Royal College of Obstetricians and Gynaecologists

Consent Advice No. 2

December 2008

DIAGNOSTIC LAPAROSCOPY

This is the second edition of this guidance, which was previously published in October 2004 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, England/Welsh Assembly Government/Scottish Government/Department of Health, Social Services and Public Safety, Northern Ireland. It should be used in conjunction with RCOG Clinical Governance Advice, *Obtaining Valid Consent*.[1] Please refer to RCOG Green-top Guideline No. 49, *Preventing Entry-related Gynaecological Laparoscopic Injuries*.[2]

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 dedicated patient information. 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.

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 above descriptors are based on the RCOG Clinical Governance Advice, *Presenting Information on Risk*.[3] They are used throughout this document.

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

CONSENT FORM

1. Name of proposed procedure or course of treatment

Diagnostic laparoscopy.

2. The proposed procedure

Describe the nature of laparoscopy. Explain the procedure as described in the patient information.

Note: If other procedures are anticipated (such as hydrotubation, tissue biopsy, ovarian cyst aspiration, treatment of endometriosis or division of adhesions) these must be discussed and a separate consent obtained.

3. Intended benefits

To find the cause of 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.

4. Serious and frequently occurring risks[4,5,6]

It is recommended that clinicians make every effort to separate serious from frequently occurring risks. Women who are obese, 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 be advised that laparoscopy may not identify an obvious cause for presenting complaint.

4.1 Serious risks

Serious risks include:

- the overall risk of serious complications from diagnostic laparoscopy, approximately two women in every 1 000 (uncommon)
- damage to 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
- death; three to eight women in every 100 000 undergoing laparoscopy die as a result of complications (very rare).

4.2 Frequent risks

Frequent risks include:

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

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

- Laparotomy
- Repair of damage to bowel, 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 to identify the problem. 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/tapes) given to the woman prior to surgery. The RCOG produces patient information on pelvic inflammatory disease, pelvic pain and endometriosis.[7,8,9]

9. Anaesthesia

Where possible, the woman must be 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 with obesity there are increased risks, both surgical and anaesthetic.

References

1. Royal Royal College of Obstetricians and Gynaecologists. *Obtaining Valid Consent*. Clinical Governance Advice No. 6. London: RCOG; 2008 **[www.rcog.org.uk/womens-health/clinical-guidance/obtaining-valid-consent]**.
2. Royal College of Obstetricians and Gynaecologists. *Preventing Entry-related Gynaecological Laparoscopic Injuries*. Green-top Guideline No. 49. London: RCOG; 2008 **[www.rcog.org.uk/womens-health/clinical-guidance/preventing-entry-related-gynaecological-laparoscopic-injuries-green]**.
3. Royal College of Obstetricians and Gynaecologists. *Presenting Information on Risk*. Clinical Governance Advice No. 7. London: RCOG; 2008 **[www.rcog.org.uk/womens-health/clinical-guidance/presenting-information-risk]**.
4. Brosens I, Gordon A, Campo R, Gordts S. Bowel injury in gynecologic laparoscopy. *J Am Assoc Gynecol Laparosc* 2003;10:9_13.
5. Chapron C, Querleu D, Bruhat M, Madelenat P, Fernandez H, Pierre F, *et al*. Surgical complications of diagnostic and operative gynaecological laparoscopy: a series of 29,966 cases. *Hum Reprod* 1998;13:867–72.
6. Jansen FW, Kapiteyn K, Trimbos-Kemper TC, Hermans J, Trimbos JB. Complications of laparoscopy: a prospective multicentre observational study. *Br J Obstet Gynaecol* 1997;104:595–600.
7. Royal Royal College of Obstetricians and Gynaecologists. *Acute Pelvic Inflammatory Disease (PID):What the RCOG Guideline Means for You*. London: RCOG; 2004 [**www.rcog.org.uk/womens-health/clinical-guidance/acute-pelvic-inflammatory-disease-pid**].
8. Royal Royal College of Obstetricians and Gynaecologists. *Long-term Pelvic Pain: Information for You*. London: RCOG; 2006 [**www.rcog.org.uk/womens-health/clinical-guidance/long-term-pelvic-pain-information-you**].
9. Royal Royal College of Obstetricians and Gynaecologists. *Endometriosis: What You Need to Know*. London: RCOG; 2007 [**www.rcog.org.uk/womens-health/clinical-guidance/endometriosis-what-you-need**- know]

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

The Consent Advice review process will commence in 2012 unless otherwise indicated

Patient identifier/label

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear) *Diagnostic laparoscopy.*

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

I have explained the procedure to the patient, 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 women in every 1000 (uncommon)*
- *Damage to 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*
- *3–8 women in every 100 000 undergoing laparoscopy die as a result of complications (very rare)*
- *Hernia at site of entry*

Frequent risks:

- *Bruising*
- *Shoulder-tip pain*
- *Wound gaping*
- *Wound infection*

Any extra procedures which may become necessary during the procedure

☐ blood transfusion

☐ other procedure (please specify) *Laparotomy, repair of damage to bowel, bladder, uterus or blood vessels*

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 leaflet/tape has been provided *The RCOG produces patient information on Pelvic Inflammatory Disease, Pelvic Pain and Endometriosis*

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation

Signed ..... Date .....

Name (PRINT) ..... Job title .....

Contact details (if patient wishes to discuss options later)

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 s/he can understand

Signed ..... Date .....

Name (PRINT) .....

Top copy accepted by patient: yes/no (please ring)