Module 1: Clinical skills

Capabilities in Practice: be able to successfully work within the health organisations

SOURCES:

TOG: CONSENT IN CLINICAL PRACTICE: 2015; 17: 251

RCOG: PRESENTING INFORMATION ON RISK: CLINICAL GOVERNANCE ADVICE NO. 7 DECEMBER 2008

TOG: DECISION-MAKING FRAMEWORK IN GYNAECOLOGY FOR PATIENTS WHO LACK MENTAL CAPACITY 2018; 20: 31

RCOG: OBTAINING A VALID CONSENT:CLINICAL GOVERNANCE ADVICE NO. 6 JANUARY 2015

TOG: LITIGATION IN GYNAECOLOGY 2014;16:41

TOG: MEDICOLEGAL UPDATE ON CONSENT: 'THE MONTGOMERY RULING' 2016: 18: 171

THE MENTAL CAPACITY ACT 2005

Knowledge requirements under Module 1:

- In the syllabus, two heads of knowledge are required:
- Understand the important elements in an obstetric and gynaecological history taking

AND

- Understand the principles and legal issues surrounding informed consent, with particular awareness of the implications for the unborn child, post mortem examinations, consent to surgical procedures including sterilisation, parental consent and Fraser guidelines and medical certification
- However, the first head on O&G history will be covered under other areas to be followed e.g. under core surgical skills. This module will concentrate on consent and special areas surrounding its ambit

The scope of module

At the end of this module, you should be able to answer question on:

- What are the elements of a valid consent i.e. there must be 1. capacity. 2. that it is "informed" and 3.that it is given voluntarily and can be withdrawn at any time, including the mother's rights over the foetus
- The ambit of the **Mental Capacity Act 2005**
- Capacity in special situation e.g. < 16 year olds, emergency, advanced directive
- The elements of a properly informed consent e.g. informing of material risks and the best ways to do so
- Special situations in consent e.g. minor procedures, sterilisation, post-mortem, multimedia images, termination of pregnancy etc.

Valid consent

What constitutes a valid consent?

For a valid consent, three elements must be satisfied:

- The patient must have the capacity to give consent
- The consent must be " informed"
- The consent must be given voluntarily and can be withdrawn at anytime

Let us take them in turn

Capacity

What is meant by the capacity to give consent?

For a start the relevant **Statutory provisions** for the age of consent are:

- The **Children Act 1989** states that a person 18 years or more is considered an adult and capable of giving consent.
- But for having sexual intercourse, the **Sexual Offences Act 2003** states that a child below 13 years is considered incapable of giving consent to sexual intercourse (Statutory rape)
- The **Mental Capacity Act 2005** on the other hand, was enacted to protect a person who is "unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of the mind or brain." But an important requisite is that the person must be 16 years or more. For the under 16s, see later.
- Note that because capacity plays a vital role in consent *for treatment*, the provisions in the Mental Capacity Act has relevance to Obstetrics and Gynaecology and especially where there is a disagreement between the parties

The legal body that overseas the Mental Capacity Act is the Court of Protection

*Please note that in contrast, the **Mental Health Act 2007** is applicable to "mentally disordered" person and is more relevant in psychiatry*

What are the guiding principles on capacity under the Mental Capacity Act 2005?

The Act states that:

- a person must be assumed to have capacity unless it is established that he lacks capacity.
- a person is not to be treated as **unable to make a decision** unless all practicable steps **to help him** to do so have been taken *but without success*
- a person is not to be treated as unable to make a decision merely because he makes an unwise decision.
- an act done, or decision made under the Act for or on behalf of a person who lacks capacity e.g. parent for child, must be done, or made, in his best interests

When is a person considered to have the capacity to consent?

Under Section 3 of the Mental Capacity Act , there are four heads that must be fulfilled for capacity. The person must **be able** :

- to understand the information relevant to the decision
- to retain that information,
- to use or weigh that information as part of the process of making the decision
- AND
- to communicate back his decision (whether by talking, using sign language or any other means)

How does one assess mental capacity?

- Under the Mental Capacity Act, a two stage test is applied:

  a *diagnostic* component and a *functional* component

- **First ascertain the diagnostic component:**

  determine whether there is a disturbance of or impairment in the functioning of the mind or brain sufficient enough to impair the decision making e.g. CVA, hypoxia, influence of drugs, acute pain. Note that during labour, pain per se does not mean she does not have the capacity but the consent should best be done during a pain free period

- **Then, move on to the functional component**

  i.e. determine whether she can retain and evaluate the information provided in order to reach a decision, and to communicate back any decision made

Note that it is not the rationality of the decision being made but on **how the process** by which it was made that is important

Also note that you don't need a psychiatrist to ascertain capacity; being a gynaecologist will suffice

What if there is doubt in whether the patient has the capacity to give consent?

- In the first instance it is best to consult a senior colleagues (e.g. consultant or a psychiatrist) or seek legal advice

But under the Mental Capacity Act 2005

- An **Independent Mental Capacity Advocate (IMCA)** service provides help for individuals who have no intimate support network.
- Where there's serious doubt or dispute about what's in an incapacitated person's best interests, the case can be referred to the **Court of Protection** for a ruling (the body that oversees the the provisions under the Act)
- The **Office of the Public Guardian** (formerly Public Guardianship Office), is the administrative arm of the Court of Protection and will help administer the case

What if a person feels that her capacity to consent may be affected in the future?

- The Mental Capacity Act (Section 9) gives her the right to make what we call an **advanced decision** or "living will" that concerns her "welfare" e.g. a decision can be made to refuse a specific type of treatment at some time in the future. It is legally binding
- The patient, now competent and 18 years or more, gives that **"lasting powers"** to an **attorney** who must also be an adult. However the advanced decision must be registered with the Public Guardian
- The attorney may make proxy decisions regarding medical treatment in the best interests of the patient e.g. the attorney may even refuse life-sustaining treatment for the patient, provided the patient has specifically and explicitly empowered them to do so and in writing

NB: you must distinguish advanced decision from and advanced statement. Advanced statements set out the patient's preferences, wishes, beliefs and values regarding her future care e.g. a spiritual belief to be incorporated in her care. These are not legally binding but persuasive especially in the event the patient has lost her capacity.

The take home points

- Know the grounds for a valid consent
- The age of consent and the statutory provisions
- Have an in-depth knowledge under the provisions of the Mental Capacity Act and its governing body
- Know the validity of an advanced decision under the Mental Capacity Act

Capacity in special situations

What if the child is below 16 years?
Gillick competence and the Fraser ruling

- Generally, consent from parent is advisable but involve the child in discussion

Gillick competence (named after Gillick, the appellant mother): General guidelines

- In the case of *Gillick v West Norfolk (1985),* children under 16 **can consent** if they have sufficient understanding and intelligence to fully understand what is involved in a proposed treatment i.e. able to understand, retain, use and weigh this information, and communicate their decision.
- If the child does not pass the Gillick competence test then, parental consent is needed
- Note however, that parents cannot override the competent consent of a young person (16 to 17 years) to treatment that the doctor considers is *in their best interests*.

Fraser (named after one of the Law Lords) ruling on competence: more specific to *contraceptive advice and now sexual health*. Under the rule:

- The patient must show sufficient maturity and intelligence to understand the nature and implications of the proposed treatment
- She cannot be persuaded to tell her parents or to allow the doctor to tell them
- She is likely to begin or continue having sexual intercourse with or without contraceptive treatment
- Her physical or mental health is likely to suffer unless she received the advice or treatment
- It is in her best interests.

Note that after the Sue Axton case, rules are now expanded for sexually transmitted disease and termination of pregnancy

What if the child <16 refuses consent for treatment?

- Refusal of consent can be over-ridden by parents and the courts if the refusal is not in the best interest of the child

but it is best to involve

1. other members of the multi-disciplinary team 2. an independent advocate 3. a designated doctor for child protection.

- A word of caution: the decision must be individualised e.g. one must differentiate between relatively risk free treatment and high risk procedures in refusing that treatment

What if it is an emergency?

This will depend on whether the patient is conscious or unconscious

The unconscious patient

- BMA directive

"In an emergency, where consent cannot be obtained, doctors should provide medical treatment that is in the patient's best interests and is immediately necessary to save life or avoid significant deterioration in the patient's health. If, however, the patient is an adult and there is clear evidence of a valid advance refusal of a particular treatment (such as a refusal of blood by a Jehovah's Witness) that treatment should not be given. If a patient has appointed a welfare attorney, or there is a court-appointed deputy or guardian, this person where practicable must be consulted about treatment decisions.'

The conscious patient:

- Obtaining a consent is vital. Written and signed. If verbal it must be witnessed by another health care professional and recorded in the notes
- The patient's concerns must be taken into consideration
- All material information tailored to her needs must be given
- The patient must not be influenced by family, friends or any other third party
- The right to withdraw must be respected

What if the patient does not speak English?

- Professional interpreters where possible, should be used
- Hospital staff as interpreters are not acceptable except in an emergency situation
- Family members as interpreters are unacceptable as they can influence the decision
- If no interpreter is available, it does not invalidate a consent and one must proceed if it is the best interest of the patient

Can a "substituted judgement" be made on behalf of an incapacitated person?

A good example is the situation where a father directs the Health Authorities to withdraw life saving treatment for his daughter

The Mental Capacity Act 2005 provides strict guidelines in such circumstances

- Firstly it must be in the best interest of the patient
- In coming to that decision, the best medical practice guidelines and common law principles must be applied
- The Court of Protection has the right to overrule or reject any decision that is deemed not to be in the best interest of the individual.

Consent must be informed

What are the essential elements involved in an informed consent?

The important issues that must be discussed are:

- She understands the nature of the condition for which she is to be treated for
- The prognosis after treatment
- Any material risks involved in the treatment
- The likely consequences and the risks if she opts not to have treatment
- Any reasonable or alternative treatments available to her
- Any uncertainties in her mind that she may have about the proposed treatment

What is meant by an informed consent?

The Mental Capacity Act 2005 lays down the criteria for a properly informed consent. The information given to the patient must be such that she is:

- Able to understand information relevant to the decision
- Able to retain that information
- Use or weigh it as part of a decision

AND

- communicate their decision effectively, by any means

NB: Central to an informed consent is that the patient knows and understands the risks involved in the treatment

What is the standard required in disclosure of risks?

- The leading case on disclosure of risks is the Supreme Court's decision in *Montgomery v Lanarkshire Health Board* (2015) UKSC 11. The issue surrounding the case was whether a risk of shoulder dystocia in a diabetic mother (9-10%) should have been told to the mother
- The Court held for the patient stating that:

*'The doctor is under a duty to **take reasonable care** to ensure that the patient is aware of any **material risks** involved in any recommended treatment, and of **any reasonable alternative** or variant treatments.* This has now been called the "Montgomery ruling"

- It replaces the *Bolum* or *Siddaway t*est where it was a doctor's duty to warn patients of risks was based on whether *they had* ***acted in line with a responsible body of medical opinion.***

This begs the next question: what is meant by a "material risk"

What is meant by a "material risk"?

- The test of materiality in *Montgomery* is 'whether, in the circumstances of the particular case, *a reasonable person* in the patient's position would be likely to attach significance to the risk, **or** the doctor is or should reasonably be aware that the *particular patient* would be likely to attach significance to it'.

Note that there are two components to it:

- *an objective one*: a reasonable person in the patient's position would be likely to attach significance to the risk i.e. the " reasonable patient" test e.g. the risk of urinary fistula in an anticipated difficult hysterectomy

and

- *a subjective one*: "the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it' e.g. a particular post- menopausal lady may still want her ovaries preserved.

Is there a best way to inform risks?

- The important thing is that she must be able to understand and conceptualize the risk. Avoid giving figures like percentage or attributable risks or relative risks. It is best to express risk in simple terms e.g. if 100 people have this procedure, five of them will have this complication
- Numerical aids are another way as recommended by the RCOG 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

From: RCOG: Clinical Governance Advice No. 6 January 2015

Note that the RCOG has come up with a series of Consent Advice Guidelines for the risks involved in gynaecological and Obstetric procedures e.g. laparoscopy, hysteroscopy, tubal ligation. Caesarean section
These will be covered in late modules when the specific procedures are discussed

Are there times when information should **not be given** or consent asked for?

- The following are some situations:
- at the same time as when she is undergoing a gynaecological examination.
- during periods of pain while she is in labour
- just prior to being wheeled-in into the operating theatre. Note that if the consent is to be obtained immediately before the operation by the operating doctor, it is vital that she has been offered the opportunity to discuss the issues in a clinic visit or by a preoperative assessment unit.
- in front of close friends and relatives-especially if they are overbearing and have significant control in the decision making

Are there official documents that must be followed in taking a consent?

- Yes there is. The England/ Welsh Assembly Government/Department of Health, Social Services and Public Safety, Northern Ireland have come up with a Consent Form 1 for Obstetric and Gynaecological procedures

In essence it requires:

- The name of the proposed procedure or treatment
- What is likely to be involved in the procedure e.g. expected length of stay in hospital, the medication, anaesthesia, size of incision, medication etc.
- What are the intended benefits
- Any serious complications (e.g. death, DVT, return to theatre)
- Any unavoidable complications(e.g. risk of hysterectomy in doing a myomectomy)
- Any common and/or frequent risks (e.g. infections, bleeding, scarring)
- Any extra procedures which may become necessary during the surgery e.g. blood transfusion, appendicectomy
- Any procedures which she feels should not be carried out without further discussion with her e.g. removal of ovaries at hysterectomy

The consent must be given voluntarily and can be withdrawn at anytime

Note: The right to refuse treatment is a patient's right

- The refusal to undergo treatment is a patient's right **even if** it may be detrimental to her own or her baby's health.

The case of St Georges Healthcare NHS v S (1998) is illustrative. The patient refused a Caesarean because of severe pre-eclampsia. A court order was applied for and the patient was finally delivered by Caesarean section. On appeal by the patient, the Court held that she was unlawfully detained and her right to autonomy was taken away

- A person who is deemed to have capacity to consent is entitled to withdraw their consent to treatment at any given time.

If the procedure has already commenced, the procedure should be stopped when and if it is safe to do so. The necessity of the procedure must subsequently be explained without coercion or pressure.

- However if one is to overrule a patient's decision, only a Court order can do so and on the grounds that she lacks capacity.

In the case of Re MB (Adult, medical treatment) [1997] the mother refused a Caesarean section for footling breech presentation because of needle phobia. A Court order was applied on the grounds that she lacked capacity. The mother was delivered by Caesarean section. On appeal by the mother subsequently, the Court held for the Health Authorities stating that her needle phobia impaired her ability to make a rational, informed decision on the information given to her.

Does the mother's rights override the unborn child's rights?

- This is a difficult area and even the Courts have had difficulty.
- The general rule is that the mother's rights take precedence over the unborn child's rights on the grounds of autonomy. Some decided cases are illustrative
- In *Airedale NHS Trust* it was held that " *if the patient is capable of making a decision, ….a doctor has no right to proceed in the face of objection even if it is plain to all that adverse consequences or even if death may ensue*"
- *St Georges Health Care NHS Trust* the mother had severe pre-eclampsia but she refused a Caesarean section despite being told that both she and the baby may not survive. The Court ordered the mother to be delivered by Caesarean section. On appeal by the mother the Court of Appeal criticized the decision of the lower Court for allowing the section because it was an affront to her autonomy
- In *ReF (in utero)* an attempt was made to make the fetus a ward (under the jurisdiction of the court) of the court but it failed because the Court held that the fetus does not have a legal standing

Special situations in consent

Source: RCOG: Obtaining a valid consent:Clinical Governance Advice No. 6 January 2015

What are the precautions when taking a consent for screening tests e.g. for genetic anomalies

It is essential that the woman is made aware of the:

- The purpose of the test
- The uncertainties and implications of the screening e.g. false positive or false negative rates
- and ensuring her that the information she requires is being provided from approved sources such as the RCOG or other relevant national bodies

Can a girl under 16 give consent for her termination of pregnancy?

- Girls under 16 years of age are able to give their consent to undergo medical or surgical termination of pregnancy provided that they are considered to have the capacity (Fraser ruling)
- It is not essential but advisable to involve a parent or responsible adult
- The putative father cannot override or withhold consent for abortion.

What if there is parental disagreement i.e. where the husband and wife disagree?

- It is usually sufficient to have consent from one parent.
- If parents cannot agree, resolve the dispute informally
- If the dispute cannot be resolved, legal advice should be sought on whether one should apply for a Court order

Who must take the consent for elective procedures?

- It must usually be taken by the surgeon doing the operation; but it can be delegated provided the delegated doctor is
- 1. suitably trained
- 2. has knowledge of the procedure and its inherent risks
- 3. is up to date with the information

When is it appropriate to *retake* a consent?

When:

- sufficient time has passed since the initial consent
- there has been a material change/changes in the patients condition
- new information has now become available on the risks or alternative lines of management available

What is the scope of consent in gynecological procedures?

- **Pelvic examination**: verbal, in presence of chaperone, documented
- **Breast examination**: verbal, in presence of chaperone, documented
- **Unexpected pathology requiring surgery**: can proceed if prior discussion
- An important thing Is whether the unexpected pathology is related to the patients primary problem? e.g. mild endometriosis at laparoscopy for infertility. Here surgery can proceed if the issue has been discussed. If no prior consent – proceed but reasons for surgery recorded and patient informed as soon as possible
- Notwithstanding, the following must be discussed **prior to** pelvic surgery:

  tissue sampling of a lump
  oophorectomy during hysterectomy
  appendicectomy
  hysterectomy during myomectomy
  proceeding from laparoscopy to laparotomy.

What is the scope of consent in gynecological procedures? (cont)

- **Unexpected pregnancy**: If discovered at the start of a hysterectomy, including for cancer, the operation should be rescheduled

Notwithstanding, a potentially viable pregnancy should not be terminated without the woman's consent (Abortion Act 1967). But an unexpected ectopic pregnancy should be removed because it is reasonable to presume that the patient would wish this.

- **Outpatient procedures** e.g. hysteroscopy : written consent form with documentation in notes
- **Termination of pregnancy**: if under16 can give consent if deemed to be Gillick competent. Advisable but not essential that parent involved. Putative father cannot override or with hold consent

What are the special precautions for consent for sterilization?

- If doubt exist about mental capacity: there must be legal consultation or referred to the courts
- Consent should **not** be taken during labour unless discussed during antenatal period and consent already provisionally agreed
- The consent should not be obtained just prior to Caesarean section because there is every chance of a regret
- The risk of failure for the sterilization procedure must be explained

Is a consent needed by the patient if students or trainees are present?

Yes there is:

Explicit consent of women is required :

- during gynaecological and obstetric consultations
  in operating theatres as observers and assistants
  if clinical pelvic examination is being done
- However, written consent must be obtained for pelvic examination

  of anaesthetised women by students

Is consent needed for multimedia images of surgical procedures?

- For laparoscopic findings, ultrasound, radiology images etc. no consent is needed if they form part of the management of the patient
- If they are to be used for education or teaching, written consent must be obtained and the use must not be wider than that to which consent has been given
- If the patient is recognizable in the images, consent and clear instructions must be obtained from her
- Images of interesting findings should not be taken with personal smartphones. Neither are they allowed to be duplicated or shared.

What is the scope of consent in obstetric procedures?

- **General ultrasound examination**: verbal consent
- **If for screening**: the nature and purpose of the examination and the detection rate for defined common conditions should be discussed including the uncertainties and implications of screening
- **Admitted in labour or induction**: "summarised information concerning possible procedures and interventions" that may be involved
- **If during labour**: consent taken between contractions. Pain per se does not invalidate a properly executed consent
- **Narcotic and epidural analgesia**: written consent needed and explanation of risks and effects
- **Emergency assisted vaginal deliveries**: verbal consent with witness
- **Emergency Caesarean section**: written consent

If consent refused despite convincing: do not proceed with surgery

What form of consent is required for a post mortem examination?

A post-mortem examination will be carried out if it's been requested by:

- a coroner – because the cause of death is unknown, or following a sudden, violent or unexpected death. No consent is required
- a hospital doctor – to find out more about an illness or the cause of death, or to further medical research and understanding. Here the post-mortem can only be carried out with consent. Sometimes a person may have given their consent before they died.
- The Human Tissue Authority recommends that the next of kin should be given at least 24 hours to consider for the decision about the post-mortem examination

What are the consequences of not taking a valid consent

The GMC provides clear advice on this issue:

- There can be charges of professional misconduct which ultimately may affect a doctor's registration.
- If consent is not obtained in cases where it should be and the patient has come to harm, this could lead to legal claims and criminal charges of assault or battery

Thank you