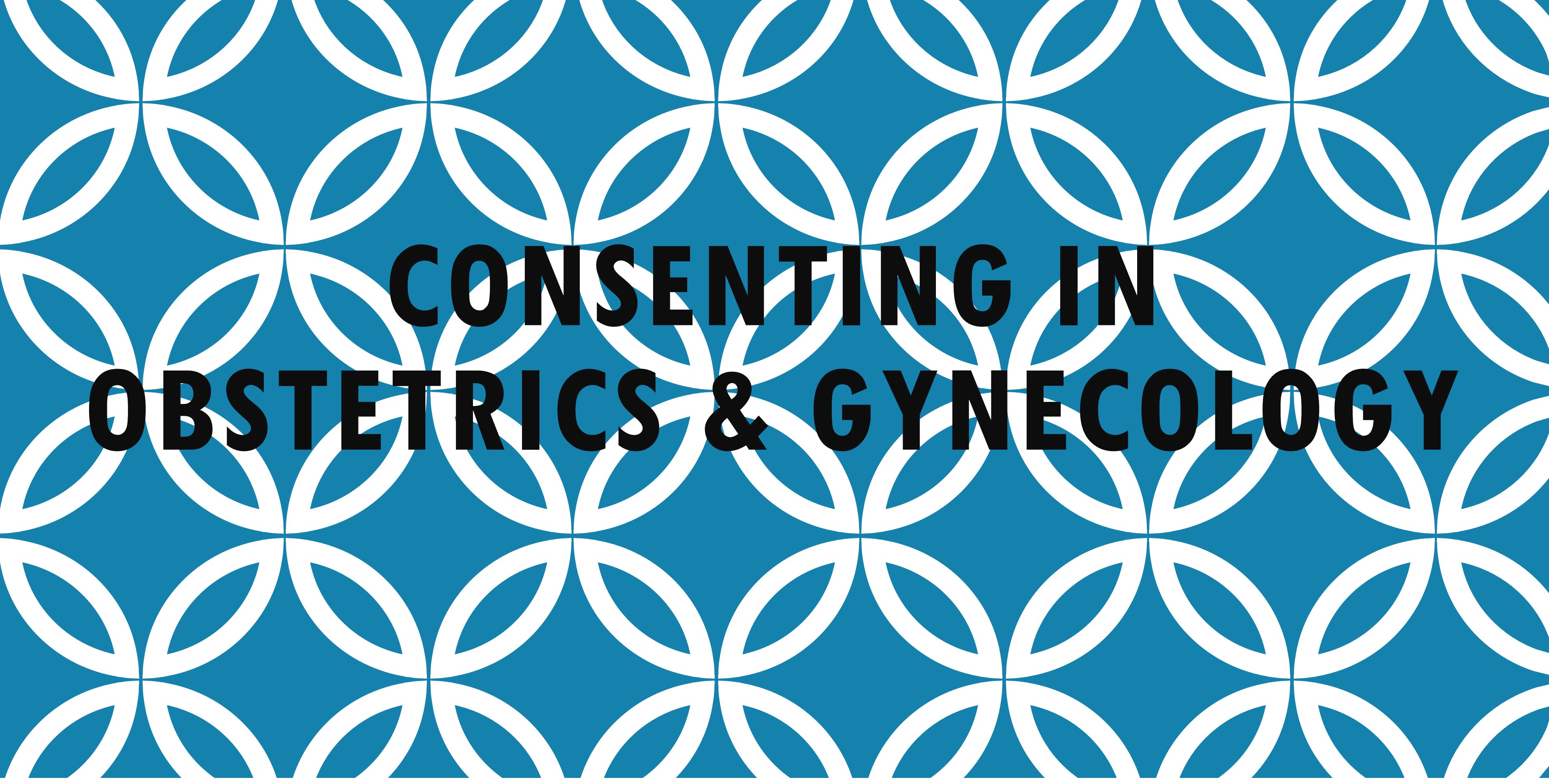

CONSENTING IN OBSTETRICS & GYNECOLOGY

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WHAT IS INFORMED CONSENT?

The Second Principle of Practice: Ethical Practice

Encompasses four main principles

- Nonmaleficence
- Beneficence
- Justice
- AUTONOMY: the right of self-determination

The concept of informed consent is derived directly from the principle of autonomy.

Informed consent is when physician **adequately discloses** the proposed plan, its **risks** and **benefits**, and **alternative approaches** to allow a **competent patient** to **understand** the plan for medical care. This is followed by the **patient's decision** to accept or decline.

Five concepts must be considered in establishing informed consent:

- Voluntariness
- Capacity
- Disclosure
- Understanding
- Decision

CONTENTS OF THE CONSENT

1. Patient's full understanding of the nature of their condition, its prognosis, likely consequences and the risks of receiving no treatment.

2. The proposed procedure and reason behind it.

Expected length of stay in hospital

Medication

Anesthesia

Surgery (including site and size of any incision and any likely scarring)

Recovery \ likely impact on daily and personal life (e.g. time off work, driving, lifting, sexual activity)

The need for vaginal examination during the procedure

Examination of removed tissue (storage/disposal)

Video recording and/or photography

3. Intended benefits:

Clearly describe to the patient how she can expect the intervention to help her condition or illness.

4. Risks:

Avoid saying “high or low risk” or percentages when discussing risk.

- It is preferable to use frequencies (eg. if 100 people have this procedure, five of them will have this complication).

Inform the patient of any risks associated with her medical history,

- Eg. obesity, previous surgery, pre-existing medical conditions, smoking.

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

It is important to make a clear distinction to the patient serious risks from frequent risk

Serious risks: Occur with varying frequency depending on the procedure are:

Death, venous thrombosis, pulmonary embolism, return to theatre, trauma to bowel, bladder, ureter and major blood vessels

Frequent risks:

Infection, bruising, bleeding, scarring, adhesions, urinary frequency or incontinence, anemia, fatigue.

Unavoidable risks: Specific risks of any particular procedure, eg. hysterectomy at the time of myomectomy for life-threatening bleeding. Even if the risk is small (1–2%), the patient should be informed.

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

Blood transfusion

Hysterectomy during myomectomy

Proceeding from laparoscopy to laparotomy

Tissue sampling of a lump

Oophorectomy during hysterectomy

Appendectomy

6. Anesthesia.

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

THE *PREPARED* SYSTEM: A CHECKLIST TO GUIDE PATIENT AND PROVIDER IN THE PROCESS OF INFORMED CONSENT

P	lan	The course of action being considered
R	eason	The indication or rationale
E	xpectation	The chances of benefit and failure
P	references	Patient-centered priorities (utilities) and cultural preferences affecting choice
A	lternatives	All other reasonable options
R	isks	The potential for harm from treatment
E	xpenses	All direct and indirect costs
D	ecision	Fully informed collaborative choice and consent

Modified from Reiter RC, Lench JB, Gambone JC: Consumer advocacy, elective surgery, and the "golden era of medicine." *Obstet Gynecol* 74:815–817, 1989.

SHOULD CONSENT BE VERBAL OR WRITTEN?

Verbal Consent

- It is mainly required in cases where **examination of females** is required.
- **Tests necessitating removal of body fluids.**
- **Radiological exam**
- Brief oral consent **at the time of a complication** is appropriate. Full written consent is then obtained at a later stage.

Written Consent

Written consent is mainly mandatory for medicolegal reasons. It should be taken for every invasive diagnostic/therapeutic procedure.

It should be taken in the patient's language.

SPECIAL CASES IN OBTAINING CONSENT

Emergencies

Incompetence: Incompetent patients may not be able to give informed consent.

Waiver: Patients may waive their rights to receive information.

Therapeutic privilege

PATIENTS WHO CANNOT PROVIDE AN INFORMED CONSENT:

Minors: Those under the age of 18 in Jordan, who are generally considered incompetent to make informed consent decisions. Parental consent should be obtained, but exceptions exist for emergency treatment (e.g., blood transfusions).

If **a patient loses decision-making capacity** and has not prepared an advance directive, a close person to the patient (surrogate) should be discussed with about what the patient would have preferred.

- Also seek the advice of an experienced colleague and consider seeking legal advice on appropriate management.
- If refusal of consent prior to losing capacity, the patient’s wishes should be respected, even at the expense of the fetus.

Priority of surrogates

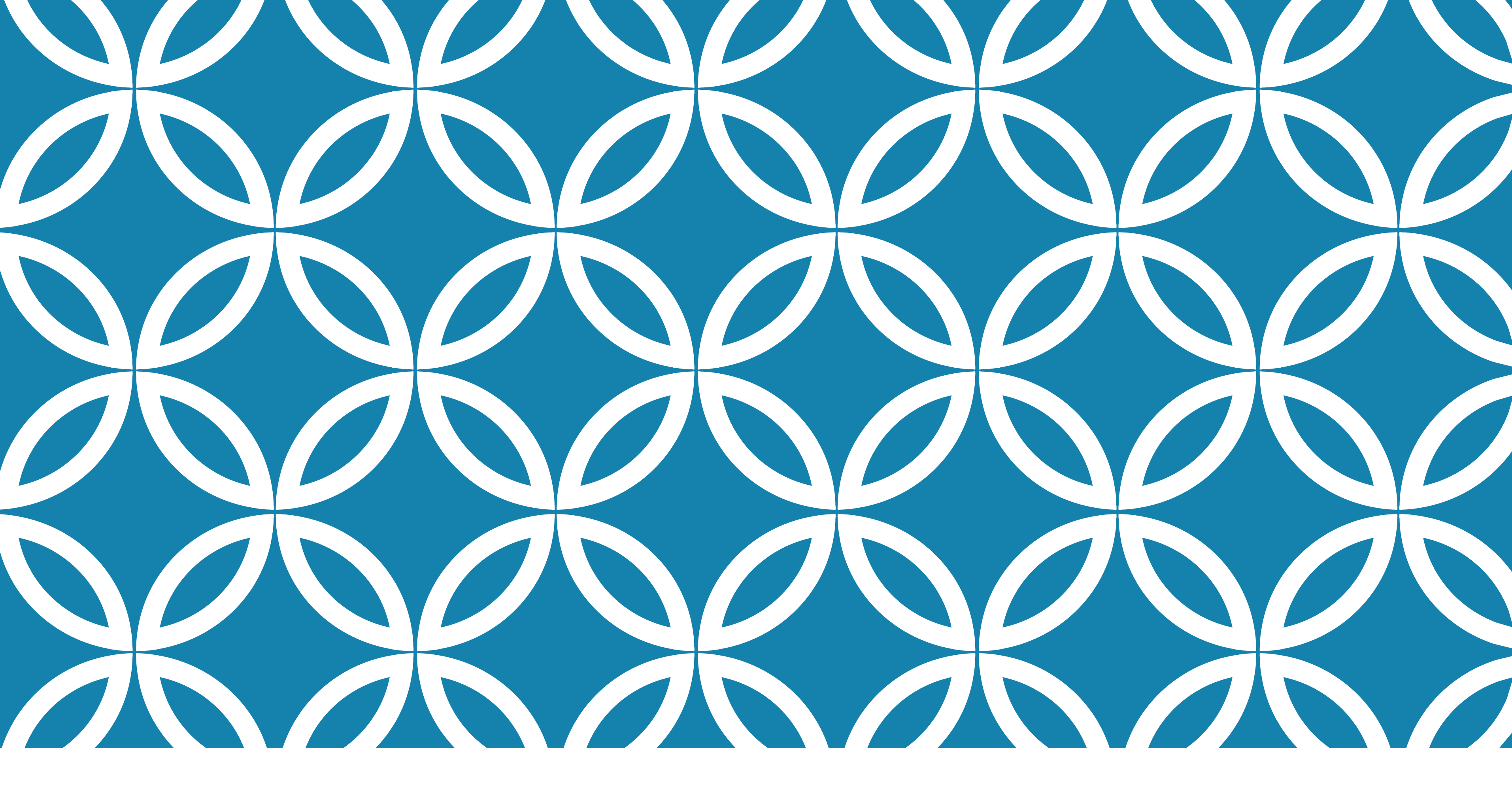
Spouse -> Adult children -> Parents -> Siblings -> Other relatives

WHAT TO DO IN THE CASE OF AN UNANTICIPATED EMERGENCY?

The classic example of this is abdominal hysterectomy for postpartum hemorrhage to save life. In such cases:

The opinion of an experienced colleague or other specialist must be sought before undertaking additional procedures.

Where possible, prior consent to treat any problem that could reasonably be expected to arise should be obtained and documentation of any procedures to which the patient would object.



INFORMED CONSENT IN OBSTETRICS

HOW TO TAKE CONSENT FROM A WOMAN IN PAIN/LABOR?

Consenting labouring women is recognized to be challenging and therefore it is uncertain that pregnant women(whether in pain or under the influence of analgesia) would experience true informed consent during labour.

As a result, it is best to inform the women about all possible or predictable problems during the antenatal period.

During labor, when obtaining consent for procedures such as vaginal examination, episiotomy, operative deliveries, or epidural placement, it is essential to provide information during the intervals between contractions.

HOW TO TAKE CONSENT FOR ASSISTED VAGINAL DELIVERIES, EMERGENT C/S AND PERINEAL REPAIR?

In cases of emergencies, **verbal** consent should be obtained in the presence of a witness (another healthcare professional) and should be recorded along with the reason to proceeding to an emergency delivery. *No written consent is required.*

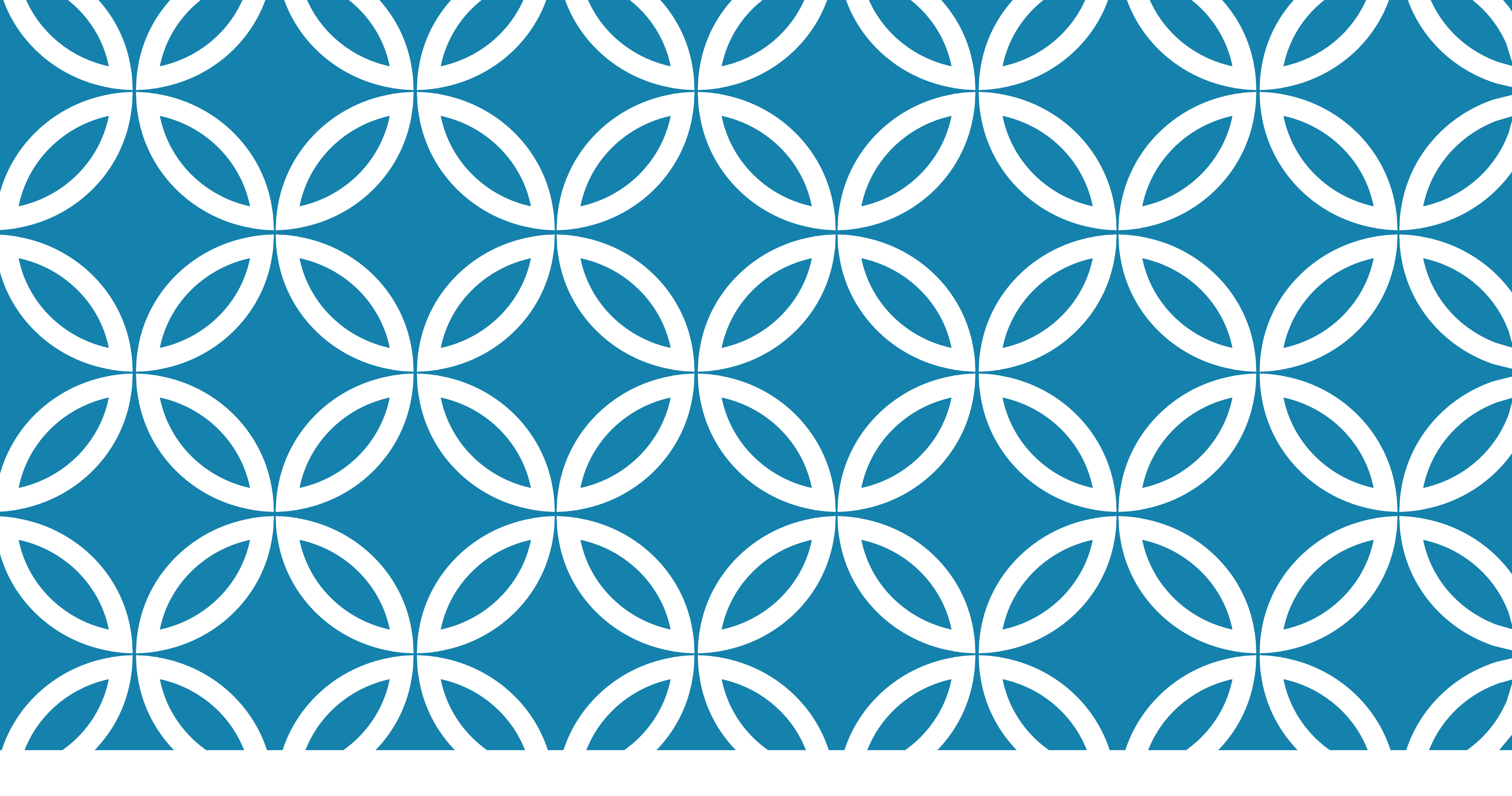
If a woman who seems to be competent, refuses proceeding to emergency delivery after being explained all the consequences and risks to her and the fetus, her decision must be respected.

Verbal consent is acceptable for a perineal repair under local anesthesia (following vaginal or assisted vaginal delivery). However, **written** consent should be taken if more extensive repair is needed for example under GA.

HOW TO TAKE CONSENT FOR ULTRASOUND EXAMINATION IN PREGNANCY?

Written consent for ultrasound screening is **not** considered to be necessary.

However, women should be informed about the reasons behind any scans. Additionally, all women have the right to request information and discuss any concerns with their doctors.



INFORMED CONSENT IN GYNECOLOGY

HOW TO TAKE CONSENT IN GYNECOLOGICAL EXAMINATIONS?

Pelvic examination

1) Gynecologist must know why the exam is necessary (diagnostic/ screening)

2) Chaperone must be present

3) Verbal consent should be taken with the presence of the chaperone

4) Consent should be specific (vaginal/rectal/both)

5) In cases where patient refuses the presence of a chaperone, doctor must explain the importance of their presence and must arrange the chaperone to be in a range of distance in which it is possible to be heard and this should be documented as well(declining chaperone and the new arrangements).

HOW TO TAKE CONSENT IN GYNECOLOGICAL EXAMINATIONS?

Breast examination

1) Verbal consent should be obtained in the presence of a chaperone
2) No evidence supporting routine breast examination in pregnant women/ gynecological patients.

UNEXPECTED PATHOLOGY

If the unexpected pathology is **minor**, treatment can be performed if the woman has been made aware of the types of minor treatment that she could receive and has already given consent to the consequences of the treatment. For example, minor endometriosis.

If such preoperative discussion has not occurred then additional treatment should **not** take place. These occur in cases where the problem is related to the women's complaint.

In cases where complications occurs during surgery such as trauma which is **life threatening**, corrective surgery should be done as it is life saving then explanation should be given to the woman as soon as possible.

All women undergoing hysterectomy, should provide consent for the possibility of performing an oophorectomy. If no consent was received beforehand then the doctor must record their decision and the reason behind it.

UNEXPECTED PREGNANCY

Pregnancy should be **excluded** before any surgical procedure

If a pregnancy is discovered at the start of a hysterectomy, the operation should be **rescheduled.**

An unexpected **ectopic** pregnancy should be removed, assuming that the woman would wish this as the surgeon acted in favor of a life saving treatment.

HOW TO TAKE CONSENT FOR TISSUE SAMPLES?

Specific consent for the removal of tissue for the purpose of histological examination is **not** required.

The woman must understand and be aware that tissue sample may be removed during the procedure for which consent **must** be taken.

Consent should be taken if the tissue sample is to be used for **research**.

Following fetal loss, written consent is needed for procedures to be done to the fetus such as taking samples for testing, teaching and research.

INFERTILITY

Couples must understand the treatment implications of their decision.

Each type of treatment has its **own** consent form

Important points in the consent form(IVF):

Couple must understand how the drug works and the side effect (OHSS- which is life-threatening) and no guarantee that the oocyte would be fertilized, even if there was fertilization there is no guarantee that the embryo is of suitable quality to be transferred and that there is no assurance that the pregnancy would result in the delivery of a normal living child.

STERILIZATION

Both partners must agree on that decision

Full informed consent of person receiving treatment is necessary

Their family has been completed

<u>Important points in the consent form:</u>

The procedure is irreversible and permanent

The couple would not be able to conceive after

The couple should be informed about other birth control options and have rejected them and chose

OBTAINING LEGAL ADVICE

In cases where the woman lacks the mental capacity to consent, an appropriate dialogue with family, carers and multidisciplinary team should be done.

If there were any differences of opinions about her and her best interest, this is when a doctor would step up and consult experienced colleagues and seek legal advice on appropriate management

If the woman lost mental capacity after refusing consent to treatment following previous discussion, her decision should be respected as if she was competent, even if it was at the expense of the fetus.

Appendix I: Female sterilisation consent to treatment form

Patient identifier/label ....

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

Female sterilisation

Statement of health professional (*to be filled in by health professional with appropriate knowledge of the proposed procedure, as specified in the consent policy, and preferably capable of performing the procedure themselves)*

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

The intended benefits

To prevent pregnancy permanently.

Serious and frequent risks

- Failure of the procedure resulting in unplanned pregnancy: the lifetime failure rate is 2–5 per 1000 at 10 years (uncommon).
- If future pregnancy occurs, there is a greater chance that it may be ectopic (pregnancy outside the womb) than may occur naturally.
- Regret, leading to request for reversal.
- Failure to complete the procedure by the chosen method
- Absolute irreversibility of hysteroscopic sterilisation may lead to request for IVF.

Any extra procedures which may become necessary during the procedure

- Laparotomy (open surgery) for repair of damage to bowel, bladder, uterus or blood vessels.
- 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.I have discussed the permanent nature of the procedure.

The following information has been provided ....

The 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)*

....

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 she can understand.

Signed .... Date

.... Name *(print)*

....

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

Patient identifier/label

Name of proposed procedure or course of treatment

(include brief explanation if medical term not clear) *Total/subtotal abdominal hysterectomy.*

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: *While menstrual bleeding is guaranteed to be abolished by total hysterectomy, the effect on pelvic pain and premenstrual symptoms is not guaranteed and the likelihood of this effect should be discussed.*

Serious risks:

- *Damage to the bladder and/or the ureter (7 women in every 1000) and/or long-term disturbance to the bladder function (uncommon)*
- *Damage to the bowel, 4 women in every 10 000 (rare)*
- *Haemorrhage requiring blood transfusion, 23 women in every 1000 (common)*
- *Return to theatre, 7 women in every 1000 (uncommon)*
- *Pelvic abscess/infection, 2 women in every 1000 (uncommon)*
- *Venous thrombosis or pulmonary embolism, 4 women in every 1000 (uncommon)*
- *Risk of death within 6 weeks is 32 women in every 100 000 (rare)*

Frequent risks:

- *Wound infection, bruising, delayed wound healing or keloid formation*
- *Numbness, tingling or burning sensation (this is usually self-limiting but could take weeks or months to resolve)*
- *Frequency of micturition and urinary tract infection*
- *Ovarian failure*

Any extra procedures which may become necessary during

☐ the procedure blood transfusion

☐ other procedure (please specify) *Repair to bladder, bowel or major blood vessels; oophorectomy for unsuspected disease*

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 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)

THANK YOU