Processes of consent in palliative care research

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Informed consent on a bad day

• Combining a thick legal “flack jacket”, full information disclosure and an impersonal relationship
The “no” principle

• Consent to research premised on agreement
• This makes the ethics of consent to research simpler than consent to treatment
  – Research – ethical agreements
  – Treatment – ethical agreements/non-agreements
• The emphasis for research consent thus becomes:
  – Ensuring informed, non-coerced agreement
  – Ensuring capacitous agreement (including advanced directives)
Barriers to consent to research

• Psychological biases of everyday life
  – “just show me where to sign”
  – Framing effects
  – Forgetting
  – Therapeutic misconception
  – Influence from others
Therapeutic misconception

• Correcting the therapeutic misconception
  Research not treatment

• Overcorrecting the therapeutic misconception
  Research not treatment
    • Scientific method not personal care
      – Indifference not hope
Influence from others

• Undue influence
  – Money as bribe
  – Not wanting to antagonise those close to one’s own care (healthcare professionals)
  – Authority of researcher and institution – power imbalance
  – Pushy people one is dependent upon (family)
• Due influence
  – Money as a symbol of appreciation
  – Wanting to help those one believes are trying to help others (healthcare professionals)
  – Authority of researcher and institution - trustworthiness
  – Caring co-dependents (family)
Model 1

Capacity (screen)

High risk!

Low risk!

Consent!

Capacity assessment

Incapacity!

Proxy!

Resource expensive!

Marginal cases!

Problem of fluctuating capacity!

Mechanises the first contact!
False negatives/False positives!
The consent process
What it is like gaining consent for research

Going through the patient information sheet and obtaining the signature...

1. The unproblematic encounter
2. The problematic encounter
3. The non-starter encounter
Palliative care settings

- Unconsciousness, frank confusional states
- Anxiety and depression, confusional states
- Physical frailty +/- anxiety +/- pain
The unproblematic encounter

For projects where deterioration/fluctuation of capacity expected

• Discussing capacity needs to be part of the consent process – how good are we at that?
• Probably the most important question to ask and document is: “who do you want to be your proxy?” – can we accept health professionals (paid carers) as answers?
The problematic consent

• Understanding the vulnerabilities of potential participants.
  – Language & communication
  – Trust & fear
  – Pain
  – Psychopathology, e.g. anxiety/depression, cognitive impairment

• Enabling consent - involving a proxy who knows the potential participant better (extending the decision-making resources/community)
  – Family
  – Legal representative
  – Health professionals?
The non-starter encounter

• Identifying appropriate proxies early
• Advanced directives not common, may lack applicability and still the issue of safeguarding requiring a proxy
• Proxy burden?
Model 2

**Non-starter**
Incapacity

**Problematic**
Neither incapacity nor capacity

**Unproblematic**
Capacity

Proxy

Interview with proxy involvement

Consent (participant signs)

Enabled consent (participant signs with documentation proxy involved)

Capacity assessment (if consent remains problematic)
Arguments for model 2

1. Intuitive for healthcare researchers
2. Avoids the cost and complexity of lots of formal capacity screens and capacity assessments
3. In cases where consent problematic involving proxies to enable consent may increase trust in the process
4. Consistent with the MCA structure - though MCA position on health professionals (paid carers) as potential proxies may need refinement