

Royal College of Obstetricians and Gynaecologists
Setting standards to improve women's health

The Care of Women Requesting Induced Abortion

Evidence-based Clinical Guideline Number 7



September 2004

GUIDELINE

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Abbreviations

ACOG	American College of Obstetricians and Gynecologists
βhCG	beta human chorionic gonadotrophin
BMA	British Medical Association
bpas	British Pregnancy Advisory Service
CEMD	Confidential Enquiries into Maternal Deaths in the UK
CI	confidence interval
CMO	Chief Medical Officer
COC	combined oral contraceptive
COG	Clinical Outcomes group
D&C	dilatation and curettage
D&E	dilatation and evacuation
DARE	Cochrane Library Database of Reviews of Effectiveness
DH	Department of Health
DSH	deliberate self harm
EP	ectopic pregnancy
FFPRHC	Faculty of Family Planning and Reproductive Health Care
FHPM	Faculty of Public Health Medicine
FIGO	International Federation of Gynecology and Obstetrics
fpa	Family Planning Association
GMC	General Medical Council
GP	general practitioner
GUM	genitourinary medicine
hCG	human chorionic gonadotrophin
HFEA	Human Fertilisation and Embryology Authority
HIV	human immunodeficiency virus
HTA	Health Technology Assessment
IUD	intrauterine device
IUS	intrauterine system
KCl	potassium chloride
MDU	Medical Defence Union
MVA	manual vacuum aspiration
NCI	National Cancer Institute
NCSC	National Care Standards Commission
NHS	National Health Service
NMC	Nursing and Midwifery Council
NSAID	nonsteroidal anti-inflammatory drug
OR	odds ratio
OOR	overall odds ratio
PCO	primary care organisation
PID	pelvic inflammatory disease

POP	progestogen-only pill
RCN	Royal College of Nursing
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	randomised controlled trial
Rh	rhesus
RR	relative risk
UKCC	United Kingdom Central Council for Nursing, Midwifery and Health Visiting
VAS	visual analogue scale
WHO	World Health Organization
WHOMEK	World Health Organization medical eligibility criteria

Development of the guideline

This guideline on abortion care was first developed in 2000 by a multi-professional working group (referred to here as the Guideline Development Group). The group was convened by the Royal College of Obstetricians and Gynaecologists (RCOG) and supported by funding awarded by the Department of Health (DH). Members included nominees of the RCOG, the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Royal College of General Practitioners, the Faculty of Public Health, the British Pregnancy Advisory Service (bpas), a nurse counsellor and a consumer representative nominated by the RCOG Consumers' Forum. All members of the group made formal declarations of interest at the outset and these were recorded. This record is kept on file at the RCOG. The College was of the opinion that the interests declared did not conflict with the guideline development process.

The development of this updated version of the guideline was led by Dr Gillian Penney FRCOG, who chaired the Guideline Development Group and is Honorary Director of the Clinical Effectiveness Unit of the FFPRHC. Funding was again provided by the Department of Health. The development process incorporated a single meeting of an expert advisory group (referred to here as the Guideline Update Group) in December 2003. The members were:

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Chapter 1

Introduction and methodology

1.1 The guideline topic

Induced abortion is one of the most commonly performed gynaecological procedures in Great Britain, with around 186 000 terminations performed annually in England and Wales¹ and around 11 500 in Scotland.² The Abortion Act does not apply in Northern Ireland and no official abortion statistics are collected.

At least one-third of British women will have had an abortion by the time they reach the age of 45 years.³ Over 98% of induced abortions in Britain are undertaken because of risk to the mental or physical health of the woman or her children.^{1,2} This guideline has been developed in relation to the care of women seeking abortion on such grounds. Separate RCOG publications address legal, ethical and service issues relating to the minority of abortions undertaken because of fetal abnormality.^{4,5,6} The recommendations in this guideline do not address the special issues relating to abortion for fetal abnormality.

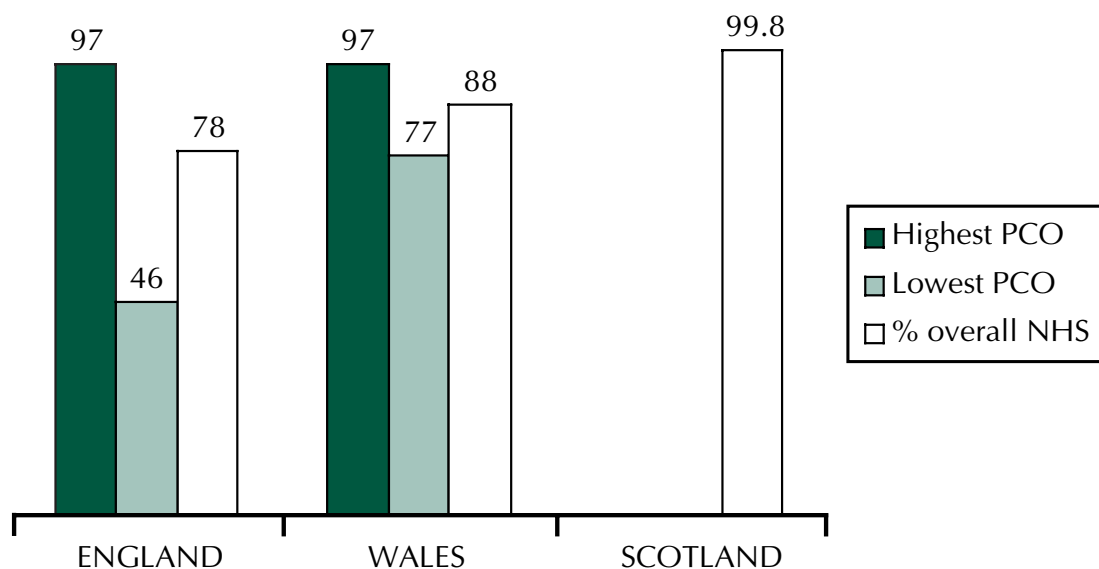


Figure 1.1 Range of NHS-funded abortion provision among individual PCOs in England and Wales, and in Scotland; for each country, the bars show the percentage of abortions which are NHS-funded. Primary Care Organisations (PCOs) with the highest, mean and lowest levels of provision are shown (data for England and Wales from Abortion Statistics.¹ Scottish data not routinely published at PCO-equivalent level)²

There are large geographical variations in access to NHS-funded abortion. In Scotland in 2002, 99.8% of abortions took place in NHS hospitals.² In England and Wales in 2002, of a total of 175 569 abortions for residents of England and Wales, 73 053 (42%) took place in NHS hospitals, 64 045 (36%) were funded by the NHS under agency arrangements with charitable sector providers, and 38 471 (22%) were obtained privately.¹ In England in 2002, women resident in 83 of 304 (27%) primary care organisations (PCO) had less than 75% of their abortions NHS-funded.¹ Figure 1.1 summarises 2002 figures on levels of NHS-funded abortion provision among individual primary care organisations.

Gestation at abortion represents an indicator of accessibility and responsiveness of services. Figure 1.2 summarises the proportions of all abortions performed in different gestation bands for England, Wales and Scotland.

Because of these varying arrangements for provision, the clinical management of women requesting abortion spans a number of care sectors and involves a range of professionals. Abortion care was therefore considered by the RCOG to be a particularly appropriate topic for multidisciplinary guideline development.

The groups which have developed this guideline view induced abortion as a healthcare need and reiterate the recommendation of the RCOG Working Party on Unplanned Pregnancy (1991)⁷ that “health authorities should accept responsibility for the abortions needed by women resident in their districts”. Although this guideline addresses the discrete topic of abortion care, the guideline developers strongly support the concept that abortion care should be provided as an integral part of broader sexual health services.

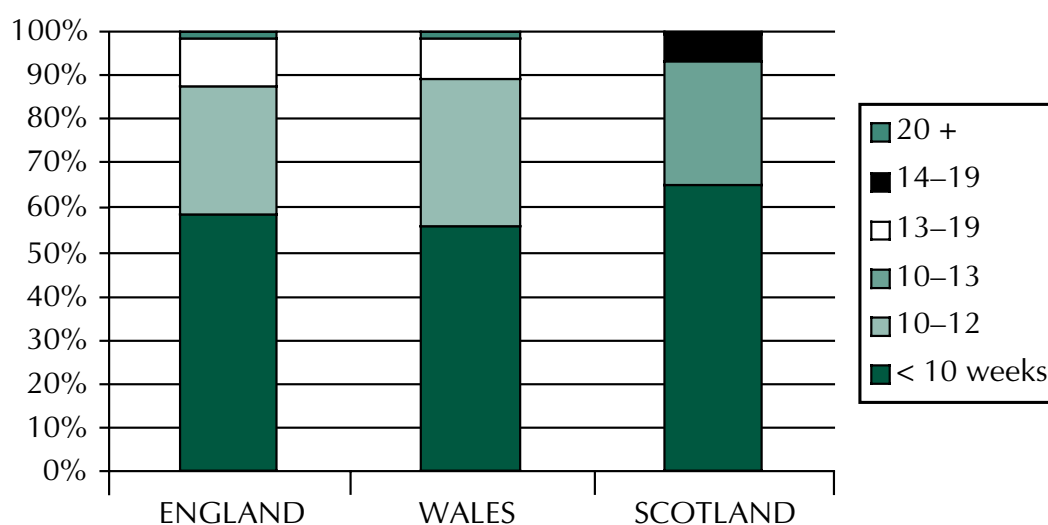


Figure 1.2 Proportion of legal abortions carried out in different gestation bands, 2002

In 2001, the Department of Health published *The National Strategy for Sexual Health and HIV*.⁸ This document highlighted inequalities in access to abortion and reiterated the waiting time targets included within the 2000 edition of this guideline. The RCOG is encouraged by the fact that “addressing the disparities that exist in abortion services” is listed among the targets for the strategy. The provision of abortion as an integral part of broader sexual health services is reflected in the proposal within the strategy to “develop managed networks for sexual health services with a broader role for those working in primary care settings and with providers collaborating to plan services jointly so that they deliver a more comprehensive service to patients”.⁸ Sexual health strategies developed by the National Assembly of Wales and by the Scottish Executive include similar targets for abortion care.

In 1999, the International Federation of Gynecology and Obstetrics (FIGO) published eight recommendations regarding induced abortion for ‘non-medical’ reasons. The summary recommendation was that “after appropriate counselling, a woman has the right to have access to medical or surgical induced abortion, and that healthcare services have an obligation to provide such services as safely as possible”.⁹ In 2003, the World Health Organization (WHO) published *Technical and Policy Guidance on Safe Abortion*¹⁰ to assist health systems in making legal abortion safe and accessible. Again, the RCOG is encouraged by the support voiced by FIGO and WHO for the concept of safe abortion care.

Unwanted pregnancies occur because women are unable to regulate their fertility by contraception alone. The complexities of managing sexual behaviour and the fallibility of contraception mean that some unwanted pregnancies are inevitable. The causes of unwanted pregnancies and the reasons why legal abortion remains a healthcare need were clearly summarised by the Birth Control Trust in their document, *Abortion Provision in Britain*,³ published to mark the 30th anniversary of the 1967 Abortion Act.

1.2 Aim of the guideline

Clinical guidelines have been defined as systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions.¹¹

The aim of this guideline is to ensure that all women considering induced abortion have access to a service of uniformly high quality. It is hoped that the guideline will be implemented across all relevant healthcare sectors and will promote a consistent standard, regardless of the sectors in which an individual woman is managed.

1.3 For whom is the guideline intended?

The guideline has been developed under the auspices of the RCOG for its Fellows and Members practising in the United Kingdom. The guideline may also be of interest to other professional groups who share in caring for women considering abortion: primary care teams, family planning clinic staff, gynaecology nurses, staff participating in non-NHS assessment centres and clinics, and all those professionals providing abortion counselling. Those with responsibilities for planning abortion services, for example directors of public health, NHS trust managers and managers of primary care groups, may also find the guideline helpful.

In this guideline, the term ‘clinician’ is used to refer to all healthcare professionals who participate in direct clinical patient care. Thus, the term includes doctors, nurses and midwives.

The guideline has been developed in relation to abortion legislation and available resources in England, Wales and Scotland. The different issues surrounding induced abortion in countries with different legislation and with different levels of resources and facilities are not considered.

1.4 Local protocol development

It is anticipated that this national guideline will be used as the basis for the development of local protocols or guidelines which will take into account local service provision and the needs and preferences of the local population. Such local adaptation should take place in a similar multidisciplinary group in consultation with all stakeholders affected by the recommendations. It is essential that commissioners of health care, as well as general practitioners, specialists and service users take part in such a process.¹²

1.5 Methods used in the development of the guideline

Literature search strategy

The aim of the literature review was to identify and synthesise relevant evidence within the published literature, thus enabling clinical practice recommendations to be based on evidence wherever possible.

In developing the earlier version of this guideline in 2000, searches were carried out for each topic of interest. The electronic database, MEDLINE (Ovid version), was searched for the period January 1966 to 1999, including foreign language publications. The searches were performed using relevant MeSH (medical subject headings) terms and text words. In addition, the electronic database EMBASE was searched between 1974 to 1999, to identify publications, usually European, not indexed on MEDLINE. The Cochrane Library, up to Issue 2 (1999), was searched to identify systematic reviews, meta-analyses and controlled clinical trials. Reference lists of non-systematic review articles and studies obtained from the initial search were trawled and journals in the RCOG library were hand-searched to identify articles not yet indexed. There was no systematic attempt to search the 'grey literature' (conferences, abstracts, theses and unpublished trials).

In developing this edition, similar literature searches were carried out covering the period 1999 to September 2003. Details of all literature searches are available on application to the FFPRHC Clinical Effectiveness Unit.

The 2000 guideline included a short section on managing the complications of abortion. The Guideline Update Group considered that this topic had been addressed somewhat superficially. It lay outwith the main scope of the guideline and would be better omitted. Recommendations on complications of abortion have therefore been restricted to those included in information for women (Chapter 5).

Sifting and reviewing the literature

For both the original and updating literature searches, a preliminary scrutiny of titles and abstracts was undertaken and full papers were obtained if they were relevant to the topic. Articles not relevant to the subject in question were rejected, as were articles where relevant outcomes were not reported. For all the subject areas, published systematic reviews or meta-analyses were used, if available. If these did not exist, randomised controlled trials were sought. For subject areas where

a body of systematic review or randomised trial evidence was available, studies of less robust designs were not systematically sought. Where there were no relevant published randomised controlled trials, other appropriate experimental or observational studies were sought.

Synthesising the evidence

Identified articles were assessed methodologically and the best available evidence was used to form and support the recommendations. If a good systematic review, meta-analysis or randomised controlled trial existed in relation to a topic, studies of a weaker design were ignored. The evidence was synthesised using qualitative methods. These involved summarising the content of identified papers in the form of evidence tables and agreeing brief recommendation statements that accurately reflected the relevant evidence. Quantitative techniques (meta-analysis) were not performed by the guideline development team because of time constraints and the difficulty of combining studies of various designs.

Forming and grading the recommendations

The definitions of the types of evidence used in this guideline originate from the US Agency for Health Care Policy and Research (Table 1.1).¹³ Recommendations were based on, and explicitly linked to, the evidence that supports them. Recommendations were derived from available research evidence using consensus methods. Where there were areas without available research evidence, consensus was again used.

As part of the consensus process, members of the Guideline Development Group were circulated with questionnaires on which draft recommendations were listed. For each recommendation, members were asked to indicate if they thought that the recommendation should be included as it stood, included with modifications or excluded. This questionnaire approach ensured that all group members, not just the more vocal, had an equal opportunity to express their views on recommendations. Examination of the questionnaire responses enabled the more contentious recommendations to be identified for more detailed discussion at subsequent group meetings. The Update Group used an informal consensus process to agree modified recommendations.

The recommendations were then graded according to the level of evidence upon which they were based. The grading scheme used was formulated by the Clinical Outcomes Group and recommended by the NHS Executive.¹³

The strength of the evidence on which each recommendation is based is shown in Table 1.2. It is accepted that, in this grading system, the evidence itself is not graded according to quality, although

Table 1.1 Levels of evidence

Level	Evidence
Ia	Evidence obtained from meta-analysis of randomised trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well-designed controlled study, without randomisation
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study
III	Evidence obtained from well designed non-experimental descriptive studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Table 1.2 Forming recommendations

Grade of recommendation	Evidence level
A	Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (<i>evidence levels Ia, Ib</i>)
B	Requires the availability of well-conducted clinical studies, but no randomised clinical trials on the topic of the recommendation (<i>evidence levels IIa, IIb, III</i>)
C	Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (<i>evidence level IV</i>)
Good practice points ✓	Recommended best practice based on the clinical experience of the Guideline Development Groups

it is discussed narratively in the text supporting each recommendation. It is also accepted that randomised controlled trials may not always be the most appropriate study design (for example, to investigate diagnostic tests).¹³ Similarly, there may be clinical questions that cannot easily be answered by experiment but nevertheless represent good practice. Such recommendations will automatically be graded C or ✓.

The validity of some grade C and ✓ recommendations may be questionable, as they are not based upon incontrovertible evidence. However, the views of the 2000 Guideline and Update Groups combined with comments from extensive peer review, as detailed below, suggest that the recommendations with this grading are acceptable to a wide body of expert opinion.

Scope and methods of peer review

Successive drafts of the original guideline were written and discussed by the Guideline Development Group. At the fourth draft stage, a formal peer review process was undertaken. Each member of the group suggested names of individuals or organisations from the area of practice that they represented. The draft guideline was submitted to these individuals or organisations with a request for appraisal and comment. The comments made by the peer reviewers were taken into consideration by the Guideline Update Group before the final guideline was generated. Under the independent guideline appraisal system approved by the NHS Executive, the guideline was sent to a further group of reviewers who particularly concentrated on the methodology used in its development.

For this edition, the second draft of the guideline was circulated for peer review to relevant individuals chosen by the Department of Health and the RCOG. The draft was also posted on the RCOG website and comments invited from any Member or Fellow. Comments received were reviewed by the development team and changes were made to the document where necessary. A final draft was then approved by the RCOG Guidelines and Audit Committee.

1.6 Implementation and review

This updated guideline was published in 2004. The RCOG will maintain a watching brief on the need to review recommendations in the light of new research evidence.

Chapter 2

Summary of recommendations

2.1 Organisation of services

- ✓ 1. Abortion services should have local strategies in place for providing information to both women and healthcare professionals on the choices available within the service and on routes of access to the service.
- ✓ 2. Access to services should be ensured for women with special needs. For example, as appropriate, special arrangements should be made for non-English-speaking women and a woman doctor should be available.
- ✓ 3. It is helpful if the referring doctor is able to provide the first signature on Certificate A. If a woman refers herself, or if the referring doctor is not willing to support the abortion, it must be possible for the woman to be assessed by a second doctor within the abortion service.
- ✓ 4. Any woman considering induced abortion should have access to clinical assessment.
- ✓ 5. Appropriate information and support should be available for those who consider but do not proceed to abortion.
- B** 6. The earlier in pregnancy an abortion is performed, the lower the risk of complications. Services should therefore offer arrangements that minimise delay (for example, a telephone referral system and a formal care pathway with arrangements for access from a wide range of referral sources, not just general practitioners).
7. Service arrangements should be such that:
 - ideally, all women requesting abortion are offered an assessment appointment within 5 days of referral.
 - as a minimum standard, all women requesting abortion are offered an assessment appointment within 2 weeks of referral.
 - ideally, all women can undergo the abortion within 7 days of the decision to proceed being agreed.
 - as a minimum standard, all women can undergo the abortion within 2 weeks of the decision to proceed being agreed.
- C**
 - as a minimum standard, no woman need wait longer than 3 weeks from her initial referral to the time of her abortion.
 - women should be seen as soon as possible if they require termination for urgent medical reasons.

- ✓ 8. The assessment appointment should be within clinic time dedicated to women requesting abortion.
- ✓ 9. In the absence of specific medical, social or geographical contraindications, induced abortion may be managed on a day case basis.
- C 10. An adequate number of staffed inpatient beds must be available for those women who are unsuitable for daycase care. In a typical abortion service, up to 5% of women will require inpatient care.
- ✓ 11. As far as possible, women admitted for abortion should be cared for separately from other gynaecological patients.
- ✓ 12. Women having second-trimester abortions by medical means must be cared for by an appropriately experienced midwife or nurse. Ideally, they should have the privacy of a single room.

2.2 Information for women

- B 13. Verbal advice should be supported by accurate, impartial printed information that the woman considering abortion can understand and may take away to consider further before the procedure.
- ✓ 14. The use of nationally developed patient information (such as that produced by the RCOG or fpa) ensures accuracy and readability. Services are encouraged to adapt national information to reflect local circumstances or to supplement a national leaflet with a sheet summarising local details.
- ✓ 15. Information for women and professionals should emphasise the duty of confidentiality by which, as for any form of health care, all concerned with the provision of induced abortion are bound.
- ✓ 16. Clinicians providing abortion services should possess accurate knowledge about possible complications and sequelae of abortion. This will permit them to provide women with the information they need in order to give valid consent.
 - B 16.1 The risk of haemorrhage at the time of abortion is low. It complicates around 1 in 1000 abortions overall. The risk is lower for early abortions (0.88 in 1000 at less than 13 weeks; 4.0 in 1000 at more than 20 weeks).
 - B 16.2 The risk of uterine perforation at the time of surgical abortion is moderate. The incidence is of the order of 1–4 in 1000. The risk is lower for abortions performed early in pregnancy and those performed by experienced clinicians.
 - B 16.3 Uterine rupture has been reported in association with mid-trimester medical abortion. However, the risk is very low, at well under 1 in 1000.
 - B 16.4 Cervical trauma: the risk of damage to the external cervical os at the time of surgical abortion is moderate (no greater than 1 in 100). The risk is lower when abortion is performed early in pregnancy and when it is performed by an experienced clinician.

- B** 16.5 Failed abortion and continuing pregnancy: all methods of first-trimester abortion carry a small risk of failure to terminate the pregnancy, thus necessitating a further procedure. The risk for surgical abortion is around 2.3 in 1000 and for medical abortion between 1 and 14 in 1000 (depending on the regimen used and the experience of the centre).
- B** 16.6 Post-abortion infection: genital tract infection, including pelvic inflammatory disease of varying degrees of severity, occurs in up to 10% of cases. The risk is reduced when prophylactic antibiotics are given or when lower genital tract infection has been excluded by bacteriological screening.
- B** 16.7 Breast cancer: induced abortion is not associated with an increase in breast cancer risk.
- B** 16.8 Future reproductive outcome: there are no proven associations between induced abortion and subsequent ectopic pregnancy, placenta praevia or infertility. Abortion may be associated with a small increase in the risk of subsequent miscarriage or preterm delivery.
- B** 16.9 Psychological sequelae: some studies suggest that rates of psychiatric illness or self-harm are higher among women who have had an abortion compared with women who give birth and to nonpregnant women of similar age. It must be borne in mind that these findings do not imply a causal association and may reflect continuation of pre-existing conditions.

2.3 Pre-abortion management

The abortion decision

- C** 17. Clinicians caring for women requesting abortion should try to identify those who require more support in decision making than can be provided in the routine clinic setting (such as those with a psychiatric history, poor social support or evidence of coercion). Care pathways for additional support, including access to social services, should be available.

Blood tests

- C** 18. Pre-abortion assessment should include:
- measurement of haemoglobin concentration
 - determination of ABO and rhesus blood groups with screening for red cell antibodies
 - testing for other conditions such as haemoglobinopathies, HIV, and hepatitis B and C if indicated in the light of clinical features, individual risk factors or local prevalence.
- B** 19. It is not cost effective routinely to crossmatch women undergoing induced abortion.

Cervical cytology

- ✓** 20. Assessment prior to induced abortion may be viewed as an opportunity to ascertain each woman's cervical cytology history. Women who have not had a cervical smear within the interval recommended in their local programme may be offered one within the abortion service.

- ✓ 21. If a cervical smear is taken within the abortion service, then mechanisms are essential to ensure that the smear result is communicated to the woman, acted on appropriately and recorded within the local cervical cytology programme.

Ultrasound scanning

- B 22. All services must have access to scanning, as it can be a necessary part of pre-abortion assessment, particularly where gestation is in doubt or where extrauterine pregnancy is suspected. However, ultrasound scanning is not considered to be an essential prerequisite of abortion in all cases.
- C 23. When ultrasound scanning is undertaken, it should be in a setting and manner sensitive to the woman's situation. It is inappropriate for pre-abortion scanning to be undertaken in an antenatal department alongside women with wanted pregnancies.

Prevention of infective complications

- A 24. Abortion care should encompass a strategy for minimising the risk of post-abortion infective morbidity. As a minimum, services should offer antibiotic prophylaxis.
- B Ideally, services should offer testing for lower genital tract organisms with treatment of positive cases.
- C 25. The following regimens are suitable for periabortion prophylaxis:
- metronidazole 1 g rectally at the time of abortion
plus
 - doxycycline 100 mg orally twice daily for 7 days, commencing on the day of abortion
- OR
- metronidazole 1 g rectally at the time of abortion
plus
 - azithromycin 1 g orally on the day of abortion.

2.4 Abortion procedures

- ✓ 26. As a minimum, all services should be able to offer abortion by one of the recommended methods for each gestation band.
- B 27. Ideally, abortion services should be able to offer a choice of recommended methods for each gestation band.

Surgical methods

- B 28. Conventional suction termination should be avoided at gestations below 7 weeks.
- B 29. Early surgical abortion using a rigorous protocol (which includes magnification of aspirated material and indications for serum β hCG follow-up) may be used at gestations below 7 weeks, although data suggest that the failure rate is higher than for medical abortion.
- B 30. Conventional suction termination is an appropriate method at gestations of 7–15 weeks, although, in some settings, the skills and experience of practitioners may make medical abortion more appropriate at gestations above 12 weeks.

- ✓** 31. During suction termination, the uterus should be emptied using the suction curette and blunt forceps (if required) only. The procedure should not be completed by sharp curettage.
- B** 32. Suction termination is safer under local anaesthesia than under general anaesthesia. Consideration should be given to making this option available, particularly for low-gestation procedures.
- C** 33. If conscious sedation is used in place of general anaesthesia to reduce the pain and anxiety associated with surgical abortion, it should be undertaken only by trained practitioners and in line with Department of Health guidance.
- A** 34. For first-trimester suction termination, either electric or manual aspiration devices may be used, as both are effective and acceptable to women and clinicians. Operating times are shorter with electric aspiration.
- A** 35. For gestations above 15 weeks, surgical abortion by dilatation and evacuation (D&E), preceded by cervical preparation, is safe and effective when undertaken by specialist practitioners with access to the necessary instruments and who have a sufficiently large caseload to maintain their skills.
- B** 36. Cervical preparation is beneficial prior to surgical abortion and should be routine if the woman is aged under 18 years of age or at a gestation of more than 10 weeks.
- C** 37. Abortion regimens containing misoprostol are not licensed within manufacturers' summaries of product characteristics. European Community regulations permit doctors to prescribe unlicensed regimens and permit pharmacists to dispense and nurses to administer medicines prescribed outside of a product licence. Women should be informed if a prescribed treatment is unlicensed.
- B** 38. Based on available evidence, the following regimen appears to be optimal for cervical preparation prior to first- or second-trimester surgical abortion. This advice is based on considerations of efficacy, adverse-effect profile and cost:
 - * misoprostol 400 micrograms (2 x 200-microgram tablets) administered vaginally, either by the woman or a clinician, 3 hours prior to surgery.

The following regimens are licensed within manufacturers' summaries of product characteristics and are also appropriate for cervical preparation prior to first- or second-trimester surgical abortion:

 - gemeprost 1 mg vaginally, 3 hours prior to surgery
 - mifepristone 600 mg orally 36–48 hours prior to surgery.

Medical methods

- B** 39. Medical abortion using mifepristone plus prostaglandin is the most effective method of abortion at gestations of less than 7 weeks.
- A** 40. Medical abortion using mifepristone plus prostaglandin continues to be an appropriate method for women in the 7–9 week gestation band.

* This regimen is unlicensed.

- A** 41.* For early medical abortion a dose of 200 mg of mifepristone in combination with a prostaglandin is appropriate.
- A** 42.* Misoprostol (a prostaglandin E₁ analogue) is a cost-effective alternative for all abortion procedures for which the E₁ analogue gemeprost is conventionally used (that is, early medical abortion, cervical priming, mid-trimester medical abortion).
- B** 43. Based on available evidence, the following regimen appears to be optimal for early medical abortion up to 9 weeks (63 days) of gestation. This advice is based on considerations of efficacy, adverse-effect profile and cost:
- * mifepristone 200 mg orally followed 1–3 days later by misoprostol 800 micrograms vaginally. The misoprostol may be administered by a clinician or self-administered by the woman. For women at 49–63 days of gestation, if abortion has not occurred 4 hours after administration of misoprostol, a second dose of misoprostol 400 micrograms may be administered vaginally or orally (depending upon preference and amount of bleeding).
- The following regimen is licensed within manufacturer’s summary of product characteristics and is also appropriate for early medical abortion up to 9 weeks (63 days) of gestation:
- * mifepristone 600 mg orally followed 36–48 hours later by gemeprost 1 mg vaginally.
- A** 44. Medical abortion using the following regimen is a safe, effective and acceptable alternative to surgical abortion for women between 9 and 13 weeks of gestation:
- * mifepristone 200 mg orally followed 36–48 hours later by misoprostol 800 micrograms vaginally. A maximum of four further doses of misoprostol 400 micrograms may be administered at 3-hourly intervals, vaginally or orally (depending on the amount of bleeding).
- B** 45. For mid-trimester abortion (13–24 weeks of gestation) medical abortion with mifepristone followed by prostaglandin is an appropriate method and has been shown to be safe and effective.
- A** 46. For mid-trimester medical abortion, a dose of *200 mg of mifepristone is adequate.
- B** 47. Surgical evacuation of the uterus is not required routinely following mid-trimester medical abortion. It should only be undertaken if there is clinical evidence that the abortion is incomplete.
- A** 48. Based on available evidence, the following regimen appears to be optimal for mid-trimester medical abortion. This advice is based on considerations of efficacy, adverse-effect profile and cost:
- * mifepristone 200 mg orally, followed 36–48 hours later by misoprostol 800 micrograms vaginally, then misoprostol 400 micrograms orally, 3-hourly, to a maximum of four oral doses.
- The following regimen is licensed within manufacturer’s summary of product characteristics and is also appropriate for mid-trimester medical abortion.
- * mifepristone 600 mg orally, followed 36–48 hours later by gemeprost 1 mg vaginally every 3 hours, to a maximum of five pessaries.

* This regimen is unlicensed.

General

- B** 49. Some women will require analgesia after surgical abortion or during and after medical abortion. Requirements for analgesia vary and there is no benefit in routine administration of prophylactic analgesics. Services should make available a range of oral and parenteral analgesics in order to meet women's needs.
- B** 50. Routine histopathological examination of tissue obtained at abortion procedures is unnecessary.

2.5 Aftercare

Rhesus prophylaxis

- B** 51. Anti-D immunoglobulin G (250 iu before 20 weeks of gestation and 500 iu thereafter) should be given, by injection into the deltoid muscle, to all nonsensitised RhD negative women within 72 hours following abortion, whether by surgical or medical methods.

Post-abortion information and followup

- ✓** 52. Following abortion, women must be given a written account of the symptoms they may experience and a list of those that would make an urgent medical consultation necessary. They should be given a 24-hour telephone helpline number to use if they feel worried about pain, bleeding or high temperature. Urgent clinical assessment and emergency gynaecology admission must be available when necessary.
- C** 53. Each woman should be offered, or advised to obtain, a follow-up appointment (either within the abortion service or with the referring clinician) within 2 weeks of the abortion.
- ✓** 54. On discharge, each woman should be given a letter that includes sufficient information about the procedure to allow another practitioner elsewhere to deal with any complications.
- C** 55. Referral for further counselling should be available for the small minority of women who experience long-term post-abortion distress. Risk factors are ambivalence before the abortion, lack of a supportive partner, a psychiatric history or membership of a cultural group that considers abortion to be wrong.

Contraception following abortion

- B** 56. Before she is discharged following abortion, future contraception should have been discussed with each woman and contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion.
- B** 57. Intrauterine contraception can be inserted immediately following a first- or second-trimester termination of pregnancy.
- B** 58. Sterilisation can be safely performed at the time of induced abortion. However, combined procedures are associated with higher rates of failure and of regret on the part of the woman.

Chapter 3

Legal and ethical aspects of abortion

3.1 The Abortion Act

Current abortion legislation in Great Britain is based on the Abortion Act 1967,¹⁴ the modifications introduced by the Human Fertilisation and Embryology Act 1990¹⁵ and, for England and Wales, on further amendments made in 2002 (summarised in Statutory Instrument 2002 No. 887).¹⁶ Legal requirements apply to certification and notification of abortion procedures. A certificate signed by the two medical practitioners authorising the abortion must be retained for a period of at least 3 years and the operating practitioner must complete a notification form and forward it to the Chief Medical Officer for the relevant UK country. Within the terms of the Abortion Act, only a registered medical practitioner can terminate a pregnancy: the notification form must be signed by the doctor taking responsibility for the procedure. In practice, a nurse or midwife may administer the drugs used for medical abortion once these have been prescribed by the doctor concerned.

For England, the 2002 amendments to the Abortion Act¹⁶ changed the content of the HSA4 form through which medical practitioners notify the Chief Medical Officer of every abortion performed. Guidance notes on completing the amended form have been published.¹⁷ Wales has also adopted the amended HSA4. Key features of the 2002 amendment are:

- to increase the timescale for notification from 7 to 14 days
- to include the General Medical Council (GMC) registration number of the practitioner terminating the pregnancy
- to allow the option of identifying the woman only by her hospital or clinic or NHS reference number, rather than by her full name
- to include data on ethnicity
- to specify if feticide was undertaken as part of the abortion procedure
- to specify if *Chlamydia* screening was offered.

The Abortion Act does not apply in Northern Ireland. Some abortions are performed there and categorised as therapeutic. Abortion is available if the woman has a serious medical or psychological problem that would jeopardise her life or health if the pregnancy continued, if she has severe learning difficulties or if a fetal abnormality is detected. It is unclear at what gestations such abortions may be performed and no official abortion statistics are collected.¹⁸ A judicial review of medical practices relating to abortion services in Northern Ireland, initiated by the fpa, is currently under appeal. This review may result in clarification of the status of abortion in Northern Ireland.

Statutory grounds for termination of pregnancy

Abortion is legal in Great Britain if two doctors decide in good faith that a particular pregnancy is associated with factors that satisfy one or more of five grounds specified in the Regulations of the Abortion Act^{14,16} and Section 37 of the Human Fertilisation and Embryology Act 1990:¹⁵

- A** The continuance of the pregnancy would involve risk to the life of the pregnant woman greater than if the pregnancy were terminated.
- B** The termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman.
- C** The pregnancy has not exceeded its 24th week and the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman.
- D** The pregnancy has not exceeded its 24th week and the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the existing child(ren) of the family of the pregnant woman.
- E** There is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.

The Regulations also permit abortion to be performed in an emergency on the basis of the signature of the doctor performing the procedure, which may be provided up to 24 hours after the termination. The emergency grounds are:

- F** To save the life of the pregnant woman.
- G** To prevent grave permanent injury to the physical or mental health of the pregnant woman.

Most abortions are undertaken on grounds C or D: that the pregnancy has not exceeded its 24th week and that continuance would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the woman or of the existing children of her family.

As an illustration, in England and Wales in 2002, the vast majority (94%) of abortions were undertaken under ground C and 4% under ground D. Grounds A and B together accounted for just over 1% of abortions and a similar proportion were under ground E. The proportion of ground C abortions has risen steadily since 1992, with a corresponding reduction in grounds B and D cases. Abortions are rarely performed under grounds F or G: in 2002 there was one case reported.¹ Similarly, in Scotland in 2002, 98.5% of abortions were undertaken on grounds C or D, 0.2% on grounds A or B and 1.2% on ground E. No abortions on the emergency grounds (F or G) have been notified in Scotland during the last three years.²

The WHO definition of health is “a state of physical and mental wellbeing, not merely an absence of disease or infirmity”.¹⁹ Most doctors apply this broad definition of health in interpreting the Abortion Act. Thus, to meet the terms of the Act, a woman need not have a psychiatric illness when she makes her abortion request but there must be factors that would involve risk to her mental health if the pregnancy were to continue. Thus, the abortion is not carried out for social reasons, although a woman’s social circumstances may be taken into account in assessing the risks to her health.

The requirements of the Abortion and Human Fertilisation and Embryology Acts are discussed further within **Chapter 4**, Organisation of services.

3.2 Good professional practice

Doctors providing abortion care are bound by the same duties of a doctor, as laid down by the GMC,²⁰ as for all other aspects of their clinical practice. These principles of good practice bear repetition here:

- make the care of your patient your first concern
- treat every patient politely and considerately
- respect patients' dignity and privacy
- listen to patients and respect their views
- give patients information in a way they can understand
- respect the right of patients to be fully involved in decisions about their care
- keep your professional knowledge and skills up to date
- recognise the limits of your professional competence
- be honest and trustworthy
- respect and protect confidential information
- make sure that your personal beliefs do not prejudice your patients' care
- act quickly to protect patients from risk if you have good reason to believe that you or a colleague may not be fit to practice
- avoid abusing your position as a doctor
- work with colleagues in the ways that best serve patients' interests.

The United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) (now the Nursing and Midwifery Council) published a Code of Professional Conduct²¹ and Guidelines for Professional Practice²² equivalent to the GMC's *Duties of a Doctor*. The guidance provided in these documents is similar in spirit and in actual wording to the *Duties of a Doctor* summarised above (the content of these two documents has now been combined in the Nursing and Midwifery Council's Code of Professional Conduct).²³

3.3 Confidentiality

All women seeking abortion have the right to confidentiality from all clinical and ancillary staff. Only in exceptional circumstances, where the health, safety or welfare of a minor, or other persons, is at risk should information be disclosed to a third party. Similarly, if a minor is a ward of court or in care disclosure may be considered appropriate.²⁴

Data on all women undergoing abortion must be collected on the HSA4 form or other relevant form, for the Chief Medical Officer. These data are not anonymised and, although names and addresses are not generally recorded, date of birth, postcode and reference number may allow the woman to be identified. Forms are held securely and only individuals authorised by the Chief Medical Officer have access. Information can be disclosed in rare instances, within the terms of the Abortion Regulations. Women should be informed that abortion procedures are notified centrally, but can be reassured as to the confidentiality and security of the data.

3.4 Professionals' rights: conscientious objection to abortion

The Abortion Act¹⁴ has a conscientious objection clause which permits doctors to refuse to participate in terminations. The scope of the Act's conscientious objection clause was clarified in a Department of Health Parliamentary answer²⁵ and in a circular, Health Service Guidance

HSG(94)39.²⁶ The British Medical Association (BMA) has produced a helpful overview on the law and ethics of abortion, based on a comprehensive review of relevant legal documents.²⁷ The following represents a summary of the BMA's conclusions relating to interpretation of the conscientious objection clause:

- Doctors may refuse to participate in terminations but are obliged to provide necessary treatment in an emergency, when the woman's life may be jeopardised.
- Doctors with a conscientious objection may not impose their views on others, but may explain their views to a patient if invited to do so.
- The Parliamentary answer²⁵ clarifies that the conscientious objection clause was only intended to be applied to participation in treatment. Subsequently, however, hospital managers have been asked to apply the principle, at their discretion, to those ancillary staff involved in handling fetuses and fetal tissue.
- Refusal to participate in paperwork or administration connected with abortion procedures lies outside the terms of the conscientious objection clause.
- Practitioners cannot claim exemption from giving advice or performing the preparatory steps to arrange an abortion where the request meets the legal requirements. Such steps include referral to another doctor, as appropriate.
- The conscientious objection clause may be used by medical students to opt out of witnessing abortions.

In law, nurses have similar rights to conscientious objection. These are summarised in the NMC Code of Professional Conduct.²³ Like doctors, nurses have the right to refuse to take part in abortion but not to refuse to take part in emergency treatment.

3.5 Issues relating to consent to treatment

The 2000 guideline contained advice on patient consent based on the following sources: the Medical Defence Union's *Consent to Treatment*,²⁸ the BMA's *Law and Ethics of Abortion*,²⁷ and the GMC's guidance *Seeking Patients' Consent*.²⁹ In 2001, the Department of Health published comprehensive guidance in its *Reference Guide to Consent for Examination or Treatment*.³⁰ The advice which follows has been updated with reference to the latter document.

Competent adults

In the case of an adult woman (that is, aged over 18 years), for consent to be valid it must be given voluntarily, on the basis of appropriate information, and the woman must have the capacity to consent to the intervention in question. The GMC has summarised criteria for valid consent:²⁹

- the woman must have sufficient capacity to understand the procedure and its alternatives
- the consent must be voluntary
- the decision must be based on sufficient and accurate information.

A good working test for assessing capacity to consent to or refuse medical treatment was outlined by Mr. Justice Thorpe³¹ and has been reiterated in the BMA document.²⁷ This test is based on the patient having the ability:

- to take in and retain treatment information
- to believe the information
- to weigh the information, balancing risks and needs.

Non-competent adults

Under English law, no one can consent to treatment on behalf of another adult (that is, someone over the age of 18 years) who is unable to give consent for herself (an ‘incapable’ adult). Parents, relatives or healthcare professionals, therefore, cannot consent on behalf of such an adult. An authoritative text³² provides reassurance that provided the terms of the Abortion Act are complied with, a High Court declaration is not required. Rather, the professional’s assessment of the woman’s best interests should be the basis of the decision where the woman lacks the capacity to give valid consent.

The Medical Defence Union’s *Consent to Treatment*²⁸ provides similar reassurance that while certain procedures (such as sterilisation or donation of organs or bone marrow) would require application to court before being undertaken on a non-competent adult, this does not apply to abortion. The document does advise, however, that if a practitioner is in any doubt about what constitutes the best interests of a non-competent adult patient, then a second opinion should be sought from ‘another appropriate doctor’.

In Scotland, the Adults with Incapacity (Scotland) Act 2000³³ provides a framework for medical treatment of incapacitated adults (that is, those aged 16 years or more). The Act works alongside common law, which allows treatment in an emergency to people who are unable to give consent. If an adult lacks the capacity to make healthcare decisions and no proxy decision maker is appointed, a certificate of incapacity must be issued in order to provide care or treatment. Once a certificate has been issued, doctors can act under the general authority to treat. There are provisions within the Incapacity (Scotland) Act on the treatment of patients with mental disorder. Under the Incapacity (Scotland) Act, in addition to meeting the requirements of the Abortion Act, approval of a practitioner appointed by the Mental Welfare Commission is required before abortion can be performed. Guidance on interpretation and application of the Adults with Incapacity (Scotland) Act has been provided by the BMA.³²

Competent minors

Young people aged 16–17 years

By virtue of Section 8 of the Family Law Reform Act 1969, people aged 16 or 17 years are entitled to consent to their own medical treatment. However, unlike adults, the refusal of a competent person aged 16 or 17 years may, in certain circumstances, be overridden by a person with parental responsibility or by a court. In order to establish whether a young person aged 16 or 17 years has the requisite capacity to consent to an intervention, the same criteria as for adults should be used. If the requirements for valid consent are met, it is not legally necessary to obtain consent from a person with parental responsibility. However, it is good practice to involve the young person’s family in decision making, unless the young person specifically wishes to exclude them.

Young people aged under 16 years

The House of Lords ruling in the Gillick case was followed by the issuing of guidance by the Department of Health in the form of a Health Circular [HC(FP)(86)1].³⁵ The legal position was stated as “any competent young person, regardless of age, can give valid consent to medical treatment”.

The same working test for assessing capacity to consent to treatment outlined by Mr. Justice Thorpe³¹ and described above in relation to the competent adult can be applied in the case of a young person. Following the Gillick case, Lord Fraser provided the Fraser criteria²⁸ to guide doctors asked

to provide contraception for girls aged under 16 years who refuse to involve their parents. These criteria are worded to apply only to provision of contraception, but provide guidance similar to that provided by Mr Justice Thorpe.

A doctor is justified in proceeding without the parent's consent or knowledge if:

- the girl will understand his advice
- he cannot persuade her to inform her parents or to allow him to inform the parents that she is seeking contraceptive advice
- she is likely to begin or to continue having sexual intercourse with, or without, contraceptive advice
- unless she receives contraceptive advice or treatment her physical or mental health, or both, are likely to suffer
- her best interests require him to give her contraceptive advice, treatment, or both, without parental consent.

Doctors have an obligation to encourage a young person to involve her parents but generally should not override the patient's views. Only in the most exceptional cases, perhaps where the pregnancy is thought to have resulted from child abuse, incest or exploitation, may a breach of confidentiality be justifiable. In such cases, the patient must be informed that confidentiality cannot be guaranteed and offered all necessary help and support.

Legislation in Scotland relating to consent for medical, surgical and dental procedures is based on the Age of Legal Capacity (Scotland) Act 1991. Under the terms of this Act, the situation regarding age of consent (16 years) and the rights of a competent minor to give their own consent are the same as for the rest of the UK.

Wards of court

The main exception to this general guidance is if the young woman is a ward of court. In such cases, the courts would need to approve a termination. It is therefore particularly important that medical records make it clear if a child is a ward of court.

Similarly, if a young woman seeking abortion is in the care of a local authority she should be encouraged to involve the local social services. If, in such a case, the young woman refuses consent to such sharing of information, then individual legal advice should be sought. Again, the advice of the BMA²⁷ and MDU²⁸ is similar on this issue.

Non-competent minors

Only a holder of 'parental responsibility', or the court, can give consent to treatment on behalf of a minor. Adults who do not hold parental responsibility cannot give such consent. In rare cases, where a young person seeking abortion is not felt to be competent to provide valid consent and where a parent (or other holding parental responsibility) cannot give consent on the child's behalf, then it may be wise to obtain a court order. Similar advice is provided in both the BMA²⁷ and MDU²⁸ publications.

3.6 Abuse of children and vulnerable people

There are special difficulties in managing suspected child abuse, incest or abuse of the very vulnerable in abortion services. The need for a decision on a termination may be urgent because of

advanced gestation and both the girl and any accompanying adult usually conceal the truth from assessing staff. The girl may have travelled away from her home area to assist with the concealment. Staff must be alert to the possibility of abuse, particularly when the girl refuses to involve her parents or general practitioner, or is accompanied by a controlling adult such as a male relative who wishes to remain particularly close to her.

When abuse is suspected, the primary concern must be the wellbeing of the girl and any siblings. Clear protocols must be in place for all assessors, medical staff, nurses and counsellors on action to be taken should abuse be suspected. It is suggested that all services should designate a small number of doctors and counsellors to assess all girls under 16 years. Within the terms of confidentiality, it would be their responsibility to liaise with the appropriate social services child protection group when there is strong evidence that a girl has been abused or when other children are likely to be at risk. Further guidance has been issued as an addendum to *Working Together – Under the Children Act 1989*.³⁶ Similar considerations can arise in the case of vulnerable women (perhaps because of mental handicap).

The duty of a doctor who learns of such an allegation or has other reason to suspect abuse is to protect the child and secure the best possible outcome for that child. The accepted professional, ethical view is that where a doctor believes that a patient (whether or not that patient is a child) may be the victim of abuse or neglect, the patient's interests are paramount, and will usually require a doctor to disclose information to an appropriate responsible person or officer of a statutory agency. In the case of children, the responsibilities of doctors are set out in the document, *Child Protection: Medical Responsibilities. Guidance for Doctors Working with Child Protection Agencies*.³⁶

Disclosure is not invariably required but it is usual in order that the interests of the child, which are paramount, may be protected. A doctor may be called upon to justify before the court or the statutory professional body, the GMC, the action that he or she has taken. When such concerns arise in the context of abortion, whether during counselling or subsequently, the duty of the doctor is clear, and those who practise in this field should ensure that they are familiar with the procedures to be observed. A doctor should also bear in mind that other children in a family may be in need of protection. The report of the Climbie Enquiry³⁷ includes healthcare recommendations which clarify the actions which individual clinicians and NHS trusts should take in cases where deliberate harm of a child is identified.

3.7 Rights of the spouse or partner

The decision to terminate a pregnancy rests with the woman and her doctors. Legally, the woman's spouse and/or the putative father of the child has no rights to demand or refuse a termination.³⁸ In individual cases which attracted much media attention (Kelly, 1997; Hansell, 2001) male partners brought unsuccessful legal actions in attempts to prevent women obtaining abortions.

3.8 Disposal of fetal tissue

For fetuses born dead at or before 24 weeks of gestation, Department of Health guidance HSG(91)19 on the disposal of fetal tissue applies.³⁹ It states that "all fetuses and fetal tissue from termination of pregnancy must be incinerated" but also that "full account should be taken of any personal wishes that have been expressed about disposal which require some other method to be used". The Royal College of Nursing (RCN) published guidance for nurses and midwives on *Sensitive Disposal of All Fetal Remains* in 1991.⁴¹

Other methods of disposal chosen by the woman or couple may include a privately arranged cremation or burial. The opportunity to do this will vary, depending on the policies of the local crematoria and burial authorities, who can exercise discretion. Alternatively, the woman or couple may decide to bury the fetus themselves. The Department of Health has advised that there is no legal prohibition on where the fetus is buried, provided that no danger is caused to others and there is no interference with any rights that other people may have over the land used.

In general, abortion service providers arrange for fetal material to be incinerated but some have chosen to have a contract with the local crematoria or burial authorities for cremation or burial. However, if a woman requests that she be allowed to make alternative private arrangements as set out above, there is no legal obstacle to this.

Among women who have an early medical abortion (up to 63 days), a small minority choose to pass the products of conception outside of hospital or clinic premises. The Department of Health advises that abortion service providers should make provision for a woman to return products of conception to the provider for disposal if she so wishes. A woman or couple should be made aware that information on disposal options is available if they wish to have access to it. If they then decide not to receive any information about, or take part in, the disposal of the fetal tissue, their wishes should be respected.

Further information on the disposal of fetal tissue from pregnancies lost before 24 weeks will soon be available from the Department of Health.

Terminations carried out after 24 weeks of gestation are required by law to be registered as stillbirths and for the body to be buried or cremated. However, these circumstances lie outwith the scope of this guideline, which focuses on abortions undertaken on Grounds 'C' and 'D', restricted to pregnancies under 24 weeks.

Chapter 4

Organisation of services

In the view of the Guideline Development Group and the Update Group, the aim of an abortion service is to provide high-quality, efficient, effective and comprehensive care, which respects the dignity, individuality and rights of women to exercise personal choice over their treatment. Ideally, an abortion service should be an integral component of a broader service for reproductive and sexual health, encompassing contraception and management of sexually transmitted infections.

4.1 Access and referral to abortion services

RECOMMENDATION 1



Abortion services should have local strategies in place for providing information to both women and healthcare professionals on the choices available within the service and on routes of access to the service.

RECOMMENDATION 2



Access to services should be ensured for women with special needs. For example, as appropriate, special arrangements should be made for non-English-speaking women and a woman doctor should be available.

RECOMMENDATION 3



It is helpful if the referring doctor is able to provide the first signature on Certificate A. If a woman refers herself, or if the referring doctor is not willing to support the abortion, it must be possible for the woman to be assessed by a second doctor within the abortion service.

RECOMMENDATION 4



Any woman considering induced abortion should have access to clinical assessment.

RECOMMENDATION 5



Appropriate information and support should be available for those who consider but do not proceed to abortion.

Evidence supporting recommendations 1 to 5

Recommendations based on group consensus.

RECOMMENDATION 6

B The earlier in pregnancy an abortion is performed, the lower the risk of complications. Services should therefore offer arrangements that minimise delay (for example, a telephone referral system and a formal care pathway with arrangements for access from a wide range of referral sources, not just general practitioners).

Evidence supporting recommendation 6

The absolute risk of complications at the time of abortion is low. For example, a retrospective cohort study of 83 469 procedures⁴² reported 571 immediate complications (0.7%). The complications included haemorrhage (greater than 500ml), cervical laceration, uterine perforation, retained products, infection and maternal death.

Against this background of low absolute risk, level IIb evidence (from large cohort studies)^{42–45} suggests that increasing gestational age is associated with an increasing relative risk of complications of abortion. For example, the study of Ferris *et al.* from Ontario⁴² found odds ratios for immediate complications of 1.3 (95% CI 1.02–1.63) at 9–12 weeks of gestation and of 3.3 (95% CI 2.23–5.00) at 17–20 weeks, compared with procedures at or below 9 weeks.

Similarly, a US cohort study of over 82 000 women showed that the relative risk of serious complications increased by 1.42 (95% CI 1.30–1.55) for every 2-week increment in gestation beyond 12 weeks.⁴⁵ Below this gestation, there was no significant overall increase in serious complications but there was an increase specifically for haemorrhage requiring transfusion: the relative risk for each 2-week gestation increment was 2.0 (95% CI 1.10–3.64) below 12 weeks and 1.48 (95% CI 1.33–1.65) beyond this age.

A MEDLINE search covering the years 1976–2003 revealed only one study suggesting that later abortion is as safe as that undertaken earlier (15–20 weeks versus less than 15 weeks). This was a relatively small cohort study of 3772 women.⁴⁶

Level III evidence, in the form of a before-and-after study, is available to show that organisational change (in the form of a telephone referral service with the provision of dedicated outpatient appointment time) is reflected in earlier abortion.⁴⁷

The supporting evidence cited in this section is summarised in Evidence table 1 in the Appendix.

4.2 Waiting times in abortion services

RECOMMENDATION 7

Service arrangements should be such that:

- ideally, all women requesting abortion are offered an assessment appointment within 5 days of referral.
- as a minimum standard, all women requesting abortion are offered an assessment appointment within 2 weeks of referral.

- ideally, all women can undergo the abortion within 7 days of the decision to proceed being agreed.
- as a minimum standard, all women can undergo the abortion within 2 weeks of the decision to proceed being agreed.
- C** • as a minimum standard, no woman need wait longer than 3 weeks from her initial referral to the time of her abortion.
- women should be seen as soon as possible if they require termination for urgent medical reasons.

Evidence supporting recommendation 7

The Birth Control Trust⁴⁸ suggested 5 and 7 days as appropriate targets for referral to assessment and assessment to procedure intervals, respectively. These same targets were endorsed by a consensus survey of Scottish gynaecologists.⁴⁹ The Guideline Development Group supported these target intervals as an ideal towards which services might aspire.

The *National Strategy for Sexual Health*,⁸ published in 2001, reiterated the RCOG minimum standard that women should “have access to an abortion within 3 weeks of the first appointment with a GP or other referring doctor”.

The Guideline Update Group emphasised that these targets refer to the offer of an appointment for assessment or an abortion procedure. Some women will choose not to take up the first appointment either because they wish to have more time to reach a decision or for a range of individual reasons. The Update Group also emphasised the importance of services working towards waiting times shorter than these targets. A report from the fpa advocates a target of 72 hours for the assessment to procedure interval, with 1 week as the minimum standard.⁵⁰

4.3 Settings for abortion care

Approval of independent sector places to undertake termination of pregnancy

The Abortion Act (Subsection 3) requires that termination of pregnancy is carried out in an NHS hospital or in a place approved by the Secretary of State. Before giving approval to a non-NHS place, the Secretary of State must be satisfied that the proprietor will comply with certain conditions. Since 1 October 1999, the document, *Procedures for the Approval of Independent Sector Places for the Termination of Pregnancy*,^{51,52} has governed approval of non-NHS places in England wishing to undertake abortion procedures.

The aims of the procedures^{51,52} are to ensure that there is compliance with the legal requirements, that places provide the best quality of care for women, and that they have sound management and organisational arrangements. The documents highlight the importance of authoritative professional standards of care, supported by guidelines to assist in achieving them, complemented by arrangements for audit of the service and of clinical practice. It is expected that this guideline on induced abortion will be adopted by independent sector providers, alongside the NHS, in support of these aims.

Until April 2002, the Department of Health undertook regular inspections of independent sector abortion establishments to ensure adherence with the procedures. In April 2002, the National Care Standards Commission (as of 1 April 2004, the Healthcare Commission) became fully operational and, for England, now includes these Department of Health inspection responsibilities within its remit. The Commission is a national, independent body established under the Care Standards Act

2000. It is responsible for regulating a wide range of services including care homes, children's homes, private hospitals and clinics. National minimum standards have been published which apply to all settings for independent health care.⁵³ This document contains a specific section on termination of pregnancy establishments, which includes five individual standards. In brief, these standards cover:

- adherence to the Healthcare Commission core and acute services standards⁵³ and to the procedures for the approval of independent sector places for the termination of pregnancy^{51,52}
- provision of appropriate information for patients both before and after the procedure
- confidentiality of consultations and records
- sensitive disposal of fetal tissue
- emergency transfer arrangements for complications of abortion.

Medical abortion in settings other than NHS hospitals or places approved by the Secretary of State

The 1990 amendment to the Abortion Act introduced a subsection 1(3a)¹⁶ which indicated that the Secretary of State has power "in relation to treatment consisting primarily in the use of such medicines as may be specified in the approval and carried out in such manner as may be so specified, to approve a class of places". This subsection acknowledges that medical abortion might appropriately be carried out in places different from those approved for surgical abortion. Thus, a mechanism exists within the law for places to be approved specifically for medical abortion. To date, no places in England have been approved under Subsection 1(3a). However, two early medical abortion pilots, which will be run from non-traditional settings that meet the legal requirements, will enable the Department of Health to define a 'class of place'.

Since publication of the first edition of this guideline in 2000, reports have appeared in the international literature on the effectiveness⁵⁴⁻⁵⁹ and acceptability⁶⁰⁻⁶² of 'home medical abortion'. These publications describe regimens for early medical abortion where, following hospital or clinic administration of mifepristone, the abortion is completed by use of the prostaglandin, misoprostol, self-administered at home. Studies in a number of settings, including the USA, Vietnam, Tunisia and Guadeloupe, indicate that a 'home' regimen is both effective and acceptable. To date, there are no published reports of experience in UK settings and no recommendation on home medical abortion can be made for UK practice.

Currently, Department of Health advice is that, for medical abortion to be undertaken within the law, both components of the treatment regimen (mifepristone and a prostaglandin) must be administered in an NHS hospital or in an approved private-sector place. In some settings, a family planning or sexual health clinic has been regarded as comprising part of an NHS hospital and mifepristone has been administered there.

RECOMMENDATION 8



The assessment appointment should be within clinic time dedicated to women requesting abortion.

Evidence supporting recommendation 8

Recommendation based on group consensus.

RECOMMENDATION 9

- ✓ In the absence of specific medical, social or geographical contraindications, induced abortion may be managed on a day case basis.

RECOMMENDATION 10

- C An adequate number of staffed inpatient beds must be available for those women who are unsuitable for daycase care. In a typical abortion service, up to 5% of women will require inpatient care.

Evidence supporting recommendations 9 and 10

Daycase care is recognised as a cost effective model of service provision. The availability of abortion as a daycase procedure can minimise disruption to the lives of women and their families. Before 1999, under the Abortion Act the set of requirements known as the Assurances restricted daycase abortion in non-NHS settings to procedures performed before 14 weeks of gestation. Within the NHS, however, the introduction of treatment with mifepristone prior to mid-trimester abortion with prostaglandin reduced induction to abortion intervals to an extent such that many women undergoing these procedures may also be managed as day cases. In a series of 500 women undergoing mid-trimester prostaglandin abortion, over two-thirds were managed as day cases.⁶³

Reasons why women might need to undergo induced abortion as inpatients rather than day cases include:

- medical problems requiring assessment prior to anaesthetic
- social indications, such as lack of an adult companion at home
- geographical factors, such as distance or transport problems
- patient choice
- planned day case requiring overnight stay because of surgical or medical problems.

The Guideline Development Group suggested that up to 10% of women managed in a typical abortion service would require inpatient care for medical, social or geographical reasons (or a combination of these). As an illustrative guide, unpublished daycase figures for women managed during 1998 in the population-based abortion service in Aberdeen were presented. The overall daycase rate was 90%. The Aberdeen service serves a geographically scattered population, including women resident in Orkney and Shetland. It would be expected, therefore, that services in other settings might have a lower requirement for inpatient care on geographical grounds.

The abortion charity bpas has provided figures for the percentage of women undergoing abortion within their service requiring an overnight stay. Of 45 241 women, 4.9% required an overnight stay. All 42 243 women who underwent abortion at gestations of less than 16 weeks were managed as day cases. On the basis of these data, the Update Group felt that 5% was a more realistic figure for overnight stay requirement in a typical service. The availability of beds for those women who require an overnight stay must be agreed locally to reflect local circumstances.

RECOMMENDATION 11

- ✓ As far as possible, women admitted for abortion should be cared for separately from other gynaecological patients.

RECOMMENDATION 12



Women having second-trimester abortions by medical means must be cared for by an appropriately experienced midwife or nurse. Ideally, they should have the privacy of a single room.

Evidence supporting recommendations 11 and 12

These recommendations are based on the consensus view of the Guideline Development Group.

Chapter 5

Information for women

RECOMMENDATION 13

B Verbal advice should be supported by accurate, impartial printed information that the woman considering abortion can understand and may take away to consider further before the procedure.

RECOMMENDATION 14

✓ The use of nationally developed patient information (such as that produced by the RCOG or fpa) ensures accuracy and readability. Services are encouraged to adapt national information to reflect local circumstances, or to supplement a national leaflet with a sheet summarising local details.

Evidence supporting recommendations 13 and 14

It is important that all information shared in the initial consultation is backed up by good-quality, accurate, impartial, written information that is well presented and easy to understand. It has generally been found that patients want to receive written information about medical and surgical interventions and that patients given written information are more likely to express satisfaction with the patient–health professional relationship.^{64–66} A 2002 study examined the quality of information relating to medical abortion available to the public on the Internet.⁶⁷ Incorrect and inappropriate information was common. The ease with which women can access such information reinforces the importance of provision by abortion care professionals of accurate, locally relevant information.

The RCOG report, *Communication Standards in Gynaecology: Surgical Procedures*,⁶⁸ endorses the use of information leaflets and recommends that: “it should become part of the culture that people are given the appropriate leaflets”. A randomised controlled trial has shown that providing leaflets improves knowledge of contraception in relation to oral contraceptive pill use.⁶⁹

In one study, a formal content analysis was undertaken on 44 patient leaflets used by NHS and private providers of abortion services in England and Wales.⁷⁰ Adequacy of information was low in relation to medical abortion, surgical abortion and aftercare. Readability scores were also poor.

The RCOG produced information for women (*About Abortion Care*)⁷¹ based on the 2000 edition of this guideline and the fpa also developed a leaflet⁷² in a format to match its other patient information. The RCOG’s updated information is published in 2004. Clinicians are advised to access the most recent patient information from the RCOG website (www.rcog.org.uk) and to base local leaflets on this information. A local supplement could be used alongside RCOG or fpa information.

In addition to providing written information, the needs of women who cannot read must be taken into account. The same information may need to be available on an audiotape for those who are blind or visually impaired, or who have limited literacy skills. Consideration should also be given to providing the information in a range of languages to suit local racial representation.

RECOMMENDATION 15



Information for women and professionals should emphasise the duty of confidentiality by which, as for any form of health care, all concerned with the provision of induced abortion are bound.

Evidence supporting recommendation 15

This recommendation was based on the consensus view of the 2000 Guideline Development Group. In November 2003, the Department of Health published an NHS Code of Practice on Confidentiality.⁷³ This document provides clarity and transparency regarding the responsibilities of NHS staff regarding patient confidentiality.

RECOMMENDATION 16



Clinicians providing abortion services should possess accurate knowledge about possible complications and sequelae of abortion. This will permit them to provide women with the information they need in order to give valid consent.

Evidence supporting recommendation 16

In the view of the Guideline Development Group and of the Update Group, clinicians involved in abortion care should be equipped to provide women with accurate information relating to the following topics:

- that abortion is safer than continuing a pregnancy to term and that complications are uncommon.
- description of the method(s) of abortion available within the local service for particular gestations.
- immediate complications including: haemorrhage, uterine perforation, cervical lacerations and anaesthetic complications. Women must be informed that, should one of these complications occur, further treatment in the form of blood transfusion, laparoscopy or laparotomy may be required.
- complications in the early weeks following abortion, including: incomplete abortion requiring re-evacuation, continuing pregnancy requiring a further abortion procedure, pelvic infection, and short-term emotional distress.
- long-term effects which may, rarely, be associated with abortion, including: miscarriage or preterm birth and psychological problems.
- conditions where an association with abortion has been postulated but where evidence provides reassurance (such as breast cancer and infertility).

The following represents a summary of currently available evidence relating to significant sequelae of, and postulated associations with, induced abortion. In summarising the degree of risk of the various complications and sequelae associated with abortion, we have used the scheme proposed by Calman in 1996, outlined in Table 5.1.⁷⁴ While preparing this guideline update, we identified a review article on long-term physical and psychological health consequences of induced abortion, published in 2002.⁷⁵ This section of the guideline draws heavily on that review.

Table 5.1 Calman scheme describing degree of risk of complications and sequelae associated with abortion

Term	Degree of risk
Negligible	< 1 in 1 000 000
Minimal	1 in 1 000 000 to 1 in 100 000
Very low	1 in 100 000 to 1 in 10 000
Low	1 in 10 000 to 1 in 1000
Moderate	1 in 1000 to 1 in 100
High	> 1 in 100

RECOMMENDATION 16.1

B The risk of haemorrhage at the time of abortion is low. It complicates around 1 in 1000 abortions overall. The risk is lower for early abortions (0.88 in 1000 at less than 13 weeks; 4.0 in 1000 at more than 20 weeks).

Evidence supporting recommendation 16.1

The above rates of haemorrhage at the time of abortion are taken from National Office for Statistics abortion statistics⁷⁶ and represent reports from practitioners in England and Wales via the notification process. Criteria for reporting are ill-defined and it is not known whether or not all these cases required transfusion. Unpublished data from independent abortion providers in the UK suggest overall rates of haemorrhage requiring transfusion of the order of 0.5 in 1000 procedures. In a Danish cohort study, heavy bleeding was registered as a complication in 4.4 in 1000 abortions.⁷⁷

RECOMMENDATION 16.2

B The risk of uterine perforation at the time of surgical abortion is moderate. The incidence is of the order of 1–4 in 1000. The risk is lower for abortions performed early in pregnancy and those performed by experienced clinicians.

Evidence supporting recommendation 16.2

Evidence table 2 summarises rates of uterine perforation reported in case series that were identified during the development of the previous edition of this guideline. Series for inclusion were selected on the basis of study size (more than 4000 subjects). The more recent Danish cohort study⁷⁷ (56 117 subjects), published in 2002, reported a rate of uterine perforation of 2.3 in 1000 abortions. A 1999 Australian report⁷⁸ on 13 907 abortions found a perforation rate of 0.86 in 1000.

RECOMMENDATION 16.3

B Uterine rupture has been reported in association with mid-trimester medical abortion. However, the risk is very low, at well under 1 in 1000.

Evidence supporting recommendation 16.3

Case reports^{79–82} have described uterine rupture in women undergoing mid-trimester medical abortion. The regimens used varied: mifepristone and misoprostol,⁷⁹ vaginal misoprostol alone,⁸² laminaria and misoprostol,⁸⁰ or misoprostol and oxytocics.⁸¹ A retrospective review of over 600 women having mid-trimester abortion, by postaglandin E₂, oxytocin, or a combination, suggested that caesarean section is a risk factor for rupture, with an almost 20-fold increase in risk (OR 20.8, 95% CI 14.1–104.00).⁸³ More recent retrospective reviews of women undergoing first and second trimester medical abortion with various regimens have not identified any cases of uterine rupture.^{84,85}

RECOMMENDATION 16.4

B Cervical trauma: the risk of damage to the external cervical os at the time of surgical abortion is moderate (no greater than 1 in 100). The risk is lower when abortion is performed early in pregnancy and when it is performed by an experienced clinician.

Evidence supporting recommendation 16.4

Evidence table 3 summarises incidences of cervical injury during first-trimester surgical abortion, as reported in large case series identified during development of the earlier edition of this guideline. The report from Schulz⁸⁶ (rate 10.3 in 1000) is based on carefully collected and clearly defined data. The findings are typical of practice in large hospitals in the USA in the mid-1970s and of the results obtained when a significant proportion of the operators were trainees. The rate observed by Ferris⁴² (0.7 in 1000) is also based on well-organised data collection and may be more typical of today's practice. The 100-fold range in the evidence in Evidence table 3 reflects the lack of an agreed definition of cervical injury and substandard data collection. Cervical injury is more frequent with D&E in the second trimester.

The 2002 Danish cohort study⁷⁷ identified 50 cases of cervical injury among 56 117 abortions (0.89 in 1000).

RECOMMENDATION 16.5

B Failed abortion and continuing pregnancy: all methods of first-trimester abortion carry a small risk of failure to terminate the pregnancy, thus necessitating a further procedure. The risk for surgical abortion is around 2.3 in 1000 and for medical abortion between 1 and 14 in 1000 (depending on the regimen used and the experience of the centre).

Evidence supporting recommendation 16.5

The quoted rate of failure from the Kaunitz study of 33 090 cases when suction termination was performed at 12 weeks or below was 2.3 per 1000 abortions.⁸⁷ The rate was increased for multiparous women, for abortions at 6 weeks or below, or when small cannulae were used. Other risk factors were: if the procedure was performed by a junior, or if the woman had uterine abnormalities. In the 2002 Danish series of surgical abortions, the rate of 're-evacuation not caused by bleeding' was 5.3 in 1000 (no information was provided as to the proportion of these required for continuing pregnancy).⁷⁷

For mifepristone and misoprostol medical abortions at gestations up to 63 days, a series of 2000 cases quoted surgical intervention being needed in 2.5% (1.4% for incomplete abortion, 0.4% for

missed abortion, 0.6% for continuing pregnancy and 0.2% to exclude ectopic pregnancy).⁸⁸ An update on this series (4132 cases) was published in 2002.⁸⁹ Overall, the continuing pregnancy rate was 0.3% but was only 0.1% in 2131 women managed using a modified regimen (discussed in Chapter 7 of this guideline). A series of 3161 mifepristone and gemeprost medical abortions at gestations up to 63 days had a continuing pregnancy rate of 1.4%.⁹⁰

Kahn *et al.*⁹¹ have published a meta-analysis on efficacy of medical abortion. They provide 'viable pregnancy' rates for various medical abortion regimens and various gestation bands. For the mid-gestation band (50–56 days) the summary viable pregnancy rate for the mifepristone and misoprostol regimens is calculated as 2.6% and for mifepristone with other prostaglandins regimen 2.9%. A comparative review of medical and surgical methods for early abortion quoted continuing pregnancy rates of 0.9% for mifepristone/misoprostol abortion and 0.5% for vacuum aspiration.⁹²

RECOMMENDATION 16.6

B Post-abortion infection: genital tract infection, including pelvic inflammatory disease of varying degrees of severity, occurs in up to 10% of cases. The risk is reduced when prophylactic antibiotics are given or when lower genital tract infection has been excluded by bacteriological screening.

Evidence supporting recommendation 16.6

Genital tract infection, including pelvic inflammatory disease, is a recognised complication of abortion. Incidence rates among the control groups in trials of prophylactic antibiotics for abortion suggest that infective complications occur in up to 10% of cases.^{93–98} Post-abortion infection may result in the long-term sequelae of tubal infertility or ectopic pregnancy,⁹³ as well as causing morbidity in the immediate post-abortion period. Studies have shown that the presence of *Chlamydia trachomatis*, *Neisseria gonorrhoea*^{99–101} or bacterial vaginosis^{102,103} in the lower genital tract at the time of abortion is associated with an increased risk.

The 2002 Danish cohort study on short-term complications of surgically induced abortions reported a rate of infective complications of only 12 in 1000.⁷⁷ However, this study included only those complications evident before the woman left hospital following her abortion.

RECOMMENDATION 16.7

B Breast cancer: induced abortion is not associated with an increase in breast cancer risk.

Evidence supporting recommendation 16.7

The evidence considered by the Guideline Development Group regarding breast cancer risk focused on two carefully conducted meta-analyses.^{104,105} These two reviews reached different conclusions about the nature of any association. The first systematic review, by Wingo *et al.*,¹⁰⁴ was included in the Cochrane Database of Reviews of Effectiveness and met the quality criteria required by the Cochrane group. The review included 28 case–control and cohort studies. Although four studies found that the association between breast cancer and induced abortion reached statistical significance, the authors felt that a definitive conclusion could not be reached because of inconsistent findings across studies. The conflicting review by Brind *et al.*¹⁰⁵ examined the same studies and concluded that induced abortion was a significant, independent risk factor for breast cancer, with an odds ratio of 1.3. (95% CI 1.2–1.4) These two meta-analyses were independently

assessed for the previous edition of this guideline. The methodological assessor concluded that both were carefully conducted reviews and that the Brind *et al.* study¹⁰⁵ had no major methodological shortcomings and could not be disregarded.

The subsequent review on long-term physical and psychological consequences of induced abortion by Thorp *et al.*⁷⁵ included consideration of breast cancer risk. This review summarised four previous reviews,^{104–107} including those by Wingo *et al.*¹⁰⁴ and Brind *et al.*¹⁰⁵ While acknowledging the methodological shortcomings of the studies included and the potential influence of the moral values of individual reviewers, Thorpe *et al.*⁷⁵ concluded that a significant positive association between induced abortion and breast cancer could not easily be dismissed because the only quantitative review (by Brind *et al.*¹⁰⁵) found a significant positive association (OR 1.3, 95% CI 1.2–1.4).

In August 2003, the American College of Obstetricians and Gynecologists (ACOG) published a Committee Opinion Paper on induced abortion and breast cancer risk.¹⁰⁸ ACOG summarised the findings of the most methodologically rigorous of the previously reviewed studies (cohort rather than case–control studies and those based on linkage of registry data, rather than women’s self-reports) and showed a slight reduction in breast cancer risk associated with past abortion. ACOG also reviewed four studies published since 2000^{109–112} and the summary report of a National Cancer Institute workshop on early reproductive events and breast cancer, held in March 2003.¹¹³ The National Cancer Institute concluded that “induced abortion is not associated with an increase in breast cancer risk”, giving this statement a ‘strength of evidence’ rating of 1 (well established). The ACOG Committee on Gynecologic Practice concluded, “Rigorous recent studies argue against a causal relationship between induced abortion and a subsequent increase in breast cancer risk”.

Evidence table 5 summarises studies relating to induced abortion and breast cancer published since 1999. The table includes those studies reviewed by ACOG in reaching its committee opinion.

NOTE: As this guideline was going to press, a major systematic review was published which lent further support to these conclusions.¹¹⁴

RECOMMENDATION 16.8

B Future reproductive outcome: there are no proven associations between induced abortion and subsequent ectopic pregnancy, placenta praevia or infertility. Abortion may be associated with a small increase in the risk of subsequent miscarriage or preterm delivery.

Evidence supporting recommendation 16.8

Studies relating to abortion and future reproductive outcomes identified during development of the previous edition of this guideline are summarised in Evidence table 6. Women with a previous induced abortion appeared to be at an increased risk of infertility in countries where abortion is illegal but not in those where abortion is legal. Published studies strongly suggested that infertility is not a consequence of uncomplicated induced abortion.^{115–117} There are some discrepancies among studies¹¹⁸ but none of these studies was of sufficient power to detect a small association. There was a similar lack of consensus over the effect of previous induced abortion on rates of preterm delivery. Two studies^{119,120} found an association, while two others^{121,122} failed to do so. Most studies focusing on complications associated with abortion by dilatation and evacuation assessed the safety of the procedure, and none looked at the effect on future reproductive outcome. The earlier edition of this guideline stated that there was no conclusive evidence to support an association between induced abortion and infertility or preterm delivery. However, it may be that there is an association between

induced abortion complicated by pelvic infection and tubal infertility. Such an association is more likely in cases complicated by uterine perforation or abdominal surgery to repair uterine injury, which may result in peritubal adhesions (or the loss of the uterus).

The 2002 review on long-term physical and psychological consequences of induced abortion by Thorp *et al.*⁷⁵ provides an update on relationships between abortion and a range of subsequent adverse reproductive outcomes.

Miscarriage

Thorp *et al.* reviewed two cohort and three case–control studies examining associations between induced abortion and miscarriage. None found a significant association. Moreover, those that analysed data according to the number of abortions found no dose–response effect. More recent studies identified during development of this updated guideline have, however, reported less reassuring findings. A Danish study showed an increased risk of miscarriage among women who became pregnant within three months of an abortion.¹²³ A cohort study from Shanghai included 2953 pregnant women: 1502 whose previous pregnancy was terminated by vacuum aspiration and a reference cohort of 1451 primigravidae.¹²⁴ After adjustment, the odds ratio for first-trimester miscarriage between the ‘abortion’ and ‘reference’ cohorts was 1.72 (95% CI 1.09–2.72).

Preterm birth

Thorp *et al.* appraised ten case–control and 14 cohort studies relating to abortion and subsequent preterm birth or low birth weight. Twelve of the studies showed a positive association and seven showed a dose–response effect. Thorp *et al.* highlighted the fact that large, recent cohort studies based on register linkage consistently show a positive association. More recent studies identified during development of this guideline update have reported mixed findings. A French cohort study¹²⁵ involving 12 432 women suggested that “a history of induced abortion increases the risk of preterm delivery, particularly for women who have had repeated abortions”. A small Swedish case–control study¹²⁶ involved 312 cases of preterm birth and 424 controls who delivered at term. A history of two or more induced abortions was not associated with preterm birth, whereas a history of two or more miscarriages was. Among those studies that suggest a significant association between abortion and preterm birth, the elevation in risk ratio is between 1.3 and 2.0.

Placenta praevia

Thorp *et al.* reviewed one cohort and two case–control studies examining associations between induced abortion and subsequent placenta praevia. All found a positive association. They also appraised a meta-analysis of observational studies on abortion and placenta praevia. These studies were of variable quality and showed substantial heterogeneity but again showed a positive association. More recent studies identified during development of this guideline update have, however, reported more reassuring findings. A Danish cohort study based on national registry data linkage involved 15 727 women whose first pregnancy was terminated and a reference cohort of 46 026 women.¹²⁷ No association with placenta praevia was seen. A case–control study from the USA involved 192 cases of placenta praevia and 622 controls.¹²⁸ The investigators concluded that risk of placenta praevia might have increased in a dose–response fashion with sharp curettage abortions, but that vacuum aspiration did not confer an increased risk.

Ectopic pregnancy

Thorp *et al.* reviewed seven case–control and two cohort studies relating to abortion and subsequent ectopic pregnancy. Only two of the nine studies reported a positive association; these were relatively small case–control studies which relied on self-report of previous abortion. Large studies based on record linkage showed no association.

Subfertility

Thorp *et al.* appraised three case–control and four cohort studies relating to abortion and subfertility. Two relatively small case–control studies, both from Greece, showed a positive association. Other studies found no association. Thorp *et al.* commented on methodological limitations of all studies. All studies reviewed by Thorp *et al.* date from before 1999. No relevant new studies were identified during the update literature search.

RECOMMENDATION 16.9

B Psychological sequelae: some studies suggest that rates of psychiatric illness or self-harm are higher among women who have had an abortion compared with women who give birth and to nonpregnant women of similar age. It must be borne in mind that these findings do not imply a causal association and may reflect continuation of pre-existing conditions.

Evidence supporting recommendation 16.9

The view of the Guideline Development Group on this topic was largely based on a review undertaken by Dagg.¹²⁹ He reviewed the existing literature in relation to both the psychological sequelae of abortion and the sequelae for the mother and the child when abortion was denied. He concluded: “Adverse sequelae occur in a minority of women, and when such symptoms occur, they usually seem to be the continuation of symptoms that appeared before the abortion and are on the wane immediately after the abortion. Many women denied abortion show ongoing resentment that may last for years”.

In preparing this update, we studied a more recent review by Thorp *et al.*⁷⁵ We independently reviewed the studies cited in that paper and also more recently published studies. The most robust and sizeable of these studies are summarised in Evidence table 7. Note, however, that four of these six studies were undertaken in countries with much higher underlying suicide rates than those seen in the UK.

Chapter 6

Pre-abortion management

6.1 The abortion decision

RECOMMENDATION 17

C Clinicians caring for women requesting abortion should try to identify those who require more support in decision making than can be provided in the routine clinic setting (such as those with a psychiatric history, poor social support, or evidence of coercion). Care pathways for additional support, including access to social services, should be available.

Evidence supporting recommendation 17

This guideline has been developed for clinicians working in abortion services and relates to the care of women requesting induced abortion. Women will have received varying degrees of pregnancy counselling and support prior to attendance at an abortion service and will vary in their degree of certainty about the abortion decision. All women attending an abortion service will require discussion of the implications of their intended course of action and will require support in reaching their final decisions and choices. Abortion service professionals must be sensitive to the different stages of decision making that individual women have reached, and must be able to provide the degree of support and counselling required by each individual.

The Guideline Development Group favoured the use of the term ‘support’ rather than ‘counselling’ to describe these routine responsibilities of an abortion service, but acknowledged that any of three recognised forms of counselling may be required by women considering or undergoing induced abortion. For the minority of women who require formal, therapeutic counselling, services should have formal care pathways in place with access to trained counsellors with appropriate expertise. A review from the American Psychological Association¹³⁰ has summarised the literature on factors associated with negative responses to abortion and with difficulties in decision making.

Counselling has been defined as, “the process of enhancing a subject’s ability to assess and understand the index situation, evaluate options and make an informed choice or decision. This entails sensitive provision of comprehensive information in a nondirective or nonjudgmental manner”.¹³¹ The provision of counselling is viewed as an essential element of fertility regulation services.¹³¹ The HFEA Code of Practice¹³² identifies three different types of counselling, all of which are to be regarded as distinct from simple information exchange:

Implications counselling: aims to enable the person concerned to understand the implications of the proposed course of action for themselves and for their family.

Support counselling: aims to give emotional support at times of particular stress.

Therapeutic counselling: aims to help people with the consequences of their decision and to help them resolve problems which may arise as a result.

6.2 Blood tests

RECOMMENDATION 18

C Pre-abortion assessment should include:

- measurement of haemoglobin concentration
- determination of ABO and rhesus blood groups with screening for red cell antibodies
- testing for other conditions such as haemoglobinopathies, HIV, and hepatitis B and C if indicated in the light of clinical features, individual risk factors or local prevalence.

Evidence supporting recommendation 18

A Health Technology Assessment systematic review,¹³³ looking at routine preoperative testing, found that haemoglobin was lower than 10.0–10.5 g/dl in less than 5% of patients. In 2003, NICE published a guideline on the use of routine preoperative tests for elective surgery.¹³⁴ Recommendations relating to full blood count were consensus-based, in view of a lack of directly relevant evidence. NICE did not recommend routine full blood count for adults undergoing ‘intermediate’ surgical procedures. Nevertheless, due to the nature of surgical abortion and the possibility of excessive blood loss, routine haemoglobin estimations are recommended by both the Guideline Development Group and the Update Group.

The ‘group and screen’ procedure undertaken by the blood transfusion service laboratories should include not only ascertainment of the woman’s ABO and rhesus blood groups, but also screening for IgG antibodies that can damage red blood cells at 37°C. Ascertainment of rhesus group is required in order that Anti-D prophylaxis can be instituted as appropriate. Screening for red cell antibodies is required to alert staff to any difficulties that may be encountered should subsequent crossmatching and blood transfusion be required.

In the previous edition of this guideline, screening for hepatitis and HIV were recommended on a selective basis, as was testing for haemoglobinopathies. The routine offer of testing for HIV as part of antenatal care was introduced in 1999 and the offer of HIV testing to all new attenders at genitourinary medicine clinics is a component of the 2001 National Strategy for Sexual Health and HIV.⁸ These initiatives have prompted discussion in a number of quarters about the appropriateness of offering HIV testing routinely to abortion attenders. A study published in 1999 examined patients’ attitudes to HIV testing in five north London abortion clinics.¹³⁵ Data were cited indicating that HIV prevalence was up to three times higher in women seeking abortion, compared with women seeking antenatal care (2002 data from the Department of Health relating to inner London showed an HIV prevalence of 1 in 108 among abortion attenders and of 1 in 171 among antenatal attenders). An attitude survey indicated that around 70% of abortion attenders would welcome discussion about HIV and counselling regarding testing.

Local abortion service protocols should include policies on the offering of HIV tests. Local policies should take account of local prevalence of HIV and resource constraints. Where services choose to offer HIV testing in the context of abortion care, local protocols must ensure that valid consent is obtained for this specific element of care.

It may be appropriate to offer immunisation to women at high risk of hepatitis B, regardless of the results of pre-abortion testing. High-risk groups include intravenous drug users and sex workers. When managing such patients, abortion service staff should seek guidance from their local virology department regarding the need for immunisation and the appropriate vaccine course.

RECOMMENDATION 19

B It is not cost effective routinely to crossmatch women undergoing induced abortion.


Evidence supporting recommendation 19:

Figures supplied by the abortion charity bpas indicated that in 1998 only 0.2% of clients required blood transfusion. The Guideline Development Group was of the view that this rate of transfusion was of the same order as that found in the NHS sector. The group concluded that it is not cost effective to request crossmatched blood routinely for women undergoing abortion. In most NHS abortion services, a blood bank is available on site and it was felt that the most cost effective strategy for those instances where blood transfusion is required is simply to initiate crossmatching on the basis of a newly submitted specimen of the woman's blood, as and when the need arises. When abortion is undertaken in settings that are remote from a blood bank, policies of saving women's serum at the blood bank and the availability of O Rh-negative blood at the abortion centre may be considered for inclusion in local protocols.


In developing local protocols, services must include contingency plans for the very small number of women, usually at 15 weeks of gestation or beyond, experiencing life-threatening haemorrhage. In about 50% of these, haemorrhage will be associated with disseminated intravascular coagulation. For independent abortion clinics, these protocols must include arrangements for transfer to a specialist acute hospital.

6.3 Cervical cytology

RECOMMENDATION 20

 Assessment prior to induced abortion may be viewed as an opportunity to ascertain each woman's cervical cytology history. Women who have not had a cervical smear within the interval recommended in their local programme may be offered one within the abortion service.

RECOMMENDATION 21

 If a cervical smear is taken within the abortion service, then mechanisms are essential to ensure that the smear result is communicated to the woman, acted on appropriately and recorded within the local cervical cytology programme.

Evidence supporting recommendations 20 and 21

Within a spirit of providing holistic care, clinicians may view a woman's attendance within an abortion service as an opportunity to review broader aspects of her reproductive health care. Offering to undertake cervical cytology for any woman who has not had a cervical smear taken

within the interval recommended within her local programme represents one such aspect of health care (it should be noted that women aged under 20 years need not be offered screening, as national cytology programmes begin at age 20 years). The Guideline Development Group were of the view that, particularly where abortion care is provided within the NHS in the woman's local gynaecology unit, then expansion of the role of the abortion service to embrace these broader aspects of care is appropriate. However, the group also felt that offering cervical cytology should not be considered an essential function of an abortion service. Indeed, where abortion services are provided through agency arrangements with charitable sector providers, the service might lack appropriate mechanisms for ensuring that results of cytology are followed up appropriately.

6.4 Ultrasound scanning

RECOMMENDATION 22

B All services must have access to scanning, as it can be a necessary part of pre-abortion assessment, particularly where gestation is in doubt or where extrauterine pregnancy is suspected. However, ultrasound scanning is not considered to be an essential prerequisite of abortion in all cases.

RECOMMENDATION 23

C When ultrasound scanning is undertaken, it should be done in a setting and manner sensitive to the woman's situation. It is inappropriate for pre-abortion scanning to be undertaken in an antenatal department alongside women with wanted pregnancies.

Evidence supporting recommendations 22 and 23

During the triennium 1994–96, one death as a direct consequence of a legal abortion was reported through the Confidential Enquiries into Maternal Deaths in the UK (CEMD).¹³⁶ On the basis of this one case, the CEMD report recommends: "Ideally, all women should undergo ultrasound examination before termination of pregnancy to establish gestational age, viability and site". In the 1997–99 triennium, two deaths followed termination of pregnancy. Neither was directly attributable to the surgical procedure and no recommendations were made relating to the care of women undergoing induced abortion.¹³⁷

The Guideline Development Group was of the view that, while ultrasound may be useful in pre-abortion assessment, its use was not mandatory in all cases. However, abortion services must have access to appropriate ultrasound facilities for those women for whom scanning is clinically indicated. A literature search by the Guideline Development Group failed to identify any randomised trials relating to the value of ultrasound prior to abortion. The recommendations were therefore based on evidence from the observational studies summarised here. Goldstein *et al.*¹³⁸ studied 250 consecutive pregnancies at 12 weeks of gestation or less. In 1.6% (four cases) the gestational age assessed by ultrasound was greater than 12 weeks and the women were referred for alternative methods of abortion. The study does not demonstrate whether or not clinical examination would have also detected the discrepancies. Kaali *et al.*¹³⁹ reported a before-and-after study to evaluate the benefits of adding routine ultrasonography to their abortion protocol. These authors concluded that adding ultrasonography (plus semiquantitative serum hCG testing) to their earlier protocol streamlined care and reduced the number of clinic visits. Burnhill and Armstead¹⁴⁰

reported on their experience with over 7000 first-trimester abortions and concluded that routine use of ultrasound ‘when gestational age is unclear’ is an essential measure in reducing the incidence and severity of abortion complications.

Two studies identified during development of this guideline update compared ultrasound assessment with clinical examination in the context of abortion care. A study from the USA¹⁴¹ included 1016 women seeking medical abortion. Before women underwent ultrasound scanning, experienced clinicians assessed gestation using a combination of clinical history and bimanual pelvic examination. Clinicians correctly assessed gestational age as no more than 63 days in 87% of women. In only 1% of their assessments did clinicians underestimate gestational age (that is, assess women as under 63 days when they were actually greater than 63 days), which might have increased the woman’s chance of failure of medical abortion and requirement for surgical intervention. The investigators concluded that “medical abortion can be safely performed without sonography”.

A second US study compared clinical gestation assessments by both experienced (faculty) and inexperienced (resident) clinicians with ultrasound assessments in 245 women.¹⁴² Even when examined by the faculty gynaecologist, 8% of women had clinical estimates that differed by more than 2 weeks from the ultrasound assessment (clinical gestation was an overestimate in 3.7% and an underestimate in 4.5%). The authors argued that a discrepancy in either direction might cause problems during surgical abortion in terms of unnecessarily excessive or inadequate cervical dilatation.

The 2000 guideline recommendation that “when ultrasound scanning is undertaken, it should be done in a setting and manner which are sensitive to the woman’s situation” was based on previous guidance documents and the consensus view of the Guideline Development Group. A study from South Africa, published in 2002, examined the clinical usefulness of ultrasound before termination and the consequences for women of visualisation or non-visualisation of ultrasound images.¹⁴³ Five hundred women being scanned prior to abortion were randomly allocated to having the ultrasound screen turned away or in its normal position. This study had a number of methodological problems, but indicated that the scan produced ‘clinically useful’ information in only 3% of cases. However, when asked about their preferences both immediately after the abortion and 6–12 weeks later, the majority of women (over 90% immediately post-abortion) favoured having a scan prior to an abortion. The majority of these women favoured a scan ‘with visualisation’ of the image. Thus, in trying to provide ultrasound ‘in a manner which is sensitive to the woman’s situation’, clinicians should not assume that the image should be concealed.

6.5 Prevention of infective complications

RECOMMENDATION 24

- A** Abortion care should encompass a strategy for minimising the risk of post-abortion infective morbidity. As a minimum, services should offer antibiotic prophylaxis.
- B** Ideally, services should offer testing for lower genital tract organisms with treatment of positive cases.

RECOMMENDATION 25

C The following regimens are suitable for periabortion prophylaxis:

- metronidazole 1 g rectally at the time of abortion plus
- doxycycline 100 mg orally twice daily for 7 days, commencing on the day of abortion OR
- metronidazole 1 g rectally at the time of abortion plus
- azithromycin 1 g orally on the day of abortion.

Evidence supporting recommendation 24 and 25

Genital tract infection, including pelvic inflammatory disease, is a recognised complication of abortion. Incidence rates among the control groups in trials of prophylactic antibiotics for abortion suggest that infective complications occur in up to 10% of cases.^{93–98} Post-abortion infection may result in the long-term sequelae of tubal infertility or ectopic pregnancy,⁹³ as well as causing morbidity in the immediate post-abortion period. Studies have shown that the presence of *C. trachomatis*, *N. gonorrhoea*^{99–101} or bacterial vaginosis^{102,103} in the lower genital tract at the time of abortion is associated with an increased risk.

Level Ia evidence from a meta-analysis of randomised trials published by Sawaya *et al.*¹⁴⁴ demonstrated that the use of antibiotic prophylaxis at the time of abortion was associated with a reduction in the risk of subsequent infective morbidity by around 50%.

Other authors have argued that bacteriological screening of the lower genital tract before abortion, with treatment of those found to be carrying genital tract organisms, would be a more appropriate strategy.^{94,99–103} In England and Wales at present, some regions are participating in *Chlamydia* screening programme rollout exercises. In these regions, all women aged under 25 years should be offered *Chlamydia* screening as part of the programme.

Blackwell *et al.*¹⁴⁵ advocate a third strategy, a ‘belt and braces’ approach, whereby all women undergoing abortion receive a prophylactic regimen effective against bacterial vaginosis and *Chlamydia* but are also screened for sexually transmitted infections (gonorrhoea and *Chlamydia*). This strategy combines the benefits of the other two approaches – but also combines the costs.

Penney *et al.*¹⁴⁶ compared prophylaxis and a ‘screen and treat’ strategy in terms of both clinical and cost effectiveness in a randomised trial. Using a formal costing methodology, they quantified the relevant costs to the NHS of instituting one or other strategy. The primary outcomes measured were the prevalence of post-abortion infective morbidity as assessed by the general practitioner, prescription rates and hospital reattendances. 1672 women were recruited. The prevalence of *C. trachomatis* was 5.6%, *N. Gonorrhoea*, 0.19%, and bacterial vaginosis, 17.5%. The results indicated that universal prophylaxis can be provided at a cost of less than 50% that of screening with treatment and follow-up of positive cases. This study suggested that universal prophylaxis was at least as effective as a policy of ‘screen and treat’ in minimising short-term infective sequelae of abortion and could be provided at less cost.

The Guideline Development Group was of the view that all abortion services should have in place some form of strategy for reducing the risk of post-abortion infective sequelae. As a minimum, this should comprise antibiotic prophylaxis effective against both *C. trachomatis* and bacterial vaginosis. The group also considered that, where resources permit and provided that it is acceptable

to women and their partners, services may offer screening for sexually transmitted infections, with follow-up and partner notification for positive cases.

In developing this guideline update, we identified seven studies directly addressing the prevention of infective complications of abortion. Three publications described clinical trials of prophylactic antibiotic regimens. A Scandinavian randomised, double-blind, placebo-controlled trial involving 1655 women evaluated the efficacy of preoperative treatment with clindamycin cream in reducing post-abortion infective morbidity.¹⁴⁷ Based on microscopy of vaginal smears, 20% of subjects had bacterial vaginosis and a further 13% had 'intermediate flora'. In these two groups combined, treatment with clindamycin cream reduced the incidence of infective morbidity by a factor of four. A UK randomised, double-blind, placebo-controlled trial evaluated the efficacy of rectal metronidazole in reducing post-abortion infective morbidity in women with bacterial vaginosis.¹⁴⁸ Based on microscopy of vaginal smears, 29% of women attending this abortion service had bacterial vaginosis. The trial involved 273 women who tested positive. The study indicated that perioperative metronidazole might reduce the risk of infective morbidity by a factor of two; however, the study had limited power and the finding was not statistically significant. A randomised trial involving 800 women compared regimens of 7 days and 3 days of doxycycline (100 mg twice daily) for peri-abortion prophylaxis.¹⁴⁹ The investigators concluded that shortening oral doxycycline prophylaxis from 7 to 3 days had no adverse effect on the incidence of post-abort infection. In this trial, 44% of subjects were lost to followup, the study had limited power and the authors concluded that further trials were needed to enable their findings to be applied more generally.

Four publications described case series or local experience relating to the implementation of 'screen and treat' strategies in clinical practice. A UK (Stevenage) study aimed to assess the relative benefits of testing for *C. trachomatis* or universal antibiotic prophylaxis in an abortion service.¹⁵⁰ The investigators describe a series of 100 women tested for *C. trachomatis* prior to abortion. Six were positive. Nine sexual partners were identified, of which four were positive for *C. trachomatis*. On the basis of this series, the investigators argued that prophylaxis would be a waste of resources, as 94% of women would have been treated unnecessarily, and women positive for *C. trachomatis* would be reinfected by their untreated partners. A broadly similar UK (Sheffield) study assessed the value of a 'screen and treat' policy by review of 100 consecutive *Chlamydia*-positive women identified within an abortion service.¹⁵¹ Of these, 72 attended a follow-up genitourinary clinic appointment; 89 sexual partners were notified and 62 attended for treatment. The investigators concluded that their experience showed the relative success of a 'screen and treat' policy, which may confer greater benefit for women and make a significant impact on the reservoir of infection in the community. A further UK (Nottingham) study described experience with implementing a 'screen and treat' policy.¹⁵² The investigators described the journey of care for 40 women testing positive for *C. trachomatis* or *N. gonorrhoeae* managed by their local strategy. Within this model of care, the genitourinary medicine service is notified of positive cases directly by the microbiology laboratory, women are contacted directly by the genitourinary medicine service and treatment instituted, ideally prior to the abortion. Only two of 31 women who proceeded to abortion had been treated adequately before or at the time of abortion. The investigators concluded that it was essential to organise services so that treatment could be given before surgical intervention. The final UK (Edinburgh) publication was entitled *Can a busy abortion service cope with a screen-and-treat policy for chlamydia trachomatis infection?*¹⁵³ In a series of 2058 patients, the prevalence of *C. trachomatis* was 6%. Positive results were available before surgical abortion for 97% and before medical abortion for 76%. Most women (94% surgical; 84% medical) were seen at the genitourinary medicine clinic but only 25% of notified partners attended. The authors reflected on the deficiencies of their current strategy and on the resource implications of possible solutions.

Evidence to support specific antibiotic regimens for periabortion prophylaxis remains scant. The Guideline Update Group considers that the chosen regimen should cover both anaerobic vaginosis and *C. trachomatis*. The doxycycline and azithromycin regimens suggested here are those recommended in manufacturers' summaries of product characteristics for treatment (rather than prophylaxis) of uncomplicated chlamydial infections.^{154,155} An updated guideline from the US National Abortion Federation recommends antibiotics at the time of surgical abortion but does not suggest a specific regimen.¹⁵⁶ Recent UK¹⁵⁷ and US¹⁵⁸ guidelines on the management of victims of sexual assault recommend either the 7-day doxycycline regimen or the immediate-dose azithromycin regimen for prophylaxis in that context. The recommended regimens suggested here are those with which the guideline developers have experience. Other regimens may be equally appropriate.

6.6 Feticide prior to late abortions

The RCOG's 1996 guidance on termination of pregnancy for fetal abnormality emphasised that a legal abortion must not be allowed to result in a live birth.⁴ Theoretically, such an event could result in a doctor being accused of murder if a 'deliberate act' (that is, legal abortion) were to be followed by a live birth and the subsequent death of the child because of immaturity. The same document included the guidance that for "terminations after 21 weeks, the method chosen should ensure that the fetus is born dead".

Very few abortions on grounds 'C' or 'D' are undertaken at such gestations. Those few are, for the most part, undertaken within the specialist independent sector. When the method of abortion chosen is surgical (D&E) by a specialist practitioner, the nature of the procedure ensures that there is no risk of a live birth. When medical abortion is chosen, then special steps are required to ensure that the fetus is dead at the time of abortion. An Appendix to the RCOG's *Termination of Pregnancy for Fetal Abnormality* report summarises the available methods.⁴ A more recent RCOG Statement has summarised additional sources of information on late abortion and feticide.⁶

A retrospective case series from the USA is of interest. It demonstrated that feticide with potassium chloride significantly reduced the prostaglandin requirement for mid-trimester medical abortion, compared with similar procedures conducted without feticide.¹⁵⁹

Chapter 7

Abortion procedures

Abortion on grounds relating to the physical or mental health of the mother or of her existing children can be performed within the law at gestations up to 24 weeks. At all gestations up to this limit, abortion can be performed by either surgical or medical (that is, by means of drugs) methods. Depending on the gestation at which a woman presents for abortion, different abortion techniques are appropriate. Figure 7.1 summarises those abortion methods considered by the Guideline Update Group to be appropriate for use in UK abortion services for women presenting in different gestation bands. As this guideline focuses on abortion for maternal health reasons, methods for abortion beyond 24 weeks are not discussed. Such procedures would usually be undertaken on the grounds of fetal abnormality, and lie outwith the scope of this guideline. General recommendations about abortion procedures are discussed first, followed by recommendations relating to specific techniques.

RECOMMENDATION 26



As a minimum, all services should be able to offer abortion by one of the recommended methods for each gestation band.

RECOMMENDATION 27



Ideally, abortion services should be able to offer a choice of recommended methods for each gestation band.

Evidence supporting recommendations 26 and 27

The Guideline Development and Update Groups view induced abortion as a healthcare need. They therefore consider that services for a population should be able to provide abortion, by at least one recommended method, for women at any gestation at which abortion is permitted within the law. Abortion late in the second trimester is uncommon and requires special expertise and particular staff attitudes. For many services, it may be appropriate for late abortions to be provided through agency arrangements with the specialist charitable sector providers.

Level III evidence from a number of patient surveys confirms that women value being offered a choice of methods appropriate to the gestation at which they present.^{160–162}

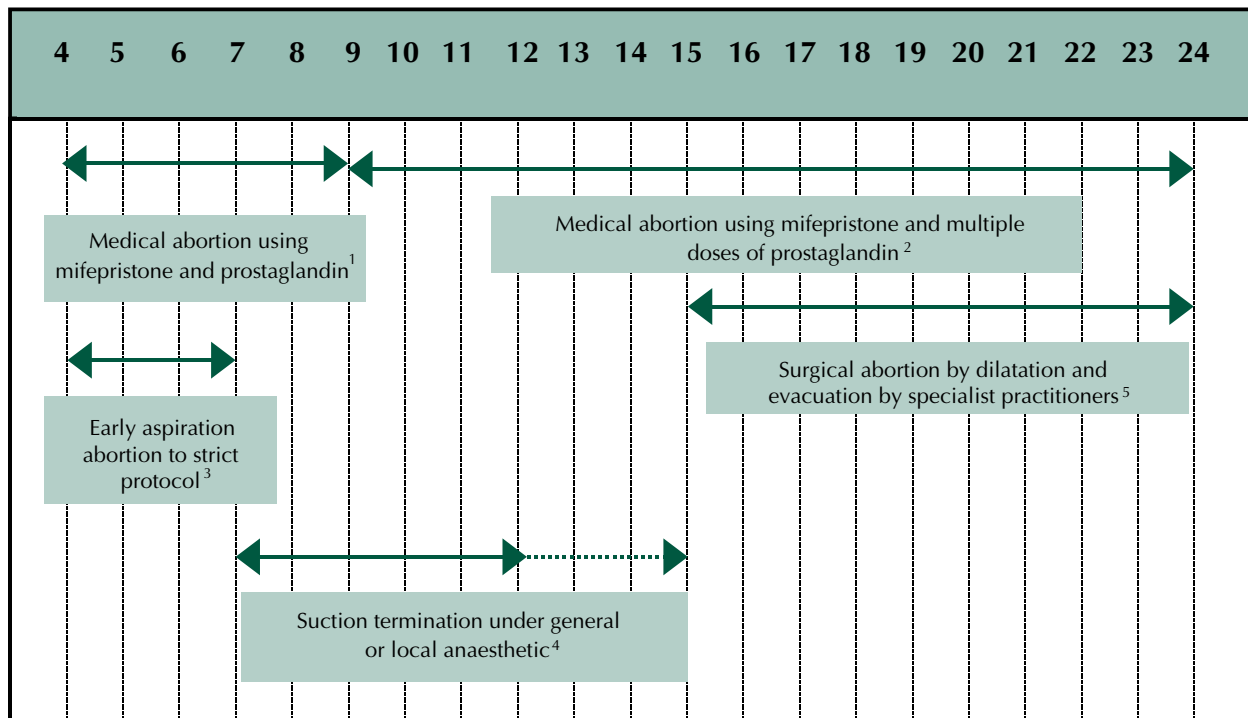
7.1 Surgical methods of abortion

Surgical abortion in very early pregnancy

RECOMMENDATION 28

B Conventional suction termination should be avoided at gestations below 7 weeks.

Gestation (weeks from date of last menstrual period)



- 1 Medical abortion using a single oral dose of the anti-progesterone, mifepristone, followed by a single dose (vaginal or oral) of prostaglandin (also known as pharmacological or non-surgical abortion).
- 2 Medical abortion using a single oral dose of the anti-progesterone, mifepristone, followed by multiple doses (vaginal or oral) of prostaglandin (also known as pharmacological or non-surgical abortion).
- 3 Surgical abortion by means of suction aspiration (using electric or manual suction) at gestations below 7 weeks. To increase confidence that the gestation sac has been removed, protocols include safeguards such as magnification of aspirate and follow-up serum β hCG estimation.
- 4 Conventional suction termination using electric or manual suction, under general or local anaesthetic. The uterus is emptied using a suction curette. Sharp curettage with metal instruments is not employed.
- 5 Surgical abortion at later gestations using a combination of suction (usually electric) curettage and specialised forceps.

Figure 7.1 Summary of abortion methods appropriate for use in UK abortion services for women presenting in different gestation bands

Evidence supporting recommendation 28

Suction terminations performed at less than 7 weeks of gestation are three times more likely to fail to remove the gestational sac than those performed between 7 and 12 weeks (level IIIb evidence).⁸⁷ Thus, for women presenting at less than 7 weeks of gestation, an alternative recommended technique should be chosen. If conventional suction termination is the only method of abortion available within a service, then the procedure is better deferred until the pregnancy exceeds 7 weeks of gestation.

RECOMMENDATION 29

B Early surgical abortion using a rigorous protocol (which includes magnification of aspirated material and indications for serum β hCG follow-up) may be used at gestations below seven weeks, although data suggest that the failure rate is higher than for medical abortion.

Evidence supporting recommendation 29

Creinin and Edwards have described a personal series (level III evidence) of early surgical abortions undertaken to a rigorous protocol developed at Planned Parenthood of Houston and Southeast Texas, USA.¹⁶³ Their protocol included pre-abortion urinary pregnancy testing and ultrasound assessment, inspection under magnification of aspirated products and follow-up by serum β hCG estimation in those women in whom no gestation sac is verified in the aspirate. Using this protocol, the authors reported a complete abortion rate of over 99% in 2399 procedures performed at less than six weeks of gestation.

Both major UK abortion charities (bpas and Marie Stopes International) have introduced early surgical abortion techniques within their UK clinics. bpas has introduced a protocol that conforms to that described above, using local anaesthesia. Marie Stopes International has introduced manual vacuum aspiration (MVA) without anaesthesia. Low failure rates and high patient acceptability are reported (J Murty, oral presentation RCOG/FFPRHC Medical Gynaecology Meeting 1999).

The Guideline Development Group was unable to identify any randomised controlled trials comparing such surgical techniques for very early abortion with contemporary methods of medical abortion. A number of randomised trials have compared historical prostaglandin-only medical abortion regimens with vacuum aspiration.¹⁶⁴⁻¹⁶⁸ The results of these studies did not strongly favour either method.

In developing this edition of the guideline, the Guideline Update Group identified a randomised comparison of medical abortion using methotrexate and misoprostol versus manual vacuum aspiration under local anaesthesia for pregnancies up to 49 days of gestation.¹⁶⁹ This small study of 50 women did not have the power to determine differences in efficacy. Among those women who did not initially have a strong preference between medical and surgical abortion, however, the side effect profile and acceptability were significantly better for surgical, compared to medical, abortion.

The Planned Parenthood Federation of America has published a case series of 1132 surgical abortions undertaken at less than 6 weeks of gestation in three of their clinics.¹⁷⁰ Among women who were followed up at 2 weeks, the continuing pregnancy rate was 2.3%. This is higher than the rate of 0.13% reported by Creinin and Edwards¹⁶³ in their personal series of surgical abortions undertaken at less than 6 weeks of gestation, and higher than the rate of 0.1% among women at less than 49 days of gestation reported by Ashok *et al.* in a UK series of early medical abortions.⁸⁹ In view of this finding, the Guideline Update Group advises that very early surgical abortion should be used only with caution in UK practice.

A small randomised trial has investigated the usefulness of a specially lubricated cannula for early surgical abortion.¹⁷¹ Results were inconclusive and no recommendation can be made.

Suction termination

RECOMMENDATION 30

B Conventional suction termination is an appropriate method at gestations of 7–15 weeks, although, in some settings, the skills and experience of practitioners may make medical abortion more appropriate at gestations above 12 weeks.

RECOMMENDATION 31

✓ During suction termination, the uterus should be emptied using the suction curette and blunt forceps (if required) only. The procedure should not be completed by sharp curettage.

Evidence supporting recommendations 30 and 31

In current UK practice, suction termination of pregnancy is the standard method at gestations of 9–12 weeks. This was the only method the Guideline Development Group was able to recommend for this gestation band. However, a pilot study had indicated that medical abortion was also effective at these gestations.¹⁷² Subsequent studies, discussed below in Section 7.2, have confirmed that both surgical and medical methods are safe, effective and acceptable in this gestation band.

It is accepted UK practice that suction curettage is preferable to sharp curettage for surgical abortion. A Cochrane review published in 2001 included only two trials (dating from the 1970s) comparing the two methods.¹⁷³ There were few statistically significant differences between the methods, but vacuum aspiration was associated with shorter operating times.

In routine practice, clinicians differ in the techniques they use to ensure that the uterus has been completely emptied at the end of a suction termination. In the experience of the Guideline Update Group, there is no need to undertake sharp curettage at the end of the suction evacuation. The 'gritty' sensation resulting from the completely emptied uterus clamping down around the suction curette provides sufficient assurance. A report of a comparative trial highlighted the risks (including Asherman's syndrome) of sharp curettage and suggested routine intraoperative ultrasound as a means of obviating the need for sharp curettage.¹⁷⁴ In the experience of the Update Group, neither procedure is required as a routine.

The method of choice at gestations of 12–15 weeks varies according to the skills and experience of local clinicians. The Guideline Development and Update Groups were of the view that surgical abortion by conventional suction termination, without the need for specialised instruments, can be undertaken up to 15 completed weeks of gestation if local clinicians have gained experience with this method. Alternatively, medical abortion using mifepristone and prostaglandin is appropriate at all gestations.

A cohort study from Oxford has shown that morbidity after first-trimester abortion is directly related to gestation and inversely related to the seniority of the surgeon.¹⁷⁵ This finding suggests that abortion procedures, particularly those at 12 weeks and above, should not be delegated to the most junior team member.

Anaesthesia for surgical abortion

RECOMMENDATION 32

B Suction termination is safer under local anaesthesia than under general anaesthesia. Consideration should be given to making this option available, particularly for low-gestation procedures.

RECOMMENDATION 33

C If conscious sedation is used in place of general anaesthesia to reduce the pain and anxiety associated with surgical abortion, it should be undertaken only by trained practitioners and in line with Department of Health guidance.

Evidence supporting recommendations 32 and 33

In the 1970s, the relative safety of suction terminations performed with either local or general anaesthesia had not been clearly established. To compare the safety of these two anaesthetic techniques a number of observational and partially randomised studies were undertaken. The evidence from three relevant studies that were selected on quality grounds by the Guideline Development Group are shown in Evidence table 8.

A more recent study from India examined women's preferences for general or local anaesthesia during first-trimester surgical abortion.¹⁷⁶ Given the choice, 60 of 100 women chose general anaesthesia. Women in both local and general anaesthesia groups were satisfied but women who had local anaesthesia were more likely to recommend it to friends. The findings suggested that women see advantages in local anaesthesia and some are willing to accept additional short-term pain in exchange for these advantages.

Women and clinicians in the UK are relatively unfamiliar with abortion under local anaesthesia. It is suggested that services choosing to introduce abortion under local anaesthesia might offer this for low-gestation procedures in the first instance.

Paracervical block is accepted as standard local anaesthesia for first-trimester surgical abortion. However, the technique for paracervical block itself is not standardised. A randomised trial compared two-point and four-point injection techniques for chlorprocaine and found no difference in pain ratings.¹⁷⁷ It has been argued that the use of a local anaesthetic agent is unnecessary and that tissue distension with an inactive agent such as saline would produce the same effect. However, in the same trial, women injected with chlorprocaine reported significantly less pain than others injected with saline. A further randomised trial compared two-point paracervical block with lignocaine and with water.¹⁷⁸ Again, the placebo group experienced significantly more pain than the group treated with the active agent. A third trial compared reported pain in women undergoing abortion immediately after three-point paracervical block with lidocaine and in women with a 3–5 minute delay between the paracervical block and the procedure.¹⁷⁹ There were no significant differences in pain or satisfaction between the groups.

Conscious sedation is used in place of general anaesthesia by some abortion providers, particularly in the charitable sector. Conscious sedation regimens typically include an intravenous opioid (such as fentanyl) plus an intravenous sedative (such as midazolam or propofol). In 2002, the Department of Health published an Expert Group report¹⁸⁰ on conscious sedation in termination of pregnancy and, in 2001, the Academy of Medical Royal Colleges published a report, *Implementing and*

*Ensuring Safe Sedation Practice for Healthcare Procedures in Adults.*¹⁸¹ The recommendations in these reports must be followed closely by any service choosing to offer conscious sedation.

A placebo-controlled, randomised trial evaluated the efficacy of intravenous fentanyl in reducing pain associated with first-trimester suction abortion under paracervical block.¹⁸² The use of fentanyl reduced immediate post-abortion pain by one point on an 11-point scale; the investigators questioned the clinical significance of a reduction of this magnitude. A further placebo-controlled randomised trial evaluated intravenous midazolam plus fentanyl for conscious sedation in conjunction with paracervical block for suction abortion up to 12 weeks of gestation.¹⁸³ There were no statistically significant differences between study groups in pain scores; nevertheless, women in the conscious sedation group reported better satisfaction levels. A further trial, with both randomised and patient preference components, evaluated sedation with oral lorazepam prior to suction curettage under local anaesthetic.¹⁸⁴ Use of lorazepam had no objective impact on anxiety or pain scores.

Electric or manual aspiration

RECOMMENDATION 34

A For first-trimester suction termination, either electric or manual aspiration devices may be used, as both are effective and acceptable to women and clinicians. Operating times are shorter with electric aspiration.

Evidence supporting recommendation 34

Relevant randomised trials are summarised in Evidence table 9.

Mid-trimester surgical abortion

RECOMMENDATION 35

A For gestations above 15 weeks, surgical abortion by dilatation and evacuation (D&E), preceded by cervical preparation, is safe and effective when undertaken by specialist practitioners with access to the necessary instruments and who have a sufficiently large caseload to maintain their skills.

Evidence supporting recommendation 35

In 2002, a retrospective cohort study of 297 women compared the complication rates of D&E and contemporary methods of medical abortion, specifically misoprostol.¹⁸⁵ Overall, women who underwent medical abortion were significantly more likely to have a complication than women who underwent D&E (29% versus 4%). Women who underwent medical abortion with misoprostol were less likely to have complications than women who underwent medical abortion using other regimens, but still had more complications than those who underwent D&E (22% versus 4%). The most common complication of medical abortion was retained products of conception requiring surgical evacuation but, even when these were excluded, women who underwent medical abortion still had more complications, including one case of uterine rupture.

The use of real-time ultrasound scanning during D&E can reduce the perforation rate. Darney and Sweet studied the value of intraoperative ultrasound between 16 and 24 weeks of gestation,

comparing 353 elective abortions performed without ultrasound with 457 in which ultrasound was routinely employed.¹⁸⁶ All operations were carried out in the same clinic with the same technique, but subjects were not randomly allocated. The rate of uterine perforation was 0.2% in the scanned group compared to 1.4% in the unscanned.

Historically, it has been considered that D&E is a risk factor for subsequent adverse pregnancy outcomes, including cervical weakness, pregnancy loss and preterm birth. A retrospective case series included 600 women who underwent mid-trimester D&E between 1996 and 2000.¹⁸⁷ Interpretation of the findings is difficult, as no reference cohort of women who had not undergone D&E was described. Nevertheless, rates of adverse pregnancy outcomes appeared similar to those of unselected populations. The authors concluded that “second-trimester D&E is not a risk factor for mid-trimester pregnancy loss or spontaneous preterm birth”.

D&E is the standard method at gestations above 15 weeks in the non-NHS abortion service in England, although it has not found general favour among gynaecologists working in the NHS. D&E can be undertaken safely only by gynaecologists who have been trained in the technique, have the necessary instruments and have a caseload sufficient to maintain their skills. For gynaecologists lacking the necessary expertise and caseload, and for their patients, mid-trimester medical abortion using mifepristone plus prostaglandin is appropriate.

Published evidence provides reassurance on the safety and efficacy in mid-trimester of both D&E and medical abortion using mifepristone plus prostaglandin. Other methods of mid-trimester abortion have been described. These include:

- ‘intact D&X’ (also termed partial birth abortion)¹⁸⁸
- two-stage procedures involving two general anaesthetics (in which the membranes are ruptured and the umbilical cord divided, followed, some days later, by D&E)
- medical abortion using instillation of various agents.

There are scant published data on the safety of these methods and, to our knowledge, intact D&X has never been used in the UK. These mid-trimester abortion methods are not recommended for UK practice.

Cervical priming for surgical abortion

RECOMMENDATION 36

B Cervical preparation is beneficial prior to surgical abortion and should be routine if the woman is aged under 18 years of age or at a gestation of more than 10 weeks.

RECOMMENDATION 37

C Abortion regimens containing misoprostol are not licensed within manufacturers’ summaries of product characteristics. European Community regulations permit doctors to prescribe unlicensed regimens and permit pharmacists to dispense and nurses to administer medicines prescribed outside of a product licence. Women should be informed if a prescribed treatment is unlicensed.

RECOMMENDATION 38

B Based on available evidence, the following regimen appears to be optimal for cervical preparation prior to first- or second-trimester surgical abortion. This advice is based on

considerations of efficacy, adverse-effect profile and cost:

- * misoprostol 400 micrograms (2 x 200-microgram tablets) administered vaginally, either by the woman or a clinician, 3 hours prior to surgery.

The following regimens are licensed within manufacturers' summaries of product characteristics and are also appropriate for cervical preparation prior to first- or second-trimester surgical abortion:

- gemeprost 1 mg vaginally, 3 hours prior to surgery¹⁸⁹
- mifepristone 600 mg orally 36–48 hours prior to surgery.¹⁹⁰

B

Evidence supporting recommendations 36–38

For surgical abortion, it is well established that young age is a risk factor for cervical damage⁸⁶ and that increasing gestation (particularly among multiparae) is associated with increasing risk of uterine perforation.⁴³ Use of a cervical priming technique reduces the risks of both these complications;^{86,43} it is therefore recommended, at least among these high-risk groups. The studies cited above relate to the use of mechanical priming agents (laminaria) that are favoured in the USA. There is less direct evidence to support the efficacy of the pharmacological priming favoured in the UK. However, one large multicentre randomised trial¹⁹¹ demonstrated that routine cervical priming with a prostaglandin significantly reduced the risk of short-term complications of first-trimester suction termination.

Evidence table 10 summarises studies comparing various methods of cervical priming which were reviewed by the Guideline Development Group. More recent studies are summarised in Evidence table 11. The previous edition of this guideline recommended misoprostol, 400 micrograms, administered vaginally, 3 hours prior to abortion as the most cost-effective priming regimen. This recommendation was based principally on the trial of Singh *et al.*¹⁹² The balance of published evidence to date still suggests that this misoprostol regimen is cost effective and associated with a low incidence of adverse effects. Trials have shown that it is feasible for women to self-administer the vaginal tablets without loss of efficacy. Further studies have suggested that the sublingual route of administration results in a rapid onset of action. However, this route may be associated with increased adverse gastrointestinal effects. The use of other agents, such as nitric oxide donors and danazol for cervical priming, is the subject of current research but cannot yet be recommended in routine practice.

The World Health Organization's *Technical and Policy Guidance on Safe Abortion* recommends "cervical preparation before surgical abortion for durations of pregnancy over 9 weeks for nulliparous women, for women younger than 18 years old, and for all women with durations of pregnancy over 12 weeks".¹⁰ This recommendation differs slightly from our own but is based on interpretation of similar data by a different group of experts.

The use of misoprostol tablets for abortion procedures by the vaginal route constitutes an unlicensed indication and an unlicensed route of administration. However, the EC Pharmaceutical Directive 65/65/EEC specifically permits doctors to use "licensed medicines for indications or in doses or by routes of administration outside the recommendations given in the licence".¹⁹³ This is endorsed in articles in *Drug and Therapeutics Bulletin*¹⁹⁴ and *Prescribers' Journal*.¹⁹⁵ The latter article emphasises that patients should be properly informed before a drug is prescribed for an unlicensed indication. Clearly, this would be of particular importance if there is even a small risk of continuing

* This regimen is unlicensed.

pregnancy. Drugs prescribed by doctors outside the license can be dispensed by pharmacists and administered by nurses and midwives. In developing this guideline update, specific advice was sought from the Nursing and Midwifery Council on this point. The response from their Professional Advisory Service emphasised the necessity for signed local protocols or individual prescriptions in respect of any substance prescribed outside the terms of its product licence. It confirmed that, provided a medical practitioner has prepared and signed a local protocol or individual prescription, midwives, health visitors or nurses should comply with the request to administer the agent.

7.2 Medical methods of abortion

Early medical abortion (gestations up to 9 weeks)

RECOMMENDATION 39

B Medical abortion using mifepristone plus prostaglandin is the most effective method of abortion at gestations of less than 7 weeks.

RECOMMENDATION 40

A Medical abortion using mifepristone plus prostaglandin continues to be an appropriate method for women in the 7–9 week gestation band.

RECOMMENDATION 41

A * For early medical abortion a dose of 200 mg of mifepristone in combination with a prostaglandin is appropriate.

RECOMMENDATION 42

A * Misoprostol (a prostaglandin E₁ analogue) is a cost-effective alternative for all abortion procedures for which the E₁ analogue gemeprost is conventionally used (that is, early medical abortion, cervical priming, mid-trimester medical abortion).

RECOMMENDATION 43

B Based on available evidence, the following regimen appears to be optimal for early medical abortion up to 9 weeks (63 days) of gestation. This advice is based on considerations of efficacy, adverse-effect profile and cost:

- * mifepristone 200 mg orally followed 1–3 days later by misoprostol 800 micrograms vaginally. The misoprostol may be administered by a clinician or self-administered by the woman. For women at 49–63 days of gestation, if abortion has not occurred 4 hours after administration of misoprostol, a second dose of misoprostol 400 micrograms may be administered vaginally or orally (depending upon preference and amount of bleeding).

* This regimen is unlicensed.

The following regimen is licensed within manufacturer's summary of product characteristics and is also appropriate for early medical abortion up to 9 weeks (63 days) of gestation:

B

- mifepristone 600 mg orally followed 36–48 hours later by gemeprost 1 mg vaginally.¹⁹⁰

Evidence supporting recommendations 39–43

The Guideline Development Group summarised existing systematic reviews of the studies that resulted in the combined mifepristone plus prostaglandin regimens which are in current UK use for early medical abortion. Single agent regimens have been reviewed and found to have unacceptable failure rates. Bygdeman reviewed a number of single agents and recommended that they be abandoned in favour of combination therapies.¹⁹⁶ In 2002, Jain *et al.* published the findings of a randomised trial directly comparing regimens of vaginal misoprostol alone and of mifepristone plus vaginal misoprostol in women up to 56 days of gestation.¹⁹⁷ Complete abortion rates were 88% and 96%, respectively ($P < 0.05$). Single agent regimens are not considered to have a role in UK practice, where mifepristone is readily available, and are not considered further in this guideline.

The literature search for the previous edition of this guideline identified no randomised controlled trials of methotrexate plus prostaglandin compared with mifepristone plus prostaglandin. Methotrexate alone and in combination with misoprostol had been investigated by a number of groups. Grimes reviewed a number of trials looking at the role of methotrexate alone or in combination with misoprostol for induced abortion.¹⁹⁸ He concluded that methotrexate was effective when given in combination with misoprostol. Efficacy was optimal if the misoprostol was given 7 days after the methotrexate. Comparing the results of the methotrexate plus misoprostol regimens included in Grimes' review with those of mifepristone plus misoprostol discussed below, the poorer success rates, longer treatment to abortion intervals and higher continuing pregnancy rates are significant.

In 2002 findings were published from a multicentre randomised trial comparing methotrexate plus misoprostol and mifepristone plus misoprostol regimens.¹⁹⁹ Abortions induced with mifepristone completed faster than those induced with methotrexate but the overall success rates, adverse effects and complications were similar. Acceptance rates were slightly higher with mifepristone than methotrexate. In this study, the methotrexate regimen included an 'optimal' dose of misoprostol (800 micrograms vaginally) whereas the mifepristone regimen included a 'suboptimal' dose (400 micrograms orally). It would be expected that the advantage of the mifepristone regimen would have been more pronounced had comparable doses of misoprostol been used. Although methotrexate regimens may have a place in those countries where mifepristone is unavailable, they are not considered further in this guideline as it focuses on abortion care in the UK.

Recommendation 39 is based on a systematic review of cohort studies of combined mifepristone plus prostaglandin regimens for early medical abortion, which concluded that the complete abortion rate falls as gestation advances.²⁰⁰ Thus, unlike the situation with conventional suction termination, medical abortion is at its most effective at the earliest stages of pregnancy (level IIb evidence).

Evidence reviewed for the previous edition of this guideline indicated that medical and surgical abortion had similar efficacy and acceptability in the early first trimester. This evidence provided the basis for the recommendation that, wherever possible, women should be offered a choice of methods. Two authoritative reviews comparing options for early abortion have since been published.^{92,201} A Cochrane review included only five trials, some involving single-agent medical regimens.²⁰¹ The reviewers concluded that more trials were needed to address efficacy and women's

preferences. A comparative review by Bygdeman and Danielsson concluded: “Both methods are equally well accepted provided the woman is allowed to choose. It is not possible to state which method is best. Medical termination of early pregnancy will not replace, but is an alternative to, vacuum aspiration and ideally both methods should be available to give the woman a choice”.⁹²

The manufacturer’s summary of product characteristics for mifepristone recommends a dose of 600 mg prior to prostaglandin administration for early medical abortion.¹⁹⁰ However, evidence from a randomised trial (level Ib evidence) indicates that a dose of 200 mg has similar efficacy when compared with 400 mg or 600 mg.²⁰² Level III evidence from large case series has confirmed that complete abortion rates as high as any described using the manufacturer’s recommended regimen are achievable with a 200 mg mifepristone regimen.^{83,84}

The WHO multicentre trial cited in the previous edition of this guideline used gemeprost as the prostaglandin.²⁰² The WHO has since conducted a similar trial using misoprostol involving 1589 women in 17 centres internationally.²⁰³ At gestations up to 35 days, doses of 200 mg and 600 mg of mifepristone in combination with misoprostol 400 micrograms orally were compared. Both regimens had similar efficacy.

The earlier WHO multicentre trial included women at gestations up to 56 days.²⁰² The WHO has since conducted a similar trial involving 896 women at gestations of 57–63 days in ten centres internationally.²⁰⁴ Doses of 200 mg and 600 mg of mifepristone in combination with gemeprost 1 mg vaginally were compared. Again, both regimens had similar efficacy.

The WHO has also conducted a further multicentre trial (1224 women at gestations of less than 57 days in 13 centres internationally) to investigate the effects of further reducing the dose of mifepristone.²⁰⁵ Four regimens were compared:

- mifepristone 50 mg + gemeprost 0.5 mg
- mifepristone 50 mg + gemeprost 1 mg
- mifepristone 200 mg + gemeprost 0.5 mg
- mifepristone 200 mg + gemeprost 1 mg.

The success rate was significantly related to the dose of mifepristone but not to the dose of gemeprost. Women receiving only 50 mg of mifepristone had a failure rate 1.6 times higher than women receiving 200 mg.

A single centre trial (80 subjects) has evaluated a dose of 100 mg mifepristone in combination with misoprostol doses of 400 micrograms orally or 800 micrograms vaginally.²⁰⁶ The regimen including 800 micrograms vaginal misoprostol was significantly more effective than the oral regimen. In this study, the vaginal regimen achieved a complete abortion rate of 100%, suggesting that a dose of 100 mg mifepristone may be adequate. Verification from studies in other centres is required before this dose is adopted in routine practice.

The conventional PGE₁ analogue used for abortion procedures is gemeprost. A 1-mg pessary (used for early medical abortion, cervical priming and for each dose in mid-trimester abortion) costs approximately £20. A series of studies reviewed by the Guideline Development Group demonstrated that the alternative E₁ analogue, misoprostol, which costs around £1 per dose, is also effective in all three contexts.^{207–213} Moreover, misoprostol is more effective if administered vaginally rather than orally.^{198,207,213}

Data available in 2000, relating to the use of vaginal misoprostol for early medical abortion indicated that, at gestations up to 7 weeks, misoprostol is as effective as gemeprost.⁸⁸ However, at gestations of 7–9 weeks, the continuing pregnancy rate may be higher when misoprostol is used.²¹⁰

The Guideline Development Group advised that clinicians opting to substitute misoprostol for early medical abortion in the interests of economy might prefer to use gemeprost in the 7–9 week gestation band. A subsequent large case series⁸⁹ has shown that using mifepristone in combination with two doses, rather than a single dose, of misoprostol abolishes this gestation effect. Evidence table 12 summarises studies relating to regimens for early medical abortion published since 1999. Together with the older studies reviewed by the Guideline Development Group in Evidence table 13, these form the basis for the regimens recommended above.

Medical abortion in the late first trimester (9–13 weeks)

RECOMMENDATION 44

A Medical abortion using the following regimen is a safe, effective and acceptable alternative to surgical abortion for women between 9 and 13 weeks of gestation:

- * mifepristone 200 mg orally followed 36–48 hours later by misoprostol 800 micrograms vaginally. A maximum of four further doses of misoprostol 400 micrograms may be administered at 3-hourly intervals, vaginally or orally (depending on amount of bleeding).

Evidence supporting recommendation 44

Gouk *et al.* described a case series of 253 women at 63–83 days of gestation.²¹⁴ Women were managed using a regimen comprising mifepristone 200 mg followed 36–48 hours later by a single dose of misoprostol 800 micrograms vaginally. The complete abortion rate was 94.5%, rising to 95.7% after repeat misoprostol administration in three women.

Ashok *et al.* described a randomised trial involving 368 women at 9–13 weeks of gestation.²¹⁵ Subjects were randomly allocated to surgical abortion by vacuum aspiration under general anaesthesia or medical abortion with mifepristone 200 mg followed 36–48 hours later by up to three doses of misoprostol. The first dose comprised 800 micrograms vaginally. If abortion did not ensue, a maximum of two further doses (400 micrograms) of misoprostol were given at 3-hourly intervals either orally or vaginally depending on vaginal bleeding. The complete abortion rates (women not requiring a second procedure) were 94.6% in the medical group and 97.9% in the surgical group (difference not significant). Adverse effects were higher in the medical group but 70% indicated that they would opt for the same method in the future.

The same group has subsequently reported a consecutive series of 483 women at 64–91 days of gestation managed using this regimen.²¹⁶ In a routine clinical service in the UK, 54% of women in this gestation band opted for medical abortion. The complete abortion rate was 94.8% and was gestation-related. In this series, up to five doses of misoprostol were permitted, the mean number of doses being 2.3.

Vyjayanthi and Piskorowsky have reported a small case series (25 women) at 9–12 weeks of gestation, managed using mifepristone 200 mg followed by gemeprost 1 mg to a maximum of five doses.²¹⁷ The complete abortion rate was 96% and all but one of the women were managed as day cases.

* This regimen is unlicensed.

Mid-trimester medical abortion

RECOMMENDATION 45

B For mid-trimester abortion (13–24 weeks of gestation) medical abortion with mifepristone followed by prostaglandin is an appropriate method and has been shown to be safe and effective.

RECOMMENDATION 46

A For mid-trimester medical abortion, a dose of *200 mg of mifepristone is adequate.

RECOMMENDATION 47

B Surgical evacuation of the uterus is not required routinely following mid-trimester medical abortion. It should only be undertaken if there is clinical evidence that the abortion is incomplete.

RECOMMENDATION 48

A Based on available evidence, the following regimen appears to be optimal for mid-trimester medical abortion. This advice is based on considerations of efficacy, adverse-effect profile and cost:

* Mifepristone 200 mg orally, followed 36–48 hours later by misoprostol 800 micrograms vaginally, then misoprostol 400 micrograms orally, 3-hourly, to a maximum of four oral doses.

The following regimen is licensed within manufacturer’s summary of product characteristics and is also appropriate for mid-trimester medical abortion:

Mifepristone 600 mg orally, followed 36–48 hours later by gemeprost 1 mg vaginally every 3 hours to a maximum of five pessaries.¹⁹⁰

Evidence supporting recommendations 45–48

Second-trimester medical abortion with mifepristone followed by a prostaglandin is effective and is associated with considerably shorter induction to abortion intervals than methods using prostaglandin alone or supplemented by oxytocin infusion.^{218–220} As discussed above, the dose of mifepristone recommended for first-trimester medical abortion is 200 mg.²⁰² Likewise, evidence from a randomised trial resulted in a similar recommendation for the dose of mifepristone in second-trimester abortions.²²¹

In a series of 500 cases of mid-trimester medical abortion⁶³ only 9.4% of cases needed surgical evacuation following medical abortion. In a similar series of 956 women, the rate was 11.5%.²⁷⁴

The recommended regimens are based on evidence reviewed by the Guideline Development Group and summarised in Evidence table 14.

* This regimen is unlicensed.

Three studies published since 1999 relating to combined mifepristone and prostaglandin mid-trimester regimens have been identified.

Ngai *et al.* reported a randomised trial of 142 women at 14–20 weeks of gestation, comparing vaginal (200 micrograms, 3-hourly) and oral (400 micrograms, 3-hourly) misoprostol after mifepristone 200 mg.²²³ The efficacy of the two regimens was similar (complete abortion rate: 81% oral versus 75% vaginal). Although adverse effects were significantly higher in the oral group, this route was preferred by women.

Tang *et al.* reported on a case series of 956 women at 12–24 weeks of gestation managed using a regimen comprising mifepristone 200 mg followed by gemeprost 1 mg vaginally 6-hourly for 24 hours, followed by gemeprost 1 mg 3-hourly for 12 hours, if required.²²² Overall, 96.4% and 98.8% aborted within 24 and 36 hours, respectively. This combination was found to be safe and effective.

Bartley and Baird reported on a randomised trial of 100 women at 12–20 weeks of gestation, comparing gemeprost and misoprostol regimens.²²⁴ All subjects received mifepristone 200 mg; the gemeprost group then received 1 mg vaginally every 6 hours for 18 hours; the misoprostol group then received one dose of 800 micrograms vaginally followed by 400 micrograms orally 3-hourly for 12 hours. Complete abortion rates, induction to abortion intervals, surgical evacuation rates and adverse-effect profiles were similar in the two groups.

7.3 Analgesia for abortion care

RECOMMENDATION 49

B Some women will require analgesia after surgical abortion or during and after medical abortion. Requirements for analgesia vary and there is no benefit in routine administration of prophylactic analgesics. Services should make available a range of oral and parenteral analgesics in order to meet women's needs.

Evidence supporting recommendation 49

In routine clinical practice, analgesia is offered to women following surgical abortion and both during and after medical abortion. There is little research evidence to guide the choice of analgesic regimens. In a large case series of early medical abortion, data on analgesic use were available for over 3000 women.⁸⁹ Of these, 37% required no analgesia, 58% received oral analgesia only (paracetamol 500 mg plus dihydrocodeine 10 mg) and 5% received parenteral opiate (morphine 10 mg). Data on analgesic use⁶³ were reported for 178 women undergoing mid-trimester medical abortion in the same centre. Of these, 26% required no analgesia, 36% received oral analgesia and 38% parenteral opiate (regimens as above).

A case series of 2747 women from the USA includes data on analgesic use in a home abortion setting;²²⁵ 79% of women used an oral narcotic analgesic on the day of misoprostol administration. This level of use was higher than the 27% reported by the same investigators in a series of 2121 women undergoing supervised medical abortion.²²⁶

A placebo-controlled, randomised trial evaluated the efficacy of ibuprofen or acetaminophen with codeine in the context of early medical abortion with methotrexate and misoprostol.²²⁷ The agents were taken at the time of misoprostol administration, prior to the onset of pain. Severe pain scores were reported by almost one-quarter of women. There were no significant differences in pain scores

between treatment groups. The authors concluded that pain experienced in medical abortion causes significant distress and more research is needed to reduce it.

A further randomised trial evaluated prophylactic analgesia with rectal paracetamol and codeine prior to suction abortion under general anaesthesia.²²⁸ Women experienced relatively little post-abortion pain and there were no significant differences between treatment groups. The authors concluded that preoperative prophylactic analgesia is unnecessary in this group of women. A similar trial evaluated the efficacy of paracetamol given rectally at the end of suction abortion under general anaesthesia.²²⁹ Again, it was concluded that routine prophylactic analgesia was not justified.

A randomised trial published in 2003 evaluated the use of a nonsteroidal anti-inflammatory drug (NSAID), diclofenac, at the time of cervical priming with oral misoprostol prior to suction termination under sedation with sublingual lorazepam.²³⁰ Again, the authors concluded that the routine use of the analgesic resulted in no significant pain reduction. This study provided reassurance that cotreatment with a NSAID did not reduce the efficacy of misoprostol cervical priming (NSAIDs inhibit the production of endogenous prostaglandins and concerns have been expressed that they might attenuate the effects of exogenous prostaglandins).

A randomised trial evaluated aromatherapy to reduce anxiety before abortion and found no benefit.²³¹

7.4 Histopathology

RECOMMENDATION 50

B Routine histopathological examination of tissue obtained at abortion procedures is unnecessary.

Evidence supporting recommendation 50

Three prospective cohort studies have examined the usefulness of routine histopathological examination of tissue obtained at abortion.^{232–234} The first study²³² included both induced (990) and spontaneous (475) pregnancy losses. The investigators found that the histological result was sometimes inconsistent with the clinical diagnosis and resulted in unnecessary investigation and treatment. They concluded that there was no obvious benefit from routine histological examination.

The second study included 676 women undergoing surgical abortion at very early gestations (less than 6 weeks).²³³ These investigators found that surgeons' tissue inspection poorly predicted abnormal outcomes but that pathologists' examinations performed even less well. Again, the conclusion was that routine pathology examination confers no clinical benefit.

The third study involved review of histological findings from 1000 consecutive induced abortions at 7–13 weeks of gestation.²³⁴ Pathological findings were reported in 5.6% of cases. These included one diagnosis of fetal polycystic kidney disease. The authors argued that this information enabled the woman to undergo prenatal diagnosis in future pregnancies. On this basis, they argued a case for routine histological examination of abortion material. However, in reality, none of the pathologies reported influenced the immediate care of the woman.

In 2002, the Royal College of Pathologists published guidance on histopathology of limited or no clinical value.²³⁵ This document advised that for 'social' termination of pregnancy, specimens should not be sent to the laboratory if fetal parts are visible.

Chapter 8

Aftercare

8.1 Rhesus prophylaxis

RECOMMENDATION 51

B Anti-D IgG (250 iu before 20 weeks of gestation and 500 iu thereafter) should be given, by injection into the deltoid muscle, to all nonsensitised RhD negative women within 72 hours following abortion, whether by surgical or medical methods.

Evidence supporting recommendation 51

The previous version of this guideline endorsed a 1999 recommendation from the Guidelines and Audit Committee of the RCOG that RhD negative women should be given anti-D IgG immunoprophylaxis following abortion.²³⁶ The recommended dose is 250 iu before 20 weeks of gestation and 500 iu thereafter. A 500-iu dose gives protection for fetomaternal haemorrhage of up to 4 ml. It is recommended that a test for the size of fetomaternal haemorrhage should be performed in the case of procedures undertaken after 20 weeks of gestation. This may be the traditional Kleihauer acid elution test or the more accurate flow cytometry, where available. If the test indicates a fetomaternal haemorrhage of greater than 4 ml, an additional 125 iu/ml of red cells should be administered.²³⁶ This RCOG guideline was updated in 2002, but the recommendations relating to anti-D after induced abortion were unchanged.²³⁷ The guideline specifically states that anti-D should be injected into the deltoid muscle, as injections into the gluteal region often reach only the subcutaneous tissues and absorption may be delayed.

A structured review appraised ten published studies relating to the necessity for anti-D prophylaxis for early first-trimester abortion.²³⁸ This review concluded that, although evidence to support the use of prophylaxis in the first trimester is sparse, there is theoretical evidence of its necessity. Studies indicate that fetomaternal haemorrhage in the first trimester is of sufficient volume potentially to cause immunosensitisation.

It should be noted that it is fruitless to administer anti-D IgG to RhD negative women who, on antibody screening, are found to be sensitised already. Anti-D should not therefore be administered to such women, as it is wasteful of anti-D and unnecessarily exposes women to any risks inherent in human blood products. Inadvertent administration of prophylactic anti-D IgG to an already sensitised woman, however, would not of itself cause any harm to her.

8.2 Post-abortion information and followup

RECOMMENDATION 52

- ✓ Following abortion, women must be given a written account of the symptoms they may experience and a list of those that would make an urgent medical consultation necessary. They should be given a 24-hour telephone helpline number to use if they feel worried about pain, bleeding or high temperature. Urgent clinical assessment and emergency gynaecology admission must be available when necessary.

RECOMMENDATION 53

- C Each woman should be offered, or advised to obtain, a follow-up appointment (either within the abortion service or with the referring clinician) within 2 weeks of abortion.

RECOMMENDATION 54

- ✓ On discharge, each woman should be given a letter that gives sufficient information about the procedure to allow another practitioner elsewhere to deal with any complications.

RECOMMENDATION 55

- C Referral for further counselling should be available for the small minority of women who experience long-term post-abortion distress. Risk factors are ambivalence before the abortion, lack of a supportive partner, a psychiatric history or membership of a cultural group that considers abortion to be wrong.

Evidence supporting recommendations 52–55

A follow-up appointment within 2 weeks of the procedure is a requirement of early medical abortion (although it becomes optional if complete abortion is confirmed on the day of the procedure). The Birth Control Trust has advocated early follow-up as a routine for all women following abortion.²³⁹ The first 2 weeks is when immediate complications of abortion will present and when any problems with contraception should be resolved. The recent fpa publication, *Early Abortions*, includes similar recommendations on aftercare.⁵⁰

8.3 Contraception following abortion

RECOMMENDATION 56

- B Before she is discharged following abortion, future contraception should have been discussed with each woman and contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion.

RECOMMENDATION 57

- B Intrauterine contraception can be inserted immediately following a first- or second-trimester termination of pregnancy.

RECOMMENDATION 58

B Sterilisation can be safely performed at the time of induced abortion. However, combined procedures are associated with higher rates of failure and of regret on the part of the woman.

Evidence supporting recommendations 56–58

The initiation of contraception immediately following induced abortion has advantages. The woman is known not to be pregnant, her motivation for effective contraception is high and she is already accessing health care. In addition, it has been shown that ovulation occurs within a month of first-trimester abortion in over 90% of women.²⁴⁰

Hormonal contraception

The World Health Organization's *Medical Eligibility Criteria for Contraceptive Use* (WHOMECEC) provides evidence-based recommendations on eligibility for contraceptive use.²⁴¹ The combined oral contraceptive pill is the most common method of contraception by women aged 16–49 years, with 18% of those using any form of contraception choosing this method.²⁴² WHOMECEC recommends that benefits of the combined oral contraceptive pill immediately following first- or second-trimester termination of pregnancy outweigh any risks. Similarly, progestogen-only contraceptive pills, implants and injectables can be started immediately following termination of pregnancy. Ideally, these methods should be commenced at the time of termination, when contraceptive protection is immediate. If started after this time, additional barrier contraception is required for 7 days (combined) or for 2 days (progestogen-only).²⁴³

Two randomised trials have assessed the effects of combined oral contraception commenced immediately after early medical abortion.^{244,245} Both studies concluded that it is safe to offer combined oral contraception immediately after medical abortion, as it does not affect duration or amount of vaginal bleeding or the complete abortion rate.

Intrauterine contraception

Systematic reviews that included nine randomised trials and a total of 4476 woman years of data suggested that the insertion of a copper-bearing intrauterine contraceptive device (IUCD) at the time of surgical termination of pregnancy was safe and practical.²⁴⁶ However, these multicentre trials included IUCDs that are rarely used in current clinical practice (Lippes loop, Copper 7 and TCu 200). Expulsion rates were shown to be higher for insertions following second-trimester termination than for those following first-trimester termination. Delaying insertion following second-trimester termination was advised but no time frame was given. There was insufficient evidence available to compare the safety and efficacy of IUCDs inserted immediately after abortion versus delayed insertion. WHOMECEC, however, recommends that there are benefits of intrauterine contraception immediately following first-trimester termination (unrestricted use) or second-trimester termination (benefits generally outweigh any risks).²⁴¹

In one trial, no difference was found in the readmission rates for pelvic infection following termination in 229 women having an IUCD inserted at the time of first-trimester termination, compared with 594 women not having an IUCD inserted.²⁴⁷ No prophylactic antibiotics were used and IUCD continuation rates at 1 year were 72.8%. A small randomised trial investigated bleeding patterns associated with an IUCD or a levonorgestrel-releasing intrauterine system (LNG-IUS) inserted following termination of pregnancy or following menstruation.²⁴⁸ Results suggest that

bleeding patterns with IUCDs are similar whether inserted following termination or postmenstrually but the number of subjects lost to follow-up was high in both groups. Women having an LNG-IUS inserted following surgical termination described fewer bleeding problems compared with women having an LNG-IUS inserted postmenstrually. This was postulated to be due to an enhanced effect of levonorgestrel on the endometrium following removal of most of the superficial endometrium during the surgical procedure.

Non-randomised comparative studies provide further evidence to support the safety, efficacy and acceptability of immediate post-abortion intrauterine contraception.^{249–251}

There are few data specifically relating to IUCD insertion following medical termination of pregnancy. We suggest that an IUCD may be inserted immediately (within 48 hours) following first- or second-trimester medical abortion. Otherwise, insertion should be delayed until 4 weeks following medical abortion (as for postpartum insertions).²⁴¹

Sterilisation

The lifetime failure rate for sterilisation is approximately 1 in 200.²⁵² The RCOG evidence-based guideline on male and female sterilisation highlighted that there is potentially a higher failure rate associated with sterilisation at the time of abortion.²⁵² The Medico-legal Committee of the RCOG has commented: “In view of the increased failure rate of sterilisation procedures on those currently pregnant, it is questionable whether such operations should be carried out at all”.²⁵³

Two cohort studies have shown that the immediate and short-term complications of sterilisation performed at the time of abortion are similar to the total morbidity associated with the two procedures when performed separately.^{254,255} Earlier reports, based on statutory notifications, overestimated complications, owing to most sterilisations being performed by laparotomy, as opposed to the laparoscopic techniques now favoured.

Apart from the potential increased risk of failure, the possibility of feelings of regret has been voiced as a reason for performing sterilisation as an interval procedure. Regret associated with sterilisation may be hard to predict.²⁵⁶ In one randomised trial, where women had requested sterilisation at the time of abortion, they were randomised to a combination or interval procedure.²⁵⁴ Of women allocated to the ‘interval’ group, 33% failed to attend for sterilisation, suggesting a change of mind once they had been able to distance themselves from the abortion itself. This study emphasises the need for careful counselling relating to sterilisation in association with abortion.

Chapter 9

Standards for audit and service accreditation

The Guideline Development Group and Update Group are committed to the concept of integrated clinical effectiveness activities. It is fundamental to this concept that guideline development is complemented by related audit activity. Abortion services at local level are encouraged to conduct regular audit of the care they provide. The recommendations within this guideline can serve as criteria for audit. Suggestions for audit of abortion services were provided within the RCOG document, *Effective Procedures in Gynaecology Suitable for Audit*.²⁵⁷ Some illustrative examples of these audit suggestions, with modifications in the light of this new guideline, are summarised below.

9.1 Organisation of services

- ✓ The local primary/secondary care interface could be audited by assessing whether decision-to-appointment intervals fall within guideline targets.
- ✓ The case notes of women undergoing abortion could be assessed to determine the percentage performed as day cases.

9.2 Information for women

- ✓ Local services could audit the extent to which they provide accurate and unbiased information regarding induced abortion, especially with regard to potential sequelae. This could be assessed using a patient survey.

9.3 Pre-abortion management

- ✓ Where neither antibiotic prophylaxis is given nor screening for sexually transmitted infections performed, the reasons should have been documented in the case notes.
- ✓ Case notes of women undergoing abortion could be scrutinised to determine the percentage in which antibiotic prophylaxis was given or screening for lower genital tract infection performed and positive results acted upon.

9.4 Abortion procedures

- ✓ Case note review could be conducted to see which prostaglandin E₁ analogue is being used for abortion procedures.

- ✓ The doses of mifepristone used for early and mid-trimester abortion could be audited in a case note review against the 200-mg standard.
- ✓ Women undergoing surgical abortion could have their case notes reviewed to determine the percentage prescribed cervical ripening agents.
- ✓ The percentage of women in the high-risk group (18 years or gestation under 10 weeks) prescribed cervical priming agents could be audited.
- ✓ The percentage of women offered and accepting local anaesthesia could be reviewed.

9.5 Aftercare

- ✓ All Rh negative women undergoing induced abortion could have their case notes examined to determine the percentage who did not receive anti-D immunoglobulin or who received it but at an inappropriate dose.

Appendix: Evidence tables

Evidence table 1. Studies relating to the relative safety of abortion at increasing gestations

Authors	Ref.	Size of study	Study type	Outcome
Grimes <i>et al.</i>	43	67 175	Multicentre, prospective, observational cohort study (up to 13 weeks and later)	RR 1.4 (95% CI 1.2–1.7) associated with each 2-week increment in gestation
RCGP/RCOG	44	6105	Multicentre, prospective cohort study, observational with controls (up to 17 weeks)	Compared with abortion at < 9 weeks: <ul style="list-style-type: none"> operations at 9–12 weeks had 5-x risk of haemorrhage operations at > 12 weeks had 7-x risk of haemorrhage Increasing gestation was a factor in increasing the overall morbidity rate but did not reach statistical significance
Jacot <i>et al.</i>	46	3772	Retrospective cohort study; single centre (compared < 15 weeks with 15–20 weeks)	Fewer complications in later gestation group ($P = 0.056$): 5.1% < 15 weeks 2.9% 15–20 weeks
Buchler <i>et al.</i>	45	82 030	Multicentre, prospective, observational cohort study (up to 24 weeks)	Increased risk of serious complications if > 12 weeks; below 13 weeks, nonsignificant increase with gestation; after 12 weeks, RR for each 2-week increment in gestation 1.42 (95% CI 1.30–1.55) Increased risk of febrile morbidity at > 12 weeks: RR 1.43 (95% CI 1.21–1.69); RR for transfusion 2.00 (95% CI 1.10–3.64) for each 2-week gestation increment at < 12 weeks; RR for transfusion 1.48 (95% CI 1.33–1.65) for each 2-week gestation increment at > 12 weeks
Ferris <i>et al.</i>	42	83 469	Retrospective database cohort study, multi-centre; abortions at all gestations	Complications at: ≤ 9 weeks: 1 9–12 weeks: 1.3 (95% CI 1.02–1.63) 17–20 weeks 3.3 (95% CI 2.23–5.00)
Glasier and Thong	47	1988: 2204; 1989: 2210	Surgical abortions up to 20 weeks; before-and-after study	Change of referral system in November 1988 Analysed notes for first half of 1989; only referrals from family planning service were compared in the before and after study (88 before and 71 after) Outcome of change in referral system: <ul style="list-style-type: none"> reduction in wait to be assessed from 11 to 5 days increase in proportion of abortions performed at early gestations (from 40% to 60% at ≤ 9 weeks and from 21% to under 10% at ≥ 12 weeks)

Evidence table 2. Studies relating to the rate of uterine perforation during termination of pregnancy

Authors	Ref.	Size of study	Gestation	Perforation rate
Andolsek <i>et al.</i>	258	3004 in Ljubljana 1466 in Singapore	7–12 weeks	1.3 in 1000 in Ljubljana 1.4 in 1000 in Singapore
Lindell <i>et al.</i>	259	84 850	< 18 weeks	145 (1.7 in 1000)
Hakim-Elahi <i>et al.</i>	260	170,000	First trimester	16 (0.09 in 1000)
Kaali <i>et al.</i>	139	(a) 6408 (b) 706 b = at time of laparoscopic sterilisation	First trimester	Before direct visualisation: (a) 8 (1.3 in 1000) (b) 2 (2.8 in 1000) Unsuspected perforations: 12 (15.6 in 1000) True incidence in the laparoscopic group was 14 (2 + 12) in 706 or 19.8 in 1000
Heisterberg <i>et al.</i>	262	5851	≤ 9 weeks 10–12 weeks All gestations	10 (0.4 in 1000) 12 (0.3 in 1000) 22 (0.4 in 1000)
RCGP/RCOG	44	6105	9–12 weeks	22 (3.6 in 1000) Women treated in private sector had one-third the risk of trauma compared with NHS
Grimes <i>et al.</i>	286	67 175	Up to 24 weeks (86% < 13 weeks)	0.9 in 1000
King	263	11 885	8238 in first trimester 3647 in second	9 perforations ? all first trimester if so 1.1 in 1000 perforation rate
Hodgson <i>et al.</i>	264	104 453	< 14 weeks	10 (1.1 in 1000)
Nathanson <i>et al.</i>	265	26 000	First trimester	36 (1.4 in 1000)
Beric <i>et al.</i>	266	14 261 by curettage 22 905 by vacuum aspiration	Up to 12 weeks	18 (1.2 in 1000) 13 (0.4 in 1000)

Evidence table 3. A summary of the incidence of cervical injury during first-trimester abortion by vacuum aspiration reported in illustrative large case series

Study	Ref.	Gestation	Abortions (n)	Cervical injury	Rate/1000
Andolsek <i>et al.</i>	258	7–12 weeks	6655	4	0.6
Ferris <i>et al.</i>	42	87% < 13 weeks	83 460	63	0.7
RCGP/RCOG	44	88% < 13 weeks	6105	11	1.8
Jacot <i>et al.</i>	46	5–14 weeks	3225	1	0.3
Hakim-Elahi <i>et al.</i>	260	Up to 14 weeks	170 000	18	0.1
Heisterberg <i>et al.</i>	262	First trimester	5851	5	0.8
Schulz <i>et al.</i>	86	≤ 12 weeks	15 438	159	10.3

Evidence table 4. A summary of the incidence of cervical injury during second-trimester abortion by dilatation and evacuation in illustrative large case series

Authors	Ref.	Gestation	Abortions (n)	Cervical injury	Rate/1000
Jacot <i>et al.</i>	46	15–26 weeks	547	0	
Schulz <i>et al.</i>	86	13–20 weeks	6213	72	11.6
Peterson <i>et al.</i>	267	14–16 weeks	9916	109	11.6

Evidence table 5. Studies relating to induced abortion and subsequent breast cancer risk

Authors	Year	Ref.	Study design	Subjects (n)	Conclusions
Thorp <i>et al.</i>	2002	75	Narrative review		Cannot exclude a significant association; OR 1.3 (95% CI 1.2–1.4)
Tavani <i>et al.</i>	1999	268	Case–control	579 cases 668 controls	Abortion was not related to risk of breast cancer at age < 40 years; OR 0.87 (95% CI 0.63–1.22)
Marcus <i>et al.</i>	1999	269	Case–control	862 cases 790 controls	Abortion during adolescence does not influence breast cancer risk; RR 1.2 (95% CI 0.6–2.7)
Fioretti <i>et al.</i>	1999	270	Case–control	1041 cases 1002 controls	Abortion was not related to breast cancer risk in nulliparous women; OR 0.97 (95% CI 0.64–1.47)
Newcomb and Mandelson	2000	271	Case–control	138 cases 252 controls	Abortion was not related to risk of breast cancer; RR 0.9 (95% CI 0.5–1.6)
Lasovich <i>et al.</i>	2000	112	Cohort	37 247	No excess risk of breast cancer among women who reported having an abortion; RR 1.1 (95% CI 0.8–1.6)
Tang <i>et al.</i>	2000	111	Case–control	463 cases 2201 controls	Abortion does not increase risk of breast cancer; RR 0.9 (95% CI 0.7–1.2)
Robertsona <i>et al.</i>	2001	272	Case–control	624 cases 624 controls	Abortion was not associated with a statistically significant elevated risk in any parity group
Sanderson <i>et al.</i>	2001	109	Case–control	1459 cases 1556 controls	There was no relation between abortion and breast cancer; OR 0.9 (95% CI 0.7–1.2)
Goldacre <i>et al.</i>	2001	110	Case–control	28 616 cases 325 456 controls	Abortion does not increase the risk of breast cancer; OR 0.83 (95% CI 0.74–0.93)
Ye <i>et al.</i>	2002	273	Cohort and case–control	267 040 (cohort) 652 cases	694 controls Abortions are not an important cause of breast cancer; RR 0.51 (95% CI 0.31–1.50)
Mahue-Giangreco <i>et al.</i>	2003	274	Case–control	744 cases 744 controls	Does not support the hypothesis that abortion increases breast cancer risk; OR 0.71 (95% CI 0.49–1.02)
Becher <i>et al.</i>	2003	275	Case–control	706 cases 1633 controls	A history of abortion showed no significant effect
Erlandsson <i>et al.</i>	2003	276	Case–control	1759 cases 1759 controls	Abortion is not associated with an increased risk of breast cancer; OR 0.80 (95% CI 0.64–1.00)
Paoletti <i>et al.</i>	2003	277	Cohort	92 767	There is no relationship between breast cancer and induced abortion; RR 0.91 (95% CI 0.82–0.99)

Note: as this guideline was going to press, a major systematic review¹¹⁴ was published which lent further support to these conclusions

Evidence table 6. Studies relating to future reproductive outcomes

Authors	Ref.	Size of study	Type of study	Outcome
Infertility				
Daling <i>et al.</i>	115	105 medical histories 199 control cases	Retrospective case-control	Nonsignificant association between prior abortion and secondary infertility (RR 1.35, 95% CI 0.71–2.43)
Daling <i>et al.</i>	116	127 with known diagnosis of tubal infertility 395 women who conceived a child at same time as infertile women began attempt to become pregnant	Population-based case-control	Nonsignificant association between prior abortion and secondary infertility (RR 1.15, 95% CI 0.70–1.89)
Hernadi <i>et al.</i>	117	850	Cohort study (within multicentre trial)	Nonsignificant association between prior abortion and secondary infertility Cumulative pregnancy rates at 30 months were 96.9 (abortion group) and 98.7% (controls)
Tzonou <i>et al.</i>	118	84 women with secondary infertility 168 pregnant controls	Case-control study	Small significant association between prior abortion and secondary infertility (RR 2.1, 95% CI 1.1–4.0)
Preterm delivery				
Dalaker <i>et al.</i>	121	619 terminations 619 pregnancies continued to delivery	Cohort	Groups compared for subsequent complications such as first- and second-trimester abortion, cervical weakness, preterm delivery, ectopic pregnancy and sterility; total complication rate was 24.3 in the abortion group and 20.2 in the controls
Berkowitz	119	175 mothers of singleton preterm infants 313 mothers of singleton term infants	Case-control	Significant risk factor for preterm delivery included induced abortion in previous pregnancy
Meirik <i>et al.</i>	122	429 post-abortion 391 controls	Cohort	No association between induced abortion and preterm delivery
Maritius <i>et al.</i>	120	106 345 singleton births	Cross-sectional survey	Association between preterm delivery and previous induced abortion (OR 1.8, 95% CI 1.57–2.13)

Evidence table 7. Induced abortion and subsequent mental health

Authors	Ref.	Location (epoch)	Subjects and study design	Outcomes	Findings
Reardon and Cogle	278	USA (1984–91)	293 abortion 128 unplanned birth Longitudinal cohort	Depression (CES-D score > 15)	Risk of high depression score, abortion versus unplanned birth: Adj. OR 1.54 (95% CI 0.91–2.61)
Gissler <i>et al.</i>	279	Finland (1987–94)	1347 suicides in women aged 15–49 years Register linkage to pregnancy events in previous year (retrospective cohort)	Suicide	Suicide rates: – all women 15–49: 11.3 in 100 000 – after birth: 5.9/100,000* – after miscarriage: 18.1 in 100 000* – after abortion: 34.7 in 100 000* (* significant different from ‘all women’)
Morgan <i>et al.</i>	280	Wales (1991–95)	143 attempted suicides in women aged 15–49 years Register linkage to pregnancy events (retrospective cohort)	Attempted suicide	Attempted suicide rates: – after birth: 1.9 in 1000 – after miscarriage: 4.3 in 1000 – after abortion: 8.1 in 1000 ‘Deterioration in mental health may be a consequential side effect of induced abortion’
Reardon <i>et al.</i>	281	California (1989–97)	50 260 women, 1st pregnancy abortion 83 690 women, 1st pregnancy, delivery Register linkage to death certificates (cohort)	Suicide	Age adjusted relative risk of suicide; women with one pregnancy only; abortion versus delivery: 2.54 (95% CI 1.14–5.67)
Gilchrist <i>et al.</i>	282	UK (1976–79)	Women with ‘unplanned’ pregnancies: 6151: no abortion request 6410: obtained abortion 379: abortion refused 321: requested but changed mind (cohort)	Any psychiatric illness Deliberate self-harm	Total psychiatric disorders similar after abortion or delivery Deliberate self-harm more common in ‘abortion group’: RR 1.7 (95% CI 1.1–2.6) and ‘abortion refused group’: RR 2.9 (95% CI 1.3–6.3)
Reardon <i>et al.</i>	283	California (1989–93)	Women with pregnancies in 1989, no psychiatric admission in previous year 15 299 abortion 41 442 birth Record linkage to psychiatric admissions (cohort)	Psychiatric admissions	First-time psychiatric admission rates during 4 years after pregnancy event Adjusted OR, abortion group versus delivery group: 1.7 (95% CI 1.4–2.1)

Evidence table 8. Studies relating to local versus general anaesthesia

Author	Ref.	Size of study	Type of study	Outcome
De Jonge <i>et al.</i>	284	142	Prospective randomised trial	Randomised into 2 groups: – those for evacuation under systemic analgesia – those under general anaesthesia Both groups compared in terms of safety, efficacy, acceptability, blood consumption and time delay between admission and evacuation Significantly less blood use in ward group (37 units for 13 patients) than in theatre group (65 units for 24 patients) ($P < 0.003$) Significantly less time taken between admission and evacuation in ward group (median 7 hours 15 minutes) theatre group (median 12 hours 38 minutes) ($P < 0.003$) Evacuation under fentanyl and midazolam was safe, effective and acceptable for majority of patients compared with evacuation users
MacKay <i>et al.</i>	285	4147 GA 5389 LA	Randomised trial	Women who had D&E under general anaesthesia had a relatively high risk of complications of 2.6 (95% CI 1.4–4.9) compared with women who underwent D&E under local anaesthesia LA for second trimester appears to be both safer and less expensive than GA
Grimes <i>et al.</i>	286	36 430	Case study	Significant differences between LA and GA for specific complications LA associated with higher rates of febrile and convulsive morbidity GA higher rates of haemorrhage, cervical injury and uterine perforation

D&E = dilatation and evacuation; GA = general anaesthesia; LA = local anaesthesia

Evidence table 9. Studies comparing manual with electric vacuum aspiration, randomised controlled trials

Study	Year	Ref.	Participants	Intervention(s)	Findings
Edelman <i>et al.</i>	2001	287	114 at <77 days	Electric versus manual vacuum aspiration (LA)	Electric suction gave shorter operating times Objective pain measures similar; noise of electric suction increased subjective pain
Hemlin and Moller	2001	288	200 at <56 days	Electric versus manual vacuum aspiration (under LA/GA according to preference)	No differences in efficacy No information on operating time or patient preference
Bird <i>et al.</i>	2001	289	42 at <77 days	Electric versus manual vacuum aspiration (LA)	No major differences in acceptability (no information on other outcomes)
Bird <i>et al.</i>	2003	290	127 at <11 weeks	Electric versus manual vacuum aspiration (under LA)	Similar patient acceptability (no information on other outcomes)
Dean <i>et al.</i>	2003	291	84 at <10 weeks	Electric versus manual vacuum aspiration (LA + conscious sedation)	Operating times, blood loss, complications, similar Patient pain and satisfaction similar 19% 'bothered' by noise in electric group

GA = general anaesthesia; LA = local anaesthesia

Evidence table 10. Cervical priming, randomised controlled trials (first-trimester abortion)

Author	Ref.	Population	Intervention	Results	Comments
Kajanoja <i>et al.</i>	292	239 nulliparous women undergoing vacuum aspiration first trimester TOP: 147 treatment; 146 placebo	Randomised, double-blind, placebo-controlled, 6-centre study: – single 1-mg gemeprost vaginal suppository for dilatation of the cervix uteri – placebo Suppository inserted 3 hours before vacuum aspiration	Preoperative os diameter was significantly greater in women treated with gemeprost. Further mechanical dilatation was either unnecessary or significantly easier than in placebo-treated women. A significant reduction in operative blood loss in the gemeprost group	
MacKenzie <i>et al.</i>	293	1030 women for first-trimester aspiration TOP	Single-centre prospective randomised trial: – gemeprost 1-mg pessary 1–4 hours before surgery – PGE ₂ 10-mg pessary	Gemeprost pessaries produced marginally greater cervical dilatation and less operative blood loss than PGE ₂ , with a reduction in distressing preoperative adverse effects. Postoperative adverse effects and later complications were infrequent and similar for the two groups	Gemeprost 1-mg pessaries are to be preferred to PGE ₂ pessaries
Urquhart and Templeton	220	40 primigravidae at 10–13 weeks of gestation	RCT of: – placebo – 600 mg single oral dose of mifepristone 48 hours prior to vacuum aspiration under GA	In 35% of treated women, there was no need for further dilatation prior to evacuation of the uterus. All women in placebo group required further dilatation. In those women receiving mifepristone who did require further dilatation, initial dilatation of the cervix was significantly greater and significantly less force was required to dilate the cervix to 9 mm. Perioperative blood loss was reduced. No serious complications or adverse effects	Mifepristone for cervical priming is safe and effective and has advantages over prostaglandins and hydrophilic cervical dilators
Osmer <i>et al.</i>	294	50 primigravidae scheduled for TOP in first trimester	Placebo-controlled double-blind randomised study: – 500 micrograms PGE ₂ gel applied intracervically 6 hours before curettage – placebo gel applied intracervically 6 hours before curettage	No abortion or vaginal bleeding occurred in any of the women. After 500 micrograms PGE ₂ gel, mean free passability was significantly higher than in placebo group. Prostaglandin pretreatment led to a significant increase in dilation. Adverse effects: 17 of the 25 PGE ₂ -treated women complained of lower abdominal pain; gastrointestinal adverse effects were observed. In placebo group there were no undesired symptoms. No intra- or postoperative complications occurred in PGE ₂ gel-treated group	
Henshaw and Templeton	295	90 primigravid women for late first-trimester vacuum aspiration TOP between 9 and 13 weeks	RCT of: – 200 mg mifepristone orally 36 hours before operation – placebo – 1-mg gemeprost vaginal pessary 3–4 hours preoperatively	No significant differences between active treatment groups in: baseline cervical dilatation; force required to dilate cervix; volume of intraoperative blood loss. Both drugs were significantly more effective than placebo. Significantly fewer women in mifepristone group had adverse effects than in gemeprost group	Mifepristone oral route easier and cheaper

Evidence table 10. Cervical priming, randomised controlled trials (first-trimester abortion) (continued)

Author	Ref.	Population	Intervention	Results	Comments
el-Refaey <i>et al.</i>	211	90 primigravid women requesting termination between 9 and 13 weeks	RCT groups of: – gemeprost – vaginal misoprostol – controls	Both induced clinical and histochemical changes that were significantly different from controls and were likely to have therapeutic value. Misoprostol is cheap, easily stored and associated with few adverse effects	Cervical predilatation with misoprostol may be considered in all women having surgically induced abortions
Ngai, Tang <i>et al.</i>	296	75 women (primiparous and multiparous) undergoing vacuum aspiration between 6 and 12 weeks	– oral misoprostol – placebo group	In nulliparous women, median cervical dilatation in treatment group was significantly greater than that in placebo group (7.8 mm versus 3.7 mm). In multiparous women, difference was also statistically significant (9.8 mm versus 6 mm). Ease of dilatation, assessed subjectively by the operating surgeons, was significantly improved in treatment group. Significant reduction in duration of operation and mean blood loss in treatment group. Adverse effects encountered in treatment group were mild and well accepted by the women	Oral misoprostol is an effective and safe method for cervical dilatation prior to vacuum aspiration in first-trimester pregnancy
Ngai, Yeung <i>et al.</i>	297	64 nulliparous women, 6–12 weeks of pregnancy, undergoing vacuum aspiration TOP	Randomised to: – 400 micrograms misoprostol orally – 1 mg vaginal gemeprost at 12 hours prior to vacuum aspiration – 1 mg vaginal gemeprost at 3 hours prior to vacuum aspiration	Median cervical dilatation at vacuum aspiration in the misoprostol group was significantly greater than that in the gemeprost group (8 mm versus 7 mm). Preoperative adverse effects were significantly less frequent in the misoprostol group. Ease of dilatation assessed subjectively by the operating surgeons was improved significantly in the misoprostol group. Duration of operation and blood loss were similar in both groups	Since misoprostol is also much cheaper and more convenient to use, authors conclude that oral misoprostol is better than vaginal gemeprost for cervical dilatation prior to vacuum aspiration in first-trimester pregnancy
Ngai, Yeung <i>et al.</i>	298	100 nulliparous women undergoing TOP between 8 and 12 weeks of gestation	Prospective randomised trial. Group 1: placebo and misoprostol 400 micrograms 36 and 12 hours respectively before vacuum aspiration Group 2: 200mg mifepristone and placebo 36 and 12 hours respectively prior to operation	No significant differences in: – baseline cervical dilatation – incidence of side effects – amount of blood loss – duration of procedure.	Misoprostol and mifepristone are of similar effectiveness for cervical priming prior to vacuum aspiration in nulliparous women
Lawrie <i>et al.</i>	299	60 consecutive women scheduled for daycase suction TOP	Randomised to: – 400 micrograms oral misoprostol, self-administered 12 hours before surgery – 800 micrograms vaginally, 2–4 hours prior to surgery	No significant differences between oral and vaginal treatment groups in relation to basal dilatation, cumulative force to achieve 9-mm dilatation or gastrointestinal adverse effects. Those in oral group experienced more severe pain and heavier preoperative bleeding. 2 women in oral group experienced incomplete abortion at home after taking misoprostol and one other patient required early admission because of heavy bleeding	Because of unpredictability of action of oral misoprostol, with incomplete abortion or heavy bleeding occurring prior to admission in three women, authors cannot recommend the dosage schedule evaluated in this study for routine clinical use

Evidence table 10. Cervical priming, randomised controlled trials (first-trimester abortion) (continued)

Author	Ref.	Population	Intervention	Results	Comments
Fong <i>et al.</i>	300	60 women undergoing vacuum aspiration abortion	Randomisation to: – 200 micrograms misoprostol vaginally – 400 micrograms misoprostol vaginally	Only 7 (23.3%) of 200-micrograms group achieved a dilatation of ≥ 8 mm, compared with 29 (96.7%) in 400-micrograms group. Mean cervical dilatation in 200-micrograms and 400-micrograms groups were 6.4 mm and 8.2 mm, respectively. No conferred benefit from increasing insertion to aspiration interval beyond 3 hours	Vaginal application of 400 micrograms misoprostol appears to be the optimum dose for preabortion cervical priming in first trimester
Singh <i>et al.</i>	192	121 women undergoing vacuum aspiration abortion	Randomisation to: – 200 micrograms misoprostol vaginally – 400 micrograms misoprostol vaginally – 600 micrograms misoprostol vaginally – 800 micrograms misoprostol vaginally Vacuum aspiration was performed 3–4 hours after the insertion of misoprostol tablets	29 (96.7%) women in 400-micrograms group and all in 600-micrograms and 800-micrograms groups achieved cervical dilation of at least 8 mm. Success rate for 200-micrograms group was only 23.3%, significantly less efficacious than 400-micrograms dose (OR 95.3, 95% CI 10.9–830.9) No significant difference among 400-, 600- and 800-micrograms groups with respect to achieving cervical dilation at least 8 mm. 800 micrograms was associated with significantly more adverse effects than 600 micrograms (preoperative and intraoperative blood loss, abdominal pain, products of conception at os, fever higher than 38°C). When 400 micrograms and 600 micrograms were compared, higher dose also was associated with significantly more adverse effects	Vaginal application of 400 micrograms misoprostol is optimal dose for vacuum aspiration preabortion cervical dilation in first-trimester nulliparae

Evidence table 11. Studies relating to cervical priming prior to surgical abortion, published since 1999

Study	Study type	Year	Ref.	Subjects	Interventions	Findings
Misoprostol prior to MVA: placebo-controlled trials						
Okanlomo <i>et al.</i>	RCT	1999	301	136 1st trimester	Misoprostol 600 micrograms orally x 2 versus placebo x 2, 12 and 4 hours prior to MVA	At gestations > 8 weeks, priming reduced operative time and blood loss
de Jonge <i>et al.</i>	RCT	2000	302	287 1st trimester	Misoprostol 600 micrograms versus placebo self-administered vaginally 2–4 hours prior to MVA	Self-administration of this regimen is feasible, safe and effective
Misoprostol: route and dose						
Singh <i>et al.</i>	RCT	1999	303	60 nulliparous, 1st trimester	Misoprostol: 400 micrograms vaginally 3 hours prior to suction versus 600 micrograms vaginally 2 hours prior to suction	400 micrograms/3 hours regimen is more effective and has fewer adverse effects
Singh <i>et al.</i>	RCT	1999	304	180 nulliparous, 1st trimester	Misoprostol: 400 micrograms vaginally 3 hours prior to suction versus 600 micrograms vaginally 2 hours prior to suction versus 800 micrograms vaginally 2 hours prior to suction	400 micrograms/3 hours regimen is more effective and has fewer adverse effects
Henry and Haukkamaa	RCT	1999	305	199 1st trimester	Misoprostol 200 micrograms vaginally, > 4 hours prior to suction versus gemeprost 1 mg > 3 hours prior to suction	Similar efficacy; significantly fewer adverse effects with misoprostol
Ngai <i>et al.</i>	RCT	1999	306	225 nulliparous, 1st trimester	Placebo versus misoprostol: oral 200 micrograms; oral 400 micrograms; vaginal 200 micrograms; vaginal 400 micrograms; 3 hours prior to suction	Efficacy and adverse effects of 400 micrograms orally and 400 micrograms vaginally is similar
Singh <i>et al.</i>	RCT	1999	307	120 nulliparous, 1st trimester	Misoprostol 200 micrograms in water, vaginally versus misoprostol 200 micrograms in acetic acid, vaginally 3–4 hours prior to suction	No difference in efficacy or adverse effects
Carbonell <i>et al.</i>	RCT	2001	308	900 up to 63 days	Misoprostol 400 micrograms orally 8 hours prior to suction versus misoprostol 400 micrograms, self-administered vaginally 4 hours prior to suction	Vaginal self-administration was more effective with a much lower frequency of adverse effects
Todd <i>et al.</i>	Ret. cohort	2002	309	110 at 14–18 weeks	Misoprostol 600 micrograms buccally 2–4 hours prior to D&E versus laminaria tents 12 hours prior to D&E	Similar efficacy
Tang <i>et al.</i>	RCT	2002	310	40 1st trimester	Misoprostol 400 micrograms: sublingual versus oral versus vaginal versus vaginal + water 6 hours prior to suction	Serial serum levels showed the sublingual route had greatest bioavailability and earliest peak level
Saxena <i>et al.</i>	RCT	2003	311	100 1st trimester	Misoprostol 400 micrograms sublingually 3 hours prior to suction versus no priming	Sublingual misoprostol was effective and acceptable compared with no priming
Vimala <i>et al.</i>	RCT	2003	312	60 1st trimester	Misoprostol 400 micrograms sublingually versus placebo, 2 hours prior to suction	Sublingual misoprostol was effective compared with placebo but had significant adverse effects
Comparisons of various priming agents						
Maclsaac <i>et al.</i>	RCT	1999	313	106 1st trimester	Misoprostol 400 micrograms orally versus misoprostol 400 micrograms vaginally versus <i>Laminaria</i> tent, 4 hours prior to suction	Vaginal misoprostol most effective and acceptable of the 3 regimens
Ashok <i>et al.</i>	RCT	2000	314	90 1st trimester	Misoprostol 800 micrograms vaginally 2–4 hours prior to suction versus mifepristone 200 mg orally 24 or 48 hours prior to suction	Mifepristone 48 hours prior most effective. Acceptability similar

Evidence table 11. Studies relating to cervical priming prior to surgical abortion, published since 1999 (continued)

Study	Study type	Year	Ref.	Subjects	Interventions	Findings
Facchinetti <i>et al.</i>	RCT	2000	315	36 nulliparous, 1st trimester	Placebo versus 1% intracervical nitroprusside gel 6 hours prior to suction versus 2% nitroprusside gel 3 hours prior to suction	Both regimens of nitroprusside were effective compared with placebo, with no significant adverse effects
Ledingham <i>et al.</i>	RCT	2001	316	66 nulliparous, 1st trimester	Isosorbide mononitrate 40 mg vaginally versus misoprostol 400 micrograms vaginally versus both agents together, 3 hours prior to suction	No advantage of combining isosorbide mononitrate with misoprostol
Zalanyi	RCT	2001	317	52 nulliparous, 1st trimester	200 mg danazol vaginally x 3 over 2 days versus placebo, both followed by misoprostol 200 micrograms vaginally 5 hours prior to suction	Pretreatment with danazol enhances the effect of misoprostol in a manner similar to antigestagen
Lindelius <i>et al.</i>	Ret. cohort	2003	318	622 1st trimester	Lamicel® tent, 1–4 hours prior to suction versus gemeprost 1 mg 2–8 hours prior to suction	No information on efficacy. Complication rate higher with Lamicel
Ekerhovd <i>et al.</i>	RCT	2003	319	90 nulliparous, 1st trimester	Misoprostol 400 micrograms, vaginally, versus gemeprost 1 mg, 3–4 hours prior to suction	Similar efficacy. No information on adverse effects

Evidence table 12. Studies relating to combined early medical abortion regimens with mifepristone (oral) and prostaglandin, published since 1999

Authors	Study type	Year	Ref.	Subjects (timing)	Intervention(s)	Findings
Trussell and Ellertson	SR	1999	320	Multiple trials, including 13 mifepristone/misoprostol	Various mifepristone–misoprostol regimens	‘Success’ rates: 85–100%
Schaff <i>et al.</i>	CS	1999	55	933 (up to 56 days)	Mifepristone 200 mg + misoprostol 800 micrograms vaginally (self-administered at home)	Complete abortion rate: 97% Continuing pregnancy: 0.5% Acceptability: 94%
Takkar <i>et al.</i>	RCT	1999	321	101 (up to 56 days)	Mifepristone 200 mg + Meteneprost® (Cayman Chemical Co., Ann Arbor, MI) 5 mg vaginally or misoprostol 600 micrograms orally	Misoprostol regimen significantly more effective
Sandstrom <i>et al.</i>	RCT	1999	322	64 (up to 56 days)	Mifepristone 600 mg + gemeprost 1 mg 24 hours later or gemeprost 1 mg 48 hours later	No difference in efficacy or adverse effects
Kahn <i>et al.</i>	Meta-anal.	2000	91	54 studies, including 18 mifepristone/misoprostol	Various regimens	Efficacy decreases with increasing gestation: ≤ 49 days: success 94–96% 50–56 days: 91% ≥ 57 days: 85–95% ≥ 2 misoprostol doses improves efficacy at some gestations
Schaff <i>et al.</i>	CS	2000	323	1137 (up to 63 days)	Mifepristone 200 mg + misoprostol 800 micrograms vaginally (self-administered at home or clinician administered, according to preference) 48 hours later. Option of 2nd dose of misoprostol at follow-up	Complete abortion rate: 97% up to 56 days 96% at 57–63 days Continuing pregnancy: 0.44% Acceptability 91%
Aubeny and Chatellier	RCT	2000	234	237 (up to 49 days)	Mifepristone 600 mg + misoprostol 400 micrograms orally or vaginally. Option of 2nd dose of misoprostol at 3 hours	Complete abortion rate: 98.7% No significant difference between groups
ICMR Task Force	RCT	2000	325	893 (up to 63 days)	Mifepristone 200 mg + Meteneprost® 5 mg vaginally or misoprostol 600 micrograms orally	Similar efficacy. More adverse effects in oral misoprostol group
Bartley <i>et al.</i>	CS	2000	90	3161 (up to 63 days)	Mifepristone 200 mg + gemeprost 0.5 mg vaginally	Complete abortion rate: 96.2% Continuing pregnancy: 1.4% Efficacy was better at lower gestations and in nulliparous women
Schaff <i>et al.</i>	RCT	2000	326	2295 (up to 56 days)	Mifepristone 200 mg + misoprostol 800 micrograms vaginally (self-administered at home) 1 day versus 2 days versus 3 days later. Option of 2nd dose of misoprostol at follow-up	Complete abortion rate: 97.2% Continuing pregnancy: 0.7% No difference between groups, i.e. misoprostol can be given any time between 1 and 3 days after mifepristone
Pymar <i>et al.</i>	CS	2001	327	40 (up to 49 days)	Mifepristone 200 mg + misoprostol 800 micrograms vaginally (self-administered at home) 6–8 hours later. Option of 2nd dose of misoprostol at 48 hours	Complete abortion rate: 98%
Bartley <i>et al.</i>	RCT	2001	328	999 (up to 63 days)	Mifepristone 200 mg + misoprostol 800 micrograms or gemeprost 0.5 mg vaginally	Complete abortion rate: 98.7% (misoprostol) versus 96.2% (gemeprost) “vaginal misoprostol is the preferred prostaglandin because of fewer failures particularly at > 49 days”
Xu <i>et al.</i>	Prosp. cohort	2001	329	192; 35 with scarred uterus (up to 49 days)	Mifepristone 25 mg twice daily for 3 days + misoprostol 600 micrograms orally	Regimen appeared safe and effective in women with scarred uterus
Creinin <i>et al.</i>	RCT	2001	330	86 (up to 49 days)	Mifepristone 600 mg + misoprostol 400 micrograms orally 6–8 hours later versus 48 hours later. Option of 2nd dose of misoprostol at 48 hours	6–8 hour regimen was significantly less effective

Evidence table 12. Studies relating to combined early medical abortion regimens with mifepristone (oral) and prostaglandin, published since 1999 (continued)

Authors	Study type	Year	Ref.	Subjects (timing)	Intervention(s)	Findings
Schaff <i>et al.</i>	RCT	2001	331	1168 (up to 63 days)	Mifepristone 200 mg + misoprostol 400 micrograms orally x 2, 2 hours apart, versus misoprostol 800 micrograms vaginally (self-administered at home) 1 day later	Complete abortion rate: 90% (oral misoprostol) versus 97% (vaginal misoprostol): "vaginal misoprostol is more effective"
Allen <i>et al.</i>	CS	2001	332	4393 (up to 63 days)	Mifepristone 200 mg + misoprostol 800 micrograms vaginally (after varying time intervals)	Complete abortion rate 97.4%
Fox <i>et al.</i>	CS	2002	333	80 (at 50 to 63 days)	Mifepristone 200 mg + misoprostol 800 micrograms vaginally 6–8 hours later. Option of 2nd dose of misoprostol at 48 hours	These pilot results suggest the regimen is effective
Ashok <i>et al.</i>	CS	2002	89	4132 (up to 63 days)	Mifepristone 200 mg + misoprostol 800 micrograms vaginally. Option of 2nd dose of misoprostol (400 micrograms) at 4 hours	Complete abortion rate: 98% (incorporating the 2nd dose option into the regimen reduced the continuing pregnancy rate and eliminated the gestation-effect on overall efficacy)
Schaff <i>et al.</i>	RCT	2002	334	1045 (up to 63 days)	Mifepristone 200 mg + misoprostol 400 micrograms orally (x 1 or x 2) 2 hours apart versus misoprostol 800 micrograms vaginally (self-administered at home) 1 day later	Complete abortion rate: 84% (400 micrograms oral misoprostol) versus 92% (800 micrograms oral misoprostol) versus 96% (vaginal misoprostol): "vaginal misoprostol is more effective"
Tang <i>et al.</i>	RCT	2002	335	150 (up to 63 days)	Mifepristone 200 mg + misoprostol 800 micrograms orally (with misoprostol 400 micrograms twice daily for 7 days) versus misoprostol 800 micrograms vaginally (with misoprostol 400 micrograms twice daily for 7 days) versus misoprostol 800 micrograms vaginally	1-week course of misoprostol did not diminish post-abortion bleeding
Tang <i>et al.</i>	CS	2002	336	100 (up to 63 days)	Mifepristone 200 mg + misoprostol 800 micrograms sublingually	Complete abortion rate: 94%: "further trials needed to compare with vaginal route"

Routes as indicated; prostaglandin administered 48 hours after mifepristone, except where stated; CS = case series; Meta-anal. = meta-analysis; Prosp. cohort = prospective cohort; RCT = randomised controlled trial; SR = systematic review

Evidence table 13. Studies comparing various regimens used in first-trimester abortions

Authors	Ref.	Gestational limits	Regimen	Subjects (n)	Reported success rate (%)	P	Results and conclusions
Oral misoprostol or vaginal gemeprost following mifepristone (200 mg, 400 mg or 600 mg)							
Sang <i>et al.</i>	337	≤63 days of amenorrhoea	50 mg oral mifepristone followed by 4 doses 25 mg oral mifepristone at 12-hour intervals + 600 micrograms oral misoprostol 48 hours later	284	94.4	1.0	Success defined as complete abortion without surgical intervention. Subjects whose outcome was undetermined were counted as failures (3 in group 1 and 1 in group 2). Maximum duration not stated. Conclusion: misoprostol in combination with mifepristone was as effective as PG05 vaginal suppository
			200 mg oral mifepristone + 600 micrograms oral misoprostol 48 hours later	141	94.6		
McKinley <i>et al.</i>	338	≤63 days of amenorrhoea	200 mg oral mifepristone + 600 micrograms oral misoprostol 48 hours later	110	93.6	1.0	Success defined as complete abortion without surgical intervention. Maximum duration not stated. Conclusions: 1) recommended dose of mifepristone could be reduced from 600 mg to 200 mg without the loss of clinical efficacy 2) combination of mifepristone and 600 micrograms misoprostol is a highly effective alternative to vacuum aspiration for inducing women <50 days of amenorrhoea 3) at gestations of > 56 days, this combination may result in too many incomplete abortions to be clinically effective
			600 mg oral mifepristone + 600 micrograms oral misoprostol 48 hours later	110	93.6		
World Health Organization	191	7–28 days of menstrual delay	200 mg oral mifepristone + 1 mg vaginal gemeprost 48 hours later	388	93.8	0.95	Success defined as complete abortion without surgical intervention. Subjects whose outcome was undetermined (including 6 who did not take or vomited the mifepristone tablets) were counted as failures (5 in group 1; 5 in group 2; 7 in group 3). Subjects not meeting inclusion criteria were excluded. Maximum duration not stated. Conclusion: for termination at early pregnancy a single dose of 200 mg mifepristone is as effective as currently recommended dose of 600 mg, when used in combination with vaginal pessaries of 1 mg gemeprost
			400 mg oral mifepristone + 1 mg vaginal gemeprost 48 hours later.	391	91.8		
			600 mg oral mifepristone + 1 mg vaginal gemeprost 48 hours later.	389	94.3		
Oral misoprostol versus vaginal gemeprost following mifepristone (200 mg)							
Baird <i>et al.</i>	210	≤63 days of amenorrhoea	200 mg oral mifepristone + 0.5 mg vaginal gemeprost 48 hours later	391	96.7	0.164	Success defined as complete abortion without surgical intervention. 2 women with elective surgical intervention before prostaglandin and 21 women LFU excluded. Maximum duration 12–16 days after administration of prostaglandin. Recommended dose of mifepristone and gemeprost can be reduced without impairing clinical efficacy in pregnancies < 63 days amenorrhoea
			200 mg oral mifepristone + 600 micrograms oral misoprostol 48 hours later	386	94.6		

Evidence table 13. Studies comparing various regimens used in first-trimester abortions (continued)

Authors	Ref.	Gestational limits	Regimen	Subjects (n)	Reported success rate (%)	P	Results and conclusions
<i>Oral misoprostol versus vaginal misoprostol following mifepristone</i>							
el-Refaey <i>et al.</i>	207	≤ 63 days of amenorrhoea	600 mg oral mifepristone + 800 micrograms oral misoprostol 36–48 hours later	130	86.9	<0.001	Success defined as complete abortion without surgical intervention after administration of misoprostol. Maximum duration 14 days after misoprostol administration. Incidence of vomiting and diarrhoea significantly higher in oral group
			600 mg oral mifepristone + 800 micrograms vaginal misoprostol 36–48 hours later	133	94.7		

Evidence table 14. Studies comparing various agents used in second-trimester medical abortions

Authors	Ref.	Population	Intervention	Results	Comments
<i>Mifepristone versus placebo</i>					
Rodger and Baird	218	100 women at 12–18 weeks	Double-blind randomised trial of 600 mg oral mifepristone or placebo tablets, 36 hours before the administration of gemeprost pessaries	Median interval between administration of prostaglandin and abortion was significantly shorter in mifepristone group (6.8 hours) compared with placebo group (15.8 hours). Women pretreated with mifepristone required significantly fewer gemeprost pessaries to induce abortion and experienced significantly less pain than the women who received placebo	
<i>Mifepristone: different doses and routes</i>					
el-Refaey and Templeton	213	70 women at 13–20 weeks	2 different routes of administration: vaginal or a combination of vaginal and oral Pre-treated with mifepristone	Abortion achieved in 97% (95% CI 90–100%) of cases without resort to other prostaglandin agents Mean induction–abortion time for the studied population was 6.4 hours (95% CI 5.6–7.0 hours). No significant difference was found between routes of administration	Authors recommend that, following pretreatment with mifepristone, misoprostol is used as the prostaglandin of choice to induce abortion in the 2nd trimester
Webster <i>et al.</i>	221	70 women 13–20 weeks	600 mg mifepristone or 200 mg mifepristone 36–48 hours prior to misoprostol	Geometric mean induction–abortion interval was 6.9 hours (95% CI 5.8–8.4) and 6.9 hours (95% CI 5.8–8.2) in the 600 mg and 200 mg groups, respectively (not significant). Median dose of misoprostol was 1600 micrograms (3 doses) in each group. Analgesic requirements and prostaglandin-related adverse effects similar between groups. Overall, 11.4% of women required surgical evacuation of the uterus as a result of retained placenta	Dose of mifepristone used in second-trimester abortion can be reduced from 600 mg to 200 mg
Frydman <i>et al.</i>	339	35 women undergoing TOP for fetal or maternal indications at 15–34 weeks	Randomised double-blind study of 150 mg or 450 mg mifepristone as pretreatment prior to prostaglandins	No toxicity or maternal morbidity was recorded. In 3 women, onset of labour occurred spontaneously before prostaglandin administration	
<i>Mifepristone versus Laminaria tents</i>					
Ho <i>et al.</i>	340	62 women undergoing TOP in 2nd trimester, 14–20 weeks	Prospective randomised comparative trial of: 600 mg mifepristone 36 hours before administration of gemeprost – medium-sized <i>Laminaria</i> tent inserted 12 hours before gemeprost Pregnancies in both groups were terminated with vaginal gemeprost, 1 mg every 3 hours up to a maximum of 5 mg/day	Median induction–abortion interval in mifepristone group (7.5 hours) was significantly shorter than that in <i>Laminaria</i> tent group (11 hours) and significantly fewer gemeprost pessaries were required. There was no significant difference in the amount of narcotic analgesia required or incidence of adverse effects between the 2 groups	Mifepristone is more effective than <i>Laminaria</i> tent in shortening the induction–abortion interval in termination of 2nd trimester pregnancies

Evidence table 14. Studies comparing various agents used in second-trimester medical abortions (continued)

Authors	Ref.	Population	Intervention	Results	Comments
Jain and Mishell	341	68 women 12–22 weeks of gestation with either an intrauterine fetal death ($n = 40$) or medical or genetic indications for TOP ($n = 30$)	Women were randomised to receive 200 micrograms misoprostol vaginally every 12 hours with ($n = 35$) or without ($n = 33$) intracervical placement of <i>Laminaria</i> concurrently with the 1st dose of misoprostol	Rate of abortion 24 hours after initiation of treatment was 69.7% in women receiving misoprostol alone and 68.6% in women treated with misoprostol and <i>Laminaria</i> . Abortion rates 48 hours after initiation of treatment were 84.8% and 91.4%, respectively, an insignificant difference. There were no significant differences in incidence of fever, vomiting, diarrhoea, or pain	<i>Laminaria</i> tents inserted concurrently with the first dose of misoprostol do not significantly improve the abortifacient effect of vaginal misoprostol in 2nd trimester of pregnancy
Misoprostol versus gemeprost					
el-Refaey <i>et al.</i>	342	60 women 13–20 weeks of gestation pretreated with mifepristone 600 mg	Misoprostol 400 micrograms orally (up to 3 doses) followed by gemeprost vaginal pessary 1 mg up to 2 doses Gemeprost vaginal pessary 1 mg up to 5 doses	No significant differences between 2 groups in any of the main outcome measures	
Dickinson <i>et al.</i>	343	100 women 14–28 weeks of gestation	A prospective randomised, double-blind, controlled clinical trial of 1 mg gemeprost 3 hourly for 5 doses or 200 micrograms misoprostol 6 hourly for 4 doses, intravaginally. The therapeutic regimens were repeated if undelivered by 24 hours	Delivery within 24 hours occurred in 75.1% of women receiving gemeprost and 74.9% receiving misoprostol (NS). Median time from prostaglandin commencement to delivery was similar: gemeprost 13.7 hours versus misoprostol 16.9 hours (NS). NS = not significant. Significant reduction in incidence of vomiting in women randomised to misoprostol occurred (34% versus 13.2%). No significant difference in incidence of maternal fever $> 37.5^{\circ}\text{C}$, nausea, diarrhoea or placental retention	Intravaginal misoprostol performs as effectively as gemeprost in achieving delivery in the second trimester without increase in adverse effects and displaying a significant cost advantage
Nuutila <i>et al.</i>	344	81 women 12–24 weeks of gestation	Group A: 100 micrograms misoprostol intravaginally at 6-hourly intervals ($n = 27$) Group B: 200 micrograms misoprostol intravaginally at 12-hourly intervals ($n = 26$) Group C: 1 mg gemeprost intravaginally at 3-hourly intervals ($n = 28$) Regimens continued until abortion or for 36 hours	Final rates of terminations 74% in group A; 92% in group B; 89% in group C. Abortion was complete in 37%, 61%, and 32% in each group, respectively ($P = 0.03$, when group B was compared with the 2 other groups). Induction – abortion interval was longer ($P = 0.001$) in misoprostol groups than in gemeprost group. Less pain ($P = 0.01$), diarrhoea ($P = 0.001$) and vomiting ($P = 0.01$) in misoprostol groups than in gemeprost group. Mean blood loss in misoprostol groups was lower than in gemeprost group ($P = 0.001$)	Intravaginal application of 200 micrograms misoprostol at 12-hourly intervals in induction of 2nd-trimester abortion is equally effective as a standard gemeprost regimen Misoprostol causes fewer adverse effects and is cheaper and more practical to use
Eng and Guan	345	50 women 13–26 weeks	Prospective, randomised study of intravaginal misoprostol (200 micrograms 3-hourly, maximum of 6 doses versus gemeprost 1 mg 3-hourly, maximum of 5 doses	84% in misoprostol group aborted versus 68% in gemeprost group within 24 hours after initiation of therapy. In misoprostol group, abortion rate was influenced by gestational age with 100% abortion rate for those > 17 weeks of gestation compared with 67% for those with a gestational age of 13–16 weeks. Adverse effects were rare in both groups and no major complications were reported in either group	Misoprostol was at least as effective as gemeprost as an abortifacient for intrauterine death in 2nd-trimester pregnancy. It was also less costly and had few adverse effects

Evidence table 14. Studies comparing various agents used in second-trimester medical abortions (continued)

Authors	Ref.	Population	Intervention	Results	Comments
Ho <i>et al.</i>	346	50 women 14–20 weeks	200 mg mifepristone given 36–48 hours before administration of prostaglandins: Group A (<i>n</i> = 25): 400 micrograms oral misoprostol every 3 hours, up to 5 doses Group B (<i>n</i> = 25): 1 mg vaginal gemeprost every 6 hours, up to four doses	No significant difference in median induction–abortion intervals (8.7 hours in group A; 10.8 hours in group B) or incidence of adverse effects between 2 groups	Misoprostol is as effective as gemeprost in termination of 2nd-trimester pregnancy when combined with mifepristone
Wong <i>et al.</i>	347	70 women 14–20 weeks	Prospective randomised trial: Group A: 1 mg vaginal gemeprost every 3 hours for a maximum of 5 doses in 1st 24 hours Group B: 400 micrograms vaginal misoprostol every 3 hours for a maximum of 5 doses in 24 hours	Median induction–abortion interval in vaginal misoprostol group was significantly shorter than that in gemeprost group (14.1 hours versus 19.5 hours); percentage of women who achieved successful abortion within 24 hours in misoprostol group was significantly higher than that in gemeprost group (80.0% versus 58.6%). No significant difference in incidence of adverse effects between groups except for diarrhoea, which was more common in gemeprost group. Incidence of fever was more common in misoprostol group	Vaginal misoprostol is more effective than gemeprost in termination of 2nd-trimester pregnancy
Misoprostol versus other prostaglandins					
Jain and Mishell	212	55 pregnant women 12–22 weeks of gestation who were undergoing TOP for either intrauterine fetal death (<i>n</i> = 37) or medical or genetic reasons (<i>n</i> = 18)	Prospective, randomised trial of intravaginal misoprostol 200 micrograms every 12 hours versus prostaglandin E ₂ 20 mg intravaginally every 3 hours	Rate of successful abortions within 24 hours 81% with PGE ₂ and 89% with misoprostol (<i>P</i> = 0.47). All women who received misoprostol had successful abortions within 38 hours. Among those who had an abortion within 24 hours, mean interval from treatment to abortion similar in both groups (10.6 hours with PGE ₂ and 12.0 hours with misoprostol: NS). Rate of complete abortion 32% for PGE ₂ and 43% for misoprostol (NS) Adverse effects in those more frequent in women receiving PGE ₂ than receiving misoprostol	Misoprostol is at least as effective as PGE ₂ for TOP in 2nd trimester involving either a dead or a living fetus, but it is easier to administer and is associated with fewer adverse effects. It is also less costly NS = not significant
Ghorab and El-Helw	348	40 women undergoing TOP for congenital abnormalities or intrauterine fetal death 16–24 weeks	Group A: extra-amniotic prostaglandin F _{2α} Group B: intracervical misoprostol	In group A, all women aborted within 28 hours and 80% within 20 hours. Medical TOP was complete in 65% of cases In group B, all women aborted within 20 hours, 90% within 13 hours. Medical TOP was complete in 85% of cases. Induction–abortion intervals for group A and B were 16 ± 5.9 hours and 10.3 ± 4 hours, respectively (SS). The incidence of prostaglandin-associated pyrexia, vomiting and diarrhoea were significantly increased in group A (SS). Abdominal pain similar in both groups. No post-abortive haemorrhage or infection	Intracervical administration of misoprostol appears to be effective and well tolerated with fewer adverse effects and no complications. Larger, randomised comparative studies should be carried out to assess its potential advantages SS = statistically significant.

Evidence table 14. Studies comparing various agents used in second-trimester medical abortions (continued)

Authors	Ref.	Population	Intervention	Results	Comments
Yapaar <i>et al.</i>	349	340 women with poor cervical condition (Bishop score ≤ 4) undergoing TOP 14–28 weeks of gestation	Prospective randomised study: Group A: extra-amniotic ethacridine lactate ($n = 82$) Group B: intracervical PGE ₂ gel ($n = 100$) Group C: intravenous infusion of concentrated oxytocin ($n = 36$) Group D: vaginal misoprostol ($n = 49$) Group E: balloon insertion ($n = 73$)	Abortion within 48 hours in groups A to E were achieved in: A – 98.8%; B – 90%; C – 97.3%; D – 77.5%; E – 97.2%, respectively Overall median induction–abortion interval \pm SD (in hours) in each of groups A to E were as follows: 15.7 \pm 9.6; 20.0 \pm 14.5; 12.2 \pm 14.4; 24.0 \pm 22.2; 16.0 \pm 15.4	In comparison with the 5 methods, use of extra-amniotic ethacridine, intravenous concentrated oxytocin and balloon was found to provide more effective treatment than intracervical PGE ₂ and misoprostol in terms of achievement of abortion within 24 and 48 hours
Owen and Hauth	350		Misoprostol 200 micrograms intravaginally every 12 hours Concentrated oxytocin plus low-dose vaginal PGE ₂ suppositories (10 mg every 6 hours)	Success defined as an induction–delivery interval ≤ 24 hours. Analysis of 1st 30 (15 misoprostol, 15 concentrated oxytocin) women found that misoprostol was associated with a lower success rate (67% versus 87%, NS), a longer induction–delivery interval (22 hours versus 18 hours, NS), a higher rate of retained placenta requiring curettage (27% versus 13%, NS) and a higher live birth rate (50% versus 0%)	Misoprostol administered as vaginal tablets in a dose of 200 micrograms every 12 hours was not satisfactory for mid-trimester TOP in an unselected population NS = not significant
Gemeprost versus other prostaglandins					
Kjohde <i>et al.</i>	351	40 women 13–22 weeks	Open prospective randomised study of gemeprost pessaries ($n = 20$) or dinoproston gel intracervically ($n = 20$) intracervically All women were pretreated with a 3-mm diameter <i>Laminaria</i> tent applied intracervically for about 4 hours	Success rate 95% for gemeprost and 75% for dinoproston within approximately 48 hours Median abortion time calculated from insertion of <i>Laminaria</i> tent for successful cases was 22 hours for gemeprost and 24 hours 5 minutes for dinoproston (NS). Difference between dinoproston and gemeprost in parous women was statistically significant. No significant difference was found in demand for pethidine or in infection rate between groups. No major adverse effects of treatment were found	Gemeprost seems to be most appropriate of 2 noninvasive methods because of a 95% success rate within 48 hours but also due to its simplicity in design NS = not significant
Cameron and Baird	219	120 women requesting TOP 12–16 weeks of gestation	Open randomised trial of gemeprost vaginal pessaries and extra-amniotic infusion of PGE ₂	Success rates 77% and 79% for pessary and infusion groups, respectively; these rates were unaffected by parity. No significant difference in cumulative abortion rate between groups. No differences in induction–abortion interval, nor in time taken to onset of pain or bleeding. Adverse effects, experienced both during treatment and during 6 weeks after abortion, were similar in both groups	Gemeprost vaginal pessaries are an effective alternative to the extra-amniotic infusion of PGE ₂ for TOP in early 2nd trimester
Andersen <i>et al.</i>	352	152 women 12–25 weeks	Open, randomised, controlled 6-centre study of gemeprost 1 mg vaginal pessaries at 3-hourly intervals, up to a maximum of 5 mg ($n = 75$) versus a single 40-mg intra-amniotic dose of PGF _{2α} ($n = 66$)	24-hour success rate 81% in gemeprost and 64% in the PGF _{2α} group ($P < 0.02$). Mean abortion times 14.3 hours in gemeprost and 14.8 hours in PGF _{2α} groups. Mean time to onset of pain was shorter and more women experienced blood loss over 100 ml during induction in PGF _{2α} group than in gemeprost group ($P < 0.02$). Nature and severity of other adverse effects were comparable between groups	Gemeprost had significantly better efficacy and was easier and safer as compared with the PGF _{2α} treatment

Evidence table 14. Studies comparing various agents used in second-trimester medical abortions (continued)

Authors	Ref.	Population	Intervention	Results	Comments
Waldron <i>et al.</i>	353	58 women requesting TOP 14–20 weeks	Open, randomised single-centre trial of: gemeprost (16,16 dimethyl-PGE ₁ -methyl ester) pessaries versus intra-amniotic injection of PGF _{2α} combined with hypertonic saline, intravenous oxytocin and a hygroscopic cervical dilator (Dilapan®)	No significant difference in induction-delivery interval for t ₂ groups. With the exception of an increased incidence of diarrhoea in gemeprost group, there was no significant difference in other adverse effects, analgesia requirements or retained placenta	Gemeprost pessaries are an effective alternative to more invasive methods previously used for induction of 2nd-trimester TOP
Mink <i>et al.</i>	354	68 women who required TOP 14–33 weeks because of a severe maternal disease or a fetal abnormality	Dinoprost-containing gel (500 micrograms) in intracervical application in a tylose-gel in 6–8 hourly intervals Gemeprost-containing vaginal suppository (1 mg) in 12-hourly intervals	Abortion was induced in 75% of cases within 24 hours, in 89% within 36 hours using gemeprost Mean induction time for gemeprost was 19.5 hours Using dinoprost only 19% of women had an abortion within 24 hours (44% within 36 hours, respectively), mean induction time was significantly longer (38.8 hours, <i>P</i> < 0.005) Additional systemic administration of Sulprostone® was necessary in 21% of cases using gemeprost and in 5% of cases using dinoprost. Severe complications did not occur and minor adverse effects such as nausea or vomiting were observed in single cases	Gemeprost can be used in cervical priming, even after 14 weeks of pregnancy; longer application interval of 12 hours results in a reduction of adverse effects without a decrease in efficacy
Varying doses of gemeprost					
Armatage and Luckas	355	100 women 12–20 weeks	Group A: gemeprost pessary every 3 hours Group B: gemeprost pessary every 6 hours Maximum of 5 doses	Median abortion interval in group A versus B: 16 hours versus 15 hours Cumulative abortion rates in groups A and B: 98% versus 91.8% The 6-hourly group required a significantly lower total dose of gemeprost to induce abortion. There was no difference in rates of adverse effects but those receiving pessaries every 6 hours required less analgesia	This study found no advantage in giving gemeprost every 3 hours
Thong and Baird	356	100 women requesting TOP 12–19 weeks	36 hours after treatment with 200 mg mifepristone, women were allocated at random to receive either: Group A: 4 × 1 mg gemeprost by vaginal pessary every 6 hours (<i>n</i> = 50) Group B: 4 × 0.5 mg gemeprost by vaginal pessary every 6 hours (<i>n</i> = 50) If abortion had not occurred after 24 hours, 5 × 1 mg of gemeprost was administered every 3 hours to both groups of women	Median abortion interval: slightly shorter in 1-mg group (7.8 hours versus 8.4 hours, <i>P</i> = 0.5) Cumulative abortion rates at 24 hours: 98% versus 96% Women in Group A required significantly more gemeprost to induce abortion than women in Group B Parous women in both groups required significantly less of the prostaglandin to induce abortion In Group B, median abortion interval significantly longer in primigravidae than multigravidae (9.5 versus 6.1 hours; <i>P</i> < 0.02) There were no significant differences between groups in incidence of vomiting, diarrhoea or request for analgesia	In parous women, dose of gemeprost can be reduced to 0.5 mg every 6 hours within the first 24 hours without loss of clinical efficacy

Evidence table 14. Studies comparing various agents used in second-trimester medical abortions (continued)

Authors	Ref.	Population	Intervention	Results	Comments
Thong and Baird	357	TOP 12–18 weeks	Open trial of: 5 x 1 mg gemeprost every 3 hours (<i>n</i> = 50) 4 x 1 mg gemeprost every 6 hours (<i>n</i> = 50) Significantly fewer pessaries were required to induce abortion in 6-hour gemeprost group (<i>P</i> < 0.01)	Median abortion interval was slightly shorter in the 3-hourly group. Cumulative abortion rates at 24 hours were similar (88% versus 82%). In women who aborted within 1st 24 hours, significantly fewer pessaries were required to induce abortion in 6-hour treatment group than the 3-hour group. Parous women in both treatment groups required fewer pessaries to induce abortion than did nulliparous women. No significant differences between groups regarding incidence of diarrhoea, vomiting or the request for analgesia	Results suggest that number of pessaries used to induce mid-trimester abortion could be reduced by lengthening interval between insertion of pessaries within the 1st 24 hours, without loss of clinical efficacy
Others					
Ho <i>et al.</i>	358	98 women 14–20 weeks	36–48 hours after oral administration of 200 mg of mifepristone, women were given either oral or vaginal misoprostol 200 micrograms every 3 hours for a maximum of 5 doses in 1st 24 hours. Women receiving oral misoprostol also were given a vaginal placebo (vitamin B6), whereas those receiving vaginal misoprostol were given an oral placebo. If they failed to abort, a second course was given by the same route	Median induction–abortion interval in vaginal group was significantly shorter than that in oral group (9 versus 13 hours) Percentage of women aborting within 24 hours in vaginal group was significantly higher than that in oral group (90% versus 69%) Median amount of misoprostol used in vaginal group also was significantly less than that in oral group (600 micrograms versus 1000 micrograms). No significant difference in incidence of adverse effects between groups except for fatigue and breast tenderness, which were more common in oral group 76% of women preferred oral route and 24.5% of women preferred vaginal route	Vaginal misoprostol was more effective than oral misoprostol in TOP of 2nd-trimester pregnancy after pretreatment with mifepristone. However, more women preferred oral route
Thong and Baird	359	98 women for TOP 12–18 weeks of gestation	A randomised study of: – mifepristone + gemeprost – dilapan + gemeprost – gemeprost alone: a single course of 4 x 1 mg gemeprost pessaries was administered every 6 hours. If abortion had not occurred after 24 hours, a further course of 5 x 1 mg pessaries was administered every 3 hours over the next 24 hours	In 1st 24 hours after administration of gemeprost, 95%, 85% and 72% of women aborted in the mifepristone, dilapan and the control groups, respectively. Median induction–abortion interval in mifepristone group (6.6 hours) was significantly shorter than other groups and fewer pessaries were required to induce abortion. Incidence of diarrhoea and vomiting lower in mifepristone than other groups	Mifepristone in combination with gemeprost is efficacious and this regimen is associated with fewer gastrointestinal adverse effects

Evidence table 15. Use of oxytocic agents to reduce blood loss at the time of surgical abortions

Study	Ref.	Population	Intervention	Results and conclusions
Garrioch <i>et al.</i>	360	103 women admitted for outpatient vaginal TOP; most women at 9–12 weeks	Relationship investigated between use of ecbolics and blood loss, vomiting and other adverse effects Group treatments given at onset of cervical dilation were either: – physiological saline 2 ml – oxytocin 5 iu – Syntometrine® – ergometrine 5 mg	Randomised controlled trial; staff blind to trial code; method of allocation not described; no power calculation described. Most data shown as points on graph. General anaesthesia was induced with methohexitone, nitrous oxide and oxygen and additional methohexitone if required Patient self-rating was incorporated with study for comparative purposes. Use of combined preparation of oxytocic and ergometrine resulted in lowest blood losses. Ergometrine administered alone was associated with immediate nausea and vomiting but no delayed effects This randomised double-blind trial lacks written numerical detail and does not have the power to detect differences in blood loss between groups of more than about 30%. Syntometrine was significantly more effective than saline or either of other two treatments. Oxytocin was more effective than saline. Ergometrine alone, although associated with smaller mean loss, was not significantly different from saline
Ali and Smith	361	64 pregnant women > 9 weeks undergoing elective vaginal TOP	Women allocated randomly to 1 of 2 groups to receive either 10 units of Syntocinon® (1 ml) or 1 ml of saline (placebo) after cervical dilatation	Randomised controlled trial allocated by sealed envelopes. No power calculations (but powerful enough to detect a difference in blood loss of 25% with 95% confidence) Anaesthesia was standardised and surgery was performed by a single-handed gynaecologist, who assessed size of uterus and graded uterine contractions. All patients received a Cervagem® vaginal suppository 70–270 minutes before surgery. Median blood loss in Syntocinon group (<i>n</i> = 30) was 17.6 ml (range 6.1–72.7) and was significantly less than in placebo group (<i>n</i> = 34), median blood loss 24.5 ml (range 6.7–94.3; <i>P</i> = 0.02), representing a 28% reduction

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