

FIGO best practice guidance in surgical consent

E. Goknur Topcu¹ | Phil McClenahan² | Koketso Pule³ | Hajra Khattak⁴ |
 S. Eda Karsli⁵ | Marijo Cukelj⁶ | Akaninyene E. Ubom⁷ | Esraa Algurjia⁸ |
 Kubra Ozpinar⁹ | Yotin Ramon Perez¹⁰ | Rashid Bunu¹¹ | Leopoldo S. Sanabria¹² |
 Francisco J. R. Portilla¹³ | Elizabete Pumpure¹⁴ | Priyankur Roy¹⁵ | Paul Fogarty¹⁶ |
 FIGO Education Communication and Advocacy Committee

¹Department of Obstetrics and Gynecology, Istanbul Health and Technology University, Istanbul, Turkey

²Department of Obstetrics and Gynecology, Nepean Hospital, Kingswood, New South Wales, Australia

³Department of Obstetrics and Gynecology, Wits University, Johannesburg, South Africa

⁴Department of Obstetrics and Gynecology, UCL EGA Institute for Women's Health, London, UK

⁵Department of Obstetrics and Gynecology, Ankara Bilkent City Hospital, Ankara, Turkey

⁶Department of Obstetrics and Gynecology, Sestre Milosrdnice University Hospital Center, Zagreb, Croatia

⁷Department of Obstetrics and Gynecology, Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Osun State, Nigeria

⁸Department of Obstetrics and Gynecology, Al-Elwya Maternity Hospital, Baghdad, Iraq

⁹Department of Obstetrics and Gynecology, Gulhane Training and Research Hospital, Ankara, Turkey

¹⁰Department of Obstetrics and Gynecology, Hospital Central de las Fuerzas, Santo Domingo, Dominican Republic

¹¹Department of Obstetrics and Gynecology, Kenyatta National Hospital, Nairobi, Kenya

¹²Department of Obstetrics and Gynecology, Unidad Medica de Alta Especialidad, Mexico City, Mexico

¹³Department of Obstetrics and Gynecology, Instituto Nacional de Perinatologia, Mexico City, Mexico

¹⁴Department of Obstetrics and Gynecology, Riga East Clinical University, Riga, Latvia

¹⁵Department of Obstetrics and Gynecology, Roy's Clinic, Siliguri, West Bengal, India

¹⁶International Federation of Gynecology and Obstetrics (FIGO), London, UK

Correspondence

E. Goknur Topcu, Department of
 Obstetrics and Gynecology, Istanbul
 Health and Technology University,
 Stlce, İmrahor Cd. No: 82, 34275
 Beyođlu, Istanbul, Turkey.
 Email: goknurtopcu@gmail.com

Abstract

Obtaining medical consent preoperatively is one of the key steps in preparing for surgery, and is an important step in informed decision making with the patient. According to good medical practice guidelines, doctors are required to have the knowledge and skills to treat patients as well as inform them, respect their wishes, and establish trust between themselves and their patients. Valid consent includes elements of competence, disclosure, understanding, and voluntariness. Documentation of these elements is also very important. The International Federation of Gynecology and Obstetrics (FIGO) Education Communication and Advocacy Consortium (ECAC) has realized that the quality of consent varies considerably across the world and has developed simple guidelines regarding consent and procedure-specific checklists for the most common obstetric and gynecological procedures.

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KEYWORDS

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1 | INTRODUCTION

Obtaining medical consent preoperatively is one of the key steps in preparing for surgery. As part of good medical practice guidance, doctors are required to have the knowledge and skills to treat patients as well as inform them, respect their wishes, and establish trust between themselves and their patients.¹ Once these grounds are established, it is necessary to obtain informed consent prior to surgery. Obtaining valid informed consent is not only a signature on a form before the surgery, but a process whereby the patient is thoroughly informed about the procedure by their surgeon: about the benefits, risks, and alternatives, discussing the patient's concerns and wishes, and the patient providing informed and deliberate consent for the proposed treatment.^{1,2}

Obtaining medical consent is part of informed decision making with the patient that requires sufficient time, information, and clarity. Which surgery is needed to treat a disease and how that surgery is performed does not differ from one center to another. Therefore, the preoperative discussion between the surgeon and the patient should also not differ.

The International Federation of Gynecology and Obstetrics (FIGO) is dedicated to the improvement of women's health and rights and to the reduction of disparities in health care available to women and newborns, as well as to advancing the science and practice of obstetrics and gynecology. FIGO Education Communication and Advocacy Consortium (ECAC) has realized that the quality of consent varies considerably throughout the world. Therefore, FIGO ECAC decided to develop simple guidance regarding consent and procedure-specific checklists for the most common obstetric and gynecological procedures together with the World Association of Trainees in Obstetrics and Gynecology (WATOG).

To standardize medical care, it is important to understand what constitutes good consent, and FIGO has endorsed this guidance for the most common obstetric and gynecological procedures.

2 | WHAT IS GOOD CONSENT?

Elements of valid consent include:³⁻¹⁰

- competence/capacity
- disclosure
- understanding
- voluntariness.

2.1 | Capacity/competence

It must be demonstrated that the patient has the ability to understand the information provided, analyze/process that information, and make a decision that is in her best interest, based on the provided information.

Patients must have attained the legal age of competency and possess the mental capacity to give informed consent.

In the case of a minor, or when it has been established that a patient does not possess the mental capacity to give informed consent due to a serious condition or if unconscious or comatose, consent can be given by a surrogate or substitute decision maker, usually a parent, spouse, or offspring.

The patient must have the capacity to make a healthcare decision. It is important to ensure that:

- they understand that they are ill and require treatment
- they understand their treatment options and the general risks and benefits of each
- they have the capacity to make sense of the information presented and can process it rationally to reach a decision that furthers their healthcare goals
- they have the capacity to communicate their wishes.

Incapacitated patients do not lose their right of consent. Instead, it is transferred to an authorized surrogate decision maker to exercise on their behalf.

Coercion can arise from individuals who may not be present in the room, but who have a relationship of power over the patient. If we have reason to suspect this, we can ask a general question, such as "Do you feel safe and free to give consent? Are you feeling pressure from anyone to have this operation?"

2.2 | Disclosure

Patients should be provided with accurate, necessary, and relevant information to enable them make an informed and autonomous decision, taking into account their concerns and wishes. Information should be provided in clear, unambiguous, and simple language that is easily understood by the patient. In case of language differences or barriers, a professional medical interpreter/translation service should be employed.

Information provided should include the diagnosis, the name and description of the proposed procedure/intervention, the

intended benefits of the procedure, the possible complications/risks, any extra procedures that may become necessary during the procedure, alternative treatments (including no treatment and non-operative care in case of consent for surgery)—including the benefits and risks of the alternatives, and the options and risks of anesthesia.

Even though it is often impracticable to discuss every potential risk or complication with the patient, the most likely and/or serious risks must be explained. To make a rational healthcare decision, reasonable people need to know their choices and the general benefits and harms of each choice. Physicians should communicate the risks of treatment to the extent that they are common or serious. Risks should be expressed as percentages (e.g. 10%) or frequencies (e.g. 10 in every 100 people). The latter with a corresponding verbal descriptor better conveys information on risk, such as “very common” corresponds to 1/1–1/10, and “very rare” is less than 1/10000. The patient should be allowed to discuss the mode of anesthesia and its risks in detail with the anesthesiologist before the planned procedure.

2.3 | Understanding

Comprehension of the information provided must be confirmed by asking the patient to recap or summarize what has been disclosed to her, and to allow sufficient time to ask questions and clarifications. After a recap of disclosed information by the patient, any identified gaps in the patient's understanding must be addressed by repeating the misunderstood parts of the information.

2.4 | Voluntariness

Patients should be allowed to use the information disclosed to intentionally and voluntarily make a decision, without coercion or inducement. The consent process should not be a one-off event occurring immediately before the planned procedure. It should ideally, except in emergencies, involve multiple sessions and encounters, so that the patient has ample time to further discuss and reflect on the disclosed information before making a decision. Until the planned procedure has commenced, the patient reserves the right to withdraw her consent and this should be respected.

The patient must consent freely:

- Patients should not be coerced into accepting treatment by a physician.
- Making a strong treatment recommendation is persuasion, not coercion. Coercion is the use of threats that a reasonable person would not be expected to resist.

It is appropriate to document a refusal of surgery when that choice carries considerable risk.

3 | DOCUMENTATION

All of the above discussions should be fully documented in the patient's records. The patient's consent is completed by the patient signing a “consent form”, which is included in her medical records. This form is often standardized in a hospital or region, and it is usually generic and not specific to obstetrics and gynecology. Hence, it is necessary to augment it with any additional relevant information. The consent form should be countersigned by the personnel administering and witnessing the consent process. If the patient has objected to the use of a particular instrument or any procedures aside from the one planned, this should be documented in the signed consent form.

4 | CHALLENGES AND SITUATIONS DOCTORS SHOULD AVOID WHEN OBTAINING INFORMED CONSENT

Surgery produces anxiety in patients, and some display this stress more than others. Hearing their surgeon iterate a long list of things that can go wrong is frightening. Another challenge is the language barrier when a friend or family member translates the surgeon's explanations into brief sentences, with the patient receiving a fraction of the information provided. A hospital interpreter can be a valuable resource.

Informed consent requires surgeons to make reasonable attempts to answer the patient's questions. With all the information available on the Internet, patients may wish to engage in an intensive, detailed discussion, and the surgeon must be patient while facilitating their understanding of the wealth of data they have acquired.^{1,2}

Proper documentation is the only objective measurement of what the information was communicated to the patient and provides legal protection for the surgeon. The following is an example of proper documentation of an informed consent discussion:²

The patient was advised that laparoscopic hysterectomy was indicated to prevent further episodes of bleeding due to fibroids. The nature of the surgery and the risk of conversion to open laparotomy for unexpected bleeding, infection, or injury to an organ during the operation was discussed with the patient and her husband. We talked about the postoperative course and potential complications, including wound infection and herniation. I advised them of common risks for all surgery, such as pneumonia and venous thrombosis. She understood and wished to proceed with surgery. The planned date of surgery is after 2 weeks.

The dialogue and documentation of informed consent for surgery have evolved from a brief chat and a quick signature into a major and

sometimes complex component of surgical practice. We can anticipate more changes in the future in response to patient expectations regarding communication and information.

The challenge now is that there is so much information to convey, it is easy to miss an item or overlook one area or complication, and this may lead to inadequate or incomplete consent. FIGO has developed a standardized checklist that acts as an *aide memoire* to assist the consent process and to improve the documentation ultimately leading to better patient care and transfer of information.

5 | CONSENT CHECKLISTS

Downloadable and printable FIGO consent checklists for common obstetric and gynecological procedures are included below, and also as supplementary material to this article. Individual forms can be downloaded from the 'Additional information' section at the foot of this online article, and are free to use and reproduce.

A checklist of consent guidelines was established as follows:

Checklist headings

- Procedure name
 - Intended benefits
 - Alternatives considered
 - Risks
 - Frequent
 - Serious but rare
 - Possible additional procedures
 - Name, signatures, and date
-

Consent checklists for the following procedures can be found below:

- Diagnostic hysteroscopy
- Operative hysteroscopy
- Diagnostic laparoscopy
- Operative laparoscopy - removal of endometrioma
- Total laparoscopic hysterectomy
- Total abdominal hysterectomy
- Vaginal hysterectomy and vaginal repair
- Open/abdominal myomectomy
- Elective cesarean delivery
- Cesarean delivery for placenta previa
- Vaginal twin delivery
- Operative vaginal delivery
- Vaginal breech delivery.



Patient ID

DIAGNOSTIC HYSTEROSCOPY

A hysteroscopy is the examination of the inside of the vagina, cervix, and uterus under general anesthesia using a narrow telescope with a light and camera at the end.

Intended benefits

- To identify the cause of symptoms, infertility, anomalies, bleeding, abnormal smear, biopsy, etc. As this is a diagnostic procedure, it will not alter symptoms unless additional procedures are anticipated.

Alternative measures

- Ultrasound, transvaginal ultrasound, MRI, hysterosalpingography, etc.

Frequent risks

- Bleeding (0.25%), infection (0.18%–10.5%), pain (34.8%)
- Failure of performance or completion (12.0%).

Serious risks

- Cervical tears with ripening of cervix (1.4%), without (11.4%)
- Uterine perforation (0.12%–3.0%)
- Uterine hemorrhage (0.61%)
- Pelvic infection (0.6%–0.9%)
- Hyperosmolar syndrome due to extravasation of the product used for the expansion of the uterine cavity (0.2%)
- Failure to control heavy bleeding, resulting in the need for further treatment (very rare).

Possible additional procedures

- Laparoscopy and/or laparotomy in case of suspected damage, perforation, bleeding, etc.
- Antibiotics to reduce infections

- Analgesia to reduce pain
- Blood transfusion (rare).

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- Name and signature (patient) and date

- Name and signature (Medical Officer) and date

FURTHER READING

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Patient ID

OPERATIVE HYSTEROSCOPY

An operative hysteroscopy is a technique for the treatment of certain processes affecting the uterus, such as abnormal uterine bleeding or others. A hysteroscope (a thin camera) is inserted into the vagina and through the cervix to examine the inside of the uterus. The uterus is filled with fluid to make it possible to see inside and perform surgery. The surgeon will remove a structure that may be causing symptoms or perform a biopsy to aid the diagnostic process.

Intended benefits

- To obtain a biopsy
- To treat symptoms by removing structures in the endometrial cavity, e.g. polyp(s), fibroid(s), septum, adhesion(s), and retained products of conception
- To carry out endometrial ablation (an operation used to treat heavy periods, using a device to apply heat to the womb lining)
- To carry out tubal occlusion for sterilization (a procedure where a micro-insert is placed into each of the fallopian tubes).

Alternative measures

- Conservative management (management of heavy menstrual bleeding or other conditions without an invasive procedure).

Frequent risks

- Bleeding (0.25%)
- Infection (0.18%–1.05%)
- Pain (34.8%)
- Failure of performance or completion (12%).

Serious risks

- Cervical tears with cervix ripening (1.4%), without (11.4%)
- Uterine perforation (0.12%–3%)

- Uterine hemorrhage (0.61%)
- Pelvic infection (0.6%–0.9%)
- Hyperosmolar syndrome due to extravasation of the product used for the expansion of the uterine cavity (0.20%)
- Failure to control heavy bleeding, resulting in the need for further treatment (very rare).

Possible additional procedures

- Blood transfusion
- In the event of perforation, a laparotomy or laparoscopy can be performed
- In cases of failure to control bleeding, a hysterectomy can be performed (rare).

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

• Name and signature (patient) and date

• Name and signature (Medical Officer) and date

FURTHER READING

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Patient ID

DIAGNOSTIC LAPAROSCOPY

Diagnostic laparoscopy involves the insertion of a laparoscope via a sub-umbilical incision. The pelvis is temporarily inflated with gas. The pelvis is imaged through the laparoscope. The procedure may require a suprapubic incision. Discussion and consent is required for any additional anticipated procedures, e.g. hydrotubation (trans-cervical flushing of fluid through the fallopian tubes), biopsy, aspiration of a cyst, treating endometriosis, or division of adhesions.

Intended benefits

- To find the cause of symptoms—the procedure is diagnostic and will not treat symptoms unless required.

Alternative measures

- Conservative management (if possible without an invasive procedure).

Frequent risks

Note: All risks are increased in those who are obese (BMI >30 kg/m²), have had previous abdominal surgery, or have pre-existing medical conditions.

- Failure to identify disease
- Bruising
- Pain or discomfort across the shoulders due to the collection of gas used during the operation to distend your abdomen.

Serious risks

- Injury to adjacent organs or blood vessels in the pelvis, such as the bladder, bowel, or womb (0.3%)

- Infection requiring antibiotics
- Failure to gain entry to the abdominal cavity
- Uterine perforation
- The overall risk of complications is 2/1000 (0.02%)
- 1 in 12 000 women (0.008%) die as a result of complications.

Possible additional procedures

- Proceeding from laparoscopy to laparotomy
- Repairs of any injured organs
- Blood transfusion if profuse bleeding occurs
- More extensive surgery to treat an injury; this may require making a cut to open the abdomen, known as a laparotomy. This may be necessary at the time of the operation, or may require a second operation at a later date.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- Name and signature (patient) and date

- Name and signature (Medical Officer) and date

FURTHER READING

1. Royal College of Obstetricians and Gynecologists. Diagnostic laparoscopy. Consent advice no.2. 2017.
2. European Society of Gynecological Endoscopy (ESGE). Checklist Laparoscopy.

Patient ID

OPERATIVE LAPAROSCOPY—REMOVAL OF ENDOMETRIOMA

An operative laparoscopy involves the insertion of a laparoscope through a sub-umbilical incision, and abdominal incisions for trocars. The pelvis is temporarily inflated with gas. The endometrioma is removed using different techniques (stripping, coagulating, laser vaporization, etc.).

Intended benefits

- Elimination of endometriotic tissue
- To carry out adhesiolysis (division of adhesions)
- To collect tissue for histological assessment
- To preserve the maximum amount of normal ovarian tissue
- To improve pain.

Alternative measures

- Adequate analgesia
- Hormonal treatment.

Frequent risks

- Wound bruising and shoulder-tip pain (9.0%)
- Wound gaping or wound infection (1.3%)
- Unintentional removal or destruction of ovarian follicles (80.3%)
- Potential reduction in ovarian reserve (61%)
- Loss of ovaries (80.3%).

Serious risks

- Damage to the bowel, bladder, uterus, or major blood vessels, which would require immediate repair by laparoscopy or laparotomy (uncommon, 2 in 1000)

- Failure to gain entry to the abdominal cavity and to complete the intended procedure
- Hernia at the site of entry (uncommon, 1 in 100)
- Death as a result of complications (3–8 in 100000).

Possible additional procedures

- Laparotomy
- Repair of damage to the bowel, bladder, uterus, or blood vessels
- Blood transfusion
- Two- or three-step approach for large endometriomas.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- Name and signature (patient) and date

- Name and signature (Medical Officer) and date

FURTHER READING

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Patient ID

TOTAL LAPAROSCOPIC HYSTERECTOMY

A total laparoscopic hysterectomy is the removal of the uterus with or without the cervix. It is a total hysterectomy, where both the uterus and cervix (neck of the womb) are removed.

Intended benefits

- Menstruation will be stopped by total hysterectomy. However, the effect on pelvic pain and premenstrual symptoms is not guaranteed, and the likelihood of this effect should be discussed.

Alternative measures

- Vaginal hysterectomy or laparoscopically assisted vaginal hysterectomy
- Subtotal hysterectomy, where just the uterus is removed and the cervix is not
- Total abdominal hysterectomy.

Frequent risks

- Bruising, shoulder-tip pain, wound gaping, wound infection, infectious complications (9.0%)
- Delayed wound healing, keloid formation, ovarian failure, burning sensation of the scar, urinary tract infection, frequency of urination, ileus (temporary lack of movement of the intestines) (1.3%)

Serious risks

- Damage to the bowel (0.4%), bladder (0.38%), ureters (0.32%), rectum (0.06%), uterus, or major blood vessels which that would require immediate repair by laparoscopy or laparotomy (open surgery is uncommon)
- Removal of one or both ovaries for unsuspected disease
- Failure to gain entry to the abdominal cavity and to complete the intended procedure
- Hernia at site of entry (uncommon)
- Blood transfusion (3.4%)
- Thromboembolic (blood clot) complications (pulmonary embolism, venous thrombosis) (rare or very rare, 0.1%–1.2%)

- Death—women undergoing laparoscopy may die as a result of complications (very rare, 0.07%)
- Pelvic abscess/infection, bleeding, wound dehiscence (1.35%)
- Neuropathy (nerve damage) (0.2%–2%).

Possible additional procedures

- Cystoscopy (endoscopy of the bladder) (48%)
- Appendectomy (31%)
- Lymph node dissection (7%)
- Omentectomy (8%).

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

Name and signature (patient) and date

Name and signature (Medical Officer) and date

FURTHER READING

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Patient ID

TOTAL ABDOMINAL HYSTERECTOMY

Hysterectomy is the removal of the uterus. A transverse incision is made at the lower abdomen (suprapubic/midline) and the uterus and cervix are removed.

Intended benefits

- Hysterectomy is frequently performed to treat benign uterine pathology; however, it may be an option in the case of cervix dysplasia and in some stages of cervical cancer
- To control abnormal uterine bleeding.

Alternative measures

- Medical treatment, ultrasound, conservative surgery, e.g. ablation, vaginal hysterectomy, laparoscopic hysterectomy

Frequent risks

Factors that contribute to a higher risk are: age over 40 years, systemic arterial hypertension, diabetes mellitus, asthma, allergies, obesity, malnutrition, anemia, and heart, lung, neurological, hematological, or varicose diseases.

- Intra- or post-operative bleeding that requires blood transfusion (<10%)
- Formation of keloid scars and/or burning sensation of the scar (<10%)
- Surgical wound infections, pelvic abscess, and wound dehiscence (<5%)
- Bruising over the wound, pelvis, or vaginal vault (<5%)
- Removal of one or both ovaries for unsuspected disease (<5%)
- Urinary tract infection (<5%)
- After hysterectomy there will be no menstrual bleeding, and it is not possible to get pregnant.

Serious risks

- Injuries to nearby organs, such as the bladder, ureters, and bowel, for which repair will be needed (<1%)
- Vesicovaginal and intestinal fistulae (abnormal connections between the bladder and vagina or intestine and vagina) (<1%)
- Eventrations and postoperative eviscerations, descent or prolapse of the vaginal cuff (<1%)
- Venous thromboembolism can still occur, even with prophylaxis
- Death should be considered a major complication of the surgical procedure—the main causes are pulmonary embolism, venous thrombosis, and cardiac disease (rare, 32 in 100 000 cases).

Possible additional procedures

- Blood transfusion
- Removal of one or both ovaries in case of ovarian pathology (hysterectomy with bilateral salpingo-oophorectomy)
- In some cases, it is not possible to remove the entire uterus, therefore a subtotal abdominal hysterectomy should be performed (removal of the uterus without the cervix).

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- Name and signature (patient) and date

- Name and signature (Medical Officer) and date

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Patient ID

VAGINAL HYSTERECTOMY AND VAGINAL REPAIR

The vaginal hysterectomy and vaginal repair procedure involves removal of the uterus. With pelvic floor repair, it can include vaginal wall(s) reconstruction and/or urinary bladder and bowel placement to the correct anatomical position.

Intended benefits

- To improve or resolve symptoms of uterine prolapse (pressure in the vagina or lower abdomen); to resolve the feeling that “something will fall out”
- Absence of periods, loss of fertility potential
- Faster recovery and fewer days of hospitalization (minimally invasive).

Alternative measures

- Conservative treatment, such as physiotherapy or pessary placement
- Abdominal (with transverse incision to the lower abdomen) or laparoscopic (endoscopic) approach in hysterectomy.

Frequent risks

Risks are increased in women with pre-existing medical conditions (cardiovascular disease, neurological disorders), in women who had previous surgeries, or those who have fatty tissue resulting from a BMI >30 kg/m².

- Urinary infection, retention, or frequency (up to 20%)
- Surgical site infection (up to 2%)
- Vaginal bleeding or hematoma (up to 7%)
- Pain or discomfort (15%)
- Worsening of symptoms of urinary urgency (up to 30%).

Serious risks

- Injury of the adjacent urinary tract organs (0.2%) or bowel (up to 0.5%)

- Extensive bleeding requiring blood transfusion, additional surgery, or both (0.02%)
- Incomplete normal function of urinary bladder, painful intercourse, altered sexual function
- Pelvic infections/abscess (0.3%), thromboembolic (blood clot) events (0.003%)
- Recurrence of prolapse (up to 30%).

Possible additional procedures

- Blood transfusion(s) (2%)
- Laparotomy (conversion to abdominal surgery with an incision from the lower abdomen) if serious injuries of visceral organs occur.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- **Name and signature (patient) and date**

- **Name and signature (Medical Officer) and date**

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Patient ID

OPEN/ABDOMINAL MYOMECTOMY

Myomectomy is the removal of uterine fibroids. A transverse incision is made at the lower abdomen (suprapubic/midline), and the uterus is visualized. The fibroid is removed from the uterus, and the uterine defect is repaired.

Intended benefits

- To improve subfertility and symptoms of pain, urinary urgency, constipation
- To reduce menorrhagia (heavy periods) and dysmenorrhea (painful periods).

Alternative measures

- Hysterectomy if preservation of fertility is not required
- Hysteroscopic resection if the fibroid is within the uterine cavity
- Uterine artery embolization (blocking).

Frequent risks

- Bleeding requiring blood transfusion (10%)
- Postoperative ileus (temporary lack of movement of the intestines) (20%)
- Surgical site infection on skin or intra-abdominal (<5%)
- Recurrence of fibroid or adhesions (15%–50%).

Serious risks

- Injury to other organs (bladder, small or large bowel, major vessels, ureters) and repairing these injuries, such as attaching the bowel to the abdominal wall—stoma (<1%)
- Thromboembolic event—blood clots in legs, lungs, or blood vessels in the brain (<1%)
- Abnormal scarring of incision site—hypertrophic or keloid scar
- Placenta accreta in future pregnancies (very rare, <0.1%)
- Hysterectomy (very rare, <0.1%)
- Anesthetic risks—reaction to medication, pneumonia, abnormal heart rhythm (<1%).

Possible additional procedures

- Blood transfusion
- May need a cesarean delivery in future pregnancies.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

• Name and signature (patient) and date

• Name and signature (Medical Officer) and date

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Patient ID

ELECTIVE CESAREAN DELIVERY

An incision is made on the abdomen and it is opened in layers. The infant is delivered after making a cut on the uterus—usually on the lower part, but this may be occasionally made on the upper part. Sometimes an instrument, such as a vacuum extractor or forceps, may be required to deliver the baby; this is followed by delivery of the placenta and membranes. The uterus and abdominal wall are sutured in a systematic manner or layer-wise manner.

Intended benefits

- Safe delivery in cases where the infant's position is improper
- Safe delivery where the mother cannot deliver vaginally due to other medical or surgical disorders
- Safe delivery where there are fetal indications, such as non-reassuring fetal status.

Frequent risks

All risks are increased in those who are obese (BMI > 30 kg/m²), have had previous abdominal surgery, or have pre-existing medical conditions.

- Excessive bleeding/blood accumulation—the uterus usually contracts after the infant is delivered, but sometimes there may be postpartum hemorrhage. Such bleeding is controlled by using medicines, injections, compression sutures on the uterus, or ligating bleeding vessels, but rarely may require removal of the uterus (15%)
- Injury to the adjacent organs or blood vessels in the pelvis, such as urinary bladder and bowel (10%)
- Cesarean delivery may also be performed for fetal indications—neonatal morbidity noted after cesarean delivery is not due to the surgery per se, and the newborn may need resuscitation after birth (10%).

Serious risks

- Anesthesia: it is common to have drowsiness, vomiting, weakness, headache and/or temporary weakness of body parts after regional anesthesia (1%)
- Infection requiring antibiotic therapy: severe infection or sepsis may rarely occur and may require admission and management (<1%)
- Allergic reactions to any drug may occur (<1%).

Possible additional procedures

- Female sterilization
- Removal of ovarian cyst
- Removal of fibroids
- Repair of injured structures.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- Name and signature (patient) and date

- Name and signature (Medical Officer) and date

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Patient ID

CESAREAN DELIVERY FOR PLACENTA PREVIA

A transverse incision is made at the lower abdomen (suprapubic-Pfannenstiel/midline) and the uterus is visualized. The infant is delivered after making a cut on the uterus—usually on the lower part but may be occasionally made on the upper part. In most cases of placenta previa, a classical incision is preferred (cut on the upper part) over the lower part (LUSI). The placenta is sometimes left in place to prevent bleeding if it is embedded in the uterus, and medication is given to disintegrate it. The uterus and abdominal wall are sutured (stitched) in a systematic manner or layer-wise manner. The uterus sometimes might need compression sutures to stop the bleeding.

Intended benefits

- Delivery to prevent postpartum bleeding
- Risk of maternal and neonatal morbidity/mortality.

Alternative measures

- Cesarean delivery plus hysterectomy if preservation of fertility is not required.

Frequent risks

All risks are increased in those who are obese (BMI > 30 kg/m²), have had previous abdominal/uterine surgery, or have pre-existing medical conditions.

- Excessive bleeding/accumulation of blood: The uterus usually contracts after the infant is delivered, but due to abnormal placenta (adhesion to the uterine wall, displaced in lower uterus closing the cervix) there may be postpartum bleeding. Such bleeding is controlled by using medicines, injections, compression sutures on the uterus, or ligating bleeding vessels, but may sometimes require removal of the uterus (approximately 14.5%)
- Injury to the adjacent organs or blood vessels in the pelvis, such as the urinary bladder or bowel.

Serious risks

- Anesthesia: it is common to have drowsiness, vomiting, weakness, headache and/or temporary weakness of body parts after regional anesthesia (<1%)

- Infection requiring antibiotic therapy: severe infection or sepsis may rarely occur and may require admission and management (<1%)
- Allergic reactions to any drug may rarely occur (<1%)
- Need for respiratory assistance (oxygen/ventilation) (1%–2%)
- Stroke or heart attack due to strain on the heart, fluid collection in the lungs, formation of blood clots in veins leading to embolism (blood clot), further leading to damage to vital organs, loss of function of any limb or organ (<1%).

Possible additional procedures

- Subtotal hysterectomy
- Internal artery ligation
- Female sterilization
- Blood transfusion
- Repair of the bladder, ureter, bowel, blood vessels.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- **Name and signature (patient) and date**

- **Name and signature (Medical Officer) and date**

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Patient ID

VAGINAL TWIN DELIVERY

Vaginal twin delivery is the birth of twin babies through the vagina (also called the "birth canal").

Intended benefits

- Faster recovery
- Avoids the risks of cesarean delivery, such as wound complications, surgical injury (bowel injury, etc.)
- Protects from repeat risks of cesarean delivery, such as abnormal placentation, uterine rupture in a subsequent pregnancy, scar complications, adhesions, subfertility, etc.
- The adverse effects of a cesarean delivery on gut microbiota in newborns are avoided.

Alternative measures

- Cesarean delivery.

Frequent risks

- Vaginal and perineal lacerations (up to 9 in every 10 first-time mothers)
- Increased risk of postpartum bleeding (1%–5%)
- Risk of maternal pelvic floor dysfunction later in life (25%)
- Cesarean delivery may be required (40%–70%).

Serious risks

- Twin infants may become locked together during delivery (rare, 1 in 1000 to 1 in 100000 twin deliveries)
- Neck injury of the infant under challenging deliveries (rare, 0.6%–2.2%).

Possible additional procedures

- Blood transfusion
- Maneuvers can be used for breech delivery
- Cesarean delivery may be needed.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

• Name and signature (patient) and date

• Name and signature (Medical Officer) and date

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Patient ID

OPERATIVE VAGINAL DELIVERY

Operative vaginal delivery is the birth of the baby through the vagina (also called the "birth canal") by means of forceps or a vacuum device.

Intended benefits

- Faster recovery compared to a cesarean delivery
- Protects from the risks of cesarean delivery, such as wound complications, surgical injury
- Protects from the risks of repeat cesarean delivery, such as abnormal placentation, scar complications, adhesions, subfertility, etc.
- The adverse effect of a cesarean delivery on gut microbiota in the newborn is avoided.

Alternative measures

- Cesarean delivery.

Frequent risks

- Vaginal and vulval tear (7%–40%, and severe tears 0.5%–10%)
- Increased risk of postpartum bleeding (4%–20%)
- Risk of maternal pelvic floor dysfunction later in life (5%–50%)
- Facial or scalp lacerations on the baby (3%–30%, higher in forceps)
- Neonatal jaundice (10%–20%)
- Minor bleeding in the infant's head (0.4%–4.4%).

Serious risks

- Significant bleeding in the infant's head (rare, 0.3%–1.7%)
- Anal sphincter (3%–19%)/voiding dysfunction (4%–25%).

Possible additional procedures

- Blood transfusion
- Repair to bowel/bladder/ureter

- Cesarean delivery may be needed
- Removal of the uterus may be needed.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- **Name and signature (patient) and date**

- **Name and signature (Medical Officer) and date**

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Patient ID

VAGINAL BREECH DELIVERY

Vaginal breech delivery is the birth of an infant when the infant's feet or buttocks are positioned to come out of the vagina first.

Intended benefits

- Faster recovery
- Protects from the risks of cesarean delivery, such as wound complications, surgical injury (bowel injury, etc.)
- Protects from the risks of repeat cesarean delivery.

Alternative measures

- Cesarean delivery.

Frequent risks

- Vaginal (13%–40%) and perineal tear (20%–70%)
- Increased risk of postpartum bleeding (1%–8%)
- Risk of maternal pelvic floor dysfunction later in life (3%–20%).

Serious risks

- Entrapment of the infant's head may occur, and this emergency may lead to deprivation of oxygen for the infant, causing unconsciousness or death (0%–8.5%)
- Cesarean delivery may be required (30%–90%)
- Neck injury of the baby under challenging deliveries (rare, 0.2%–3%).

Possible additional procedures

- Blood transfusion
- Maneuvers can be used for breech delivery
- Cesarean delivery may be needed.

I hereby confirm that I have been fully informed about this procedure. I understand and I am aware of all the risks and benefits.

- **Name and signature (patient) and date**

- **Name and signature (Medical Officer) and date**

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AUTHOR CONTRIBUTIONS

E. Goknur Topcu and Paul Fogarty contributed to the conception of the work. All authors contributed to the data interpretation, and drafted and critically revised the manuscript.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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