read in many health contexts. (Coey, 1996; Dixon & Park, 1990; Ley, 1988; Meade & Wittbrot, 1988; Murray et al, 2001; Owens et al, 1993).

General guidelines on production of patient literature have been published and been frequently reviewed in recent years. (Centre for Health Information Quality, 1997; Centre for Health Information Quality, 2001; Glasser & Squires, 1994). Written information should include an accurate description of procedure, benefits and risks and the consequences involved. There is little evidence that these criteria have been met in the field of obstetrics and gynaecology. The RCOG guidelines have made recommendations on methods of abortion suitable for each gestation band. Women should be given accurate, impartial printed information about these methods which they can understand and take away to read before the procedure (RCOG, 2000). To

date, there are no published studies on the quality of written information for women on deciding the method of abortion within the NHS and private providers.

This study aims to assess the quality of written information about abortion methods from different providers of services in England and Wales. Its objectives are:

- To assess the methods of abortion offered by each service provider.

- To assess the readability of the information leaflet provided by each service provider.

- To assess the quality of the information content in each leaflet by the service provider.

2.2 Methods

2.2.1 Design

This study is a cross-sectional survey of information leaflets about abortion method offered by providers of abortion within England and Wales between February and July 2001.

2.2.2 Sample

To ensure that a broad range of service providers were assessed, this study includes a purposive sample of NHS district hospitals, NHS teaching hospitals and non-NHS agents. Three district hospitals from each executive region, one teaching hospital from each medical school in England and Wales and three main private abortion providers were contacted by telephone and asked to send their patient information leaflets about abortion method offered by their service.

2.2.3 Materials

A coding frame was developed for this study by the author with reference to the literature on guidelines for adequate information provision, effective decision making and RCOG guidelines on abortion service provision (Bekker et al, 1999; Centre for Health Information Quality, 2001; RCOG, 2000). The purpose of a coding frame is to extract the same type of information from each leaflet. The coding frame was piloted on the first five information leaflets received. The data extracted were discussed with the primary supervisor and then the coding frame was revised. This

process helped to increase the validity of the coding frame by ensuring the checklist within the coding frame was suitable to extract, without bias, appropriate and adequate information for the assessment of each leaflet in respect to its purpose. Appropriateness and adequacy were further double-checked by a second party.

The information elicited from service providers and leaflets is described below. The coding frame categorised four types of information: 1) explicit issues regarding informed choice about method of abortion offered, 2) readability scores, 3) quality of the information content of the leaflet, 4) others (See Appendix I for coding frame). The details of the coding frame are described below.

2.2.3.1 Provider and service provision

This part addresses the objective which is necessary to extract information about the abortion method being offered with the gestation included. In the developmental stage of the coding frame, the method of abortion available from the provider and the method offered in the information leaflet were noted. As methods of abortion offered varied with gestation, the gestation limit for methods provided was added to the coding frame (See Appendix I for coding frame).

2.2.3.2 Choices available to women

The RCOG has recommended appropriate information on abortion should also be available to those who consider, but do not proceed to abortion. (RCOG, 2000) Therefore, offering the choice of not having the abortion is as important as offering

women the methods available. Hence, the choice to continue with the pregnancy has been added in the final phase of the coding frame. (See Appendix I for coding frame)

2.2.3.3 Adequacy on information provided for abortion method

The aim was to assess the quality of the information provided with respect to facilitating informed decision making. The information provided should at least contain the pros and cons of each treatment option, including the risks, side effects and benefits of each procedure. In the context of abortion, the information should include:

- The abortion procedure for each option, the number of admissions required, the reason and way the medication is given, how the procedure is carried out.

- Explanation of the risks involved with each method should include the likelihood of bleeding, infection, retained products of conception and other risks which specifically apply to the method.

- Description of aftercare should include issues on self-care such as travel and domestic arrangements, bleeding, pain, contraception and counselling service.

In order to score the content quality, the following system was used. A mark was given for each correct description of information: a) The score for a description of the procedure and risk of termination were then added together to give a score with a full mark of 23 for surgical termination and 21 for medical termination, b) The score for a

description of aftercare for the abortion was be added up with a full mark of 11. Ideally, the inclusion of all items should be expected in all of the leaflets. As there is no minimum sufficient level of information to be included, 50% of items included were used on the assessment. The aim was to achieve half of the items mentioned on the checklist for each leaflet.

2.2.3.4 Readability score

Readability formulas are used to determine how accessible written information is to the public (Ley 1988). After the collection of five leaflets, leaflets were graded by McLaughlin's SMOG Grading (McLaughlin, 1969). Two problems were observed. The McLaughlin's SMOG Grading required three samples of 10 sentences to assess readability, two leaflets assessed were found to contain less than 30 sentences in the whole leaflet. In consequence, those leaflets were rated on their total number of sentences. Then the total score was multiplied by 30 and then divided by the number of sentences it contained. In addition, the Flesch Reading Ease score within the Microsoft Word [™] software package was also applied to the leaflets to ensure the readability assessment was reliable. Sometimes a service offered more than one leaflet to explain the different termination choices at different points in their services. Therefore, in those services that provided two or more leaflets, an equal number of sentences were picked at random from each leaflet provided. The final phase of the readability score included:

- SMOG Grading – ranging from 0 to 16, with 0 to 4 being very easy and 15 to 16 being very difficult.

- Flesch Reading Ease – ranging from 0 to 100, with 91 to 100 being very easy and 0 to 30 being very difficult.

2.2.3.5 Others

With respect to guidelines for the production of patient information, the name of the organisation involved and date of production were included in the coding frame (Duman & Farrell, 2000). In addition, confidentiality as an important issue within the provision of an abortion service has also been included in the coding frame (RCOG, 2000).

2.2.4 Procedure

The following organisations were contacted to obtain a comprehensive list of providers of abortion services within and outside the NHS sector: RCOG, Department of Health, Family Planning Association and The Abortion Law Reform Association. The DoH list of approved independent sector places for termination under the Abortion ACT 1967 was available on their website. As there is no official list for hospitals or clinics that provide abortion services within the NHS sector, three district hospitals in each executive region were purposively selected from the IHSM Health and Social Services yearbook 1999 / 2000 and contacted. The hospitals were listed in alphabetical order in each region. The first, middle and last hospital listed in each

region were contacted. If the hospital contacted did not provide an abortion service or did not provide any information leaflet, this point was noted and another district hospital listed above or below that hospital in the same region was then selected, until three sets of patient information leaflets were obtained from each region.

Patient information leaflets were also obtained from a purposive selection of teaching hospitals. Teaching hospitals explicitly linked with a medical school were contacted. Those that did not provide abortion services or an information leaflet were noted. Each NHS service provider was contacted through the gynaecology secretary or staff in the gynaecology clinic. Each provider was asked about the type of abortion available.

The three largest abortion providers in the private sector which have branches all over the UK were selected from the DOH website. They were contacted through their branch manager.

All the information leaflets collected were assessed using a coding frame as described previously. The coding frame was applied to each leaflet to assess the information content systematically.

2.2.5 Data analysis

All the data were entered and managed using the Statistical Package for the Social Sciences (SPSS) for analysis. Descriptive analysis was applied to all the data obtained

from the coding frame. Multivariate analysis was used to assess differences between different types of service provider of abortion and total scores of content quality.

2.3 Results

2.3.1 Provider and service provision

Seventy-two providers of abortion services were contacted in this study. All three private agencies offered both types of abortion and provided information leaflets for women. Fifty-two NHS district hospitals were contacted, 13 hospitals did not provide abortion services, and 12 hospitals offered abortion services but did not provide information leaflets routinely. Twenty-seven NHS district hospitals (from nine regions) offered abortion services and information leaflets.

Seventeen NHS teaching hospitals were contacted, one did not offer an abortion service and a further two offered abortion services but did not provide an information leaflet. Fourteen NHS teaching hospitals contacted offered abortion services and provided an information leaflet. Hence, forty-four sets of patient information leaflets on abortion were used in this study.

2.3.2 Service characteristics

Among all the service providers of abortion that provided patient information leaflets, the NHS district hospitals were significantly less likely to offer both abortion methods

compared to the NHS teaching hospitals and private service providers. (Chi-square = 9.867, df = 2, p = 0.007) (Table 2.1)

	NHS district hospital n = 27	NHS teaching hospital n = 14	Private agent n = 3	Total n = 44
	No. (%)	No. (%)	No. (%)	No. (%)
Surgical method	14 (52)	1 (7)	0 (0)	15 (34)
Both methods	13 (48)	13 (93)	3 (100)	29 (66)
Total	27 (100)	14 (100)	3 (100)	44 (100)

Table 2.1: Type of termination procedure provided by different service providers

Among the 44 service providers of abortion that provided patient information leaflets, only 29 of them provided both abortion methods. One of the NHS district hospitals did offer both options but only the leaflet for medical abortion was obtained. This leaflet explained only the medical option. Despite several further attempts to contact the hospital, the author was unable to find out whether or not the leaflet for surgical abortion was available. Therefore, only 28 sets of leaflets were assessed. Nearly one third of the leaflets did not include both abortion methods on offer on each of their leaflets. (Table 2.2) No significant difference was noted between NHS teaching hospitals, district hospitals and private agents. (Chi-square value = 1.667, df = 2, p = 0.435)

	NHS district hospitals n = 12	NHS teaching hospitals n = 13	Private agents n = 3	Total n = 28
	No. (%)	No. (%)	No. (%)	No. (%)
Leaflet mentioned both methods	8 (67)	8 (61)	3 (100)	19 (68)
Leaflet mentioned one method	4 (33)	5 (39)	0 (0)	9 (32)
Total	12 (100)	13 (100)	3 (100)	28 (100)

Table 2.2. Abortion method informed in the information leaflet by different service providers offering both abortion methods

All 44 sets of leaflets were assessed for their reference to women's choice to continue with their pregnancy or not. Over two thirds of leaflets did not mention that women could change their mind and continue with the pregnancy. (Table 2.3) No significant difference was noted between different service providers. (Chi-square value = 1.451, df = 2, p = 0.484)

	NHS district hospital n = 27	NHS teaching hospital n = 14	Private agent n = 3	Total n = 44
	No. (%)	No. (%)	No. (%)	No. (%)
No reference made	18 (66)	10 (72)	3 (100)	31 (70)
Made reference	9 (34)	4 (28)	0 (0)	13 (30)
Total	27 (100)	14 (100)	3 (100)	44 (100)

Table 2.3. Reference to women's choices to continue with pregnancy or not

Finally, over one third of the service providers did not included details of the gestation limit for the abortion method on offer. (Table 2.4) No significant difference was noted between different service providers. (Chi-square = 4.684, df = 2, p = 0.096)

	NHS district hospital n = 27	NHS teaching hospital n =14	Private agent n = 3	Total n = 44
	No. (%)	No. (%)	No. (%)	No. (%)
Not mention gestation limit	13 (48)	3 (21)	0 (0)	16 (36)
Mention gestation limit	14 (52)	11 (79)	3 (100)	28 (64)
Total	27 (100)	14 (100)	3 (100)	44 (100)

Table 2.4. Gestation limit informed in the information leaflet by different service provider

2.3.3 Adequacy of information provided

The content of the leaflet was divided into four main categories: description of surgical method & risks, description of medical method & risk, description of aftercare, and miscellaneous.

Among the NHS district hospitals, twenty-six leaflets on surgical abortion, thirteen leaflets on medical abortion and twenty-seven leaflets on aftercare were collected. Fewer than 70% (18/26) obtained a score of 11 or less out of 23 (less than half of the content in the checklist) on description of surgical method & risks. Over 50% (7/13) obtained a score of 10 or less out of 21 (less than half of the content on the checklist) on description of medical method & risks. Fewer than 30% (8/27) obtained a score of 5 or less out of 11(less than half of the items on the checklist) on description of aftercare.

From the NHS teaching hospitals, fourteen leaflets on surgical abortion, thirteen leaflets on medical abortion and fourteen leaflets on aftercare were collected. Over one third (5/14) obtained a score of 11 or less out of 23 in their description of surgical method & risks. Over one fifth (3/13) obtained a score of 10 or less out of 21 in their description of medical method & risks. Seven percent (1/14) obtained a score of 5 out of 11 in their description of aftercare.

All three private agencies provided leaflets on surgical and medical abortion and aftercare. Scores on the descriptions of surgical method & risks range from 9 to 11 out of 23. Scores on the description of medical method & risks range between 13 and 14 out of 21. Scores on the description of aftercare range from 5 to 8 out of 11.

Most of the leaflets scored half of the items listed on the checklist (Table 2.5). Significant differences were noted between NHS district hospitals and NHS teaching hospitals on the description of surgical method & risks ($F = 4.005$, $df = 1$, $p = 0.053$) and medical method & risks ($F = 5.293$, $df = 1$, $p = 0.030$).

	NHS district hospital n = 27		NHS teaching hospital n = 14		Private agent n = 3		Total n = 44	
	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI
Surgical method & risk score (0-23)	9	7 – 11	12	10 – 14	10	7 – 12	10	9 – 11
Medical method & risk score (0-21)	10	8 – 12	13	11 – 14	13	12 – 15	12	10 -13
Aftercare score (0- 11)	7	6 – 8	8	7 – 9	7	2 – 11	7	6 – 8

Table 2.5. Score on content of information leaflet by different service provider.

2.3.4 Readability

The SMOG Grading and Flesch Reading Ease were applied to all 44 sets of information leaflets. Flesch scores between 61 to 100 and SMOG scores between 8 to 4 indicate that the reading material is standard to very easy to read (Coey, 1996), and should be understood by about 85% of the population.

When using the SMOG Grading, none of the leaflets achieved a score of 8 or less (standard to very easy to read); thirty-three leaflets (75%) achieved a score between 11 and 14 (difficult to read); 25% achieved a score between 9 and 10 (fairly difficult to read). No significant differences were noted between NHS district hospitals, NHS teaching hospitals and private agents. (Chi-square = 1.573, df = 2, p = 0.455) (Table 2.6)

When the Flesch Reading Ease was applied, two leaflets (4%) achieved a score between 41 and 50 (difficult to read); twenty-three leaflets (53%) achieved a score between 51 and 60 (fairly difficult to read); seventeen leaflets (39%) achieved a score between 61 and 70 (standard to read); and two leaflets (4%) achieved a score between 71 and 80 (fairly easy to read). No significant differences were noted between NHS district hospitals, NHS teaching hospitals and private agents. (Chi-square = 4.072, df = 6, P = 0.667) (Table 2.6)

	NHS district hospital n = 27		NHS teaching hospital n = 14		Private agent n = 3		Total n = 44	
	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI
SMOG score	11	10 – 11	10	10 – 11	11	8 – 13	11	10 – 11
Flesch score	59	57 – 61	62	58 – 65	58	58 – 59	60	58 – 62

Table 2.6. Readability score on information leaflet by different service provider.

2.3.5 Others

The majority of the leaflets included the name of their organisation. (Table 2.7) Over one third of the leaflets have not included the date of production. (Table 2.8) No significant differences were noted between NHS district hospitals, NHS teaching

hospitals and private agents on issues of confidentiality (Chi-square = 0.161, df = 2, p = 0.923), name of organisation (Chi-square = 1.319, df = 2, p = 0.517) and date of production (Chi-square = 0.020, df = 2, p = 0.990). Two thirds of the leaflets have not mentioned the issue of confidentiality. (Table 2.9)

	NHS district hospital n = 27		NHS teaching hospital n = 14		Private agent n = 3		Total n = 44	
	No.	%	No.	%	No.	%	No.	%
Not stated organisation	2	7	0	0	0	0	2	4.5
Stated organisation	25	92	14	100	3	100	42	95.5
Total	27	100	14	100	3	100	44	100

Table 2.7. Organisation stated in information leaflet by different service provider

	NHS district hospital n = 27		NHS teaching hospital n = 14		Private agent n = 3		Total n = 44	
	No.	%	No.	%	No.	%	No.	%
Not stated date of production	10	37	5	35	1	33	16	36
Stated date of production	17	63	9	64	2	66	28	63
Total	27	100	14	100	3	100	44	100

Table 2.8. Date of production stated in information leaflet by different service provider

	NHS district hospital n = 27		NHS teaching hospital n = 14		Private agent n = 3		Total n = 44	
	No.	%	No.	%	No.	%	No.	%
Not stated confidentiality	19	70	9	64	2	66	30	68
Stated confidentiality	8	29	5	35	1	33	14	31
Total	27	100	14	100	3	100	44	100

Table 2.9. Confidentiality stated in information leaflet by different service provider

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2.4 Discussion

This study describes the quality of written information provided by abortion services in England and Wales to women choosing to have medical or surgical abortions. A quarter (14/58) of services contacted did not support verbal advice with leaflets and were not following current RCOG guidelines (RCOG, 2000). Of those abortion services that provided leaflets, a third (14/44) offered only the surgical option. Most leaflets contained incomplete information about the abortion choices and were difficult to understand. In addition, not only was the quality of this written information poor, quality varied across service providers with NHS teaching hospitals providing slightly better materials. As the leaflets were obtained by telephoning the service providers, it was impossible to ascertain who wrote the leaflet from either the telephone conversation or the leaflets. An informed decision involves women being informed by adequate and neutral information about the procedure including the risks and benefits involved (Bekker et al, 1999). This study has shown that women were provided with written information but it included incomplete information on the procedure and the risks and benefits involved. As it is the role of service providers to provide adequate information, it seems unlikely that women are being enabled to make an informed choice.

Further, this systematic analysis of the leaflets' content provides a basic appraisal of the quality of written information provided by hospitals and clinics to thousands of health care users. The 44 clinics represented in this study included a range of NHS hospitals across health regions and the three largest private service providers; it is

estimated that the leaflets evaluated within this study were, and will be, accessed by approximately 100,000 women per year (Office of National Statistics, 2000). This suggests these women are unlikely to have been enabled by the service providers to make an informed decision.

This study has shown that leaflets did not provide complete and accessible information to women, and they have not met current RCOG guidelines. However, the limitation of this design is that the content of consultation about abortion methods was not evaluated. It remains an empirical question whether or not health professionals in the abortion clinics provide sufficient information during the consultation that enables women to make informed choices. Further, there is some evidence in other health areas that good quality written information has a role to play in women's decision making about treatment choices (O'Connor et al, 1999) and is associated with better patient outcomes (Bekker, 2003; Johnston & Vogele, 1993; Ley & Llewlyn, 1995). This study did not ascertain the role of written information in women's decision making about abortion method and/ or impact on outcomes. In addition, it is likely that women obtained information from other sources such as GPs, nurses, parents, relatives, media including newspapers, magazines, TV and the internet. It is unclear how important the service provider information is, especially when women can access information from other sources.

This study is one of the first to evaluate the quality of written information about abortion methods The main strengths were firstly that the leaflets collected were

widely representative of those offered by service providers in England and Wales; and secondly their structured content analysis was informed by guidelines of good information provision. The development of the coding frame was thorough, involving several stages of discussion with a second party on its development. This procedure meant the coding frame was used as a reliable instrument to assess the leaflets. A possibility for further improvement would be to obtain a second party to reapply the coding frame to all the leaflets as a quality check. This would ensure the same result is obtained; hence the first result obtained is reliable. In addition, the coding frame can be improved by performing further assessment on how the risk of each procedure was described including issues such as variation within the figures provided, the amount of time and word description for each risk involved and whether or not the descriptions were opinionated or neutral.

Readability scores varied when the leaflets were assessed with the SMOG Grading and Flesch Reading Ease. This variation could be caused by the different factors used in the two formulas. In the SMOG Grading, only words with three or more syllables were used in the formula, while the average length of the sentences and the word length relating to syllables present were taken into account in the formula for Flesch Reading Ease.

2.5 Recommendations

The main recommendation from this research is that abortion services should provide complete, accurate, relevant and unbiased written information about abortion method choices accessible to the general population. This information should be informed by guidelines on the aims, benefits, risks and procedures of each abortion method and assessed for ease of readability. The information should also be regularly updated in the light of changing technologies and findings of their effectiveness. Further research is required to evaluate the effectiveness of good quality information and decision aids in facilitating women's decision making on treatment alternatives. Since the study was completed, the Family Planning Association has produced a leaflet on abortion which is now widely available.

2.6 Summary of the chapter

A small proportion of the service providers did not provide relevant written information despite recommendation of current guidelines. For those who provided written information, the leaflets did not contain complete information on the procedure with a balanced view of the risks and benefits involved and the language used was difficult for the general public. Without further analysis on the content of consultation about abortion methods, it is uncertain whether adequate verbal information would be provided to compensate for the inadequacy of the written information. It seems unlikely women are able to make informed decisions on the basis of written information provided by services in England and Wales.

Chapter 3 - Information provision about abortion methods during the consultation

3.1 Introduction

This chapter describes a study designed to assess the communication of information about abortion methods from clinicians to women during a routine consultation. As mentioned in chapter 1, women require comprehensive and non-directive information from the clinicians in order to make an informed choice on abortion methods (Department of Health, 2000; RCOG, 2000). Provision of comprehensive information would involve the healthcare professionals giving information on all relevant treatment options, the consequences including benefits and risks, and the likelihood and desirability of the consequences for each option (Bekker, 2003; Charles et al, 1999). The information should also be communicated in a non-directive manner by the healthcare professional. In terms of counselling on abortion methods, being non-directive would include providing complete information about both alternatives, without value-laden statements and withholding direct opinions about either abortion method (Kessler, 1992). This should provide women with sufficient information to enable them to make their decision.

From chapter 2, it was clear that leaflets provided by abortion services contain insufficient and incomplete information to enable informed choices by women. Most leaflets were also rated as difficult to read. Although some studies have explored the efficacy, acceptability and reason for choosing either abortion methods (Bachelot et al,

1992; Cabezas, 1998; Henshaw et al, 1993; Henshaw et al, 1994; Jensen et al, 1999; Jensen et al, 2000; Slade et al, 1988; Virgo et al, 1999; Wiebe, 1997; Winikoff et al, 1997), none has described the quality and quantity of information communicated to women during the consultation when they make their decision. What evidence there was from these studies suggests that women were uncertain about why they were offered one type of method and some had erroneous beliefs about these methods (Slade et al, 1999). It is unclear whether these beliefs are an issue of information provision by the clinicians or recall by women.

This study aims to describe the information provided by clinicians on abortion methods in a clinic setting. The objectives are:

- To evaluate the provision of information by the clinicians.
- To pilot the acceptability of a questionnaire to women choosing which abortion method to have

Details of the questionnaire will be discussed in Chapter 4, the focus of the study is to assess the content of the consultation.

3.2 Methods

3.2.1 Context

Within the Fertility Control Unit in St. James's University Hospital, about 1000 women per year with unwanted pregnancies of less than nine weeks gestation request an abortion. Women are usually referred from general practitioners, family planning doctors and hospital doctors from other specialties by telephone. It is routine practice

for women attending the unit requesting induced abortion to have an ultrasound scan to estimate gestation; to be informed about the abortion methods; to be asked to decide on their preferred abortion method and to be provided with an admission date for the abortion method decided. It is this consultation that was observed to assess the quality of information provided.

3.2.2 Design

A non-experimental, cross-sectional, observational study design was employed (Robson, 2002). Consultations between clinicians and women who agreed to participate were audio tape-recorded. Other methods such as interviews or questionnaires could have been used to address similar issues but there are limitations. Although these methods would not require the presence of the observer during the consultation and minimise interference to the consultation itself, it is likely the data would be subject to patient and interviewer bias (Robson, 2002). Patient bias can occur when patients have forgotten certain issues of the consultation or adjusted past cognitions to align with current choices. This can lead to a loss of valuable information when an interview or a questionnaire is conducted to obtain data after the consultation. Another source of bias can arise from the interviewer. The researcher conducting the interview can influence in the response in two ways. The questions being asked in the interview are part of the researcher's agenda but not that of the patient. Patients maybe more likely to give a socially desirable response (Robson, 2002). Filling in questionnaires avoids the researcher influencing the information obtained, but the researcher is unaware of many of the factors influencing the choice

of response to a question. For example, it is impossible to determine whether or not the respondent is giving serious attention to the questions; difference in the wording of questionnaires can produce substantial effects on response. Some patients may also consider questionnaires rather impersonal, and this may influence the quality of data obtained compared to an interview person-to- person (Robson, 2002). Audio tape-recording the consultation has three advantages over interview or questionnaire methods. The transcripts of the recordings provide a direct way of observing the interaction during the consultation. The physical presence of the observer during the consultation is avoided. No extra time is required to collect information from the patient or clinicians after the consultation. The main limitations of this method are: It is not possible to detect any non-verbal interaction during the consultation and it is that possible both the clinician and the woman may act differently as they are aware their consultation is being recorded. Although, video taping can be used to detect any non-verbal interaction during the consultation, women may be less willing to participate in the study due to fear of being identified in the video tape. This could prolong the time needed to recruit adequate participant. Also, this method has not overcome the possibility that the clinician and the woman may act differently as they are aware their consultation is being recorded.

3.2.3 Sample

This study includes a consecutive sample of consultations about abortion methods that took place in the Fertility Control Unit at St. James's University Hospital over an eight-week period in 2001. Five doctors, two female and three male, working in the

unit during this period agreed to have their consultations audio tape-recorded. None declined participation. All women aged 16 or over attending the unit requesting induced abortion for pregnancies of less than nine weeks gestation that were literate in English, were eligible for inclusion. Women with medical reasons for not having a choice between abortion methods such as chronic adrenal failure, long term corticosteroid treatment, haemorrhagic disorder, treatment with anticoagulants, known allergy to mifepristone and known psychiatric history were excluded. All those eligible were informed of the study and gave written consent (see Appendix V for consent form).

3.2.4 Sample size

As this observational study employed a qualitative design, sample sizes of 15 to 30 were considered adequate (Robson, 2002). This study aimed to collect at least 20 consultations. The final number of consultations would include a minimum of 10 consultations leading to a choice of medical abortion and another 10 leading to surgical abortion. This was to ensure the consultations collected would include a broad variety of the type and the mode of delivery of information given for both abortion methods. Recruitment continued until the number of consultations required was achieved. Each clinician had more than one consultation recorded. This sample size should be sufficient to generate adequate qualitative data to describe information provided for decisions on each abortion method.

3.2.5 Materials

3.2.5.1 Coding Scheme

The original consultation transcript included a wide range of information. The coding scheme was developed by the author in two stages, in order to manage this data (See section 3.2.5.1). This coding scheme aimed to include several categories informed by guidelines on the provision of abortion services and informed decision making (Charles et al, 1999; Human Fertilisation & Embryology Authority, 1990; O'Connor & Edwards, 2001; RCOG, 2000). The categories included within the coding scheme were developed to ensure that adequate and non-directive information could be classified (Charles et al, 1999; Bekker et al, 1999; Marteau et al, 2001; RCOG, 2000) (see Chapter 1 & 2).

All information from the consultation transcript was divided into six categories in the first stage. The six categories included: demographic information such as age, marital status, occupation, alcohol and smoking habits; general medical and surgical history; obstetrics and gynaecology history; drug history; information on abortion methods and contraception. As the primary aim of this study was to describe information provision on abortion methods, a second stage was designed to develop a scheme that categorised in-depth information on choice between abortion methods. This in-depth coding scheme was piloted on the first five transcripts to ensure that the coding scheme was exhaustive and exclusive by detecting the presence and absence of items

(Robson, 2002). The findings were then discussed with a third party (HB) to increase the reliability of each category.

3.2.5.1.1 Initial coding scheme

The initial coding scheme was divided into four themes and the presence or absence of items within each theme was assessed (See Appendix II for coding frame A). The four themes were as follows:

1) Description of the surgical and medical abortion procedure: the description of the medical procedure should include the appointment date, time scale, medication (mifepristone and misoprostol) used in the procedure with an explanation of its effect. The description of the surgical procedure should include the appointment date, time scale, medication (misoprostol) given with an explanation of its effect, type of operation and anaesthetic involved (RCOG, 2000).

2) Aftercare for the surgical and medical procedure: the description should include domestic arrangements, travel arrangements, pain and bleeding on both methods. (See Chapter 2)

3) Risks for the surgical and medical procedure with possible management: an explanation of the risks of medical abortion should include possible side effects of mifepristone and misoprostol, the risk of haemorrhage, infection, retained products of conception and continuation of pregnancy. While those of surgical abortion should

include possible side effects of misoprostol, the risk of haemorrhage, infection, retained products of conception, continuation of pregnancy, perforation of uterus and anaesthetic complication. (RCOG, 2000) (see Chapter 2)

4) General issues on abortion: It should include queries on reasons and certainty of abortion, current gestation, possibility of future regret and effect on future fertility. (RCOG, 2000)

This coding scheme only noted the absence and presence of items. The initial scheme was not exhaustive in the first application of the coding scheme. Three aspects were not covered which meant new categories were required to classify the transcript information into the revised coding scheme:

1) Issues about the degree of direction implied by the clinicians' description of the method and the variation within the description of risk involved were not accounted for. For example, clinician A may describe a certain risk by giving a figure e.g. 5% occurrence, while clinician B may describe the same risk verbally stating "a small risk". To complicate the matter further, clinician C may describe the same risk by giving a figure of 95% of non-occurrence.

2) The frequency of items being mentioned was not accounted for. Information being repeated several times in the same consultation is more likely to be recalled by the patient and may have an effect on her decision making.

3) An informed decision should involve the provision of research–based information on all treatment options and the alternatives should be weighed up (Bekker et al, 1999; Entwistle et al, 1998). Acknowledging the presence and absence of items would be insufficient to assess whether or not the patient's choice is informed or being facilitated. For example, informing a patient that there was a risk of retained products of conception with medical and surgical abortions might have a different impact on her choice compared to informing the same patient that the risk is 4% for the medical method and 0.2% for the surgical method.

3.2.5.1.2 Final coding scheme

A revised coding scheme was developed taking into account the results of the pilot coding scheme. A new theme included facts and comments that related to enabling informed or facilitated decisions. This theme included categories for making explicit choices about methods and issues including appointment date, time scale, risk of infection, risk of retained products of conception, risk of continued pregnancy, risk of perforated uterus, risk of anaesthetics, pain experienced, opportunity for providing contraception at the same time (namely intrauterine device, Implanon and sterilisation), other personal opinions on abortion methods and risk in general. The two further changes applied to each theme were the frequency of each item mentioned in a consultation and whether they were presented in a positive, negative or neutral manner. (See Appendix III for coding frame B)

3.2.6 Procedure

All women requesting induced abortion and who met the study criteria were invited to participate in the study within an eight week duration in 2001. Study information (See Appendix IV for patient information sheet) was handed out to all the women attending the unit requesting abortion for non medical reasons by the receptionist. Women who were interested in participation spoke with the clinic nurse. The recruitment was stopped when the desired number of consultations required had been achieved. Written consent was obtained from all participants before commencing audio tape-recording of their clinic consultation (See Appendix V for consent form). All consultations were transcribed by a third party. The coding frame was applied to each transcript. A pilot questionnaire was given to the women to fill in after their consultation. The completed questionnaire was then collected by the researcher before they left the clinic. Further details of the questionnaire will be discussed in Chapter 4. This study was approved by the ethics committee of the trust concerned (See Appendix XI for letter from ethics committee).

3.2.7 Analysis

Data were summarised using descriptive statistics. The result of each category was presented in two frequency tables. The first frequency table of each category recorded the number of consultations that referred to a particular category of information. The second frequency table contained more detailed frequency analysis of all utterances relating to all categories, in order to demonstrate a pattern of information provided

relating to the women's final choice on abortion method. This study is a qualitative study; the numbers are too small to be meaningful statistically, so no significance calculations are applied to the data. However, the data are presented for total group and by abortion method. Text considered to be representative of all the transcripts was used to demonstrate the information categories of the coding scheme when describing the findings.

3.3 Results

Seventy-four women were eligible for this study during the eight weeks duration. Fifty (68%) women declined to participate in the study. Of which 18 women (36%) chose to have medical abortion and 32 women (64%) chose to have surgical abortion. Twenty-four women (32%) agreed to participate in this study. Eleven out of these twenty-four women (46%) chose to have medical abortion. The other 13 women (54%) chose to have surgical abortion. All five clinicians present in the clinic during the study duration participated in the study. Clinician A had eight consultations recorded, clinician B had five, clinician C had six, clinician D had two, and clinician E had three. One tape-recording (clinician D) was lost due to faulty machinery; this participant chose surgical abortion method. The content of the consultation described below was based on the 23 tape- recordings obtained.

3.3.1 Adequacy of information provided for medical abortion

3.3.1.1 Description of procedure

Information provided about the procedure was generally comprehensive (Table 3.1).

Information provided on the action of mifepristone and an appointment date for the procedure was lacking in over half of the consultations. Although there were too few numbers to carry out tests, women choosing to have medical abortion appeared to have received more information than those choosing surgical abortion in all categories except for information on the action of mifepristone. Women who chose to have the medical abortion appeared to have received more information on the medical abortion compared to those who chose to have the surgical abortion. (Table 3.1)

Information category	Total n=23		Chose medical abortion n=11		Chose surgical abortion n=12	
	n	%	n	%	n	%
Appointment date	9	39%	7	64%	2	17%
Time scale	23	100%	11	100%	12	100%
Mifepristone given	22	96%	11	100%	11	92%
Route to give mifepristone	22	96%	11	100%	11	92%
Action of mifepristone	10	43%	4	36%	6	50%
Misoprostol given	22	96%	11	100%	11	92%
Route to give misoprostol	22	96%	11	100%	11	92%
Action of misoprostol	16	70%	8	72%	8	67%

Table 3.1 Frequency of information on the procedure of medical abortion provided by clinicians

Clinicians provided information on the procedure of medical abortion in a neutral manner in nearly all of their consultation i.e., without value judgements. The

appointment date for medical abortion was more frequently discussed in consultations for those who chose to have medical abortion. (Table 3.2)

	Total number of comment made in all 23 consultations	Number of comment made in 11 consultations who chose MTOP			Number of comment made in 12 consultations who chose STOP		
Information category	All	+ ve	- ve	Neutral	+ ve	- ve	Neutral
Appointment	27	0	0	19	0	0	8
Time scale	44	0	2	22	0	0	20
Mifepristone given	25	0	0	13	0	0	12
Route for mifepristone	23	0	0	12	0	0	11
Action of mifepristone	15	0	0	9	0	0	6
Misoprostol given	26	0	0	14	0	0	12
Route for misoprostol	25	0	0	14	0	0	11
Action of misoprostol	17	0	0	9	0	0	8

Table 3.2 Frequency of neutrality of information provided for medical procedure

The following are two examples of information on the medical method provided by two different clinicians that would have been counted within this theme of the coding frame; one a concise description and one fuller explanation.

Description 1:

"What's going to happen with the tablets is we give you a tablet by mouth now and you wait in clinic for one hour and then you go home. Nothing will happen until you come back on Wednesday and on Wednesday we put a tablet from down below, keep you with us for six hours and things will happen naturally."

Description 2:

"The medical approach was taking one tablet by mouth. What that tablet does is to stop the pregnancy progressing further. Because it acts against the hormone progesterone which is necessary for the pregnancy to continue. So when you take that tablet it blocks the action of progesterone and stops the pregnancy going on. It also has an effect on the womb such that it sort of primes the womb ready for contractions when you have the next set of tablets. Right, you're going to have two lots of different tablets. So after taking the first tablet by mouth you go home. You don't do anything. You come back about two days later. When you come back two days later you will need to stay on the ward for about four hours. When you arrive on the ward you will be given some tablets vaginally this time and what those tablets do is to make the womb start to contract, so you start getting some cramping pains, just like having severe menstrual pain and gradually you start bleeding. And during the bleed the products get expelled ....."

3.3.1.2 Description of aftercare

Provision of information on aftercare for medical abortion was generally poor (Table 3.3). Each category was mentioned in less than half of the consultations. Within the limited amount of information provided, pain and bleeding to be expected after the procedure were more likely to be mentioned for those who chose to have medical abortion compared to those who chose the surgical abortion. Women who chose to have surgical abortion were more likely to be informed about travel and follow up arrangement for medical abortion. (Table 3.3)

Information category	Total n=23		Chose MTOP n=11		Chose STOP n=12	
	n	%	n	%	n	%
Childcare	2	9%	1	9%	1	8%
Time off work	2	9%	1	9%	1	8%
Pain	7	30%	5	45%	2	17%
Bleeding	8	35%	7	63%	1	8%
Travel arrangement	2	9%	0	0%	2	17%
Follow up	5	22%	2	18%	3	25%

Table 3.3 Frequency summary of information on aftercare for medical abortion provided by clinicians

Less than a third of women received information about any aspect of aftercare. The information provided during the consultation was delivered in a neutral method (Table 3.4).

	Total number of comment made in all 23 consultations	Number of comment made in 11 consultations who chose MTOP			Number of comment made in 12 consultations who chose STOP		
Information category	All	+ ve	- ve	Neutral	+ ve	- ve	Neutral
Childcare	3	0	0	2	0	0	1
Time off work	4	0	0	2	0	0	2
Pain	8	0	0	5	0	0	3
Bleeding	8	0	0	7	0	0	1
Travel arrangement	3	0	0	0	0	0	3
Follow up	6	0	0	2	0	0	4

Table 3.4 Frequency of neutrality on information provided for medical aftercare

The following are the two examples of information on aftercare provided by two different clinicians:

Description 1:

"The first one generally is bleeding, even if things are complete to expect a bleed for a week or two like a period."

Description 2:

"After you've had the procedure you need somebody to take you home..... You can't go home on your own. You won't be able to drive back or get on the bus. You need somebody to take you home."

3.3.1.3 Description of risk

None of the categories on the consequences of medical abortion were covered in all consultations. Women who chose to have medical abortion were more likely to receive information about the consequences of medical abortion than those choosing surgical abortion. (Table 3.5)

Information category	Total n=23		Chose MTOP n=11		Chose STOP n=12	
	n	%	n	%	n	%
Haemorrhage	8	35%	7	64%	1	8%
Management of haemorrhage	3	13%	3	27%	0	0%
Infection	8	35%	7	63%	1	8%
Management of infection	4	17%	4	36%	0	0%
General failure including retained products of conception, continue of pregnancy and as a general statement	20	87%	10	91%	10	83%
Management of retained products of conception	13	57%	9	82%	4	33%
Management of continue pregnancy	7	30%	4	36%	3	25%
Management of general failure as a general statement	6	26%	5	45%	1	8%

Table 3.5 Frequency summary of information on risk of medical abortion provided by clinicians

Despite most information provided by clinicians about the risk of medical abortion being communicated in a neutral manner, a few comments in the consultations meant that certain risks were minimised by the clinician i.e. verbally 'reduced'. (Table 3.6)

	Total number of comment made in all 23 consultations	Number of comment made in 11 consultations who chose MTOP					Number of comment made in 12 consultations who chose STOP				
Information category	Neutral	Minimised	Maximised	Positive	Negative	Neutral	Minimised	Maximised	Positive	Negative	Neutral
Haemorrhage	11	2	0	0	0	8	0	0	0	0	1
Management of haemorrhage	2	0	0	0	0	2	0	0	0	0	0
Infection	9	0	0	0	0	8	0	0	0	0	1
Management of infection	5	0	0	0	0	5	0	0	0	0	0
General failure: • Retained products of conception	37	5	0	0	1	13	4	1	0	2	11
• Continue pregnancy	19	1	0	0	0	8	2	0	0	0	8
• General statement	19	0	0	0	0	12	0	0	0	0	7
Management of retained products of conception	17	0	0	0	0	12	0	0	0	0	5
Management of continue pregnancy	6	0	0	0	0	3	0	0	0	0	3
Management of general failure	6	0	0	0	0	5	0	0	0	0	1
Side effect of mifepristone	21	11	0	0	0	8	0	0	0	0	2
Management of mifepristone side effect	3	0	0	0	0	3	0	0	0	0	0
Side effect of misoprostol	4	1	0	0	0	2	0	0	0	0	1

Table 3.6 Frequency of neutrality of information provided for risk of medical method

Further, although risks were explained in a neutral manner, not all consultations provided a precise figure for risk, figures varied between consultations, and an inverse explanation of the risk involved for the procedure was only given in a few consultations. (Table 3.7)

Information category	Chose MTOP n=11		Chose STOP n=12	
	Figure quoted for the risk	Number of times inverse risk was given	Figure quoted for the risk	Number of times inverse risk was given
Haemorrhage	<1%	0	none	0
Infection	none	0	none	0
Retained products of conception	2-5%, 5%	1	5%	1
Continued pregnancy	2-5%, 3-5%	0	none	0
General failure as a general statement	2-5%, 3-4%, 3-5%, <5%, 5%	4	5%	5

Table 3.7 Figure provided for risk of medical abortion

Large variations also occurred in the details and style of description of the potential risks of the medical method and their management. The following are two different examples of descriptions obtained from the two consultations by two different clinicians:

Description 1: "If you bleed excessively, possibly some infection in the lining of the womb and you need some antibiotics sorted out, or bits and pieces from the pregnancy left behind. If a small piece are left behind, an operation is required to get rid of this, but this quite rare, about 2% - 5% chance."

Description 2: "Most people will work in about 95% of cases and most people will pass the products on the ward within that four hours. The remaining 5% may not pass the products at all. If they are not bleeding heavily we let them go home. The majority of the ones that go home without passing the products will pass the products over the next three to four days. But in order to check what has happened we bring them back the following Monday here and do a scan again to check whether they've passed the products or not. If they haven't and they are still less than nine weeks pregnant they can have a repeat course or they can have the surgical termination. They can decide which one they would like. However, if not all the products have been passed and there is a tiny amount left behind, and that can cause bleeding, pain, cramps which are a risk of infection. Now with that medical method like anything there is always a risk of side-effects. You can feel very hot during that time. You can feel very sick, you could get diarrhoea, because one of the drugs make the bowels move a lot so you may get some small rashes on the body, small spots, but they all clear away in no time. And as I mentioned before in about 5% of cases it might not work at all. During the time you are passing the products you may bleed heavy as to require a blood transfusion. It's not something that happens often. And if there is some retained products, a very small amount it may cause infection, so again, this is why we ask to see people back to make sure there isn't any in afterwards."

3.3.2 Adequacy of information provided for surgical abortion

3.3.2.1 Description of the procedure

No consultation provided information on all aspects of surgical abortion procedure. Again, issues of appointment date and the effect of misoprostol were less likely to be mentioned during consultations. Women who chose the surgical abortion were provided with more information on the surgical method compared with women choosing medical abortion. Women who chose the surgical method were all informed about the method of operation and anaesthetics involved. (Table 3.8)

Information category	Total n=23		Chose MTOP n=11		Chose STOP n=12	
	n	%	n	%	n	%
Appointment date	7	30%	3	27%	4	33%
Time scale	18	78%	8	72%	10	83%
Misoprostol given	15	65%	5	45%	10	83%
Route to give misoprostol	13	57%	4	36%	9	75%
Action of misoprostol	6	26%	2	18%	4	33%
Duration of operation	18	78%	7	64%	11	92%
Method of operation	18	78%	6	55%	12	100%
Anaesthetic	18	78%	6	55%	12	100%

Table 3.8 Frequency summary of information on the procedure of surgical abortion provided by clinicians

Most information provided on the procedure of surgical abortion was presented neutrally. (Table 3.9)

	Total number of comment made in all 23 consultations	Number of comment made in 11 consultations who chose MTOP			Number of comment made in 12 consultations who chose STOP		
Information categories	All	+ ve	- ve	Neutral	+ ve	- ve	Neutral
Appointment date	8	0	0	3	0		5
Time scale	25	1	0	8	0	0	16
Misoprostol given	17	0	0	6	0	0	11
Route for misoprostol	13	0	0	4	0	0	9
Reason misoprostol	7	0	0	2	0	0	5
Duration	20	0	0	7	0	0	13
Method	28	0	0	9	4	0	15
Anaesthetic	23	0	0	8	0	0	15

Table 3.9 Frequency on neutrality of information provided for surgical procedure

The following are two examples of description from two consultations by two different clinicians: with one short explanation and one fuller description.

Description 1:

"It is a very simple quick procedure down from down below by suction. ……. when you come in on the day of the abortion we're going to put a tablet down below just to make things easier and less complicated…… The actual procedure takes five ten minutes, but from the time you come to hospital, get seen to, go to theatre and then recover it takes about four to five hours all together."

Description 2:

"If you prefer the surgical one, then that can be done either under general anaesthetic or under local anaesthetic. General anaesthetic means that you will be asleep for about fifteen minutes, with local anaesthetic you'll be awake, but we give you an injection into the neck of the womb and that reduces the amount of discomfort and pain. Either way, the actual surgical procedure is exactly the same. We use a syringe like equipment to take out everything."

3.3.2.2 Description on aftercare

Information provision on aftercare for surgical abortion was generally inadequate. Women who chose the surgical procedure were more likely to be advised about pain and bleeding expected after the procedure in their consultations. Women who chose the medical method were more likely to be advised about bleeding, travel arrangements and follow-up in their consultations. None of the consultations covered issues on childcare and time off work. (Table 3.10)

Information category	Total n=23		Chosen MTOP n=11		Chosen STOP n=12	
	n	%	n	%	n	%
Childcare	0	0%	0	0%	0	0%
Time off work	0	0%	0	0%	0	0%
Pain	2	9%	0	0%	2	17%
Bleeding	8	35%	1	9%	7	58%
Travel arrangement	2	9%	2	18%	0	0%
Follow-up	1	4%	1	9%	0	0%

Table 3.10 Frequency summary of information on the aftercare of surgical abortion provided by clinicians

Despite minimal information being offered on aftercare following surgical abortion, those provided were given in a neutral manner. (Table 3.11)

	Total number of comment made in all 23 consultations	Number of comment made in 11 consultations who chose MTOP			Number of comment made in 12 consultations who chose STOP		
Information category	All	+ ve	- ve	Neutral	+ ve	- ve	Neutral
Childcare	0	0	0	0	0	0	0
Time off work	0	0	0	0	0	0	0
Pain	2	0	0	0	0	0	2
Bleeding	8	0	0	1	0	0	7
Travel	2	0	0	2	0	0	0
Follow up	1	0	0	1	0	0	0

Table 3.11 Frequency on neutrality of information provided for surgical aftercare

The followings are two samples of information on aftercare provided by two different clinicians:

Description 1:

"After the abortion you expect to have some pain and bleeding same duration much like a period."

Description 2:

"Normally expect a bleed for about a week or two like a period."

3.3.2.3 Description of the risk

None of the consultations covered the possible side effects of misoprostol. The consultations were most likely to include risk and management of retained products of conception and perforation of uterus. Women who chose surgical abortion were provided with more information about the risk of surgery compared to those who

chose medical abortion; in particular all their consultations covered the risk and management of retained products of conception. (Table 3.12)

Information category	Total n=23		Chosen MTOP n=11		Chosen STOP n=12	
	n	%	n	%	n	%
Side effect of misoprostol	0	0%	0	0%	0	0%
Haemorrhage	14	61%	5	45%	9	75%
Management of haemorrhage	2	9%	0	0%	2	17%
Infection	13	57%	4	36%	9	75%
Management of infection	9	39%	2	18%	7	58%
Retained products of conception	16	70%	5	45%	11	100 %
Management of retained products of conception	15	65%	4	36%	11	100 %
Continue of pregnancy	4	17%	2	18%	2	17%
Management of continue of pregnancy	3	57%	2	18%	1	8%
Perforation of uterus	19	83%	9	82%	10	83%
Management of perforation of uterus	16	70%	6	55%	10	83%
Anaesthetic risk	6	26%	4	36%	2	17%

Table 3.12 Frequency summary of information on the risk of surgical abortion provided by clinicians

Most information provided on the risks of surgical abortion was provided in a neutral manner, except that few positive comments were made concerning the risk of retained products of conception. Despite more neutral comments being made on the occurrence of retained products of conception in consultations for those choosing surgical abortion, its occurrence was more likely to be minimised. More neutral comments were also made on the occurrence of perforation of the uterus for those women choosing medical abortion and they were more likely to be minimised in consultations. (Table 3.13)

	Total number of comment made in all 23 consultations	Number of comment made in 11 consultations who chose MTOP					Number of comment made in 12 consultations who chose STOP				
Information category	All	Minimised	Maximised	Positive	Negative	Neutral	Minimised	Maximised	Positive	Negative	Neutral
Haemorrhage	15	1	0	0	0	5	0	0	0	0	9
Management of haemorrhage	2	0	0	0	0	0	0	0	0	0	2
Infection	15	0	0	0	0	5	1	0	0	0	9
Management of infection	9	0	0	0	0	2	0	0	0	0	7
Retained products of conception	28	4	0	1	0	5	7	0	1	0	12
Management of retained products of conception	16	1	0	0	0	3	0	0	0	0	12
Continue pregnancy	7	1	0	0	0	3	1	0	0	0	2
Management of continued pregnancy	2	0	0	0	0	1	0	0	0	0	1
Perforated uterus	47	14	0	0	0	14	9	0	0	0	10
Management of perforated uterus	18	0	0	0	0	6	1	0	0	0	11
Anaesthetic risk	12	3	0	0	0	6	1	0	0	0	2
Side effect of misoprostol	0	0	0	0	0	0	0	0	0	0	0

Table 3.13 Frequency on neutrality of information provided for surgical risk

Discussion of the risks of surgical abortion was not always supplemented with figures in all consultations. Also, provision of inverse risk statements for each category was not common practice. (Table 3.14)

	Chose MTOP n=11		Chose STOP n=12	
Information category	Figure quoted for the risk	Number of times inverse risk was given	Figure quoted	Number of times inverse risk was given
Haemorrhage	none	0	none	0
Infection	none	0	none	0
RPOC	3%	0	<1%, 1%, 3-5%	1
Continue pregnancy	2-5%	0	none	0
Perforation Uterus	1/200, 1/1000, 1/1000-2000	0	1/200, 1/300-500, 3-4/1000	0
Anaesthetic	none	0	none	0

Table 3.14 Figure provided for risk of surgical abortion

The details and style of description on the risks and management of surgical abortion varied between consultations. The following are two examples of descriptions from two consultations by two different clinicians:

Description 1: "It's a very quick safe procedure, but you need to understand that things can go wrong like anything on the ward, even with the tablets there are complications. With the operation the worst thing that can happen is a hole in the womb at the time of abortion. It only occurs once every two hundred patients as a complication. If it happens the patient might have to have a cut in her stomach to soothe the damage and keep the womb for future child birth, but this is very rare, once every two hundred patients. After the abortion you expect to have some pain and bleeding same duration much like a period. If you bleed excessively possibilities are either some infection, the lining of the womb needs some

antibiotics to sort it out, or it's a piece from the pregnancy left behind. If it's a piece left behind an operation is required to get ride of this, but this is quite rare one percent chance only."

Description 2: "Now being a surgical procedure there's always a small risk of something going wrong, in any surgery, there's very small risk. In this procedure there's a small risk of the instrument going through the neck of the womb. If that happens, depending on the direction it goes you've got the bladder in front of the womb, you've got bowel resting on top, you've a major blood vessel at the back like the aorta at the sides you've got the pelvic vessels as well. Any of those can be injured and if you were bleeding heavily internally we would have to open you up to repair the damage. We wouldn't wake you up to say "can we do this" we'd just go ahead. However, saying that the risk of that happening is about one out of a thousand. It's just that you don't know who that one person will be. Now all this sounds frightening. It's not, it's very rare situation, but now a days, we have to tell you everything whether you want to hear about it or not because the government insists that everybody know and this is what's been given to rise all these cases in the newspapers, so now we have to go through everything and actually write it down that we tell you. There is a small chance of regretting having the termination four or five years from now, but one can't really do anything about that."

3.3.3 General issues on abortion

Although all consultations included confirmation of certainty on the abortion decision, few discussed the possibility of regret and future fertility. Despite that,

women choosing medical abortion were more likely to be informed about possibly regretting it in the future, while those choosing surgical abortion were more likely to be informed about future fertility. (Table 3.15)

Information category	Total n=23		Chosen MTOP n=11		Chosen STOP n=12	
	n	%	n	%	n	%
Certainty of abortion	23	100%	11	100%	12	100%
Reason for abortion	9	39%	5	45%	4	33%
Current gestation	21	91%	11	100%	10	83%
Regret afterwards	3	13%	2	18%	1	8%
Future fertility	4	17%	1	9%	3	25%

Table 3.15 Frequency summary of information on general issues on abortion

Although several positive comments were made on issues regarding gestation, regret and future fertility, most of the comments were made in a neutral manner. (Table 3.16)

	Total number of comment made in all 23 consultations	Number of comment made in 11 consultations who chose MTOP			Number of comment made in 12 consultations who chose STOP		
Information category	All	+ ve	- ve	Neutral	+ ve	- ve	Neutral
Certainty	31	0	0	15	0	0	16
Reason	12	0	0	5	0	0	7
Gestation	28	3	0	8	3	0	14
Regret	5	2	0	2	0	0	1
Future fertility	4	0	0	1	1	0	2
Appointment	5	0	0	0	0	0	5

Table 3.16 Frequency on neutrality on information provided for general issue of abortion

3.3.4 Explanation of the choice between medical and surgical abortion

All consultations discussed the availability of both surgical and medical abortion. Despite the majority of clinicians encouraging autonomy in women's decision making, comparison of the different aspects of both methods was not common practice and no major difference was noted between the two groups. (Table 3.17)

Information category	Total n=23		Chosen MTOP n=11		Chosen STOP n=12	
	n	%	n	%	n	%
Offer choice of both methods	23	100%	11	100%	12	100%
Promote autonomy in decision	19	82%	8	73%	11	92%
Compare time scale	6	26%	2	18%	4	33%
Compare risk on retained products of conception	5	22%	3	27%	2	17%
Compare pain	1	4%	0	0%	1	8%
Compare appointment date	2	9%	1	9%	1	8%
Compare both method in general	10	43%	3	27%	7	58%
Compare risk of continue pregnancy	0	0%	0	0%	0	0%
Compare infection risk	3	13%	3	27%	0	0%
Compare anaesthetic risk	9	39%	4	36%	5	42%
Compare risk of perforated uterus	3	13%	2	18%	1	8%
Compare opportunity of providing contraception at the same time of procedure including sterilisation / coil	3	13%	2	18%	1	8%

Table 3.17 Frequency summary of information on explanation of choice between medical and surgical abortion

Comparisons of different aspects of both methods were all discussed in a neutral manner, except one positive comment was made when comparing the method itself. (Table 3.18)

	Total number of comments made in all 23 consultations	Number of comments made in 11 consultations who chose MTOP			Number of comments made in 12 consultations who chose STOP		
Information category	All	+ ve	- ve	Neutral	+ ve	- ve	Neutral
Offer choice of both methods	23	0	0	11	0	0	12
Promote autonomy in decision	39	0	0	16	0	0	23
Compare time scale	6	0	0	2	0	0	4
Compare risk on retained products of conception	6	0	0	4	0	0	2
Compare Pain	1	0	0	0	0	0	1
Compare appointment date	2	0	0	1	0	0	1
Compare both method in general	12	0	0	3	1	0	8
Compare risk of continue pregnancy	0	0	0	0	0	0	0
Compare risk of infection	3	0	0	3	0	0	0
Compare risk of anaesthetic	10	0	0	4	0	0	6
Compare risk of perforation of uterus	4	0	0	3	0	0	1
Compare risk of bleeding	2	0	0	2	0	0	0
Compare opportunity of providing sterilisation / coil at the same time	3	0	0	2	0	0	1

Table 3.18 Frequency on neutrality on explanation for choice between two methods

Most clinicians encouraged women to make their own choice on abortion methods but tended to choose one attribute which they thought women should make a decision on e.g. asleep or awake. The following are four examples of different descriptions on encouraging autonomy of decision from four consultations by four different clinicians, that demonstrated the diversity of counselling techniques:

Description 1: "It depends, do you prefer to be awake, or would you rather be put to sleep… This is the main issue really. Some patients are frightened to be put to sleep; they think they won't wake up if they have a general anaesthetic so they prefer the tablet. Some patients find it, not really good awaiting events happening while they are awake so they go for the operation, so it all depends on you."

Description 2: "The thing is I'm supposed to give you impartial advice and information and not direct you in a particular way. …….. That's why I've given you all the information you need. Each patient has difficult circumstances, like you said, you've been off work where you look at the potential for complications to occur with the surgical one you're probably better off and in about 95% this is just …….. plus you're most likely …….. be complete."

Description 3: "I can't tell you to go for this or that because the whole idea is, because they're both good methods and that's why they're both there, otherwise we'd just said go for surgical just go for medical, er and it's entirely your decision because it depends on what you can cope with."

Description 4: "Both of them are very safe, but depending on which one you feel more happy with really, because one is asleep, one is you know when you're awake really…….If that is your option you know I would stay stick with it, if that is the one you're happy with because what you're happy with might not be what you're neighbour thinks. Everybody's different such. So I think if you're happy with that then it's the best option for you."

3.3.5 Clinicians opinion on abortion methods

Clinicians were generally more likely to express an opinion on the medical method than surgical method, especially for those choosing the medical method. (Table 3.19)

Information category	Total n=23		Chosen MTOP n=11		Chosen STOP n=12	
	n	%	n	%	n	%
Opinion on the method on MTOP	18	78%	10	91%	8	67%
Opinion on the risk of MTOP	4	17%	1	9%	3	25%
Opinion on the method of STOP	9	39%	5	45%	4	33%
Opinion on the risk of STOP	5	21%	1	9%	4	33%

Table 3.19 Frequency summary of clinician's opinion on abortion methods

Comments that were made on the medical method were more likely to be positive and occurred more often in consultations where women chose to have a medical abortion. (Table 3.20)

	Total number of comment made in all 23 consultations	Number of comment made in 11 consultations who chose MTOP			Number of comment made in 12 consultations who chose STOP		
Information category	All	+ ve	- ve	Neutral	+ ve	- ve	Neutral
Opinion on the method on MTOP	41	19	3	3	12	1	3
Opinion on the risk of MTOP	4	1	0	0	3	0	0
Opinion on the method of STOP	11	4	2	0	4	0	1
Opinion on the risk of STOP	7	2	0	0	5	0	0

Table 3.20 Frequency of neutrality on clinicians' opinion on abortion methods

The following are two examples of comments made by two different clinicians on the two methods of abortion.

Clinician's opinion on the surgical method: "It is a very simple quick procedure done from down below by suction."

Clinician's opinion on the medical method: "But the biggest drawback is I suppose you are awake during your experiences."

3.4 Discussion

3.4.1 Summary of findings

This study was one of the first to describe the quality and quantity of information on abortion methods provided by clinicians. The aim was to assess whether the information provided was sufficient to enable informed, autonomous decision making. Information provided by clinicians on both abortion procedures was adequate but description on aftercare was lacking. Most of the risks involved with

each method were presented neutrally in the consultation. Despite that, there was a tendency for clinicians to give their personal opinion on the risks involved rather than supporting the evidence with a figure. There was also an imbalance of information provided on each method; the amount of information provided for each abortion method was directly related to the women's final choice on method. In addition, although clinicians made it explicit that the choice between methods was the woman's, information was not provided in a way that would help women to reach an informed choice.

3.4.2 Was information sufficient to enable informed decision making?

Women require comprehensive and non-directive information from clinicians in order to make an informed choice on abortion methods (Department of Health, 2000; RCOG, 2000). Provision of adequate information should include the pros and cons of each option including the consequences and be presented neutrally without being opinionated.

In this study, although adequate description on each method was given in the consultations, there was a discrepancy in the amount of information provided for each method relating to the women's choice of abortion method. Women who chose to have medical abortions seem to have received more information on the medical procedure, while those choosing to have surgical abortions seem to have received more information on the surgical procedures. It is possible that women showing more interest for a particular abortion method led to the responding clinician offering more information on that method. On the other hand, the clinician might have provided more information on a certain method leading to the

responding woman to choose a certain method of abortion (Kessler, 1981). Further research is required to assess this relationship. Information provided on the risk involved for each method discussed during consultations was incomplete.

Again, women tended to be provided with more information on the risk of a certain procedure depending on their chosen abortion method, with a tendency to minimise the risk involved and figures were not provided in all consultations. It seems women were not provided with a neutral and balanced view on each abortion method before they made their choice. In future, a description of the procedures and risks could be better presented by giving a more balanced description of the risks for each method. This information should be supported by figures or a non opinionated description of risk and its likelihood of occurrence.

Provision of aftercare information was generally poor in this study. It can be argued whether or not aftercare information should be included in the assessment, as it does not directly relate to the procedure. However, it can be associated with the consequence of a procedure; and therefore should be provided during the consultation.

When providing information, options were seldom evaluated along the same attribute. On odd occasions when options were evaluated with the same attribute, they tended to be what the health professional thought was important but not necessary for the woman.

3.4.3 Validity of findings

In the last chapter written information provided for women was found to be inadequate (See Chapter 2). A coding frame with similar categories was applied to consultations in this study. The result has also confirmed that inadequate and imbalanced verbal information was being provided which is consistent with the findings of the last chapter. Hence, women seem unlikely to make an informed decision using the written and verbal information supplied from the service provider.

The aim of the thesis is to facilitate women's decisions on abortion methods. This study assessed the content of consultations based on facts from literature related to informed decision making and guidelines on the provision of abortion service (Bekker, 2003; RCOG, 2000). Therefore, this study has been carried out appropriately to answer the research question whether women's choices have been facilitated with information provided during their consultations.

Despite provision of a comprehensive coding frame, it is difficult to decide whether some of the categories being assessed are essential for the decision making. Appointment time was not mentioned in most of the consultations. It is doubtful whether it is an essential aspect when making informed decision on the abortion method. Despite that, appointment issues can be considered by some women to be more important than the nature of the method involved based on their own values. To compare and assess consultation content, it is easy to assess information provided based on a conclusive list of possible information given.

However, it is difficult to assess whether all the information can be taken in by the patient in one single consultation; and whether they can process the information received to make an informed choice with time pressure (Maule & Edland, 1997).

The application of the coding frame in this study has ensured that each consultation has been assessed equally to minimise bias. Although no inter-rate checks have been performed by a second party to ensure accuracy of each assessment, the development of the coding frame was discussed and revised with a second party to ensure that the category involved would be adequate to answer the research question.

This study only assessed the information provided in the consultation. The information given in these consultations could have been provided following the routine procedures of the health professionals or as a response to the women's queries or prompts. Further research would be necessary to assess interactions between the health professionals and women. This would improve the understanding of how information should be provided and to ensure information provided was given in a balanced manner. For this study, audio-tape recording is the most appropriate way of gathering the verbal information provided during the consultation. None of the details of the consultation could be missed including the neutrality of the information provided. But biases can arise, as the non verbal gestures occurring during the consultation would not be picked up and these may influence the neutrality of the information given or possibly even the final decision. Information provided during these consultations can be biased, the clinicians and patients might be on their "best behaviour" when they know the

consultations are tape recorded, and they may not correlate to normal practise. More variation may be noted in unobserved circumstances. Certain information relating to the abortion procedure such as aftercare and appointment time would have been provided during the nurse specialist consultation following the clinician consultation. Further analysis of the nurse specialist consultation could provide more information but it would be beyond the criteria of this study. Informed decision making also requires knowledge of the consequences of each option prior to decision making, aftercare information should also be provided in the clinician's consultation before the women made their choice on the abortion method. Previous discussion has raised two possible correlations between the amount of information provided and the choice being made. More complex analysis could have been used to assess precisely who initiated what aspect of the consultation but this would be beyond the scope of this study.

3.4.4 Recommendations

Chapter 2 has shown that women were not provided with adequate written information on abortion methods. (The Family Planning association has produced a leaflet on abortion that is now widely available, but was not available at the time of study.) This current study showed that women have not received adequate and impartial verbal information on abortion methods during their consultation which could have compensated for the inadequacy of the written information. With inadequate written and verbal information, it seems unlikely that women will be able to make an informed choice on an abortion method.

Current information was offered in a disorganised and unbalanced fashion, it was uncertain how much information the women were able to recall from the consultation. Further research to assess how much information the women can recall after the consultation would be useful in the construction of a new training programme for the health professionals to organise their technique for effective and efficient information provision.

In the meantime, an evidence-based leaflet presented in the form of decision aid may help to provide women with accurate information in a neutral and organised fashion. It can also act as a memory prompt and provide guidance on how women can reach a decision with the information being provided. The next chapter will discuss in detail the effect of leaflets on women decision making on abortion method and whether their choice are facilitated.

Chapter 4 - A randomised controlled trial of a decision aid leaflet to facilitate women's choice between abortion methods

This chapter describes a study that evaluates the effectiveness of an evidence-based leaflet to facilitate women's informed decision making about abortion methods.

The study will describe a randomised controlled trial carried out in methods using quantitative analysis.

4.1 Introduction

In chapter 2, evidence has shown that written information provided by providers of abortion services was inadequate. In chapter 3, assessment on verbal information provided during consultations on abortion method was again shown to be insufficient. With inadequate written and verbal information on abortion methods, women would be less able to make an informed decision on the choice of abortion method that they were about to have. Literature has also shown that women might not have made an informed choice when it comes to deciding the choice of abortion method in terms of the reasoning and awareness of the availability of choice (Slade et al, 1998). Evidence from chapters 2 and 3 has also shown that the standard set by guidelines from the RCOG and the government health policy to encourage informed decision making on abortion and health care has not been met (Department of Health, 2000; RCOG, 2000).

4.1.1 Aim

The aim of this study is to assess whether an evidence-based leaflet on abortion methods presented in the form of a decision aid with average readability can facilitate the decision making process.

4.1.2 Objectives

By providing an evidence-based leaflet on abortion methods with average readability presented in the form of a decision aid, the study is to measure the following aspects:

1. To measure the leaflet's influence on the decision making outcome
2. To measure the leaflet's influence on the decision making process
3. To measure the leaflet's influence on service provision

4.2 Method

4.2.1 Design

A randomised controlled trial was employed with two arms: 1) Control group – a leaflet on contraception methods to read before their consultation (See Appendix VIII for leaflet), 2) Experimental group – a leaflet on abortion methods to read before their consultation (See Appendix VII for leaflet). Participants were randomly allocated to the experimental and control arm of the trial by opening a consecutive numbered sealed opaque envelope. Randomisation was performed by drawing a number from a box. The number of participants allocated to each group was equal in each block of ten participants. This technique ensured that equal numbers of participants within each block of ten were randomised to each

intervention. This was a surer way than simple randomisation of distributing the levels of a particular variable equally between groups to reduce type-one error (Sim & Wright, 2000).

The randomised controlled trial design is the "gold standard" for assessing treatment efficacy (Barker et al, 1998; Bowers et al, 2003; Robson, 2002). It is the only design that is able to demonstrate a link between causality and effect between intervention and outcomes. This ensures confidence in findings. Participants should be allocated by a chance mechanism with a known and equal chance of being in each trial arm. Individual variations in participants such as – age, sex, motivation, cognitive capacity and so forth – will be distributed more or less equally between the two groups immediately after randomisation. This process reduces any effect by confounding variables (Sackett, 1978). Other types of study design could have been used to study the effect of the additional written information on women's choices such as before and after the intervention. However, this is more likely to introduce bias because without the presence of a control group, it is difficult to ensure the outcome is caused by the written information rather than another cause. With the use of a randomised controlled trial, participants who have met strict criteria were recruited at the same stage of the study. This will ensure any effect detected by the study would have been caused by the provision of written information and not by other factors, such as those with a medical condition that would have limited their choice of abortion method (Barker et al, 1998; Bowers et al, 2003; Robson, 2002) or the waiting list for a consultation appointment.

In routine practice, no leaflet is given in the Fertility Control Unit prior to the consultation. In order to assess whether the content of the study leaflet has an impact on the outcome rather than the novelty of being offered a new leaflet, a comparison group with another new leaflet containing information related to care but not associated with decision making was introduced. The control leaflet providing information on post-abortion contraception, was offered to the participants. Another option would have been to offer no leaflet to the control group. For those receiving no leaflet, this design would have informed participants that they were in the experimental or control group, as all the patients were kept in a small waiting area. To minimise the placebo effect of "just providing written information" and other possible bias, a randomised controlled trial with two arms both offering different information leaflets was thought to be better to assess the effect of the study leaflet (Bowers 2003).

4.2.2 Sample

This study included all women who attended the Fertility Control Unit in St. James University Hospital over a consecutive seven month period in 2002. This unit is the only referral centre for the NHS abortion service within the Leeds area and is the largest referral centre within the Yorkshire region. About 2500 induced abortions are performed in this unit per year. Although this study could have been carried out in the community family planning clinics or GP surgeries, women attending those settings might not be certain of their decision to terminate the pregnancy, let alone which type of abortion they would like, as it was likely to be their first visit regarding an unplanned pregnancy. This study was aiming to facilitate the choice between abortion methods. The Fertility Control Unit at St.

James's University Hospital is the location where women confront the decision of the abortion method for the first time. It was considered to be the most appropriate place to carry out this study.

Women were only recruited if they had met the following recruitment criteria.

1. Unwanted pregnancies should be under nine weeks gestation. Pregnancies of nine or more week's gestation were excluded, as the RCOG guideline has only supported both abortion methods for those under nine weeks gestation (RCOG, 2000).
2. Women should be aged 16 or over, in order to obtain written consent from the participant rather than by proxy.
3. Women should be literate in English to give written consent and complete the study questionnaires.
4. Women should have no medical contraindications to medical or surgical abortion which could limit their choice of abortion method e.g. chronic adrenal failure, long term corticosteroid treatment, haemorrhagic disorder and treatment with anticoagulants, known allergy to mifepristone and misoprostol.
5. Women should not be suspected to have an ectopic pregnancy. The management of ectopic pregnancy is different and is not suitable for medical or surgical abortion.
6. Women should have no severe psychological illness that may impact on their normal decision making abilities. This precaution was to ensure the results obtained were not influenced by medical and psychological factors.

4.2.3 Sample size estimate

The choice of abortion method made by women who have abortions within the Fertility Control Unit in 2000 was used to calculate the sample size. In 2000, 34% of the attendants chose to have medical abortions, whilst the other 66% chose to have surgical abortion. In order to detect an increase of 16% uptake of medical abortion from 34% to 50% in this trial, the target sample size would need to be 328. It was designed to yield 80 % power of detecting at the 5% significance level, to detect a difference of 16% for women choosing medical abortion when the leaflets were given to them. Prior research suggests decision aids may have variable effects on the selection of healthcare options (O'Connor & Edwards, 2005). One of the secondary objectives was to detect a difference in anxiety by the treatment group. A sample size of 110 would be adequate to yield 80% power of detecting at the 5% significance level, to detect a two point difference in the STAI scale; the initial sample size of 328 would be more than adequate to detect a change in anxiety level (2-tailed). With the large number of women attending the Fertility Control Unit in St. James's University Hospital and being the "exclusive" referral centre in Leeds, the chance of being able to recruit an adequate number of participants in order to obtain a statistically significant result and the result being relevant to the local population was considered feasible.

4.2.4 Written material

4.2.4.1 Type of written material used

4.2.4.1.1 Patient information sheet for patient recruitment of the study

A one page information sheet was used to inform women about this study and invite them to participate (See Appendix VI for information sheet). It was structured according to guidelines provided by the local ethics committee. The information sheet explained the purpose of the study and how they could participate, the method of allocation randomly into two groups (each group would be offered a leaflet about some aspect of the service), and the completion of two sets of questionnaires. It was made clear on the information sheet that participation was voluntary and that they would be offered the same standard of care regardless of participation.

4.2.4.1.2 Consent form

The structure of the consent form was informed by the ethics committee guidelines. This was to ensure that women who were willing to participate in the study had read the patient information sheet and understood the study procedure (See Appendix V for consent form). Both participants and staff signed two copies of the consent form: one copy for the main investigator and the second copy for the participant.

4.2.4.1.3 Patient information leaflets

4.2.4.1.3.1 *A guide to contraception after termination* (control leaflet)

This leaflet contained contraception information (See Appendix VIII for control leaflet). It was designed to provide relevant information on contraception. This information was part of the service provided by the clinic but not related to the abortion choice. The content was informed by literature from the Family Planning Association leaflet, updated with figures from the World Health Organisation publication (Family Planning Association – contraceptive education service leaflet, WHO 2000). The information was then tailored for use after the abortion to make it relevant to the unit. The Flesch Reading Ease was applied to assess the readability of the leaflet and it was rated as standard (Flesch score = 64). The leaflet included information on the combined pill, the progestrogen-only pill, contraceptive injection, implant, coil, diaphragm with spermicide, natural family planning, condoms and sterilisation.

4.2.4.1.3.2 A guide to methods of termination (study leaflet)

This leaflet contained information on surgical and medical abortion method (See Appendix VII for study leaflet). It was informed by the RCOG guidelines and findings from chapter 2 & 3. Further details on complication rates quoted in the leaflet were obtained from a literature search on the abortion regime being used currently in the Fertility Control Unit (Ashok et al, 1998; Child et al, 2001; Schaff et al, 1999; RCOG, 2000; Centre for Health Information Quality, 2001). This leaflet included the risks and benefits of surgical and medical methods,

emphasising women's choice and other aftercare issues. A summary table included also helped women to see easily each attribute associated with each method. The Flesch Reading Ease was applied to assess the readability of the leaflet and it was rated as standard readability (Flesch score = 63).

4.2.5 Measures

Two sources were used to collect data: notes and questionnaires. The type of data collected from the two sources is elicited in the section below.

4.2.5.1 Notes

1. Participants characteristics:

The women's age and their gestational age of the pregnancy

2. Measure of decision making outcome

Choice of abortion method – the women's final choice of abortion method was obtained from the documentation of their case notes. The proportion of participants that chose to have either surgical abortion, medical abortion or continue pregnancy would then be assessed.

4.2.5.2 Questionnaires

Two sets of questionnaires were offered to all the participants. Questionnaire A containing the main measures was offered to participants to complete after their

consultation with the clinicians, just after making their decision on which abortion method to have (See Appendix IX for Questionnaire A). A shorter questionnaire B assessing outcomes was offered to participants to complete after the abortion procedure (See Appendix X for Questionnaire B). The first version of Questionnaires A and B were piloted in the study described in Chapter 3. The researcher collected the completed pilot questionnaires from the women participating in the study described in Chapter 3. Verbal feedback was obtained from the women about the questionnaire. Any misleading word in the pilot questionnaire was then removed and altered.

1. Participant's characteristics:
    - Demographic data – this included age, marital status, education level and ethnicity.
    - Reproductive history – this included number of children, previous miscarriage, previous abortion, and mode of previous delivery.

Past studies found these extraneous variables can have an impact on the effectiveness of the intervention. Some variables might be dependent and some independent. These independent variables could be held constant by randomization, in order to ensure effectiveness in randomisation (Sim & Wright, 2000). Awareness of the participant's characteristics would ensure participants were representative post randomisation and that the results would be comparable to other studies.

2. Measures of outcome

- Knowledge – No standardised measurement has been designed to study the knowledge of abortion methods. Therefore, a set of seven non-standardised questions were designed to detect basic knowledge of each abortion method including the procedure, duration of treatment, hospital stay and failure rate. The first six questions contained one correct answer within a choice of five possible answers. The last question contained one correct answer out of four possible answers. This was to assess whether the information leaflet had improved women's knowledge of abortion methods. In turn, this assessed whether women had adequate knowledge about risks and procedures to make an informed decision.
- Anxiety – The six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI) was used to measure anxiety level at the time of choice and after the procedure (Marteau & Bekker, 1992). The STAI was reliable and sensitive; it is also one of the most frequently used measures of anxiety in prenatal and obstetrics & gynaecology research. The six-item short-form STAI is valid for the study as the 20 items STAI to assess short term anxiety (Marteau & Bekker, 1992). A previous study has also found that accurate information presented as decision aids will not increase anxiety (O'Connor & Edwards, 1999).
- Decisional Conflict Scale – This standardised scale consisted of three questions measuring decision uncertainty, three questions

measuring factors contributing to uncertainty and four questions measuring perceived effective decision making (O'Connor, 1995). This standardised scale thus consisted of ten questions and was thought to be the most appropriate scale to assess the experience of decision making. Also, it was short enough to incorporate into the questionnaire and could be repeated at different intervals. The scale was applied at the time of choice and after the procedure to detect any further change with experience. On studying the level of uncertainty, its contributing factors and the perceived effectiveness would indicate the level of satisfaction women felt with their decision.

3. Measures of decision making process

- Attitude – There was no standardised scale to measure attitudes towards different abortion methods. A seven point Likert scale was constructed to assess women's attitudes towards each abortion method. The scale contained three positive points, one neutral point and three negative points ranging from "not good at all" to "very good". It was applied at the time of the decision and was repeated after the procedure to detect further changes in attitude which may be altered by the experience. An informed choice requires information to be evaluated in accordance to the patient's values. Assessing attitudes towards each abortion method gives an indication of the women's values concerning each method.

- Risk perception – There is no standardised scale to measure risk perception on treatment; therefore, a Likert scale was constructed to assess the women's perception to individual risk associated with medical and surgical abortion in accordance with other studies of risk perception (Bekker et al, 2004). The risks included in the questions were heavy bleeding, womb infection, uterine perforation, infertility, anaesthetic complication and infertility. The scale contained three positive points, one neutral and three negative, ranging from "not at all likely" to "very likely". Similar to attitude, risk perception was also part of the women's personal evaluation of the decisions which in turn offered information as to whether their choices were informed.
- Involvement in the decision – This non-standardised question asked women to rate whether or not they thought their decision should be informed, shared, and with whom it should be shared. Theoretically, the decision should be "informed" but no one has evaluated what patients think of it. The answer offered different levels of involvement to choose from: the woman's own decision, a shared decision with doctor or partner or in combination or others.
- Reason for choice of method – This was a direct question asking for the reason for their choice of method. An informed decision is one where a reasoned choice is made by a reasonable individual using relevant information about the advantages and disadvantages of all the possible courses of action, in accordance with the individual's beliefs (Bekker et al, 1999). Direct questioning of why they made

the choice would obtain the type of reason for their decision and whether they had included the process of considering risks and benefits, and then compared them with their personal beliefs when they made the decision.

4. Service provision

- Current information provision – These were direct questions on the availability of information on abortion methods available within the current health service. These included whether the women were aware of both abortion methods, the availability of choice and whether they have received written information. A further question also enquired whether women obtained useful information from the consultation. This data would provide background information on the level of information provision for the abortion method and whether it is adequate or not.
- Perceived directness of advice – These were direct questions on the influence of individuals on their choice of abortion method. Those individuals included in the questions were medical staff, partner, friends and family. The women were asked to choose the type of influence they had on their choice by choosing encouraged, neutral, discouraged or not discussed. This would obtain information from where women obtained advice and whether providers of advice were neutral.
- Assessment of leaflet – There were no standardised scales to assess different aspects of the leaflet. Therefore, Likert scales were

constructed to assess the readability and usefulness of the leaflet provided in this study. The scales contained three negative, one neutral and three positive points ranging from "none" to "all of it" when assessing ability to read through, "very difficult" to "very easy" when assessing readability, and "not at all useful" to "very useful" when assessing usefulness. The participant would be asked about the usefulness of the leaflet again after the procedure.

- Future service provision – One question enquired when information should be provided by offering the choice of before or after decision of abortion or at another time. The second question enquired where information would be distributed most effectively. The question offered different sites including hospital, GP surgery, family planning clinic, newspaper magazine and internet. The participant was asked to rate their effectiveness with a Likert scale with seven points ranging from "very helpful" to "not helpful". A further open question enquired what other information should be included.
- Pain – A visual analogue scale was applied to detect the perceived pain level after the procedure (range 0-10).
- Other changes to service – These were open questions for participants to express their opinion on other aspects of the abortion service.

The measures discussed above are summarised in Table 4.1 to illustrate which categories are measured at the time of decision, after the abortion and on both occasions.

Type of questions		At the time of choice (Questionnaire A)	After the procedure (Questionnaire B)
Character	Demographic data	Question 6-8	
	Reproductive history	Question 1-5	
Outcome	Knowledge	Question 35-41	
	Anxiety	Question 9-14	Question 1-6
	Decisional conflict	Question 25-34	Question 7-16
	Pain		Question 17
Process	Attitude	Question 23-24	Question 22-26
	Risk perception	Question 42-52	
	Involvement in decision	Question 19-20	
	Reason for chosen method	Question 21	
Service provision	Current information provision	Question 15-18, 53	Question 18
	Perceived directness of advice	Question 22 a-e	
	Future service provision		Question 19,20, 21 a-g
	Assessment of leaflet	Question 54-56	Question 27
	Other changes to service	Question 57	Question 28

Table 4.1. Measures assessed at the time of choice and after procedure

4.2.6 Procedure

4.2.6.1 Procedure to distribute written material

Written material was distributed in three stages:

First stage:

The clinic receptionist gave out the study information sheet for recruitment to all women attending the clinic for the first time.

Second stage:

The clinic staff opened a recruitment pack when women meeting the recruitment criteria had agreed to participate in the study. Each recruitment pack included:

- Two copies of the consent form. One for the participant to keep and the other for the researcher.
- A numbered (indicating study number) orange envelope containing two identical orange stickers and a leaflet, either the abortion leaflet or the contraception leaflet. On each orange sticker was the study number and a letter indicating the type of leaflet allocated i.e. abortion leaflet (T) or contraception leaflet (C). One sticker was placed on the front sheet of the patient's case notes and the other placed on the trial's record book. The leaflet was given to the participant after they had signed the study consent form.

- Questionnaire A. Participants were given the questionnaire with the leaflet and asked to complete it after the consultation. They were asked to return it to the clinic staff before leaving the clinic premises.

Third stage:

After the abortion procedure, participants were given Questionnaire B to complete about half an hour prior to discharge. They were asked to return the questionnaire to a member of staff before leaving the premises.

4.2.6.2 Procedure to carry out the study

Women attending the Fertility Control Unit were given a patient information sheet concerning the study by the receptionist when they reported at the reception area. All the women had an ultrasound scan in the clinic to assess gestation, unless carried out prior to the appointment. Women meeting the recruitment criteria were approached by a member of clinic staff to explain about the study and invite them to participate. On agreeing to participate, the clinic staff opened a recruitment pack; they were arranged in numerical order prior to the study recruitment pack being opened. The contents of the recruitment pack were described earlier. The participant then signed the consent form. They were then asked to read the leaflet contained in the recruitment pack before they had their routine consultation with the clinician. After the consultation, they were asked to fill in Questionnaire A. The participants then returned the completed questionnaire to the nursing staff when they were offered a date for their abortion procedure. This was to ensure the maximum number of questionnaires would be returned. The participants were

strongly discouraged from taking the questionnaire home to fill in as this might reduce the numbers returned. For this type of research it may be difficult to get respondents outside the hospital environment because of the sensitive issue of abortion, for instance, the women's families might not be aware of the abortion. The women would usually have their procedure performed within one to two weeks of their initial consultation. The participants were given Questionnaire B to complete half an hour prior to being discharged from their visit for the abortion procedure. The completed Questionnaire B was collected by the nursing staff before the participant left the hospital premises to maximize the return rate. If any of the questionnaires were found to be missing or not filled in, the investigator would write to the participant to fill in a further enclosed questionnaire and return with a self-addressed envelope to return the questionnaire.

The study was approved by the ethics committee of the local trust concerned (See Appendix XI for letter from ethics committee).

4.2.7 Analysis

The data were managed using SPSS.

Multivariate analyses were carried out to evaluate the following:

- Representativeness between the two groups in the trial using MANOVA. This was to ensure the outcome found in the study is a genuine effect of the intervention and not caused by two groups with different properties leading to other influences affecting the outcome.
- Representativeness between those who completed the questionnaires and those who did not using MANOVA. This was to ensure that the women

who did not fill in the questionnaire did not have different properties which could have influenced the outcome if their response were to be assessed as well.

- Effectiveness of the study leaflet after consultation using MANOVA. This was to ensure the outcome was significant and not a chance finding.
- Effectiveness of the study leaflet after the abortion procedure using MANOVA. This was to ensure the outcome was significant and not a chance finding.
- Impact of the study leaflet across two points of time with repeated measures. This was to differentiate the effect outcome under the influence of time, of the study leaflet and of both influence.

4.3 Result

Over seven months, 1177 women attended the Fertility Control Unit requesting induced abortion. Among these women, 449 were eligible and were invited to participate. One hundred and twenty-one declined to participate; uptake was 73% (328/449). Of the 328 participants randomised, 165 were randomised to the control arm; 163 were randomised to the experimental group. The average age of participants in this trial was 24.7 years old. No significant difference was noted between groups (control, experimental respectively; χ=24.6, 95% CI=23.7-25.6; χ=24.8, 95% CI=23.8-25.9; f=0.06;df=1; p=0.81). Three hundred and thirteen women returned Questionnaire A, with no significant differences noted between the two study groups (X^2= 0.76; df= 1; p= 0.38) (Table 4.2).

In relation to choice of abortion method as a primary outcome, more women chose to have surgical abortion compared to medical abortion (Table 4.3). No significant difference in the final choice of abortion method was noted between the control and experimental group (X^2= 0.77; df= 1; p= 0.38). One from the control group and one from the experimental group were found to have medical conditions after randomisation that resulted in their exclusion.

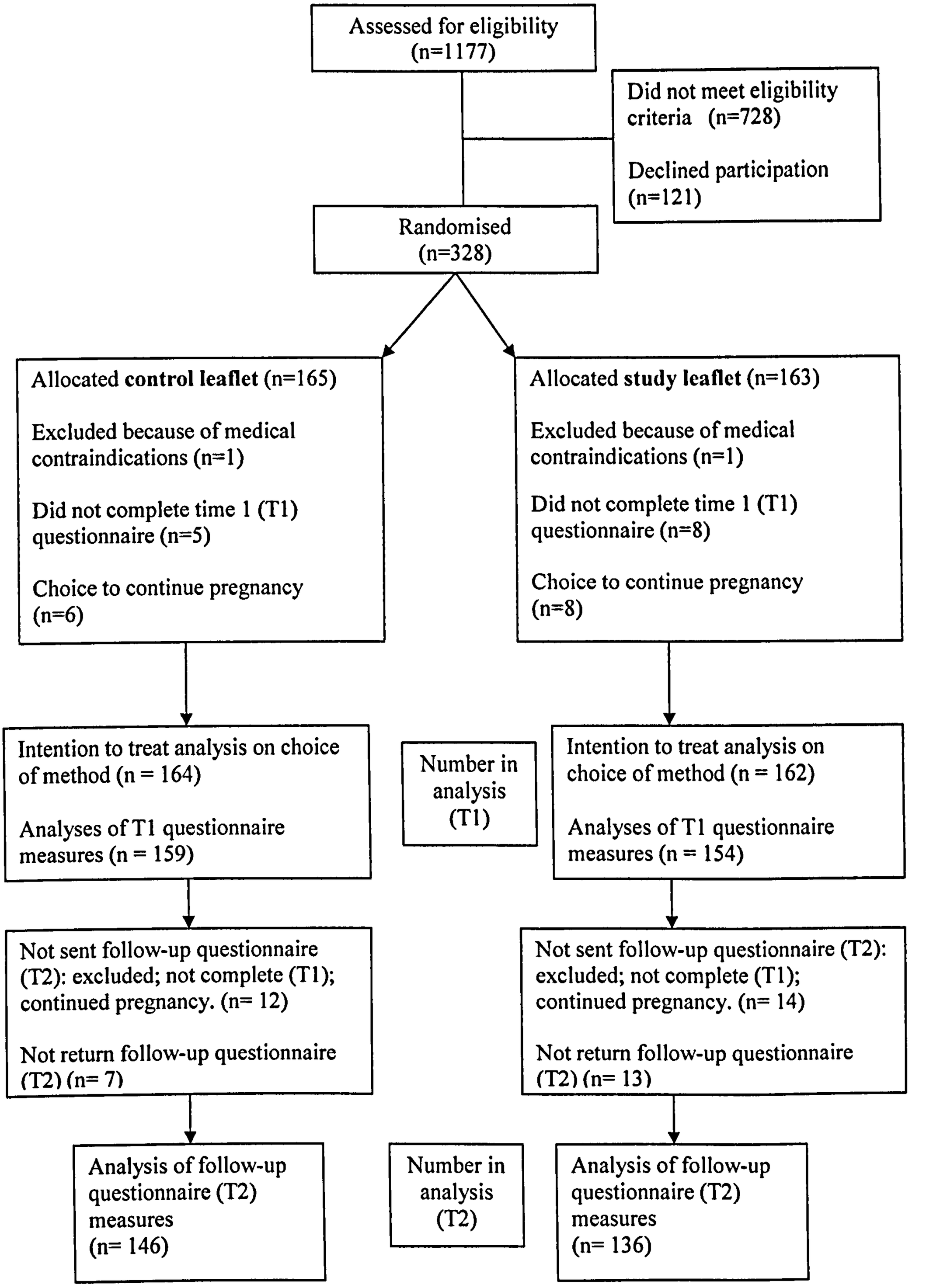

Figure 1: CONSORT flow diagram of participants through trial.

Table 4.2. Number of Questionnaire A returned by women in the trial

Questionnaire A	Total number n= 326 (%)	Control group n= 164 (%)	Experimental group n= 162 (%)
Returned	313 (96%)	159 (97%)	154 (95%)
Not returned	13 (4%)	5 (3%)	8 (5%)

Table 4.3. Final choice of abortion method chosen by women participating in the trial

Final decision	Total number n= 326 (%)	Control group n= 164 (%)	Experimental group n= 162 (%)
Medical abortion	114 (35%)	54 (33%)	60 (37%)
Surgical abortion	198 (61%)	104 (63%)	94 (58%)
Continue pregnancy	14 (4%)	6 (4%)	8 (5%)

The remainder of the analysis was carried out on those that completed Questionnaire A (n=313).

4.3.1 Demographics

Over two thirds of the participants were single, most had a partner (64%) (Table 4.4), most were white (Table 4.5) and 89% had achieved education level of GCSE level or above (Table 4.6). There were no significant different between groups.

Table 4.4. Marital status of women in the trial who have returned Questionnaire A

Marital status	Total number n= 313 (%)	Control group n= 159 (%)	Experimental group n= 154 (%)
Married / lived as married	73 (23%)	36 (23%)	37 (24%)
Single with boyfriend	129 (41%)	62 (39%)	67 (44%)
Single	85 (27%)	50 (31%)	35 (23%)
Divorced / Separated	26 (8%)	11 (7%)	15 (10%)

(X^2 =3.39; df=3, p=0.34)

Table 4.5. Ethnic origin of women in the trial who have returned Questionnaire A

Ethnic origin	Total number n= 313 (%)	Control group n=159 (%)	Experimental group n= 154 (%)
White	267 (85%)	141 (89%)	126 (82%)
Black	20 (6%)	7 (4%)	13 (8%)
Asian	12 (4%)	6 (4%)	6 (4%)
Other	14 (4%)	5 (3%)	9 (6%)

(X^2 = 3.71; df = 3; p=0.30)

Table 4.6. Education level of women in the trial who have returned Questionnaire A

Education level	Total number n=313 (%)	Control group n=159 (%)	Experimental group n=154 (%)
No formal education	35 (11%)	17 (11%)	18 (12%)
GCSE	127 (41%)	65 (41%)	62 (40%)
A Level	57 (18%)	32 (20%)	25 (16%)
Apprenticeship	32 (10%)	11 (7%)	21 (14%)
Degree or higher	62 (20%)	34 (21%)	28 (18%)

(X^2 = 4.59; df = 4; p = 0.33)

Almost half the participants had no children and there was no difference between the two groups (Table 4.7). For the 44% who had children, in the control group, 59 had a normal delivery, 11 instrumental deliveries and 14 caesarean section; in the experimental group, 57 had normal delivery, 16 instrumental deliveries and 10 caesarean section.

Table 4.7. Number of living children of participant who have returned Questionnaire A

Number of living children	Total number n=313 (%)	Control group n=159 (%)	Experimental group n=154 (%)
0	174 (56%)	90 (57%)	84 (55%)
1	56 (18%)	29 (18%)	27 (18%)
2	51 (16%)	21 (13%)	30 (19%)
3 or more	32 (10%)	19 (12%)	13 (8%)

($X^2 = 2.91$; df = 3; p = 0.41)

Over four fifths of participants had no previous experience of miscarriage (Table 4.8). Over a quarter of the participants had no previous abortion (Table 4.9). In the control group, 45 had surgical abortions, six medical abortions and two had experienced both. In the experimental group, 31 had surgical abortions, six medical abortions and one had experienced both. No significant differences were noted between the two groups.

Table 4.8. Number of previous miscarriage for participant who have returned Questionnaire A

Number of previous miscarriage	Total number n=313 (%)	Control group n=159 (%)	Experimental group n=154 (%)
0	271 (87%)	136 (86%)	135 (88%)
1	29 (9%)	16 (10%)	13 (8%)
2 or more	13 (4%)	7 (4%)	6 (4%)

($X^2 = 0.31$; df = 2; p = 0.86)

Table 4.9. Number of previous abortion of participant who have returned Questionnaire A

Number of previous abortion	Total number n= 313 (%)	Control group n= 159 (%)	Experimental group n= 154 (%)
0	223 (71%)	106 (67%)	117 (76%)
1	67 (21%)	40 (25%)	27 (18%)
2 or more	23 (7%)	13 (8%)	10 (6%)

($X^2 = 3.38$; df = 2; p = 0.19)

4.3.2 Measures of outcome

4.3.2.1 Behaviour

Amongst those who completed questionnaire A, more women chose to have surgical abortions which have the same pattern as intention to treat (Table 4.10). No significant differences in the final choice of abortion method were noted between the control and experimental group in those completing questionnaire A.

Table 4.10. Final choice of abortion method chosen by women returning questionnaire A

Final decision	Total number n= 313 (%)	Control group n= 159 (%)	Experimental group n= 154 (%)
Medical abortion	110 (35%)	52 (33%)	58 (37%)
Surgical abortion	192 (61%)	101 (64%)	91 (58%)
Continue pregnancy	11 (4%)	6 (4%)	5 (5%)

(X^2=0.86; df=2; p=0.65)

4.3.2.2 Knowledge

The mean knowledge score was 4.31 (95% CI = 4.13-4.50). Women in the experimental group had higher knowledge scores compared to women in the control group (control, experimental respectively, X = 3.58; 95% CI = 3.37 – 3.80;

X = 5.06; 95% CI = 4.82 -5.31; f = 80.03; df = 1; p=<0.001). The proportion of women obtaining a correct answer for the knowledge item was greater in the experimental group for each item except one relating to general anaesthetics (Table 4.11).

Table 4.11. Number of correct answers given for seven knowledge questions

Knowledge questions	Total number n=313 (%)	Control group n=159 (%)	Experimental group n=154 (%)	X^2	Significance (p value)
Duration of hospital stay for STOP	214 (68%)	85 (53%)	129 (84%)	33.23	< 0.001
Abortion method that cannot be completed in 1 day	208 (66%)	84 (53%)	124 (81%)	26.91	< 0.001
Failure rate of MTOP	127 (41%)	44 (28%)	83 (54%)	22.31	< 0.001
Failure rate of STOP	90 (29%)	31 (19%)	59 (38%)	13.52	< 0.001
Mode of giving medication for MTOP	197 (63%)	82 (52%)	115 (75%)	17.90	< 0.001
Duration of operation for STOP	211 (67%)	90 (57%)	121 (79%)	17.19	< 0.001
Method of abortion that required general anaesthetic	303 (97%)	154 (97%)	149 (97%)	0.00	0.96

4.3.2.3 Anxiety

The mean score on the anxiety scale (STAI) (range 20 – 80) was 53.9 (95% CI = 52.3-55.5), no significant differences were noted between the two groups (control, experimental respectively; X = 53.4; 95% CI = 51.17-55.79; X = 54.32; 95% CI = 52.20-56.44; f=0.28; df=1; p=0.60).

4.3.2.4 Decisional conflict scale

One of the decisional conflict sub-scales was significantly different between the two groups (df = 1; F = 7.14; p = 0.02), women in the experimental group showed lower uncertainty in the contributing factor compared to those in the experimental group (Table 4.12).

Table 4.12. Score on decision conflict scale for participants

	Total number n=313 (95% CI)	Control group n=159 (95% CI)	Experimental group n=154 (95% CI)	F	Significance (p value)
Decision uncertainty (low – high) (3-15)	7.75 (7.43-8.08)	7.84 (7.35-8.32)	7.66 (7.23-8.10)	0.28	0.60
Factor contributing to uncertainty (low – high) (3-15)	5.89 (5.61-6.11)	6.14 (5.83-6.45)	5.64 (5.34-5.94)	5.20	0.02
Perceived effective decision making (low – high) (4-20)	7.20 (6.95-7.45)	7.35 (7.00-7.69)	7.06 (6.70-7.42)	1.28	0.26

4.3.3 Measures of decision making process

4.3.3.1 Attitude

Overall women had a more positive attitude towards the surgical abortion method than the medical abortion method (Paired t test: mean=0.81, 95% CI=0.57-1.04, df=312, p<0.001). Women in the experimental group had a more positive attitude towards the medical abortion method compared to those in the control group (Table 4.13).

Table 4.13. Women's attitude on abortion methods

Attitude towards abortion methods	Total number n=313 (95% CI)	Control group n=159 (95% CI)	Experimental group n=154 (95% CI)	F	Significance (p value)
STOP (low – high) (0-6)	4.30 (4.1-4.5)	4.27 (4.1-4.5)	4.32 (4.1-4.6)	0.1	0.73
MTOP (low – high) (0-6)	3.49 (3.3-3.7)	3.26 (3.0-3.5)	3.73 (3.5-4.0)	5.9	0.02

4.3.3.2 Risk perception

Overall, heavy bleeding was seen as the greatest risk for medical and surgical abortion. Women's perception of the risk associated with medical and surgical abortion was rated significantly lower by those in the experimental group (table 4.14, 4.15).

Table 4.14. Women's perception of risk on medical abortion

Risk perception on MTOP	Total number n=313 (95% CI)	Control group n=159 (95% CI)	Experimental group N=154 (95% CI)	F	Significance (p value)
Heavy bleeding (low-high) (0-6)	4.4 (4.2-4.5)	4.8 (4.6-5.0)	3.9 (5.6-4.2)	22.5	<0.001
Infection (low-high) (0-6)	2.0 (1.8-2.1)	2.0 (1.8-2.2)	1.9 (1.7-2.1)	0.7	0.41
Perforation of uterus (low-high) (0-6)	1.0 (0.8-1.1)	1.1 (0.9-1.3)	0.8 (0.6-1.0)	6.0	0.02
Infertility (low-high) (0-6)	1.1 (1.0-1.3)	1.3 (1.1-1.5)	0.9 (0.7-1.1)	7.5	0.01
Incomplete abortion (low-high) (0-6)	2.3 (2.2-2.5)	2.4 (2.2-2.7)	2.2 (2.0-2.4)	2.0	0.16

Table 4.15. Women's perception of risk on surgical abortion

Risk perception on STOP	Total number N=313 (95% CI)	Control group N=159 (95% CI)	Experimental group n=154 (95% CI)	F	Significance (p value)
Heavy bleeding (low-high) (0-6)	3.6 (3.4-3.8)	3.9 (3.7-4.2)	3.2 (2.9-3.5)	15.4	<0.001
Infection (low-high) (0-6)	2.5 (2.4-2.7)	2.6 (2.4-2.8)	2.5 (2.2-2.7)	0.9	0.34
Perforation of uterus (low-high) (0-6)	2.2 (2.05-2.4)	2.3 (2.1-2.5)	2.1 (1.9-2.3)	1.6	0.20
Infertility (low-high) (0-6)	1.5 (1.4-1.7)	1.8 (1.5-2.0)	1.3 (1.1-1.5)	8.3	<0.001
Anaesthetics (low-high) (0-6)	1.8 (1.6-1.9)	1.9 (1.7-2.1)	1.6 (1.4-1.8)	3.9	0.05
Incomplete abortion (low-high) (0-6)	1.3 (1.2-1.5)	1.5 (1.4-1.7)	1.2 (1.0-1.3)	10.3	0.001

4.3.3.3 Involvement in decision

Women's views on who should make the decision on abortion method varied.

Only one woman felt the decision on abortion method should be made by the doctor alone. Sixty percent of women felt that this should be a joint decision either with her partner or her doctor. No significant differences on views were noted between the two groups (Table 4.16).

Table 4.16. Women's perception on involvement in decision of abortion method

Involvement in decision	Total n=313 (%)	Control group n=159 (%)	Experimental group n=154 (%)	df	Significant (p value)
Women only	112 (36)	50 (31)	62 (40)	6	0.57
Doctor only	1 (<1)	1 (<1)	0 (0)		
Women with her partner	48 (15)	26 (16)	22 (14)		
Women with her doctor	140 (45)	74 (47)	66 (43)		
Other	12 (4)	8 (5)	4 (3)		

4.3.3.4 Perceived directness on advice on abortion method

Thirteen percent of women said they had not discussed the abortion method with a medical professional whilst 19% of medical professionals were seen as being directive. For those who had discussed abortion methods with someone, 58% had discussed the decision with their husband or partner, 54% with a friend and 38% with a relative. No significant differences were noted between the two groups in terms of perceived directness (Table 4.17). The health professionals were less directive than family and friends (Table 4.17).

Table 4.17. Perceived directness other's advice on abortion method

		Total n=313 (%)	Control group n=159 (%)	Experimental group n=154 (%)	df	Significance (p value)
Doctor / nurses	Encourage	57 (18)	27 (17)	30 (19)	3	0.33
	Neutral	213 (68)	115 (72)	98 (64)		
	Discourage	2 (1)	1 (1)	1 (1)		
	Not discussed	41 (13)	16 (10)	25 (16)		
Husband / partner	Encourage	69 (22)	31 (19)	38 (25)	3	0.59
	Neutral	106 (34)	53 (33)	53 (34)		
	Discourage	8 (3)	5 (3)	3 (2)		
	Not discussed	130 (42)	70 (44)	60 (39)		
Friend	Encourage	53 (17)	28 (18)	25 (16)	3	0.57
	Neutral	111 (35)	57 (36)	54 (35)		
	Discourage	5 (2)	1 (1)	4 (3)		
	Not discussed	144 (46)	73 (46)	71 (46)		
Relatives	Encourage	37 (12)	17 (11)	20 (13)	3	0.85
	Neutral	74 (24)	40 (25)	34 (22)		
	Discourage	7 (2)	4 (3)	3 (2)		
	Not discussed	195 (62)	98 (62)	97 (63)		

4.3.3.5 Reason for choosing an abortion method

Over 80% of women gave one to two reasons for their choice of abortion method (Table 4.18). The most frequently generated reasons related to belief in surgical abortion, followed by belief in medical abortion and then risks involved in the procedure (Table4. 19). No differences in patterns of response were discovered between the two groups (Tables 18 & 19).

Table 4.18. Number of reason given for their choice of abortion method

Number of reason given	Total n=328 (%)	Control group n=165 (%)	Experiment group n=163 (%)	df	Significant (p value)
0	25 (8)	12 (7)	13 (8)	3	0.89
1	150 (46)	79 (48)	71 (44)		
2	120 (37)	58 (35)	62 (38)		
3	33 (10)	16 (10)	17 (10)		

Table 4.19. Reason for choosing a method for abortion

Reason to choose a method	Total group n=328 (%)	Control group n=165 (%)	Experimental group n=163 (%)
Time (e.g. quick method)	63 (19)	29 (18)	34 (20)
Advice (e.g. Recommend by another person)	8 (2)	6 (4)	2 (1)
Experience (e.g. Past experience of abortion)	21 (6)	12 (7)	9 (6)
Belief in Medical abortion (e.g. like a miscarriage)	89 (27)	50 (30)	39 (24)
Belief in Surgical abortion (e.g. do not wish to be aware of the procedure)	166 (51)	80 (48)	86 (53)
Risks (e.g. infection)	74 (23)	34 (21)	40 (25)
Side effect (e.g. side effect of anaesthetic)	2 (1)	1 (1)	1 (1)
Miscellaneous	12 (4)	3 (2)	9 (6)
Contraception (e.g. have a coil fitted at the same time)	9 (3)	4 (2)	5 (3)

4.3.3.6 Influence of the study leaflet on final choice of abortion method

The study leaflet was not associated with any influence on their final choice of abortion method (Tables 4.20, 4.21 & 4.22).

Table 4.20. Final choice for women who have not made any decision on abortion method prior to their consultation

Final choice of abortion method	Total n=163(%)	Control group N=81 (%)	Experimental group N=82 (%)	X^2	df	Significant (p value)
Surgical abortion	98 (60)	50 (62)	48 (59)	0.25	2	0.88
Medical abortion	58 (36)	28 (34)	30 (36)			
Continue pregnancy	7 (4)	3 (4)	4 (5)			

Table 4.21. Final choice for women who prefer surgical abortion or wish to avoid medical abortion prior to their consultation

Final choice of abortion method	Total n=90 (%)	Control group n=52 (%)	Experimental group n=38 (%)	X^2	df	Significant (p value)
Surgical abortion	86 (96)	49 (94)	37 (97)	0.51	1	0.48
Medical abortion	4 (4)	3 (6)	1 (3)			
Continue pregnancy	0 (0)	0 (0)	0 (0)			

Table 4.22. Final choice for women who prefer medical abortion or wish to avoid surgical abortion prior to their consultation

Final choice of abortion method	Total n=60 (%)	Control group n=26(%)	Experimental group n=34 (%)	X^2	df	Significant (p value)
Surgical abortion	8 (13)	2 (8)	6 (18)	2.73	2	0.26
Medical abortion	48 (80)	21 (81)	27 (79)			
Continue pregnancy	4 (7)	3 (11)	1 (3)			

4.3.3.7 Service Provision

Before the consultation appointment, over four fifths of participants had heard of surgical abortion, but only three fifths had heard of medical abortion (Table 4.23). Under a quarter of participants had received written information on abortion method prior to the appointment and nearly half of them were not aware that they had a choice between abortion methods (Table 4.23). Despite significantly more women in the control group having heard of surgical abortion, there was no significant difference between the two groups in women being aware of medical abortion, a choice between abortion methods or having received written information prior to their appointment (Table 4.23).

Table 4.23. Awareness of abortion method prior to clinic consultation

	Total n=313 (%)	Control group n=159 (%)	Experimental group n=154 (%)	X^2	df	Significance (p value)
Not heard of surgical abortion prior appointment	43 (14)	15 (9)	28 (18)	5.05	1	0.03
Heard of surgical abortion prior appointment	270 (86)	144 (91)	126 (82)			
Not heard of medical abortion prior appointment	125 (40)	62 (39)	63 (41)	0.12	1	0.73
Heard of medical abortion prior appointment	188 (60)	97 (61)	91 (59)			
Not received written information prior appointment	241 (77)	125 (79)	116 (75)	0.48	1	0.49
Received written information prior appointment	72 (23)	34 (21)	38 (25)			
Not aware of a choice between abortion methods	149 (48)	73 (46)	76 (49)	0.37	1	0.54
Aware of a choice between abortion methods	164 (52)	86 (54)	78 (51)			

Participants who had heard of either medical or surgical abortion were more likely to obtain the information from a medical institution or medical personnel or a friend (Tables 4.24 & 4.25). No significant differences were noted between the study groups (Tables 4.24 & 4.25).

Table 4.24. Source of information for women who have heard of surgical abortion

	Total n=249 (%)	Control group n=132 (%)	Experimental group n=117 (%)	X^2	df	Significant (p value)
Medical institution or personnel	93 (37)	45 (34)	48 (41)	7.06	6	0.32
Friends	59 (24)	30 (23)	29 (25)			
Family	13 (5)	4 (3)	9 (8)			
School	17 (7)	11 (8)	6 (5)			
Media	15 (6)	9 (7)	6 (5)			
Own experience	42 (17)	27 (20)	15 (13)			
General knowledge	10 (4)	6 (5)	4 (3)			

Table 4.25. Source of information for women who have heard of medical abortion

	Total n=173 (%)	Control group n=88 (%)	Experimental group n=85 (%)	X^2	df	Significance (p value)
Medical institution or personnel	76 (44)	38 (43)	38 (45)	8.27	6	0.219
Friends	46 (27)	26 (30)	20 (24)			
Family	9 (5)	1 (1)	8 (9)			
School	6 (3)	4 (5)	2 (2)			
Media	21 (12)	12 (14)	9 (11)			
Own experience	14 (8)	7 (8)	7 (8)			
General Knowledge	1 (1)	0 (0)	1 (1)			

4.3.4 Questionnaire B - Analysis after termination procedure

The following analysis was carried out on the 281 women who returned Questionnaire B; response rate 93% (282/302). Of those that completed both Questionnaire A & B, 35% (100/282) had a medical abortion and 65% (182/282) had a surgical abortion. There was no significant different in return rates (X^2 =1.73, df = 1, p = 0.19) or decision (X^2 = 0.48, df = 1, p = 0.49) by the experimental group.

4.3.5 Measures of outcome

4.3.5.1 Anxiety (also measured in Questionnaire A)

The mean score on the STAI scale is 42.5, no significant differences were noted between the two groups (control, experimental respectively; X = 41.8, 95% CI = 39.7 – 44.0; X = 43.3, 95% CI = 41.2 – 45.4; df = 1; p = 0.34).

4.3.5.2 Decisional conflict scale (also measured in Questionnaire A)

Within the sub-scale, women in the experimental group had a lower decisional uncertainty in contributing factors (Table 4.26).

Table 4.26. Score on decisional conflict scale on participant after abortion.

	Total (95% CI)	Control (95% CI)	Experimental (95% CI)	df	Significance (p value)
Decision uncertainty	6.8 (6.5-7.1)	6.8 (6.3-7.2)	6.9 (6.5-7.3)	1	0.68
Factors contributing to uncertainty	5.8 (5.6-6.0)	6.0 (5.7-6.3)	5.5 (5.2-5.7)	1	0.01
Perceived effective decision making	7.2 (6.9-7.5)	7.3 (6.9-7.6)	7.2 (6.8-7.5)	1	0.73

4.3.5.3 Pain

The mean pain score was 2.9 (95% CI = 2.6-3.3), no significant differences were noted between the two groups (control, experimental respectively; X = 2.7, 95% CI = 2.3-3.1; X = 3.1, 95% CI = 2.6-3.6; df=1; p=0.23).

4.3.6 Measures of service provision

Women have found the information leaflet provided in the first visit and general information given in the unit useful with no significant difference between the two groups (Table 4.27). There is a trend towards being more satisfied in the experimental group (Table 4.27).

Table 4.27. Usefulness in general information provision and leaflet provided

	Total (95% CI)	Control (95% CI)	Experimental (95% CI)	df	Significance (p value)
Usefulness in general information (Not useful to very useful)	4.8 (4.6-4.9)	4.7 (4.5-4.9)	4.8 (4.6-5.0)	0.46	0.50
Usefulness in information leaflet (Not helpful to helpful)	4.1 (3.9-4.3)	4.0 (3.7-4.2)	4.3 (4.0-4.7)	1	0.09

Over one third of women felt information on abortion should be provided when they had decided to have an abortion, with no difference between the two groups (Table 4.28).

Table 4.28. Timing on giving abortion information

When to give information	Total (%)	Control (%)	Experimental (%)	df	Significance (p value)
Decided to have abortion	98 (35%)	45 (31%)	53 (39%)	2	0.33
Considering abortion	172 (61%)	95 (65%)	77 (57%)		
Other times	11 (4%)	6 (4%)	5 (4%)		

Most women suggested that it would be helpful if information on abortion was regularly available in the hospital, GP surgery and family planning clinics with no significant difference between groups. Fewer women felt information provision in the media was helpful, significant differences were noted in the opinion concerning information in newspapers. Over half of the women in both groups suggested that if information was made available on the internet it would be helpful to them (Table 4.29).

Table 4.29. Place where information on abortion should be distributed

		Total n=281 (%)	Control n=146 (%)	Experimental n=135 (%)	X^2	df	Significance p value
Hospital	Helpful	255 (91)	136 (93)	119 (88)	2.1	2	0.35
	Maybe	15 (5)	6 (4)	9 (7)			
	Not helpful	11 (4)	4 (3)	7 (5)			
GP / Surgery	Helpful	254 (90)	136 (93)	118 (87)	2.7	2	0.25
	Maybe	18 (6)	7 (5)	11 (8)			
	Not helpful	9 (3)	3 (2)	6 (4)			
Family Planning Clinic	Helpful	250 (89)	134 (92)	116 (86)	2.6	2	0.27
	Maybe	22 (8)	9 (6)	13 (10)			
	Not helpful	9 (3)	3 (2)	6 (4)			
Newspaper	Helpful	51 (18)	28 (19)	23 (17)	9	2	0.01
	Maybe	86 (31)	55 (38)	31 (23)			
	Not helpful	144 (51)	63 (43)	81 (60)			
Magazine	Helpful	93 (33)	47 (32)	46 (34)	1.5	2	0.482
	Maybe	95 (34)	54 (37)	41 (30)			
	Not helpful	93 (33)	45 (31)	48 (36)			
Internet	Helpful	165 (59)	87 (60)	78 (58)	0.4	2	0.82
	Maybe	60 (21)	32 (22)	28 (21)			
	Not helpful	56 (20)	27 (18)	29 (21)			

4.3.7 Measure of decision making process

In general, women in the study did not regret the method they chose irrespective of which leaflet they were given (Table 4.30). Women appeared to be more likely to recommend the medical abortion compared to the surgical method (Paired t test: mean = 0.60, 95% CI = 0.30, 0.91, df = 280, p=<0.001) . However, they seemed to have a more positive attitude towards surgical abortion than the medical method after the procedure (Paired t test: mean = 1.48, 95% CI = 1.17-1.79, df = 280, p = <0.001).

Table 4.30. Opinion on abortion method

	Total (95% CI)	Control (95% CI)	Experimental (95% CI)	df	Significance (p value)
Regret (disagree – agree)	0.5 (0.3-0.6)	0.5 (0.3-0.6)	0.5 (0.3-0.7)	1	0.82
Recommend medical abortion (negative – positive)	3.1 (2.9-3.3)	3.0 (2.7-3.2)	3.2 (3.0-3.5)	1	0.14
Recommend surgical abortion (negative – positive)	2.3 (2.1-2.5)	2.4 (2.1-2.6)	2.3 (2.0-2.6)	1	0.70
Attitude on surgical abortion (negative – positive)	4.8 (4.7-5.0)	5.0 (4.7-5.2)	4.7 (4.4-4.9)	1	0.07
Attitude on medical abortion (negative – positive)	3.3 (3.1-3.6)	3.1 (2.8-3.4)	3.6 (3.3-3.9)	1	0.01

4.3.8 Comparing outcome and decision making process in Questionnaire A & B

With the changes over time, the anxiety level and decision uncertainty for both groups has reduced (Table 4.31). The factors contributing to uncertainty and perceived effective decision making has not changed over time for both groups (Table 4.31). The attitude for the surgical method for both groups has become more positive over time but has not altered for the medical method (Table 4.31).

Table 4.31. Comparison of different variables between two points of time

	Control group		Experimental group		Time	Leaflet	Time x leaflet
Variable	Mean - After decision (95% CI)	Mean - After procedure (95% CI)	Mean - After decision (95% CI)	Mean - After procedure (95% CI)	p value	p value	p value
Anxiety	53.5 (51.2 – 55.8)	42.0 (40.0 – 44.0)	54.3 (52.2 – 56.4)	43.3 (41.5 – 45.1)	< 0.01	0.36	0.78
Decision uncertainty	7.8 (7.4 – 8.3)	6.7 (6.3 – 7.1)	7.7 (7.3 – 8.2)	6.9 (6.5 – 7.3)	< 0.01	0.90	0.21
Factors contributing to uncertainty	6.1 (5.8 – 6.5)	6.0 (5.8 – 6.3)	5.7 (5.4 – 6.0)	5.5 (5.3 – 5.8)	0.29	0.01	0.94
Perceived effective decision making	7.4 (7.0 – 7.7)	7.3 (7.0 – 7.7)	7.1 (6.7 – 7.4)	7.3 (7.0 – 7.6)	0.51	0.46	0.28
Attitude for STOP	4.3 (4.1 – 4.5)	5.0 (4.7 – 5.2)	4.4 (4.2 - 4.6)	4.7 (4.4 – 4.9)	<0.01	0.47	0.02
Attitude for MTOP	3.2 (2.9 – 3.5)	3.1 (2.8 – 3.4)	3.6 (3.4 – 3.9)	3.6 (3.3 – 3.9)	0.37	0.01	0.54

4.4 Discussion

4.4.1 Summary of findings

This study was designed to investigate the impact of a leaflet on facilitating women's choice of abortion method. Unfortunately, the leaflet did not make any difference on the women's final choice of abortion method. A number of measures did differ between the control leaflets which suggested the leaflet on abortion methods did facilitate the decision making process. Firstly, the knowledge scores were higher in the experimental group. Secondly, the perception of risk of both surgical and medical method was lower in the experimental group. Thirdly,

women in the experimental group had a more positive attitude towards the medical method and less positive attitude towards the surgical method, as they had evaluated more information on each method. Fourthly, uncertainty in the contributing factor on assessment of decisional conflict was lower in the experimental group before and after the procedure, which can be perceived as making a more informed choice. Fifthly, the experimental group were more likely to find the leaflet useful prior to the procedure. The provision of more effective information has not shown to have any impact on some clinical aspects. There was no difference in the actual choice of abortion method, pain score and regret on their choice of method.

A number of items which can influence the decision making process have been studied. Most women felt the decision on abortion method should be shared with their partner or doctor. Before the consultation, most appeared to have discussed the issue with their partner, friend or relative; most have also previously obtained advice from a medical professional. In addition, a number of issues relating to women's experience of the abortion service have been identified. Before the consultation, fewer women had heard of the medical method compared to surgical. Only a minority were aware of a choice of method and had received any form of written information. For those who received information prior to their visit, it was obtained from a medical institution or a friend. Women generally supported the idea that information should be made regularly available in medical institutes, but provision via the general media except for the internet was not well supported.

4.4.2 Validity of findings and ability to generalise findings

In this study, no significant difference in demographic factors was found between women relating to their final choice regardless of their allocated group. Other studies have shown demographic factors such as education level, age, occupation, geographic origin, lower gestational age might influence the abortion method chosen (Bachelot et al, 1992; Henshaw et al, 1994; Slade et al, 1998; Wiebe, 1997). Few pieces of literature have studied the decision making process of abortion methods (Bachelot et al, 1992; Bachelot et al, 1992; Harvey et al, 2001; Henshaw et al, 1993; Slade et al, 1998; Wiebe, 1997). The proportion of women choosing the medical abortion method compared to the surgical method also varied between studies (Cabezas, 1998; Child et al, 2001; Henshaw et al, 1994; Slade et al, 1998). This was not surprising, as previous statistics have shown wide variations in the proportion of women choosing either method in different countries and region (Gupta, 1998; Thong et al, 1992). Past research has looked for similarities of women's character in abortion studies, such as choice, reasons, and experience. Most of the studies on the choice of method have asked women for the reason for their choice. The reasons given were usually related to time and beliefs about surgical or medical abortion (Bachelot et al, 1992; Henshaw et al, 1993; Slade et al, 1998; Wiebe, 1997). These findings are similar to those found in this study. The influence of medical personnel, relatives and friends on the decision have also been recognised in prior literature (Bachelot et al, 1992), the same influence has also been supported by the current study. Previous research on decision aids has shown a reduction in decision conflict and an improvement of

knowledge without altering anxiety (O'Connor et al, 1999). The same findings have been shown in this study as well.

Despite the similarities in findings compared to the past literature, this study is the first randomised controlled trial to investigate the effect on the decision making process on abortion methods with the aid of an information leaflet as a form of decision aid. The study has been carried out in a rigorous manner. Support for the validity of these findings is as follows. The similarities of the demographic data between women in either group in the study have confirmed that the two groups were effectively randomised. Any effect obtained in the study would be caused by the effect of the leaflet given rather than by other factors.

Previous research has studied the different aspects of women's choice of abortion method and experience. Despite that, inadequacy in different aspects of research methodology made generalisation of their findings difficult. Some studies recruited their participants before the women had made their choice (Bachelot et al, 1992; Henshaw et al, 1993), and others recruited theirs afterwards or as part of another trial (Harvey et al, 2001; Slade et al, 1998; Wiebe, 1997). None have used a specifically designed leaflet to study its effect on the decision concerning abortion methods. Despite most of the studies stating that their participants had been provided with adequate information on the abortion method, either verbally or in writing, none have assessed the quality of the information provided. Without a randomised controlled trial, it is difficult to assess whether or not information provided could have influenced the women's decision. One study has shown that some participants did not choose the method themselves; some had misconceptions

about the information given which limited their choice of method (Slade et al, 1998).

This current study has provided a specially designed leaflet on abortion methods with standard readability. This study has a sufficiently described objective of assessing the effect of this leaflet towards facilitating decision making. The criteria for entry to the study have been sufficiently described. Concurrent control with a group reading a control leaflet has been used in the study to minimise bias and make the treatment and control groups comparable in relevant measures. Participants have been randomly allocated to the study and control group by opening consecutive envelopes. Allocation was previously randomised by drawing numbers. The two arms of each study were clearly defined by the type of leaflet given to read. The control leaflet contained information on post-abortion contraceptive use. This was designed to minimise the chance of women being able to guess whether they were in the experimental or control group. The participants were potentially blinded to which arm of the study they were being allocated, but the health professionals could possibly identify the allocated arm of the participant unintentionally from the documentation of case notes or during the standard consultation with the participant. This could potentially influence the content of the consultation which may in turn affect the decision making process.

Previous literature has used inappropriate and inconclusive measures to study the decision making process including reasons for choice, the level of pain and anxiety (Bachelot et al, 1992; Harvey et al, 2001; Henshaw et al, 1993; Slade et al, 1998). These assessments were usually followed by further assessment on

satisfaction. This current study has assessed aspects of clinical outcomes including pain and anxiety level; reasons for choice, knowledge, risk perception and decision conflict which would be more capable to study the whole decision process and to study whether the decision was "informed" (Bekker et al, 1999); and possibly influence service provision.

This study was one of the first to ensure that women had achieved a reasonable level of knowledge when they were making their decision. In addition, prior awareness of the existence of each method has also been assessed. Only one previous study has looked at knowledge on a theoretical basis regarding the medical method, but with no real involvement on choosing either method. Even in this study, the misconceptions about the medical method were shown to be high (Virgo et al, 1999). This study has also taken into account the effect of time. Repeated measures were made of anxiety; decisional conflict and perceived usefulness of the leaflet with questions asked before and after the abortion procedure. This type of repeated measure has not been used in similar studies. The study took place in the only referral centre within an area with a large population. Consecutive participants were recruited within the target duration. The sample obtained in this study was likely to be representative of the area being studied.

The main outcome measures have been clearly classified as the decision making process. Hence the choice of outcome measures were appropriate namely the primary outcome measure has appropriately included knowledge, anxiety, decisional conflict level, pain level, attitude towards each method, risk perception,

decision involvement, reasons for choice. Other secondary outcomes including the choice of method and service provision issues have also been identified. The pre-study calculation of the required sample size reported was based on an increased uptake of medical abortion and change in anxiety level. It would be more appropriate to base the calculation of the sample size on the primary outcome, namely change in knowledge, decisional conflict level and attitude towards the method. Twenty-three percent of eligible women declined to participate in the study. This group of women may contain certain properties which may influence the outcome of the study. For example, women who have received information from other sources and have decided on the abortion method may not wish to read a further leaflet in the trial. On the other hand, women who were very anxious and unsure of their decision may not wish to join the trial due to possible stress associated with participation. Out of the 326 women in the trial, 4% did not return Questionnaire A, 13% did not return Questionnaire B. No further information could be obtained from the non-respondents such as the reason for not returning the questionnaire which might have possibly influenced the final outcome. As the treatment options of the study only involved provision of an information leaflet, not medication, the routine practise of the unit at the time involved providing a leaflet at that stage of the appointment and therefore no ethical concerns were involved. Appropriate statistical analyses including confidence intervals have been included in the main results of the study. Questionnaire B was completed immediately after the procedure to minimise the loss, as follow-up was usually held in a community clinic not at the referral centre. This time scale may be too short to study the after effect of the procedure and hence prevent assessment the full impact of the decision making process. If a centralised and compulsory

follow-up clinic is available, it would be better to fill in the follow-up questionnaire in those clinics. As abortion is a sensitive subject, some of the participants requested no contact at home; therefore sending out follow-up questionnaires was not an option.

4.4.3 Impact of service

The questionnaires have studied the impact of the leaflet on the decision making process but the impact on the consultation's content has not been assessed in any way. It is possible that the provision of written information could have shortened the consultation or could have encouraged women to ask more questions during the consultation due to improve knowledge. One of the repeated measures was to ask the usefulness of the leaflet. The answer for this measure could be misleading, so some may find contraceptive advice useful, as it was relevant in their context. On the other hand, provision of an appropriately designed leaflet is an economical way to educate patients and improve their experience. It is also of interest to know whether improvements in the understanding of abortion methods or of contraception would have any influence on future abortion rates. Significantly fewer women had heard of the medical abortion compared to the surgical method. This would suggest that more information about the medical method should be available to women in the community before their appointment to the specialist clinic. There are still a small proportion of women who have not been made aware of either method. This could probably suggest a failure of information provision by the medical profession in the community, as all those women attending the specialist clinic would have needed to be referred by a health professional in the

community. For those who had heard of either medical or surgical abortion, surprisingly more than half of them obtained their information from a non medical source. It is difficult to assess whether this other source of information was neutral and accurate. In this study, the majority of the women expressed a preference to obtain information on abortion from a medical establishment such as hospital, GP surgery and family planning clinic. Over half of the women also expressed an interest in obtaining information from the internet. This again would suggest a need for more information provision by both medical establishments and reputable websites that the general public can gain access to easily.

4.4.4 Impact on decision aid research

A leaflet on abortion methods presented in the form of a decision aid has been shown to improve knowledge and reduce decision conflict without raising anxiety. In the current study, only women who could read and write in English were recruited. Therefore women from other cultural backgrounds were more likely to be excluded. Further research would be of interest if the decision aids could be made available in other languages to study whether the same results can be achieved, despite difference in cultural background. Decision aids can possibly have an impact on the consultation. Further research with detailed analysis of the consultation after the provision of the decision aid could provide more information on the decision making process and possibly change the interaction between women and health professionals. With more understanding of the decision making process, a more appropriate decision aid could be produced to meet the needs of women rather than what the health professionals think is important.

4.4.5 Summary of the chapter

The provision of an evidence based leaflet in the form of a decision aid has improved knowledge, reduced perception of risk and lowered decisional conflict. The leaflet has not made any difference to the final decision of abortion method. However, improvements in different aspects of the decision making process have been made and the decision is more informed. Hence, the provision of an evidence based leaflet in the form of a decision aid can facilitate the making of an informed decision.

Chapter 5 - Discussion

5.1 Overview of thesis

This thesis has explored the adequacy of information provided by abortion services to enable women to make an informed choice between having a medical or surgical abortion. To enable informed decision making by women, healthcare professionals need to provide accurate information on the risks and benefits of the treatment options available. Information on the treatment choice can be provided in two forms: verbal information and written information. There has not been any prior evidence looking at quality of information provision in the abortion service (Chapter 1). The first empirical study presented in Chapter 2 showed most leaflets contained incomplete information on the procedure of abortion and the risks and benefits involved. The leaflets were difficult to understand and their quality also varied across service providers. It seems unlikely the women were enabled to make an informed choice (Chapter 2). The second empirical study in Chapter 3 used an observational study to explore whether verbal information provided in consultations was sufficient to enable informed choice. There is a discrepancy in the amount of information provided for each abortion method, and the description on aftercare was lacking. Although, clinicians made it explicit that the choice between methods was the woman's, information was not provided in a way that would help women to reach a choice. Therefore, verbal information provided in the consultation seemed unable to support informed decision making (Chapter 3). With inadequate written and verbal information provided on abortion methods, women are unlikely to be able to evaluate information relevant to the decision

alternatives and the likelihood and desirability of their consequences in accordance with their beliefs. Hence, women are unlikely to be able to make an informed choice on their treatment. The final empirical study (Chapter 4) evaluated the impact of a leaflet to support women's choice between abortion methods on their ability to make an informed decision. This leaflet did facilitate women's decision making, knowledge, perception of risk, attitude stability and reduced decision conflict (Chapter 4). However, there was no impact on the actual choice made on abortion method.

5.2 Are the research methods employed appropriate to meet the aims of research?

The research aimed to assess the adequacy of information provided to facilitate women's decision making on abortion methods. Prior studies have shown some women had erroneous views or knowledge about abortion methods (Slade et al, 1998; Virgo et al, 1999). However, none had documented the quality of information about abortion methods the women were being provided with. In addition, few had assessed other aspects associated with effective decision making (Slade et al, 1998). Prior research has looked into the women's reason for choosing medical or surgical abortion and their experience of the abortion. None has assessed whether or not the women's choices were informed. Measures used in prior research can provide some insight into women's reasoning for their choice of abortion method but none had employed measures of decision quality.

The first study (Chapter 1) and the second study (Chapter 2) have assessed directly the information provided. Also, guidelines have been used to inform the criteria with which to judge the information being provided (Bekker et al, 1999; Charles et al, 1999; Centre for Health Information Quality, 1997; Centre for Health Information Quality, 2001; O'Connor & Edwards 2001; RCOG, 2000). The first study assessed written information obtained from service providers across England and Wales. The second study employed a more in-depth and focused design to assess information provided in consultations in one centre. The results were similar in that the procedures were well described but information on benefits, risks and aftercare were variable.

The assessment of written information in current practice described in chapter two has contained a purposeful sample of NHS district hospitals, NHS teaching hospitals and non-NHS agents to ensure a broad range of service providers were assessed which are representative of the current practice. In order to ensure validity of the method being employed, coding frames have been used in the first and the second study to assess the written information obtained from different service providers and verbal information obtained from different transcripts. This can ensure that all the data has been assessed with the same system without bias. These coding frames were based on the current guidelines for abortion services and provision of a decision aids to ensure appropriate data was being extracted. Furthermore, both coding frames were piloted in the first few samples; the findings were then discussed with a second party before their further revision. This has ensured both coding frames have the robustness to extract the appropriate data from all the samples obtained and to ensure inter-rate reliability. Despite that, the

second study took place with a small study sample in a single centre which may have limited the extent to which its findings may be generalised.

The third study was performed using a large sample within a main referral centre in a single institution which could ensure a wide range of women being assessed. This ensures the results being generated were valid and can be generalised. The assessment was performed with a randomised controlled trial which is the best way to assess the effect of an intervention on outcomes i.e. the decision aid leaflet on decision quality of abortion method. The provision of a placebo (contraception leaflet) in the study seems appropriate for the group of women with an unwanted pregnancy, but without alerting them to being in the control group of the trial. The study was performed on consecutive women attending the clinic which would include a mixture of women with different demography; hence, reducing the selection bias on the study group. This study has utilised an information leaflet to assess objectively whether women's choice of abortion method has been facilitated. The content of the study leaflet was extracted from information obtained from the first two studies and combined with current guidelines to construct a more comprehensive leaflet in the form of a decision aid. The measures utilised in the questionnaires were also informed by prior studies looking at decision facilitation (Bekker et al 2004; Marteau & Bekker, 1992; O'Connor, 1995). The study employed measures associated with assessing decision quality and clinically relevant outcomes such as risk perception, decisional conflict, anxiety level and satisfaction with services.

There were aspects of the research that could be improved. The application of the coding frame used in the first two studies was not carried out by a third person, so inter-rate reliability checks could not be employed. Also, as the second and third study were carried out in one centre. There is an argument that the result may not generalised to other populations, perhaps those with a broader ethnic mix. Women who took part in the second and third study were all literate in English. The views of women who did not speak English were not included; suggesting a significant group of the service clientele have not been represented. The study has also not addressed the issue of access of information in this group of women. The third study did not look at changes to the consultation after provision of a decision aid leaflet, which could generate valuable information on the decision making process.

Overall, the studies were robust and have confidence in their findings. Although its application to abortion services was novel, some similarities were seen in the findings of prior research. Previous studies have shown that substantial proportions of patients do not feel that they have been adequately informed about their healthcare (Ley, 1988) and frequently complained about the lack of information given to them (Hayward, 1975; Ewing, 1989; Davis & Fallowfield, 1991; Deeny &McCrea, 1991). These findings indicated that the information provided was not adequate and that good information can reduce uncertainty within decision making, which is similar to the findings in other studies within the abortion services (Wiebe, 1997; Bachelot et al, 1992; Henshaw et al, 1993; Slade et al, 1998). In addition, the leaflet on abortion method presented in the form of a decision aid has shown to improve knowledge, reduce decisional conflict without raising anxiety. These findings are consistent with those of decision aids applied

to a range of healthcare settings (O'Connor & Edwards, 2001). However, the leaflet has no impact on women's choice of abortion method.

5.3 Implications on findings for service change

Provision of an evidence-based decision aid in the form of leaflet can be a simple and economic way to improve the quality of patient choice of treatment options. This leaflet meets the generic government initiatives of encouraging patient involvement in their management of their health (Department of Health, 2000) and specific guidelines on supporting choices with written information (RCOG, 2000). On information distribution, women have expressed a preference to obtain more written information from healthcare establishments such as hospitals, GP surgeries and family planning clinics. Improvement on provision of written health information may response to women's need for more information on treatment choice. Findings suggest that information on the internet may be useful. Also, it is interesting to find that women did not think media such as newspapers and magazines were a useful source for this information suggesting that they prefer to obtain information from a 'trusted' healthcare professional service. Further the assessment and monitoring of information available on the website should be performed to ensure accurate information is provided by reputable websites.

5.4 Implication of findings for future research

The randomised controlled trial has only assessed the impact of the decision aid on the decision making process. There are also possible changes or impacts on the

consultations between the women and health professionals before women make their decisions. For example, the provision of a decision aid prior to the consultation can trigger women to ask more questions on the abortion method or may shorten the consultation because women may feel their questions have already been answered by the decision aid. Some may have even made their decision based on the decision aid. Future research would be useful to study the interaction that occurs between women and health professionals including consultations with doctors and nurses. This could be performed by taping professionals' consultations with women after they have read the decision aids. Analysis could be performed on the length of consultations, content being discussed with questions asked during the consultation, and the interactions between the women and the health professional during consultation.

A contraception leaflet designed specifically for women after an abortion was being used in the control group of the randomised controlled trial. The leaflet also contained evidence based information and was presented in the format of a decision aid. A further study would be useful to assess whether this decision aid has improved the women's contraceptive use after the abortion and whether it may have reduced further incidences of unwanted pregnancy in this group. For those who have had a further abortion for unwanted pregnancy, another study could be performed on their choice of abortion method and whether it may be influenced by their previous choice or information provided. Further research on leaflets being provided in another context such as primary healthcare premises would be useful. As the internet is one of the preferred areas to obtain information, formal

evaluation on the information provided in websites would be beneficial in further direction of information provision.

5.5 Summary

This thesis is concerned with facilitating women's decision making about surgical and medical abortion. The first two studies have shown women were provided with insufficient written and verbal information on abortion methods and that it did not enable them to make an informed decision on the choice of method. In the final study, the provision of an evidence based leaflet on abortion methods has shown to have facilitated women's decision making in terms of perception of risk, knowledge improvement and reduction in decision uncertainty. Hence, a well constructed information leaflet can facilitate women in their decision making about abortion methods.

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Hospital name: _____

Study Number of Leaflet	
Hospital (district, teaching, unknown, other)	
Length (number of sentences)	
SMOG grading	
Flesch Reading Ease	
Timing of leaflet	
Offer medical / surgical / both	
1.0 Informed Choice	
1.1 told about medical / surgical / both	
1.2 told about gestation limit	
1.3 told can change mind not to terminate	
2.0 Surgical procedure	
2.1 Number of admission required	
2.2 Duration of admission	
2.3 Method to give misoprostol	
2.4 Mode of action of misprostol	
2.5 Type of anaesthetic given: local or general	
2.6 Dilatation of cervix	
2.7 Suction procedure	
2.8 Duration of procedure	
3.0 Surgical risk	
3.1 Side effect of misoprostol	
3.2 uterine perforation	
3.3 Cervical trauma	
3.3 bleeding	
3.4 Infection	
3.5 Retain product	
3.6 Continuing pregnancy	
3.7 Fertility	
4.0 Medical Procedure:	
4.1 Number of admission required	
4.2 Duration of each admission	
4.3 Method to give mifepristone	
4.4 Mode of action of mifepristone	
4.5 Method to give misoprostol	
4.6 Mode of action of misoprostol	
5.0 Medical risk:	
5.1 side effect of mifepristone	
5.1.1 nausea / vomiting	
5.1.2 Abdominal Cramp	
5.1.4 bleeding	
5.1.5 unknown effect of mifepristone on developing fetus	
5.2 bleeding	
5.3 Infection	
5.4 Retain Product	
5.5 Continuing pregnancy	
5.6 Fertility	
6.0 After care:	
6.1 Pain	
6.2 Next period	
6.3 Emotion	
6.4 Anti D for Rhesus Neg	
6.5 Travel arrangement after discharge	
6.6 Domestic arrangement after discharge	
6.7 Follow-up procedure	
6.8 Advice on sexual intercourse	
6.9 Advice on contraception	
6.10 Counselling service	
6.11 Contact number for further queries	
7.0 Others:	
7.1 Organisation	
7.2 Date of publication	
7.3 Confidentiality	

	MTOP	STOP	Total score
Quantity:			
1. Medical abortion procedure:			
1.1 Appointment date			
1.2 Time scale			
1.3 Mifepristone			
1.3.1 Mifepristone given			
1.3.2 Route for mifepristone			
1.3.3 Effect of mifepristone on foetus			
1.3.4 Side effect of mifepristone			
1.3.5 Management of SE of mifepristone			
1.3.6 Reason to give mifepristone			
1.4 Misoprostol			
1.4.1 Misoprostol given			
1.4.2 Route for misoprostol			
1.4.3 Side effect of misoprostol			
1.4.4 Reason to give misoprostol			
1.5 Description of miscarriage			
1.6 Aftercare			
1.6.1 child care			
1.6.2 Time off work			
1.6.3 Pain			
1.6.4 Bleeding			
1.6.5 Travel arrangement			
1.7 Follow up			
1.8 Method in general			
1.9 Smoking			
1.10 Alcohol			
1.11 Planning before chosen this method			
1.12 Other			
2. Medical abortion risk:			
2.1 Haemorrhage			
2.1.1 Haemorrhage risk			
2.1.2 Management for haemorrhage			
2.2 Infection			
2.2.1 Infection			
2.2.2 Management for infection			
2.3 RPOC			
2.3.1 RPOC risk			
2.3.2 Management for RPOC			
2.4 Continue pregnancy or "nothing happen"			
2.4.1 Continue pregnancy or "nothing happen" risk			
2.4.2 Management for continue pregnancy			
2.5 General failure risk			
2.5.1 General failure risk			
2.5.2 Management for general failure			
2.6 Risk in general			
2.7 Other			

	MTOP	STOP	Total score
3. Surgical abortion procedure:			
3.1 Appointment date			
3.2 Time scale			
3.3 Misoprostol			
3.3.1 Misoprostol given			
3.3.2 Route for misoprostol			
3.3.3 Reason to give misoprostol			
3.3.4 Side effect of misoprostol			
3.4 Duration of operation			
3.5 Method of operation			
3.6 Anaesthetic			
3.7 Aftercare:			
3.7.1 Child care			
3.7.2 Time off work			
3.7.3 Pain			
3.7.4 Bleeing			
3.7.5 Travel			
3.8 Follow-up			
3.9 Method in general			
3.10 Planning before chosen this method			
3.11 Other			
4. Surgical risk:			
4.1 Haemorrhage			
4.1.1 Haemorrhage risk			
4.1.2 Management of haemorrhage			
4.2 Infection			
4.2.1 Infection risk			
4.2.2 Management of infection			
4.3 RPOC			
4.3.1 RPOC risk			
4.3.2 Management of RPOC			
4.4 Continue pregnancy			
4.4.1 Continue pregnancy risk			
4.4.2 Management of continue pregnancy			
4.5 Perforation of uterus			
4.5.1 Perforation of uterus risk			
4.5.2 Management of perforation of uterus			
4.6 Anaesthetic risk			
4.7 Risk in general			
4.8 Others			
5. Abortion:			
5.1 Ask for certainty on TOP			
5.2 Ask for reason for TOP			
5.3 Gestation			
5.4 regret afterwards			
5.5 Future fertility			
5.6 Appointment date			

	MTOP	STOP	Total score
6. Comment related to deciding TOP method:			
6.1 Offer choice in both methods			
6.2 Promote autonomy in decision			
6.3 Direct comparison for MTOP vs STOP			
6.3.1 Time scale in hospital			
6.3.2 RPOC			
6.3.3 Pain			
6.3.4 Appointment date			
6.3.5 Pros & Cons of both method			
6.3.6 Method in general			
6.3.7 Continue pregnancy			
6.3.8 Infection			
6.3.9 Anaesthetic (awake / asleep)			
6.3.10 Perforation uterus			
6.3.11 Other choice			
6.3.12 contraception issue (coil / sterilisation)			
6.4 Encourage STOP			
6.5 Encourage MTOP			
6.6 Planning for method chosen			
6.6.1 Off work			
6.6.2 Appointment date			
6.6.3 Childcare			
6.6.4 Smoking			
6.6.5 Alcohol			

Appendix III

	Figure-risk	Figure-inverse risk	Minimise risk	Maximise risk	Comment +	Comment -	Comment n	Total
Quantity:								
1. Medical abortion procedure:								
1.1 Appointment date								
1.2 Time scale								
1.3 Mifepristone								
1.3.1 Mifepristone given								
1.3.2 Route for mifepristone								
1.3.3 Effect of mifepristone on foetus								
1.3.4 Side effect of mifepristone								
1.3.5 Management of SE of mifepristone								
1.3.6 Reason to give mifepristone								
1.4 Misoprostol								
1.4.1 Misoprostol given								
1.4.2 Route for misoprostol								
1.4.3 Side effect of misoprostol								
1.4.4 Reason to give misoprostol								
1.5 Description of miscarriage								
1.6 Aftercare								
1.6.1 child care								
1.6.2 Time off work								
1.6.3 Pain								
1.6.4 Bleeding								
1.6.5 Travel arrangement								
1.7 Follow up								
1.8 Method in general								
1.9 Smoking								
1.10 Alcohol								
1.11 Planning before chosen this method								
1.12 Other								
2. Medical abortion risk:								
2.1 Haemorrhage								
2.1.1 Haemorrhage risk								
2.1.2 Management for haemorrhage								
2.2 Infection								
2.2.1 Infection								
2.2.2 Management for infection								
2.3 RPOC								
2.3.1 RPOC risk								
2.3.2 Management for RPOC								
2.4 Continue pregnancy or "nothing happen"								
2.4.1 Continue pregnancy or "nothing happen" risk								
2.4.2 Management for continue pregnancy								
2.5 General failure risk								
2.5.1 General failure risk								
2.5.2 Management for general failure								
2.6 Risk in general								
2.7 Other								

Appendix III

	Figure-risk	Figure-inverse risk	Minimise risk	Maximise risk	Comment +	Comment	Comment n	Total
3. Surgical abortion procedure:								
3.1 Appointment date								
3.2 Time scale								
3.3 Misoprostol								
3.3.1 Misoprostol given								
3.3.2 Route for misoprostol								
3.3.3 Reason to give misoprostol								
3.3.4 Side effect of misoprostol								
3.4 Duration of operation								
3.5 Method of operation								
3.6 Anaesthetic								
3.7 Aftercare:								
3.7.1 Child care								
3.7.2 Time off work								
3.7.3 Pain								
3.7.4 Bleeing								
3.7.5 Travel								
3.8 Follow-up								
3.9 Method in general								
3.10 Planning before chosen this method								
3.11 Other								
4. Surgical risk:								
4.1 Haemorrhage								
4.1.1 Haemorrhage risk								
4.1.2 Management of haemorrhage								
4.2 Infection								
4.2.1 Infection risk								
4.2.2 Management of infection								
4.3 RPOC								
4.3.1 RPOC risk								
4.3.2 Management of RPOC								
4.4 Continue pregnancy								
4.4.1 Continue pregnancy risk								
4.4.2 Management of continue pregnancy								
4.5 Perforation of uterus								
4.5.1 Perforation of uterus risk								
4.5.2 Management of perforation of uterus								
4.6 Anaesthetic risk								
4.7 Risk in general								
4.8 Others								

Appendix III

	Figure-risk	Figure-inverse risk	Minimise risk	Maximise risk	Comment +	Comment	Comment n	Total
5. Abortion:								
5.1 Ask for certainty on TOP								
5.2 Ask for reason for TOP								
5.3 Gestation								
5.4 regret afterwards								
5.5 Future fertility								
5.6 Appointment date								
6. Comment related to deciding TOP method:								
6.1 Offer choice in both methods								
6.2 Promote autonomy in decision								
6.3 Direct comparison for MTOP vs STOP								
6.3.1 Time scale in hospital								
6.3.2 RPOC								
6.3.3 Pain								
6.3.4 Appointment date								
6.3.5 Pros & Cons of both method								
6.3.6 Method in general								
6.3.7 Continue pregnancy								
6.3.8 Infection								
6.3.9 Anaesthetic (awake / asleep)								
6.3.10 Perforation uterus								
6.3.11 Other choice								
6.3.12 contraception issue (coil / sterilisation)								
6.4 Encourage STOP								
6.5 Encourage MTOP								
6.6 Planning for method chosen								
6.6.1 Off work								
6.6.2 Appointment date								
6.6.3 Childcare								
6.6.4 Smoking								
6 6 5 Alcohol								

Fertility Control Unit

Medical Vs surgical termination of pregnancy: facilitating women's choice

PATIENT INFORMATION SHEET (pilot study)

Dear patient:

We would like to invite you to help us with a research project. This is entirely voluntary. Please take time to read the following carefully before you decide.

Studies have shown both surgical and medical terminations of pregnancy of under 9 weeks are safe and acceptable to women. However, there is a lack of information on how women choose one method over the other. This unit is now carrying out a study that asks women about their experiences of termination. We are interested in how women choose to have either a medical or surgical termination. The results of this study will provide us with a better understanding of what information women find useful and how we should provide this information. Your opinions are important to the running of this unit. This study will run for 2 months and we are aiming to recruit 20 women in this period. Women who attend this unit with pregnancies of less than 9 weeks will be invited to join this study.

If you choose to take part, we will need your permission to tape-record your consultation with the doctor today. Then you will be asked to complete a questionnaire after the consultation. After the termination, you will be asked to complete a further questionnaire while you are still in the hospital. All the tape-recordings and 150questionnaires are only identified by study numbers. Your name does not appear on them. All the information we obtained from the tape-recordings and questionnaires will be kept **in confidence.** All the tapes will be destroyed within one month of recording. The tape recordings will not interfere with your consultation with the doctor. The questionnaire will take about 10 minutes to complete and will not interfere with the care you receive from this unit. Sandra will come to help you if you have any problem with the questionnaire. You will still be able to choose the type of termination you prefer.

The tape-recording will tell us the quality of information given in a standard consultation, while the questionnaire will tell us how you feel the information should be provided. Information from this pilot study will then be used to construct a new information leaflet about termination methods for a future study, which will assess the effectiveness of information leaflet over a standard consultation. The result will hopefully benefit women in the same situation in the future. Participation in this study is entirely voluntary. You are free to withdraw from the project at any time and without giving a reason. Whatever your decision, this will not affect the standard of care you will receive from this unit. If you decide to help us, please tell the staff in the clinic. You will be given this information sheet to keep and be asked to sign a consent form. If you have any questions about the study, please ask Sandra. Thank you for reading this information sheet. Your help is deeply appreciated.

Sandra Wong
Clinical Research Fellow
Tel. No.: 0113 2065381

version 1 - July 01

Patient identification number for this study:

Consent form for research study

Title of project: Medical VS Surgical abortion: Facilitating women's choices.

- I have read the patient information sheet for the above study ☐
- I have had the opportunity to ask questions about the study ☐
- I understand the purpose of the study, and how I will be involved ☐
- I understand and accept that if I take part in the study, I will not gain any direct, personal benefit from it. ☐
- I understand that all information collected in the study will be held in confidence and that, if it is presented or published, no identification of individuals will be possible. ☐
- I confirm that I will be taking part in this study of my own free will, and I understand that I may withdraw from it, at any time and for any reason without my medical care or my legal rights being affected. ☐

I agree to take part in the above study

Signature and printed name (patient)

_____

Signature and printed name (person taking consent)

_____

Date _____

Fertility Control Unit

Medical Vs Surgical termination of pregnancy: Facilitating women's choices

PATIENT INFORMATION SHEET (Study)

Dear patient:

We would like to invite you to help us with a research project. This is entirely voluntary. Please take time to read the following carefully before you decide.

Studies have shown both surgical and medical terminations of pregnancy of under 9 weeks are safe and acceptable to women. However, there is a lack of information on how women choose one method over the other. This unit is carrying out a study that asks women about their experiences of termination. We are interested in how women choose to have either the medical or surgical method of termination. We are not studying the termination decision itself but the method women choose. The results will provide us with a better understanding of what information women find useful and how we should provide this. Your opinions are important to the running of this unit. The study will run for 6 months and we are aiming to recruit 328 women in this period. Women who attend this unit with pregnancies of less than 9 weeks will be invited to join this study.

If you choose to take part, you will be randomly allocated to one of the two groups today. (Random allocation means you will be allocated to a study group by chance, like tossing a coin.)

Group 1: You will only have your normal consultation with the doctor to discuss your choice on termination method. This care is usual for the clinic.

Group 2: In addition to your usual care in clinic, You will be given an extra information leaflet about the termination methods to read before your normal consultation with the doctor.

You will be asked to complete one questionnaire after the consultation. After the termination, you will be asked to complete a second questionnaire while you are still in the hospital. All the questionnaires are only identified by study numbers. Your name does not appear on them. All your answers will be kept **in confidence**. The questionnaire will take about 10 minutes to complete. Filling in the questionnaire will not interfere with the care you receive from this unit. Sandra will come to help you if you have any problem with the questionnaire. Whether you are in group 1 or 2, you will still be able to choose the type of termination you prefer.

Information from this study will be used to construct a new information leaflet for routine use in this unit. This will hopefully benefit women in the same situation in the future. Participation in this study is entirely voluntary. You are free to withdraw from the project at any time without giving a reason. This will not affect the standard of care you will receive from this unit. If you decide not to take part in this study, you will still get the routine care like group 1. Whether you wish to take part or not, it will not affect your care in this unit. If you decide to help us, please tell the staff in the clinic. You will be given this information sheet to keep and be asked to sign a consent form. If you have any questions about the study, please ask Sandra. Thank you for reading this information sheet. Your help is deeply appreciated.

Sandra Wong
Clinical Research Fellow
Tel. No.: 0113 2065381

version 1 – July 01

A guide to methods of termination

St James's University Hospital, Fertility Control Unit
Beckett Street, Leeds, LS9 7TF.
0113 2067135

Jan 2002

This leaflet is for women who have decided to have a termination. If you are uncertain about terminating the pregnancy, you do not have to read the leaflet. Let the hospital staff know and they will talk to you about other options.

This unit offers two methods of termination. Which method you have is your choice.
1. Surgical (operation)
2. Medical (tablets)

The surgical method

Women who are 14 weeks pregnant or less can have this method. This method requires one visit of 6 - 7 hours.

The visit
The staff will put four tablets into the vagina one hour before the operation. These soften the neck of the womb (cervix). Most women have no symptoms after this but some have 'period-like cramps' or light bleeding. Women usually have a general anaesthetic and are asleep during the operation. The operation requires the cervix to be stretched .The pregnancy is then removed by suction. This takes 10 – 15 minutes. No cuts are made. You can go home 2 – 3 hours later, if all goes well. You should see your own doctor for a check up within 7 – 14 days.

Risk:
5% (50 in 1000) get an infection
0.8% (8 in 1000) damage the neck of the womb (cervix)
0.4% (4 in 1000) puncture the womb (uterus)
0.2% (2 in 1000) require an operation because of retained tissue or the pregnancy continues
0.1% (1in 1000) have very heavy bleeding

The medical method

Women who are 9 weeks pregnant or less can have this method. This method requires two visits, the first last about half an hour, the second between four and six hours.

First visit:
Women take one tablet by mouth, then go home. This tablet stops the pregnancy from continuing. This starts the termination. Most women do not have symptoms. Some women have "period – like" cramp, nausea, vomiting or light bleeding.

Second visit:
Two days later, a nurse puts four tablets into vagina. These tablets cause the womb to contract and the pregnancy to miscarry. Most women miscarry in the hospital but a few happen at home. The nurse checks when the miscarriage is complete. Most women bleed and have 'period - like cramps'. Some have sickness, dizziness, hot flushes or diarrhoea. Women usually go home after 4 -6 hours.

Risk:
4% (40 in 1000) require an operation because of retained tissue or the pregnancy continues
0.5% (5 in 1000) get an infection
0.1% (1.2 in 1000) have very heavy bleeding

Both methods:

If you wish, bring a companion to the Fertility Control Unit during your hospital visits.

If your blood group is rhesus negative you will be given an injection to prevent rhesus disease in future pregnancies.

Termination is not associated with an increased risk of infertility or premature birth.

Summary:

Medical method	Surgical method
• tablets to cause miscarriage	• operation to remove pregnancy by suction
• 2 visits	• 1 visit
• *Visit 1*: lasts half an hour *Visit 2*: lasts 6 hours	• visit lasts 6 hours
• *Visit 1*: 1 tablet taken by mouth *Visit 2:* 4 tablets put in the vagina	• 4 tablets in vagina + general anaesthetic + suction operation
• 95% chance of success	• 99% chance of success
• 0.5% chance of infection	• 5% chance of infection
• Possible symptoms of tablets include period - like pain and heavy bleed	• Possible risks of general anaesthetic and damage to cervix and womb

Aftercare:

Make sure an adult takes you home by car or taxi and stays with you for 24 hours.
Do not drive, drink alcohol and make important decisions for 24 hours after the termination, especially if you have general anaesthetic.
Most women have cramps up to 48 hours. Use painkillers such as paracetamol.
Bleeding may last up to 14 days.
Do not use tampons until your second period
Most women return to work after 1-2 days.
Visit your own doctor or family planning clinic for a check up within 7 - 14 days.
Your first period should come within 6 weeks.
You can start having sex after the bleeding has stopped.
Use a reliable contraceptive.
Please see a doctor, if the following occur:

- 'Smelly' vaginal discharge
- Fever / shivering
- Severe abdominal pain
- Heavy bleeding
- Generally unwell

Counselling service

Some women have strong feelings after termination such as relief, sadness, confusion or anger. Our counsellor is available by appointment on 0113 2065897.

Patient record

This service is *confidential*. However, we will contact your own doctor unless you tell us not to.

If you have any queries, please contact us on telephone number: 0113 2067135.

Other useful address:

Contraception:

Family Planning Association
2-12 Pentonville Road, London N1 9FP
Tel. no. : 020 7837 4044

Benefits:

Department of Social Security
Helpline tel. no. : 0800 666 555

Maternity:

National Childbirth Trust
Alexander House, Oldham Terrace, London W3 6NN
Tel. no.: 020 8992 8637

Maternity Alliance
5th Floor, 45 Beech Street, London EC 2P 2LX
Tel. no. : 020 7588 8583

Adoption and foster care:

National Foster Care Association
8 Blackfriars Road, London SE1 8HA
Tel. n.: 020 7620 6400

British Agencies for Adoption and Fostering
11, Southwark Street, London SE1 1RQ
Tel. no.: 020 7407 8800

A guide to contraception after termination

St James's University Hospital, Fertility Control Unit
Beckett Street, Leeds, LS9 7TF
0113 2067135

Jan 2002

This leaflet guides you through the types of contraceptive methods available. If you wish to know more about these methods, ask the staff in this unit.

Combined pill:

Over 99% effective
Stops eggs from being released by the ovary. Causes changes which make it difficult for sperm to enter the womb and difficult for the pregnancy to occur.
It may reduce bleeding, period pains and premenstrual tension.
It may cause temporary minor side effects. Rare but serious side effects may include blood clots (thrombosis). It is not suitable for smokers over 35.
One tablet to take by mouth each day for 21 days, followed by a 7 days break before starting a new packet. To start same day or next day after the termination.

Progestogen-only pill:

Over 99% effective
Causes changes which make it difficult for sperm to enter the womb and less likely for pregnancy to occur. Stops the ovary from releasing eggs in some women some of the time.
It can be used in older women who smoke and cannot use the combined pill. It can be used during breastfeeding.
It may cause temporary minor side effects. Periods may be irregular.
One tablet to take by mouth every day with no break. To start same day or next day after the termination.

Contraceptive injection (Depo-provera):

Over 99% effective
Stops eggs from being released by the ovary. Causes changes which make it difficult for sperm to enter the womb and difficult for the pregnancy to occur.
Each injection lasts for 12 weeks. Periods become lighter or absent altogether.
Periods may become irregular before becoming lighter. Some women do not have a period. It may cause temporary minor side effects such as weight gain.
It is usually given by a doctor or nurse in the buttock. It can be given at the same time as the termination or within 5 days by your GP or family planning doctor.

Implant (Implanon):

Over 99% effective
A small flexible tube containing a hormone which is placed under the skin of the inner upper arm. Stops eggs from being released by the ovary. Causes changes which make it difficult for sperm to enter the womb and difficult for the pregnancy to occur.
It works for 3 years. Periods become lighter or absent altogether.
Periods may become irregular before becoming lighter. Some women do not have a period. It may cause temporary minor side effects such as weight gain.
Can be inserted at the time of the termination or shortly afterwards.

Coil:

98 - over 99% effective
2 types are available: Copper or hormonal
The copper coil is a small plastic and copper device which stops sperm meeting an egg or may stop an egg settling in the womb. May stop a fertilised egg.
The hormonal coil (Mirena) is a small plastic device which releases a hormone. The hormone causes changes which make it difficult for sperm to enter the womb and less likely for a pregnancy to occur. It may also stop the ovary from releasing eggs in some women some of the time.
Both types can stay in the womb for up to 5 years.
They can be taken out at anytime.
Periods may become heavier and painful for the copper coil.
Periods may become irregular before becoming lighter. Some woman may not have a period.
Can be inserted at the time of the termination or 6 weeks afterwards by your GP or family planning doctor.

Diaphragm with spermacide:

80 – 94% effective
It covers the end of the womb and stops sperm entering the womb.
It does not contain any hormones. It may protect against some sexually transmitted infections.
Putting it on can interrupt sex. Women will need to see a doctor for fitting and training. Extra spermicide is needed if you have sex again.
Fitted 6 weeks after termination by a doctor, then to put on every time before sex and to remove 6 hours after sex by the woman.

Natural family planning:

80-99% effective
Identify fertile and infertile times of the menstrual cycle.
No hormones are used. It gives a woman a greater awareness of her body.
Need to avoid sex or use a condom at fertile times of the cycle. Women may need training to use this method.
May be difficult until menstrual cycle become regular again.
Preparation such as Persona can be bought in the chemist.

Condom:
86 - 97% effective
Stop sperm from entering vagina
It may protect both partners from sexually transmitted disease.
Putting it on can interrupt sex. It may slip or split.
Use anytime you have sex after the termination.

Sterilisation (male or female):
Over 99% effective
A permanent method
In women, both tubes are blocked or cut so that the sperm cannot meet the egg.
In men, both tubes are cut so the sperm are not released outside the body.
It is permanent and you don't have to think about contraception after it has worked.
It is permanent and should not be chosen if in doubt.
The operation can be done at the time of your termination. If you or your partner wants the operation in the future, your GP can refer you to the local hospital.

Other useful address:

Family Planning Association
2-12 Pentonville Road, London N1 9FP
Tel. no. : 020 7837 4044
Website: www.fpa.org.uk

Brook Advisory Centre
165 Gray's Inn Road, London WC1X 8UD
Tel. no. : 020 7833 8488

Appendix IX

Study Number:_____

Medical versus surgical termination of pregnancy:
Facilitating women's choices
Questionnaire A

This questionnaire is part of a project looking at how women choose a method to terminate the pregnancy. It will take about 10 minutes to complete. Filling it will not interfere with your care otherwise.

Your views are very important to our study. The results will provide us with a better understanding of what information women find useful and how we should provide it for a better service.

If you have any questions, please ask Sandra Wong. Your answers are <u>confidential</u>. Only Sandra can match your study number with your name.

Thank you for your time.

Sandra Wong
Clinical Research Fellow
Fertility Control Unit
St. James's University Hospital

Tel. No.: 0113 2067135

Fertility Control Unit
St. James's University Hospital
Leeds

Appendix IX

Study Number:_____

The following questions ask you about yourself. Please answer each question by ticking the box.

1. **How many children do you have?**
   ☐0 ☐1 ☐2 ☐3 ☐more than 3

2. **If you have children before how were they delivered?(you can choose more than 1)**
   ☐Normal vaginal delivery ☐Ventouse / suction delivery ☐Forceps delivery
   ☐Caesarean section ☐Other. Please state _____

3. **Have you ever had a miscarriage?**
   ☐Yes. If yes, how many did you have? ☐1 ☐2 ☐3 ☐4 ☐more than 4
   ☐No

4. **Have you ever had an termination before?**
   ☐Yes. If yes, a) How many did you have? ☐1 ☐2 ☐3 ☐4 ☐more than 4
   b) What type of termination did you have ? ☐by an operation
   ☐by tablet / medical method
   ☐have both methods

   ☐No.

5. **What is your marital status?**
   ☐Married ☐Living as married (partner) ☐Single with boyfriend ☐Single
   ☐Other. Please state _____

6. **What is the <u>highest</u> level of education you have received? (please tick the highest)**
   ☐No formal level of education ☐GCSE equivalent ('O' level / 'CSE')
   ☐Apprenticeship (Btec /HND/ city & guilds) ☐'A'level equivalent (highers etc.)
   ☐Degree or more

7. **Do you follow a religion?**
   ☐Yes, the religion is _____ ☐No

8. **How would you describe your ethnic origin?**
   ☐White ☐Black – Caribbean ☐Black – African ☐Black – Other ☐Indian
   ☐Pakistani ☐Bangladeshi ☐Chinese ☐Other

9. **Did anyone help with your decision to this termination?**
   ☐No ☐Yes. If yes. Please tell us who _____

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicated how you feel <u>right now, at this moment</u>. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best. (STAI)
(Please circle one number for each question.)

	Not at all	somewhat	moderately	very much
10. I feel calm	1	2	3	4
11. I feel tense	1	2	3	4
12. I am upset	1	2	3	4
13. I feel relaxed	1	2	3	4
14. I feel content	1	2	3	4
15. I am worried	1	2	3	4

Study Number:_____

The following question is about your views on the different termination methods. There are no right or wrong answers. Please answer each question by ticking a box.

16. Before this appointment, had you heard of surgical termination (the operation)?
☐ No ☐ Yes. If yes, who told you about it? _____

17. Before this appointment, had you heard of medical termination (the tablet method)?
☐ No ☐ Yes. If yes, who told you about it? _____

18. Some people think there are both advantages and disadvantages to having a medical termination with tablets and pessaries. In the box below, please list the advantages and disadvantages that are important to you.

Advantages	Disadvantages

19. Some people think there are both advantages and disadvantages to having a suction termination in an operating theatre. In the box below, please list the advantages and disadvantages that are important to you.

Advantages	Disadvantages

20. Before this appointment, have you made a decision on which method of termination to have?
☐ No decision about the method ☐ To have surgical termination
☐ To have medical termination ☐ Not to have surgical termination
☐ Not to have medical termination ☐ Not aware that you will have a choice

21. What method of termination have you chosen now?
☐ Medical termination ☐ Surgical termination ☐ Undecided ☐ Continue with pregnancy

22. Why did you choose this method (as in question 21) and not the other?

Reasons (please list in the following space)

23. How much time did you spend thinking about the decision to have a surgical or medical termination? *Please circle one number*

Very little time a lot of time
0 1 2 3 4 5 6

Study Number:_____

24. Do you feel the following people encouraged you to have your chosen method of termination.
Please circle one number for each person that you spoke to about the termination.

	Did not discuss	strongly encourage	encourage	neither encouraged nor discouraged	strongly discouraged	discouraged
a) Doctor who has referred you to this clinic	0	1	2	3	4	5
b) Doctor whom you have met in this clinic	0	1	2	3	4	5
c) Nurse	0	1	2	3	4	5
d) Husband / partner	0	1	2	3	4	5
e) Friend	0	1	2	3	4	5
f) Mother	0	1	2	3	4	5
g) Other	0	1	2	3	4	5

25. Who do you think who should make the decision on the method of termination?
☐ You ☐ Your partner ☐ Doctor ☐ You and your partner ☐ You and doctor
☐ Other. Please state. _____

26. Overall, how useful was the information given during this consultation (please circle one number):

Not at all useful						very useful
0	1	2	3	4	5	6

27. Please write below what bits of information were helpful and unhelpful to you when making the decision to choose between surgical and medical termination:

Helpful information	Unhelpful information

28. Was there anything you wanted more information about?
☐ Yes. If yes, please state _____
☐ No

After reading the following statements, please circle a number that reflects how much you agree with them. (Decision conflict scale)

29. The decision to choose between medical and surgical termination was hard for me to make:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

30. I was unsure to which method of termination to choose:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

31. It was clear what the best choice was for me:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

32. I am aware of the choices I have:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

Study Number:_____

33. I feel I know what the advantages of both termination methods:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

34. I feel I know the risks and side effects of both termination methods:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

35. I feel I have made an informed choice:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

36. My decision shows what is most important for me:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

37. I expect to stick with my decision:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

38. I am satisfied with my decision:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

The following questions are to find out how you process the information you have been given. Please answer each question by ticking a box.

39. How long do women usually have to stay in this hospital for a surgical termination?

☐ 2 hours ☐ half a day ☐ 1 day ☐ 2 day ☐ don't know

40. How many visits do most women usually have to come to the hospital for a medical termination excluding the clinic appointment like today?

☐ 1 visit ☐ 2 visits ☐ 3 visits ☐ more than 3 visits ☐ don't know

41. The chance of a medical termination not having worked is(all or part of the pregnancy left behind in the womb / uterus) and need a D and C (Scrape):

☐ 0.5% ☐ 1% ☐ 5% ☐ 10% ☐ don't know

42. The chance of a surgical termination not having worked is(all or part of the pregnancy left behind in the womb)and need a D and C (scrape):

☐ 0.5% ☐ 2% ☐ 5% ☐ 10% ☐ don't know

43. How is the medication given to the women having medical termination?

☐ By mouth only ☐ By vagina only ☐ By mouth and by vagina ☐ Other method
☐ Don't know

44. How long does the procedure of surgical termination take?

☐ 15 mins ☐ 30 mins ☐ 1 hour ☐ 2 hours ☐ Don't know

Appendix IX

Study Number:_____

If you have a medical termination (tablet method), how likely do you think the following may happen to you? *Please tick one box for each event.*

	Never	Very unlikely	unlikely	maybe	likely	Very likely
46. Heavy bleeding (more than a period)						
47. Infection of the womb						
48. Perforation of uterus (going through the wall of the womb)						
49. Not being able to have children						
50. Termination not complete (part or all of the pregnancy left behind)						

If you have a surgical termination (operation method), how likely do you think the following may happen to you? *Please tick one box for each event.*

	Never	Very unlikely	unlikely	maybe	likely	Very likely
51. Heavy bleeding (more than a period)						
52. Infection of the womb						
53. Perforation of uterus (going through the wall of the womb)						
54. Not being able to have children						
55. Serious problem with anaesthetic						
56. Termination not complete (part or all of the pregnancy left behind)						

57. In general, how good is the surgical (operation) method of termination for you?

Not at all good — Very good

1 2 3 4 5

58. In general, how good is the medical (tablet) method of termination for you?

Not at all good — Very good

1 2 3 4 5

59. If you have other views on termination that you want to tell us, please use the space below.

Thank you for answering all these questions. Please return this questionnaire to the staff in clinic when you have finished.

Study number: _____

Medical versus surgical termination of pregnancy:
Facilitating women's choices
Questionnaire B

This questionnaire is part of a project looking at how women choose the method to terminate the pregnancy. It will take about 10 minutes to complete. Filling it in will not interfere with your care otherwise.

Your views are very important to our study. The results will provide us with a better understanding of what information women find useful and how we should provide it for a better service.

If you have any questions, please ask Sandra Wong. Your answers are confidential. Only Sandra can match your study number with your name.

Thank you for your time.

Sandra Wong
Clinical Research Fellow
Fertility Control Unit
St. James's University Hospital
Tel. No.: 0113 2067135

Fertility Control Unit
St. James's University Hospital
Leeds

Study number: _____

The following questions ask about your views on information given to you. Please answer each question.

1. From your experience in this unit, what information about the termination did you find helpful and unhelpful:

Helpful information (please list)	**Unhelpful information** (please list)

2. How useful was the information given to you from this unit in general? *(please circle one number)*

Not at all useful very useful

0 1 2 3 4 5 6

3. In your opinion, is there other information we should let you know before you make your decision on which termination method to have?

4. In your opinion, where should information on termination method be made available? *(please circle one number for each place)*

		Very helpful		Maybe		Not helpful
a	hospital	1	2	3	4	5
b	GP surgery	1	2	3	4	5
c	family planning clinic	1	2	3	4	5
d	newspaper	1	2	3	4	5
e	magazine	1	2	3	4	5
f	internet	1	2	3	4	5
g	others, please state _____					

5. In your opinion, when should information on the type of termination be made available? (please tick one box)

☐ when the woman has decided to have a termination ☐ when the woman is considering a termination

☐ other times, please state when _____

After reading the following statements, please circle a number that reflects how much you agree with them. (Decision conflict scale)

6. The decision to choose between medical and surgical termination was hard for me to make:

Strongly agree agree neither agree nor disagree disagree strongly disagree

1 2 3 4 5

7. I was unsure to which method of termination to choose:

Strongly agree agree neither agree nor disagree disagree strongly disagree

1 2 3 4 5

Study number: _____

8. It was clear what the best choice was for me:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

9. I am aware of the choices I have:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

10. I feel I know what the advantages of both termination methods:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

11. I feel I know the risks and side effects of both termination methods:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

12. I feel I have made an informed choice:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

13. My decision shows what is most important for me:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

14. I expect to stick with my decision:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

15. I am satisfied with my decision:

Strongly agree	agree	neither agree nor disagree	disagree	strongly disagree
1	2	3	4	5

16. Do you regret having the method of termination you have chosen?
(please circle one number)

very much				not at all
1	2	3	4	5

17. If a close friend was in a similar situation to you and ask for your opinion on <u>medical termination</u>. You would: *(please circle one number)*

strongly encourage	encourage	unsure	discourage	strongly discourage
1	2	3	4	5

18. If a close friend was in a similar situation to you and ask for your opinion on <u>surgical termination</u>. You would: *(please circle one number)*

strongly encourage	encourage	unsure	discourage	strongly discourage
1	2	3	4	5

Study number: _____

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicated how you feel right now, at this moment. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best. (STAI)

	Not at all	somewhat	moderately	very much
19. I feel calm	**1**	**2**	**3**	**4**
20. I feel tense	**1**	**2**	**3**	**4**
21. I am upset	**1**	**2**	**3**	**4**
22. I feel relaxed	**1**	**2**	**3**	**4**
23. I feel content	**1**	**2**	**3**	**4**
24. I am worried	**1**	**2**	**3**	**4**

25. In general, how good is the surgical (operation) method of termination for you?

Not at all good — Very good

1 2 3 4 5

26. In general, how good is the medical (tablet) method of termination for you?

Not at all good — Very good

1 2 3 4 5

25. If there is other information you wish to tell us, please use the space below.

Thank you for answering all these questions. Please return this questionnaire to the staff when you have finished.

Chairman Bill Kilgallon OBE
Chief Executive David Johnson

THE LEEDS TEACHING HOSPITALS

Local Research Ethics Committee

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Our Ref: 01/096

2 August 2001

Dear Dr Wong

Project No 01/096: Medical versus surgical abortion: Facilitating women's choices

Thank you for your letter of 19 July responding to comments made by members of the Ethics Committe on your study and enclosing a revised patient information sheet. I am pleased to confirm that your study has now been approved by the Committee.

We would be very interested in receiving a report of your findings at some future date.

Yours sincerely

Ann Prothero

Cc **Dr P R F Dear**
Chairman
Leeds Health Authority / St James's and Seacroft University Hospitals
Clinical Research (Ethics) Committee