Royal College of Obstetricians and Gynaecologists

Setting standards to improve women's health

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OBTAINING VALID CONSENT FOR COMPLEX GYNAECOLOGICAL SURGERY

This is the first edition of this guidance, which is complementary to other specific RCOG procedure-based consent advice. This paper should be read in conjunction with and in addition to RCOG Clinical Governance Advice No. 6: *Obtaining Valid Consent*.[1]

The purpose of this advice is to provide a good practice framework for obtaining valid consent from women who undergo complex gynaecological surgery. Many of the specific points of advice will apply to both complex laparoscopic and complex open surgery; however, the significant differences between the two access methods in terms of risks and benefits should be carefully explained.

The aim of this paper is to ensure that all women are given consistent and adequate information for consent. It is intended to be used together with dedicated procedure-specific patient information. It is optimal for the person obtaining consent to be the lead operating surgeon rather than someone trained in obtaining consent but unable to carry out such surgery. Before discharge, all women should receive clear information about how to obtain help if there are unforeseen problems when at home.

1. The proposed surgery

It is essential to allocate adequate time for discussion of the proposed surgery. The woman must be given time to reflect on the complex situation and should only give her final decision after this. The nature of laparotomy or laparoscopy should be fully discussed, and an explanation of the proposed incisions, the aims of the surgery and the procedure, as described in the appropriate patient information, should then follow. An offer of a second opinion should be considered if appropriate.

This guidance attempts to cover specific issues that require discussion prior to surgery, especially when there is doubt regarding what surgery is optimal or even possible. The guidance should be followed to avoid or reduce any postoperative patient doubt about the need for, or extent of, the surgery. Essentially, however complex the surgery, prior discussion of possible outcomes will reduce the need for later explanatory discussion if the procedure deviates from the usual or expected course. It is valuable for both documentary and medico–legal reasons to communicate specific consent discussion points in a letter to the woman's general practitioner, highlighting areas of possible deviation from a straightforward procedure. If appropriate in complex situations, the general practitioner may be communicated with on more than one occasion during the woman's management. The woman should be clear regarding the distinction between difficulties due to the complexity of the surgery, the complexity of the underlying disease or complexity due to comorbidities.

The risk/benefit profile of the proposed surgery will be the disparity between best and worst clinical outcomes. Surgeons must retain the right to refuse surgery if they feel that the risks significantly outweigh the benefits. Unrealistic expectations should be dispelled.

2. Antecedent factors

Pursuit of more detailed consent should be considered if there are situations such as the following: previous significant history (gynaecological surgery, gastrointestinal surgery, urological or urogenital surgery, a known congenital anomaly of the lower abdomen or previous corrective surgery, previous laparoscopic or open surgical evidence of significant pelvic disease), ultrasound/computed tomography/magnetic resonance imaging evidence of pelvic disease or anatomical disruption, previous evidence of significant urogenital infective processes, suspect benign disease with the possibility of malignancy or malignant disease of uncertain extent.

3. Serious risks

This will be the minima of quoted risks for the proposed operation, with additional guidance on risk if more extensive surgery becomes necessary. An attempt should be made to quantify mortality risk in the specific situation and to place this within the bands in the guidance suggested in Clinical Governance Advice No. 7: *Presenting information on risk*.[2] Every attempt should be made to establish what the woman considers a serious risk and to address this specific issue.

Prior assessment of medical and surgical history with a full discussion will ensure that the extent of the surgery undertaken is not a surprise to the surgeon or the woman. Where bowel, bladder or vascular abnormalities are suspected preoperatively, curative surgical measures for these problems should be discussed before surgery is agreed. These possibilities may include hysterectomy, oophorectomy, salpingectomy, bowel resection, stoma formation or bladder surgery, and should be placed in a realistic setting.

The outcomes of the proposed surgery should be discussed, including what loss of function is acceptable – in particular the possible loss of fertility or control of bowel/bladder function. It should be clearly established whether the risk of the above changes the balance of acceptability of the proposed surgery, and the risk/benefit balance should be reappraised. The woman must be reassured that the surgeon is capable and competent to perform the proposed surgery and, critically, is able to deal with complications at least until more specialised surgical aid is available. If significant bowel or bladder surgery is a possibility, preoperative plans to involve appropriate specialist surgeons should be overt and communicated to the woman and, ideally, consultations with them should be arranged.

It is good practice to ensure suitable preoperative preparations for this additional surgery have been made, especially as a courtesy to any incoming attending surgeon or urologist. For example, bowel preparation or the need for additional imaging in theatre may need to be considered. The woman should be reassured that postoperative specialised care is available and that this would involve specialised nursing, high-dependency or intensive care and the involvement of other professionals such as physiotherapists or psychologists. The woman requires a realistic overview of the possible need for cancellation of the surgery if optimal conditions are not available. The consequences of not performing surgery should be placed in the context of the risks of the surgery.

4. Preoperative definition of procedures that should not be carried out until there is further discussion

Every reasonable precaution to exclude unexpected pregnancy must be made prior to any planned surgery.

Other procedures that may be appropriate but not essential at the time of surgery should be discussed and the woman's wishes recorded. With complex surgery it is essential that the surgeon's boundaries are clear to both the woman and the surgeon. This is particularly important where continued fertility is an absolute prerequisite for the woman. If the surgeon is unwilling or unable to give her the reassurances she requires, the surgery should not proceed. The woman must have absolute confidence at all times that the surgeon is acting in her best interests.

Coexisting medical issues may change the balance of likelihoods; previous medical history, current medical complaints, current drug history, drug allergies and appropriate social history issues all need consideration and require documentation that they have been considered. The woman must have the mental capacity to comprehend the benefits and risks involved.

5. 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. Specialised anaesthetic techniques may be required in complex surgery, including invasive intraoperative and postoperative monitoring and, possibly, continued ventilatory support and intensive care after surgery. The anaesthetist should reassure the woman that postoperative pain relief will be a priority.

References

1. 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. *Presenting information on risk*. Clinical Governance Advice No. 7. London: RCOG; 2008 [www.rcog.org.uk/womens-health/clinical-guidance/presenting-information-risk].

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The Clinical Governance Advice review process will commence in 2013 unless otherwise stated