

Royal College of Obstetricians & Gynaecologists

# Obtaining Valid Consent

## Clinical Governance Advice No. 6

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# Obtaining Valid Consent

This is the third edition of this guidance, which was previously published in December 2008 and October 2004 under the same title. The purpose of the advice is to provide a good practice framework for obtaining valid consent in obstetrics and gynaecology. Specific advice for some individual procedures has been published separately and is available from the RCOG website: www.rcog.org.uk.

## 1. Approaching consent

To obtain informed consent the process of shared understanding and decision making between patient and clinician must be approached diligently and robustly. Before seeking a woman's consent for a test, treatment, intervention or operation, you should ensure that she is fully informed, understands the nature of the condition for which it is being proposed, its prognosis, likely consequences and the risks of receiving no treatment, as well as any reasonable or accepted alternative treatments. Uncertainties that the woman may have about the management of the condition should be discussed.

To fully support patients, you should be familiar with the issues covered by the NHS England/Welsh Assembly Government/Department of Health, Social Services and Public Safety, Northern Ireland, guidance on consent.[1–3] Guidance is also provided by the General Medical Council (GMC) and the British Medical Association.[4,5] The risks of the proposed procedure and the likelihood of complications should be presented in a fashion that the patient is able to understand. This may, in some cases, require the use of numerical aids (Table 1).[6]

**Table 1.** Presenting information on risk

| Term | Equivalent numerical ratio | Colloquial equivalent |
|---|---|---|
| Very common | 1/1 to 1/10 | A person in family |
| Common | 1/10 to 1/100 | A person in street |
| Uncommon | 1/100 to 1/1000 | A person in village |
| Rare | 1/1000 to 1/10 000 | A person in small town |
| Very rare | Less than 1/10 000 | A person in large town |

In preparing women for invasive procedures, you should bear in mind at all times that this process may be stressful for them. You should give information and obtain consent at a time and in a manner that is appropriate. GMC guidance on consent states that taking consent can be appropriately delegated, but good practice principles should be followed at all times when obtaining consent. Women must be treated with courtesy and respect and their dignity must be maintained at all times. Adequate privacy must be ensured for information giving. Women should not be given important information or asked to make decisions at the same time as undergoing gynaecological examinations.[7] Doctors should be aware that some terms may be regarded as patronising by some individuals who are not 'patients' in the traditional sense: 'pregnant woman', 'partner' and 'parent' are all generally acceptable.

The nature of the trusting doctor–patient relationship rests on confidentiality, but most women do have trusted relatives, friends or other people who may accompany her. Where possible, women should be seen on their own at some stage of the care pathway, for at least part of the consultation, as part of routine good practice. Discussions can subsequently take place in the presence of any relative, friend or other person that the woman has asked to attend to support them (bearing in mind that there exists a small proportion of overbearing and abusive partners or relatives). Some women may have a clear preference for female doctors when gynaecological examinations are necessary. This may be due to ethnic, religious or cultural background, may be related to previous trauma or may just be preferred.

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When patients are seen who do not have English as their first language, consideration should be given to the provision of an approved translation service. While the use of the patient's relatives or friends may sometimes be useful in urgent cases, it is preferable to ensure that the patient has received an unbiased interpretation of the doctor's explanation. Units should provide translated versions of written patient information wherever possible.

All women aged 18 or over are considered to have capacity to give consent unless there is evidence to the contrary. For young women and children under the age of 16, consent can be obtained from a parent or those with parental responsibility. Although parents have the legal right to give consent for treatment, where appropriate it is good practice to involve children and young people as much as possible in decisions about their care, even when they are not able to make decisions on their own. In some circumstances a young person under the age of 16 may wish to seek medical treatment without her parent's knowledge. Mature minors may acquire the right to give their consent, provided that they fulfil certain criteria and are deemed to be *Gillick* or *Fraser* competent.[8] Each case must be judged on its own merit and if there is any uncertainty you should seek advice from an experienced colleague or specialist. Although 16- and 17-year-olds and minors under the age of 16 may have the right to consent to treatment, they do not necessarily have the same right to withhold consent. Refusal of treatment may be overridden by parental consent, or the courts, however each case should be considered individually (see section 6).[9] It is important to be aware that Scottish law states that those aged 16 and over are able to give consent and also refuse consent provided that they are considered capable of understanding the nature and consequences of the treatment.

In the modern NHS, efficiencies such as placing patients directly onto waiting lists and admitting patients to hospital on the day of operation require careful attention to the organisation of consent. These initiatives have the potential to shorten or even eliminate the 'cooling-off' period during which a woman is able to reflect on her condition and the proposed treatment options. If written consent in the presence of the operating practitioner is to be obtained immediately before the operation, it is vital to ensure that she has been offered the opportunity to further discuss any intervention in a clinic visit or a visit to a preoperative assessment unit. If not, and women are being presented with information anew for the first time or are doubtful, deferral must be retained as an option in the best interests of patient care even if it means that their procedure is postponed. Such women should also be sent detailed information packs with a copy of the appropriate consent form.

The Department of Health, England/Welsh Assembly Government/Department of Health, Social Services and Public Safety, Northern Ireland, introduced four outline consent forms to be completed by practitioners undertaking treatment for differing categories of patients and procedures.[1–3] In obstetrics and gynaecology, most treatments are recommended for women able to give consent on their own behalf. For these patients who are undergoing surgical procedures, an appropriate version of the published Form 1 should be used. Local approved variations in the consent form may be developed but it is important to ensure that key relevant elements from the original national forms are retained. Appendix I provides guidance for practitioners on completing this form. Its aim is to ensure that all patients are given consistent and adequate information.

The RCOG has produced procedure-specific consent forms with guidance that can be used for a limited number of procedures. It is anticipated that, over time, more forms will be developed. Please check the RCOG website for an up-to-date list.

## 2. The scope of consent

With the exception of an unanticipated emergency, the practitioner should not exceed the scope of the authority given by the patient. The classic example of this is abdominal hysterectomy for postpartum haemorrhage to save life. In such cases, the opinion of an experienced colleague or other specialist must

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be sought before undertaking additional procedures. Where possible, prior consent to treat any problem that could reasonably be expected to arise should be obtained and documentation of any procedures to which the patient would object or would prefer to give further thought before proceeding should take place. This will apply particularly where there is uncertainty about the diagnosis or appropriate options for treatment, which may be resolved only when the patient is anaesthetised or unable to participate in decision making.

## 3. Gynaecological procedures

### *3.1 Gynaecological examination*

**Pelvic examination**

It is essential that the gynaecologist considers what information will be gained by the examination, whether this is a screening or a diagnostic procedure and whether or not the examination is necessary at the time.

The presence of a chaperone is considered essential for every pelvic examination. Verbal consent should be obtained in the presence of the chaperone who is to be present during the examination and recorded in the notes.[7,10] If the patient declines the presence of a chaperone, the doctor should explain that a chaperone is also required to help in many cases and then attempt to arrange for the chaperone to be standing nearby within earshot. The reasons for declining a chaperone and alternative arrangements offered should be documented. Consent should also be specific to whether the intended examination is vaginal, rectal or both. Communication skills are essential in conducting intimate examinations.[7]

**Breast examination**

There is no evidence to support routine breast examination in the pregnant woman, nor in the routine gynaecological patient.[7] Should examination of the breast be considered necessary for clinical reasons, verbal consent should be obtained, again in the presence of a chaperone.

### *3.2 Unexpected pathology*

Occasionally, unexpected disease, such as endometriosis or suspected cancer, may be discovered at the time of an operation, for which additional surgical procedures are indicated. If problems related to the woman's complaint, such as minor endometriosis or adhesions, are encountered during a diagnostic procedure, treatment can be performed if the woman has been made aware of the types of minor treatment that she could receive and has given her consent to the consequences of this treatment. If such a preoperative discussion has not occurred then additional treatment should not take place. Where complications of the surgery occur, for example, trauma to a viscus that in itself is life-threatening, then corrective surgery must proceed and full explanation given as soon as practical during the woman's recovery. Generally, it is unwise to proceed with any additional surgical procedures without discussing them with the woman, even if this means a second operation, unless clear boundaries about additional procedures are documented by the carers prior to the procedure.

To avoid the possibility of oophorectomy without consent being undertaken, the possible need for oophorectomy should always be discussed with all women undergoing hysterectomy and their preferences recorded. Oophorectomy at the time of hysterectomy for unexpected disease detected at surgery should not normally be performed without previous consent (see Appendix I, section 5.2). Any doctor doing so must record their decisions and the reasons for them. It is essential that the woman is informed of the event and why it occurred as soon as is practical. Except in emergency surgical cases, a pelvic mass that is nongynaecological or gynaecological but outside the remit of the operator should not be operated upon until assessment by appropriate specialists has taken place. This permits the woman to be informed of the required procedures and to give consent for the intended surgery.

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### *3.3 Unexpected pregnancy*

All reasonable steps should be taken to exclude pregnancy before embarking upon any surgical procedure.[11]

A potentially viable pregnancy should not be terminated without the woman's consent and following the processes outlined in the 1967 Abortion Act. If a pregnancy is discovered at the start of a hysterectomy, including one for cancer, the operation should be rescheduled. An unexpected ectopic pregnancy should be removed. It is reasonable to presume that the woman would wish this and would wish the surgeon to act in favour of life-saving treatment.

### *3.4 Infertility*

Specific consent to fertility treatment must follow the requirements laid down by the Human Fertilisation and Embryology Act 1990 and the Code of Practice of the Human Fertilisation and Embryology Authority 2009.[12]

### *3.5 Sterilisation*

All doctors providing women with advice on permanent forms of contraception should be aware of the current guidelines issued on sterilisation by the relevant professional bodies.[13]

If there is any doubt about a woman's mental capacity to consent to a procedure that will permanently remove her fertility, the case should receive appropriate legal input from within the responsible healthcare organisation with reference to the Mental Capacity Act 2005 or referral to the courts.

### *3.6 Outpatient gynaecological procedures*

With the increasing use of outpatient procedures in gynaecology, the importance of obtaining appropriate consent and documentation of the discussions that led to the granting of consent should not be forgotten. For most cases, a written consent form with documentation within the patient record will be the most reliable way to ensure that local systems capture a record of a discussion of the procedure and subsequent granting of consent. For some minor procedures in units with efficient preprocedure processes that include the administration of specific written information, documentation of the fact that the patient has had time to consider the supplied information and given verbal consent is an acceptable practice. However, in all such cases it is important for the doctor and any other carers in attendance during the procedure to be alert to the fact that the patient can withdraw consent at any time and if so, the procedure should be stopped as soon as possible.

### *3.7 Termination of pregnancy*

Young women under 16 years of age are able to give their consent to undergo medical or surgical termination of pregnancy provided that they are considered to have capacity (see section 1). For this age group it is advisable but not essential to involve a parent or responsible adult. It is also important to note that the putative father of a fetus cannot override or withhold consent for abortion.

## 4. Obstetrics

### *4.1 Consent by women in pain and in labour*

Care must be taken when obtaining consent from women who are in labour. This applies particularly if they are in pain or under the influence of narcotic analgesics.[14] Women who are pain-free in labour as a result of effective epidural anaesthesia can consent normally. Where possible, women should be informed during the antenatal period about predictable problems that may occur in labour. It is important for carers of women in labour to be aware that the woman may not recall such previously

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presented information during labour. If a procedure is planned, she should receive a full explanation as if she had not previously had the relevant information. RCOG patient information may be particularly helpful. It is available from: www.rcog.org.uk.

When consent has to be obtained from a woman during painful labour, such as to perform a vaginal examination, episiotomy, operative delivery or to site an epidural, information should be given between contractions. If appropriate, upon admission in labour or for induction of labour, consideration should be given to the provision of summarised information concerning possible procedures and interventions. Women should be encouraged to express their views on such procedures so that their carers are aware of the choices made by the women and act accordingly.

Consent to be sterilised should not be obtained while a woman is in labour, but an exception to this may be made if the woman has been fully informed during the antenatal period and has had an opportunity to ask questions of a senior doctor and already provisionally agreed.[13] Consent to participate in research during labour will be addressed in a separate paper.

### *4.2 Consent for assisted vaginal deliveries, emergency caesarean section and perineal repair*

Prior to emergency procedures there is scope to allow verbal consent to be obtained when it is considered to be in the interest of the woman or baby. However, if time allows written consent should be obtained for all such operations under general or regional anaesthesia.

In the emergency situation, verbal consent should be obtained which should be witnessed by another care professional. Obstetricians and the witness to verbal consent must record the decision and the reasons for proceeding to any emergency delivery without written consent.[15] If a woman who is deemed to have capacity to consent refuses assisted delivery or caesarean section, even after full consultation and explanation of the consequences for her and for the fetus, her wishes must be respected.[1–3] Following either a normal or assisted vaginal delivery, it is acceptable to obtain and document verbal consent for what is anticipated to be a straightforward perineal repair under local anaesthesia. If a more extensive repair under local anaesthetic or one under regional or general anaesthesia is to be performed then written consent should be obtained.

### *4.3 Ultrasound examination in pregnancy*

It should be considered that the woman may be unaware of the purpose of scanning in pregnancy and she should therefore be informed of the screening purposes of any scans before they are performed. Clear written advice should be given before ultrasound scanning in pregnancy. The advice should indicate the nature and purpose of the examination, together with the detection rate for defined common conditions. Detection rate figures quoted should be from reliable sources such as robust local or national data. Written consent for ultrasound screening is not currently considered necessary but women should be given the opportunity to request further information and such a discussion should be clearly documented in the patient record.[16]

## 5. Consent to screening tests in obstetrics and gynaecology

Screening (which may involve testing) healthy or asymptomatic people to detect genetic predispositions or early signs of debilitating or life-threatening conditions can be an important tool in providing effective care. However, the uncertainties involved in screening may be great; for example, the risk of false-positive or false-negative results. Some findings may potentially have serious medical, social or financial consequences, not only for the individual but also for her relatives.[17] It is therefore essential that the woman is made aware of the purpose, uncertainties and implications of screening, as well as ensuring that the information she requires is identified and provided from approved sources such as the RCOG and relevant national bodies.[16]

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## 6. Obtaining legal advice

Where the woman lacks mental capacity to consent, where there has been appropriate dialogue with family, carers and multidisciplinary teams, and where differences of opinion about her best interests cannot be resolved satisfactorily, the doctor should consult experienced colleagues and, where appropriate, seek legal advice on appropriate management, including applications to the court. Management of the patient using the Mental Capacity Act 2005 allows the appointment of an independent mental capacity advocate to speak for a person who lacks capacity and who does not have a family member or friend to assist the patient in consideration of their treatment choices if time allows.[18,19] In the case of a woman losing mental capacity after refusing consent to a treatment following previous discussion during pregnancy, even if this is at the expense of the fetus, her wishes should be respected in the same way as if she were competent.[18,19] Where there is substantial doubt as to whether the woman foresaw the present circumstances when making her wishes known, the doctor would be wise to obtain legal advice.

Doctors should seek legal advice where a woman lacks capacity to consent to a medical intervention which is nontherapeutic or controversial: for example, sterilisation.[13]

Doctors should also respect an advance decision that has been made in compliance with the Mental Capacity Act which sets out procedural requirements where such a decision refuses life-sustaining treatment such as blood transfusion in the event of life-threatening haemorrhage. Local procedures, record-keeping systems and often specific consent forms should be used in such cases. If there is doubt about the applicability of such an advance decision, or whether the woman had capacity when it was made, then legal advice should be sought.

Doctors should be aware that if any woman is unable to give consent, unless there has been a prior arrangement established formally, there is no place in law for next of kin to give consent in the patient's stead. The doctor must act only in the best interests of the woman.

If doctors decide to apply to a court, they should, as soon as possible, inform the woman and her representative of any decisions and of her right to be represented at the hearing.[19]

## 7. Multimedia images

Multimedia images taken through endoscopy, radiology and sonography are increasingly part of the patient record and stored on approved hospital data record systems. It is important to note that these images of laparoscopic findings, ultrasound pictures and X-rays do not require additional consent for use as part of the care record as consent for care purposes is implicit in the consent given for the procedure. If it is proposed that the image may be used for education or teaching, then written consent must be obtained and the use must not be wider than that to which consent has been given. If the woman will be recognisable from the image, this must be made clear to her before she gives consent. Due to the unregulated nature of taking images out of the secure environments of hospital servers, images of interesting findings should not be taken with personal smartphones or duplicated and shared using screen capture methodology.

Different situations arise when the images used for research or education purposes are to be confined within the hospital or are to be made more broadly available, such that the hospital will lose control, e.g. live surgery at conferences or journal publication. Consent for such broad use can be obtained and where possible should be confined to the specific uses to which the images will be put.[20]

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## 8. Training

Explicit consent of women is required for the presence of students:

- during gynaecological and obstetric consultations
- in operating theatres as observers and assistants
- performing clinical pelvic examination; written consent must be obtained for pelvic examination of anaesthetised women.[7]

## 9. Tissue samples

Specific consent for the removal of tissue for histological examination is not required. Women must, however, be made aware that tissue and samples may be removed in the course of the procedure for which consent is being obtained. The advice given to the woman must include the examination of these tissues and the woman should be informed that blocks and slides will be retained while the remaining sample is destroyed. The retained tissue may be used for education and training. Consent must, however, be obtained when tissue is to be used for research purposes, except where the samples are anonymised.[21]

Following fetal loss after 24 weeks of gestation and in some cases before 24 weeks when analysis of fetal remains is required, written consent should be obtained for procedures on the fetus including samples for testing or retention of any tissues for later tests, teaching and research. Parents should be provided with information about what options are available to them regarding disposal of fetal tissue, including tissue from early pregnancy loss, before they consent to examination of the remains of their child.[22] Units should have clear policies addressing the provision of this specialised consent that is normally performed by trained individuals, including nurses, midwives and doctors, using specific consent documentation.[23]

## 10. Should consent be verbal or written?

It is a common misconception that consent has to be written for it to be valid. In fact consent must be written only when the law requires it. One example in obstetrics and gynaecology is in relation to the storage and use of gametes.[24]

As outlined above, a key issue in taking consent is the recognition of the fact that consent is a process that involves supplying the patient with enough information to make a fully informed decision. Therefore what matters is not necessarily the completion of a form but during the process of taking consent that the medical records contain clear, concise notes that cover the nature of the procedure concerned, risks, benefits and alternatives, along with a record of fears or concerns raised by her.[24]

## 11. Failure to take consent

The GMC provides clear advice on consent[4] which, if not followed, can result in charges of professional misconduct which ultimately may affect a doctor's registration. If consent is not obtained in cases where it should be and the patient has come to harm, this could lead to legal claims for assault or battery, which could proceed to criminal charges in rare instances.[24] The Care Quality Commission have recently released guidance entitled *Guidance for providers on meeting the fundamental standards and on CQC's enforcement powers*.[25] In this document additional consequences of not obtaining consent where appropriate are described. These include the possibility of the prosecution of providers who fail to obtain consent.

## 12. Summary

Consent is a process during which the professional provides adequate and accurate information concerning a procedure to a patient that allows them to reach a considered decision.

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The key principles for consent to be valid are:[24]

- The patient must have capacity to make an informed decision:
  - considered competent to give consent
  - able to understand information provided
  - can communicate their decision.
- Consent must be provided voluntarily:
  - In most cases the decision to provide or withhold consent should be by the patient themselves.
  - The patient should not be coerced or influenced by carers, family or friends.
- The patient should be fully informed of the following by carers with enough time allowed to reflect and ask questions:
  - benefits and risks of the intended procedure
  - alternative management strategies
  - implications of not undergoing the proposed treatment.

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## Appendix I: Guidance for health professionals on completing the Department of Health, England/ Welsh Assembly Government/Department of Health, Social Services and Public Safety, Northern Ireland Consent Form 1 for obstetric and gynaecological procedures

This guidance is provided for health professionals to obtain patients' consent for procedures. It follows the structure of the Department of Health, England/Welsh Assembly Government/Department of Health, Social Services and Public Safety, Northern Ireland Consent Form 1. Its aim is to ensure that all patients are given consistent and adequate information. You should explain the following information while completing the corresponding section of the form.

### 1. Name of proposed procedure or course of treatment

Name and briefly explain the intervention and state the reasons that it is being offered (i.e. for the treatment of [name of condition or disease]).

### 2. The proposed procedure

You should have described to the patient what the procedure is likely to involve, including:

- expected length of stay in hospital
- medication
- anaesthesia (see below)
- surgery (including site and size of any incision and any likely scarring)
- the need for vaginal examination during the procedure
- pain
- recovery
- likely impact on daily and personal life (e.g. time off work, driving, lifting, sexual activity)
- tissue or organ removal
- tissue examination (storage/disposal)
- video, photographic and digital record-keeping.

This explanation should be supported by dedicated patient information.

### 3. Intended benefits

Clearly describe to the patient how she can expect the intervention to help her condition or illness.

### 4. Significant, unavoidable and frequently occurring risks

To ensure that patients understand the level of risk involved, it is best to avoid using verbal descriptors (such as high or low risk) or expressions of percentages when discussing risk. It is preferable to use natural frequencies and express risk in relative terms (for example, if 100 people have this procedure, five of them will have this complication). You should bear in mind that individuals (both clinicians and patients) vary in their perceptions of and attitudes to risk.

You should also inform the patient of any risks associated with her own health and medical history and record these on the form (for example: obesity, previous surgery, pre-existing medical conditions, smoking). If she chooses, the patient should be given the opportunity to discuss her own additional risks with another appropriate medical specialist before consenting. Guidance is given on national rates of some complications for specific procedures. If a clinical department or an individual surgeon has robust data for their own complication rate, this should be given alongside national figures.

It is recommended that clinicians make every effort to separate serious from frequently occurring risks.

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### *4.1 Serious risks*

Serious risks, which occur with varying frequency in certain circumstances in gynaecological procedures, are:

- death (if considered appropriate to inform the patient during the consent process)
- venous thrombosis/pulmonary embolism
- return to theatre
- trauma to bowel, bladder, ureter and major blood vessels. Reference should also be made to risks specific to the planned procedure.

### *4.2 Frequent risks*

Frequently occurring risks include:

- infection
- bruising
- scarring
- adhesions
- bleeding
- urinary frequency/loss of control
- anaemia
- fatigue.

Any consequences specific to the intended procedure should be described.

### *4.3 Unavoidable risks*

These are specific risks of any particular procedure and where possible the likelihood of the risk should be given to the patient prior to the procedure. Even if the risk is small (1–2%) and the surgeon considers this to be irrelevant, the patient should be given the opportunity to consider the risk as she may wish to consider deferment of the procedure. An example of such a risk would be hysterectomy at the time of myomectomy for life-threatening bleeding. While the surgeon may have a personal risk of less than 1% for this complication, they should still make the patient aware of this unavoidable risk.

## 5. Any extra procedures which may become necessary during the procedure

### *5.1 Blood transfusion*

Inform the patient of the frequency of blood transfusion being required during or following specific operations and record this on the form.

### *5.2 Other procedures*

Explain to the patient that, during a procedure, complications may sometimes arise whereby, if no further procedure is performed, the patient's life or quality of life could be compromised. Additional procedures which may need to take place during pelvic surgery should have been discussed with the patient in full. These may include:

- tissue sampling of a lump
- oophorectomy during hysterectomy
- appendicectomy
- hysterectomy during myomectomy
- proceeding from laparoscopy to laparotomy.

In documentation of such possible additional procedures, the patient may find it easier if she is informed of the problems that would predispose to further surgery: for example, 'hysterectomy at the time of myomectomy would only be performed in the event of heavy bleeding that could not be stopped with traditional surgical techniques'.

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## 6. What the procedure is likely to involve, the benefits and risks of any available alternative treatments, including no treatment

You should already have:

- described to the patient what the procedure is likely to involve
- provided the patient with information on alternative interventions (such as other medical, surgical or less invasive procedures) and their risks and benefits
- discussed with the patient the risks and benefits of having no treatment.

These points should be reinforced at the time of signing of the consent form.

## 7. Statement of patient: procedures which should not be carried out without further discussion

Please ensure that the patient tells you of any specific procedures that she does not wish to be carried out without further discussion and that these are recorded. Anything that the woman enters into this section must be carefully reviewed and discussed to ensure that her wishes do not put the operating surgeon in a difficult situation while the patient is under anaesthesia.

## 8. Preoperative information

You should provide the patient with relevant supporting information about the procedure (either in writing or in another format appropriate for her needs) and record this on the consent form.

## 9. Anaesthesia

You should inform the patient of the type of anaesthesia to be used and inform her that she will have an opportunity to discuss it in more detail with an anaesthetist before the procedure.

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The final version is the responsibility of the Women's Health Patient Safety Expert Group of the RCOG.

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