



Royal College of
Obstetricians &
Gynaecologists

Diagnostic Laparoscopy

Consent Advice No. 2

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Diagnostic Laparoscopy

This is the third edition of this guidance, which was previously published in October 2004 and December 2008 under the same title.

This paper provides advice for clinicians in obtaining the consent of women undergoing diagnostic laparoscopy. It follows the structure of Consent Form 1 of the Department of Health, England¹/Welsh Assembly Government²/Department of Health, Social Services and Public Safety, Northern Ireland.³ It should be used in conjunction with Royal College of Obstetricians and Gynaecologists (RCOG) Clinical Governance Advice No. 6, *Obtaining Valid Consent*.⁴

The aim of this advice is to ensure that all women are given consistent and adequate information for consent; it is intended to be used together with a dedicated patient information leaflet. Printed/preprinted consent forms should be considered to ensure that patients receive consistent information and so details of risk are not omitted. It is recommended that the advice given in this guide should form the basis of these consent forms.

In addition, after discharge, all women should have clear direction to obtaining help if there are unforeseen problems.

Clinicians should be prepared to discuss with the woman any of the points listed on the following pages. Risks may be quantified using the descriptors below.

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

The descriptors are based on the RCOG Clinical Governance Advice No. 7 *Presenting Information on Risk*,⁵ and are used throughout this document.

To assist clinicians at a local level, a fully printable page 2 of the Department of Health, England¹/Welsh Assembly Government²/Department of Health, Social Services and Public Safety, Northern Ireland,³ Consent Form 1 is included at the end of this document. This page can be incorporated into local trust documents, subject to local trust governance approval.

CONSENT FORM

I. Name of proposed procedure or course of treatment

Diagnostic laparoscopy, with or without minor treatment of problems that may be expected given the presenting problem. This includes documentation of the findings that may include photographs or video that will be retained as part of the patient records.

2. The proposed procedure

Describe the nature of laparoscopy. Explain the procedure as described in the patient information. This involves the insertion of a laparoscope through a small incision on the abdominal wall to view the peritoneal cavity and pelvic organs specifically in order to identify a cause for the patient's symptoms. This involves the use of additional small incisions to allow the use of instruments to move structure within the abdomen to allow a thorough inspection and possible treatment if agreed in advance.

Potential minor treatments, such as dye hydrotubation, excision of mild superficial endometriosis, division of filmy adhesions (bands of tissue) or tissue biopsy, should be discussed with the patient prior to surgery and documented in the patient record and/or consent form.

Other procedures that might be anticipated (such as treatment of ovarian cysts, treatment of more severe forms of endometriosis, thick or vascular adhesions) must be discussed and additional consent obtained specifically with associated additional (risk of delayed presentation with the use of energy devices) risks discussed.

There is a possibility of finding conditions that require more extensive surgery. Therefore, an indirect risk is establishing the need for more major gynaecological surgery at a later date once the patient has been able to consider the consequences of that more major surgery. In these circumstances, small samples of tissue may be taken for biopsy and analysis, but no disease modifying or curative surgery will be attempted.

3. Intended and potential benefits

To find the cause of the woman's presenting symptoms. As this is a diagnostic procedure, it is unlikely to alter symptoms. Occasionally, a minor laparoscopic procedure is appropriate to treat some of the identified causes or relieve the symptoms. It might fail to achieve a diagnosis for the woman's symptoms. It may not be appropriate to perform more advanced surgery at the time of diagnostic laparoscopy as the patient may require time to consider all further options depending on the findings of this test.

4. Significant and frequently occurring risks⁶⁻⁸

It is recommended that clinicians make every effort to separate serious from frequently occurring risks. Women who are obese or very thin; who have significant pathology; who have had previous surgery; or who have pre-existing medical conditions must understand that the quoted risks for serious or frequent complications will be increased. The risk of serious complications at laparoscopy also increases if an additional therapeutic procedure is performed. Women should also be advised that laparoscopy may not identify an obvious cause for her presenting complaint.

4.1 Serious risks

These include:

- The overall risk of serious complications from diagnostic laparoscopy is approximately 2 in 1000 women (uncommon). This includes damage to the bowel, bladder, ureters, uterus or major blood vessels which would require immediate repair by laparoscopy or laparotomy (open surgery is uncommon). However, up to 15% of bowel injuries might not be diagnosed at the time of laparoscopy.
- Failure to gain entry to the abdominal cavity and to complete the intended procedure.
- Hernia at site of entry (less than 1 in 100; uncommon).
- Thromboembolic complications (rare or very rare).
- Death; 3-8 in 100 000 women (very rare) undergoing laparoscopy may die as a result of complications.

4.2 Frequent risks

Frequent risks are usually mild and self-limiting. They may include:

- bruising
- shoulder-tip pain
- wound gaping
- infection.

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

These may include:

- laparotomy
- repair of damage to the bowel (including the possibility of a stoma), bladder, uterus or blood vessels
- blood transfusion.

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

Insertion of a laparoscope through a small incision on the abdominal wall to view the peritoneal cavity and the pelvic organs specifically to try and identify the cause of the woman's symptoms. The role of prior diagnostic imaging must be discussed, together with the option of no investigation.

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

Other procedures which may be appropriate but not essential at the time should be discussed and the woman's wishes recorded.

8. Preoperative information

A record should be made of any sources of information (such as RCOG or locally produced information leaflets; <https://www.rcog.org.uk/en/patients/patient-leaflets/>) given to the woman prior to surgery. The RCOG produces patient information on recovery after laparoscopic procedures, pelvic inflammatory disease, pelvic pain and endometriosis.⁹⁻¹²

Doctors must enter into a dialogue with patients and be even more careful to give and document:¹³

- Clear and accurate advice on the risks and benefits of a procedure, and the alternatives.¹³
- Health service organisations should amend consent to treatment policies to reflect this development and provide training to ensure that clinicians are aware of and follow the law.¹³
- Existing information sheets for procedures need to be reviewed to ensure they reflect the new position and doctors should not rely solely on these when consenting patients.¹³

9. Anaesthesia

Where relevant, the woman must be made aware of the form of anaesthesia planned and be given an opportunity to discuss this in detail with the anaesthetist before surgery. It should be noted that for women who are obese, there are increased surgical and anaesthetic risks.

References

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8. Jansen FW, Kapiteyn K, Trimbos-Kemper T, Hermans J, Trimbos JB. Complications of laparoscopy: a prospective multicentre observational study. *Br J Obstet Gynaecol* 1997;104:595–600.
9. Royal College of Obstetricians and Gynaecologists. *Acute pelvic inflammatory disease. Information for you*. London: RCOG; 2016.
10. Royal College of Obstetricians and Gynaecologists. *Chronic (long-term) pelvic pain. Information for you*. London: RCOG; 2015.
11. Royal College of Obstetricians and Gynaecologists. *Endometriosis. Information for you*. London: RCOG; 2016.
12. Royal College of Obstetricians and Gynaecologists. *Recovering well: Information for you after a laparoscopy*. London: RCOG; 2015.
13. Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) [2015] UKSC 11 [<https://www.supremecourt.uk/cases/uksc-2013-0136.html>].

Appendix I: Diagnostic laparoscopy consent to treatment form

Patient identifier/label

Name of proposed procedure or course of treatment (include brief explanation if medical term not clear)

Diagnostic laparoscopy with or without minor treatment.

Statement of health professional (to be filled in by health professional with appropriate knowledge of the proposed procedure, as specified in the consent policy)

I have explained the procedure to the patient with other possible alternatives including conservative options. In particular, I have explained:

The intended benefits

To find the cause of symptoms although sometimes no cause may be found. As this is a diagnostic procedure, it is unlikely to alter symptoms. Occasionally, a minor laparoscopic procedure is appropriate to treat some of the identified causes or relieve the symptoms.

Serious risks

- The overall risk of serious complications from diagnostic laparoscopy is approximately 2 in every 1000 women (uncommon). This includes damage to the bowel, bladder, uterus or major blood vessels which would require immediate repair by laparoscopy or laparotomy (uncommon). However, up to 15% of bowel injuries might not be diagnosed at the time of laparoscopy.
- Failure to gain entry to abdominal cavity and to complete intended procedure.
- Hernia at site of entry (less than 1 in 100; uncommon).
- Thromboembolic complications (rare or very rare).
- Death; 3–8 in 100 000 women (very rare) undergoing laparoscopy may die as a result of complications.

Frequent risks

- bruising
- shoulder-tip pain
- wound gaping
- infection.

Any extra procedures which may become necessary during the procedure

- Laparotomy
- Repair of damage to the bowel (including the possibility of a stoma), bladder, uterus or blood vessels
- Blood transfusion
- Other procedure (please specify)

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following patient information leaflet has been provided: *Laparoscopy* (<https://www.rcog.org.uk/en/patients/patient-leaflets/laparoscopy/>) available from the RCOG.

This procedure will involve

- General and/or regional anaesthesia Local anaesthesia Sedation

Signed Date

Name (print) Position

Contact details *(if patient wishes to discuss options later)*

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Statement of interpreter *(where appropriate)*

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Signed Date

Name *(print)*

Top copy accepted by patient Yes / No *(please circle as appropriate)*

Confirmation of consent (to be completed by a healthcare professional when the patient is admitted for the procedure, if the patient has signed the form in advance). On behalf of the team treating the patient, I have confirmed with the patient that they have no further questions and wish to proceed.

Signed Date

Name *(print)* Position

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The final version is the responsibility of the Joint Standing Committee for Patient Safety of the RCOG.

The guideline will be considered for update 3 years after publication, with an intermediate assessment of the need to update 2 years after publication.

DISCLAIMER

The Royal College of Obstetricians and Gynaecologists produces Consent Advice as an aid to good clinical practice. The ultimate implementation of a particular clinical procedure or treatment plan must be made by the doctor or other attendant after the valid consent of the patient in the light of clinical data and the diagnostic and treatment options available. The responsibility for clinical management rests with the practitioner and their employing authority and should satisfy local clinical governance probity.