



Setting standards to improve women's health

OBTAINING VALID CONSENT

This is the second edition of this guidance, which was previously published in 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

Before seeking a woman's consent for a test, treatment, intervention or operation, you should ensure that she 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 should be discussed.

To fully support patients, you should be familiar with the issues covered by the Department of Health, England/Welsh Assembly Government/Department of Health, Social Services and Public Safety, Northern Ireland, guidance on consent.^{1,2,3} 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

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. Good practice principles should be remembered in obtaining consent. Patients 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 and this person may accompany her. All women should be seen on their own first, for at least part of the consultation, as part of routine good practice. Discussions can then 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 women doctors when gynaecological examinations are necessary. This may be because of ethnic, religious or cultural background or may be related to previous trauma.

In the modern NHS, efficiencies such as placing patients directly on to waiting lists and admitting patients to hospital on the day of operation require careful attention to the organisation of consent. These initiatives tend 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. 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 consent forms to be completed by practitioners undertaking treatment for all categories of patients.^{1,2,3} 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, Form 1 must be used. The Appendix 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 emergency, you 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, you are strongly advised to seek the opinion of an experienced colleague or other specialist before undertaking additional procedures. You should seek prior consent to treat any problem which you think may arise and ascertain whether there are any procedures to which the patient would object or would prefer to give further thought before proceeding. 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.

Verbal consent should be obtained in the presence of the chaperone who is to be present during the examination and recorded in the notes.^{7,8} 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 this possibility and has consented to the consequences of 'minor' treatment. 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.

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, 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 non-gynaecological 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.

3.3 Unexpected pregnancy

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

A potentially viable pregnancy should not be terminated without the woman's consent.

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 2007.⁹

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.¹⁰

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 NHS trust.

Consideration should be given to use of the Mental Capacity Act 2005 or referral to the courts.

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.¹¹ 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 presented information during labour. If a procedure is planned, she should receive a full explanation as if she had not previously had information. RCOG patient information may be particularly helpful. It is available from www.rcog.org.uk.

If consent has to be obtained from a woman during painful labour, such as to perform a vaginal examination, operative delivery or to site an epidural, information should be given between contractions.

If possible, consent to irreversible procedures should be deferred.

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.¹⁰

Consent to participate in research during labour will be addressed in a separate paper.

4.2 *Consent for emergency caesarean section*

Normally, written consent should be obtained for all operations under general or regional anaesthesia. This should also be the practice in emergencies, although it is acknowledged that this may not always be possible. In such circumstances, verbal consent should be obtained.

Obstetricians must record the decision and the reasons for proceeding to emergency caesarean section without a written consent.¹²

If a competent woman refuses delivery by caesarean section, even after full consultation and explanation of the consequences for her and for the fetus, her wishes must be respected.^{1,2,3}

4.3 *Ultrasound examination in pregnancy*

Clear written advice should be given before ultrasound screening 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.¹³

5. Consent to screening

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.¹⁴ 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 wishes is identified and provided.¹³ It should also be considered that the woman may be unaware of the purpose of the 20-week anomaly scan. She should therefore be informed of the screening purposes of this scan beforehand.

6. Obtaining legal advice

Where a woman's capacity to consent is in doubt or 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 independently assess the appropriateness of planned management, if time allows.^{15,16} In the case of a woman becoming incompetent 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.^{15,16} 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 non-therapeutic or controversial; for example, sterilisation.¹⁰

If doctors decide to apply to a court, they should, as soon as possible, inform the woman and her representative of that decision and of her right to be represented at the hearing.

7. Multimedia images

Multimedia images may be part of the patient record. It is important to remember that the woman must consent not only to the image being made but also to the specific use to which it is put. 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 consents.

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. Consent for broad use in certain circumstances can be obtained.¹⁷

8. Training

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

- during gynaecological and obstetric consultation
- 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.¹⁸

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APPENDIX

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 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. Serious 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.

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.

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'.

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 which 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*

Your 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.

This Clinical Governance Advice was produced on behalf of the Consent Group of the Royal College of Obstetricians and Gynaecologists by:

Mr EP Morris FRCOG, Norwich

and peer reviewed by:

Dr S Bewley FRCOG, London; Mr JP Calvert FRCOG, Swansea; Dr DIM Farquharson FRCOG, Edinburgh; Mr MAH Habiba FRCOG, Leicester; Medical Protection Society; RCOG Consumers' Forum; Professor RW Shaw FRCOG, Nottingham.

The final version is the responsibility of the Consent Group of the RCOG.

The review date of this Clinical Governance Advice will commence in 2011 unless otherwise stated

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