Obtaining Informed Consent

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Obtaining informed consent

- **Is normally a process not a single discrete event**
- **Will only cover clinical IC in adults due to time constraints: so I won't cover**
  - ***Children* more variable legal frameworks**
  - ***Advance decisions*** (to accept or refuse Rx)
  - ***Research/teaching consent*** (as full talk in itself)
  - ***Mental illness* legislation & consent**

Obtaining informed consent

1. Informing the consent
2. Emergency treatment
    a. Capable (of giving consent)
    b. Incapable
3. Assessment of capacity to consent
4. Best Interests determination
5. Video


WHAT IS
INFORMED
CONSENT

Consent

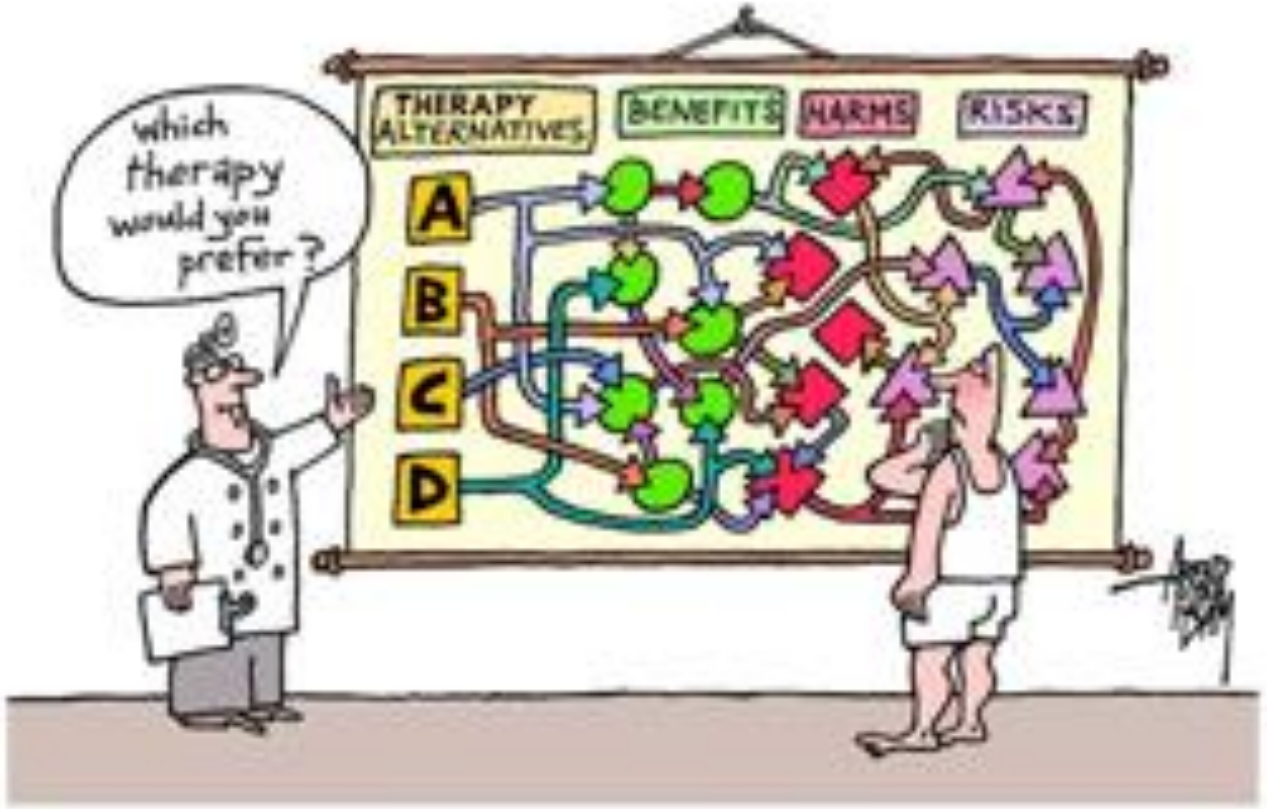
Valid consent relies upon 3 defined principles

1. **CAPACITY** *(ability to make a decision)*
2. **INFORMED** *(given all information needed to make that decision)*
3. **VOLUNTARY** *(includes right to withdraw consent at any time)*

Informing the consent

- **Effective communication is** essential
  - Clarity without overload
  - Remember non-verbal communication & that it is 2-way!
- **Tripod approach to consent process**
  1. Information material is provided which is appropriately worded/illustrated
  2. Patient centred dialogue, which is then well documented
  3. Signing of the consent form
  - Allow adequate time between each stage e.g. start in OP consult then preadmissions clinic
- If significant delay between consent & start of Rx, or if new information becomes available, then consent should be reaffirmed

Information provided……



informed consent

Information both verbal & written should be provided

Must be clear & accurate (simple language, avoid abbreviations & medical jargon)

Honesty is the best policy

Information

- Best practice to individualise - in context of that patient: background, age, occupation etc.
- Dialogue must cover following:
  - **Indication** for proposed procedure
  - **Risks** of procedure
    - ***"Any that would affect the judgement of a reasonable patient"***
    - if serious discuss even if likelihood very small: e.g. Sympathetic ophthalmia even at <1:10,000
  - **Benefit** anticipated & likely outcomes – e.g. UIAs, asymptomatic bAVM
  - **<u>Alternatives</u>**

Tips to doing it well

- **Location** – suitable & quiet/undisturbed/private
- **Timing** – in advance not on day of procedure (for non-urgent cases)
- **Time** – take time for each part & allow time between the parts of the consent process
  - *Patience & empathy are required though may be difficult to teach*
- **Connect** with patient & relatives
  - Introduce yourself, exhibit empathy/understanding, be patient
  - NB non-verbal communication
- **Teach Back** – to confirm understanding
  - Ask / Tell / Ask
  - Use open questions; bitesize chunks of information; ask about understanding/ feelings; ask if they have any questions
- **Summarise & confirm patient's decision**
  - Simple language
- **Documentation** – record consent in more detail in medical notes not just on consent form (not just for your benefit)

Emergency treatment

Emergency treatment

- **Possess capacity** – adhere to consent principles & employ best practice described as far as possible
  - Still must be informed & voluntary consent
  - Cover indications/risk/benefits/expected outcomes/alternatives
- **Lack Capacity**:
  - Record & detail capacity assessment
  - Rx must be immediately necessary *(if not then await recovery of capacity/follow due legal process)*
  - Make & record "best interests" decision
  - Discuss with & take account of views of close relatives/primary carer *(legal framework here is variable)*
    - In E+W where there is no relative/carer law requires an independent Mental Capacity Advocate *(rarely applied in immediate life threatening care decisions)*
  - If advance refusal is clear then Rx should not be given

Capacity

- In general adults are **presumed to have capacity** to consent to Rx unless clear evidence to the contrary (& confirmed by law in much of English speaking world)
- However, patients who would otherwise be competent may be temporarily incapable due to variety of factors
  - Obvious acute medical condition – coma inducing SAH; acute Lt TACS
  - Fatigue, shock, severe pain, drugs (prescribed or not)/alcohol
- **NB. Competent people may make what to medics appear to be irrational or unjustified decisions**
  - *e.g. if common refuser of vaccines no surprise if don't accept annual flu jab*
  - On occasion though further investigation of capacity may be appropriate
- Barriers to consent: do any apply?
  - Language, physical (hearing/eyesight etc.), cultural, emotional……
  - Consensus in English speaking world is that ad hoc translators should not be used for informed consent discussions
  - **Support individuals to make their own decisions**

Assessment of capacity (to consent)

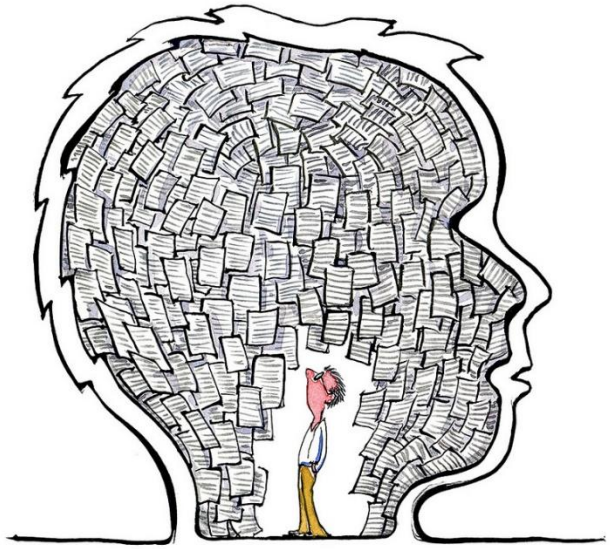
- Does patient have impairment/disturbance in mental functioning at this time? What is diagnosis & affect?
- **Checklist:**
- To demonstrate capacity patient should be able to:
  - Understand in simple language what medical treatment is, purpose and why being proposed *(with aid of translator or communication aids as required)*
  - Understand benefits, risks and alternatives
  - Understand in broad terms the consequences of not having proposed Rx
  - **Retain** the information for long enough to use & weigh info to make a decision
  - Communicate their decision (by any means)
  - Hospital must ensure appropriate translation services & aids to communication are readily available & staff know how to access them
- If unsure there are several validated mental capacity assessment decision support tools available & you can/should seek external help

Determining Best Interests

Need to take into account a number of factors, including:

- **Patient's own wishes & values** (where ascertainable)
  - Knowledge of patient's beliefs, cultural & other views that might impact on their wishes – e.g. Jehovah's witness
  - What (any reasonable) patient likely to see as **beneficial**
- **Effectiveness of the proposed treatment** particularly in relation to other options
  - If multiple Rx options generally choose **least restrictive** (of patient's future choices) e.g. reconstructive versus deconstructive; PPH hysterectomy vs uterine a. embolisation
  - **Likelihood of improvement** if Rx is provided
- **Views of those close to patient**

If a picture is worth a thousand words, a video must be better still….



A picture says more
than a thousand words

How not to do it….. Then how to do it much better…..

Video courtesy of & with the kind permission of RCS Edinburgh & Ms E Jerome

Summary

- Informed consent is a process
  - *NB. Best practice round location/timing/time*
- Information must be adequate & appropriate
  - *Address indication, risks, benefits, outcomes & alternatives*
- Address any barriers
- Assess Capacity if in any doubt
  - *Best interest decision (& clearly justifiable)*
- A smile, patience & good manners will go a long way

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Thank you!

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