Informed Consent in Critical care research

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A process by which a subject voluntarily confirmed their willingness to participate in a particular trial, having been informed of all aspects of the trial that are relevant to their decision to participate. Informed Consent is documented by a signed and dated informed consent form.
Everyone involved in the consent process should be...

- Familiar with the study
- Knowledgeable of the treatment options
- Aware of the need for informed consent
- Available for full discussion
- Understanding of the participants circumstances.
• You need to be trained and competent to perform the consenting role.

• The role can be delegated by the PI in the delegation log.

• Consent prior to ANY trial procedure- including screening bloods or QoLQs!
Communication

- Put the patient in touch with someone who can consent
- Establish their level of understanding and if English is their first language
- Dealing with patient preference for study arm
- Coping with non eligibility
- Explaining randomisation
- Breaking bad news then recruiting into research.
Establishing capacity
MCA 2005

- A person is assumed to have capacity unless it is established that they lack capacity. Can they make a decision at the point the decision is required?
- Do they understand what decision they need to make and why?
- Can they understand the consequences of making or NOT making the decision?
- Can they understand, retain, use and weigh up the relevant information?
- Can they communicate their decision? If not why not? Can it be addressed?
• Its rare for the critically ill to have capacity, especially in emergency care scenarios.

• ARDSNET- only 1% deemed competent, yet 16% consented themselves!

• What to do if they don't have capacity?

• The patients presumed will informs any decisions

• CTIMPS
CTIMPS require a legal representative to consent on the patients behalf.

- Personal legal representative, not involved in the trial, who by virtue of their relationship and is suitable to act as their legal representative for trial purposes and is available and willing to do so, throughout the intervention process.

- Professional legal representative- a person unconnected with the trial who is the patients primary medical provider or is nominated by the Trust.

- In practice, this has not proven practically possible in PHT due to timing and ethical conflicts.
Prisoners

- A vulnerable population susceptible to coercion
- Studies demonstrate decisional capacity reduced.
- The lower the capacity the greater risk of coercion
- Boredom, meeting new people, being cooperative, avoiding return to prison.
- CTIMPS always exclude prisoners. Imagine the press?
Tips and Traps

• It's about protecting the vulnerable, that's why we have these safeguards against coercive settings or undue inducements.

• Even patients who cannot consent may understand. Give them the info.

• In consenting, seek out and address THERAPEUTIC MISCONCEPTION
Therapeutic misconception

- They fail to understand that decisions about randomisation, dose, therapy will not be individualised to them.
- They hold an unreasonable belief in personal medical benefit, or mishap, if they take part.
- TM associated with greater age, low education, poor health and function and those with optimism, cancer or vascular disease.
- Present in 70% of those consenting for acute severe illnesses.
- Address this knowledge gap!
Making sure they understand

- Pitch at the right level. Forms written at age 9 level better than industry forms for achieving consent.

- Make sure they have opportunity to read the info and ask questions. You must address any queries you cannot answer immediately.

- Avoid using "treatment, therapy, medication". Do use "investigator" and "study doctor".

- Extended discussions are more successful than more paper.
• Can you tell me what will happen if you/they take part in the study?

• Will being part of the study help you/them?

• Can anything bad happen if you are part of this study?

• Can you decide not to be part of this study?

• And don't forget re-consent of subjects who regain capacity before hospital discharge?

• http://bma.org.uk/practical-support-at-work/ethics/consent-tool-kit