Should a person who is near to death *never* be enrolled as a subject in clinical research? A critical appraisal of the literature on this key question.

Dr Jenny Mullin (Core Medical Trainee - NHS Lothian, Dip Pall Care Student - Kings College London)

Introduction:

- Clinical research is research where the investigator directly interacts with subjects:
  - includes clinical trials, epidemiological & behavioural studies, outcomes research and health services research)
- The consequence of *not* researching is a poor evidence base(1). However, some argue that persons near to death should *never* be enrolled into research projects, as they are vulnerable and at risk of exploitation (2).
- A question as complex as this is unlikely to have a straightforward answer.

Aims:

This poster seeks to pick apart the ethical maze surrounding research at the end of life:

- How can we justify research on *anyone?*
- Are persons approaching the end-of-life truly vulnerable?
- What are the main ethical challenges to research at the end of life?

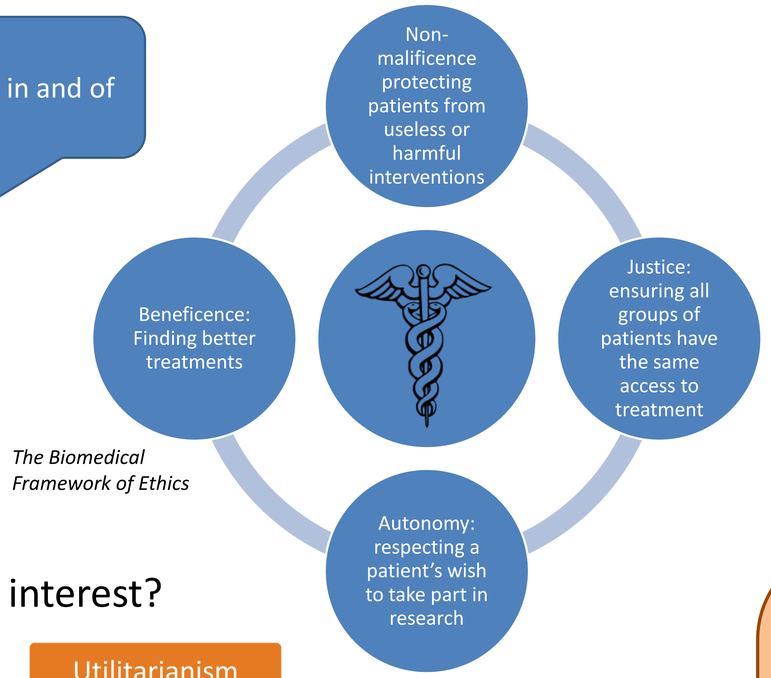
Method:

- Review of the published English-language literature
- Analysis with respect to:
  - the biomedical framework of ethics
  - philosophical theory

Analysis: Is *any* type of clinical research ethical?

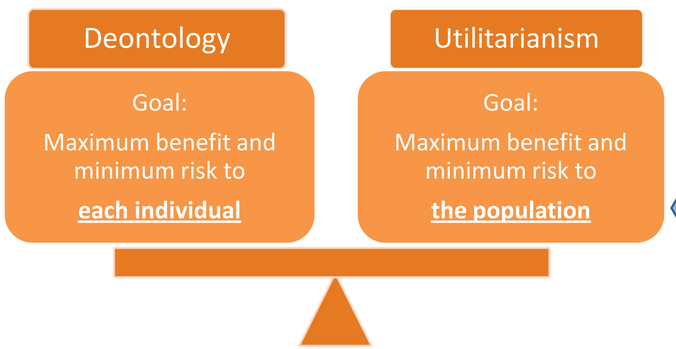
Episteme:
To gain knowledge is good in and of itself

Aristotle



The Biomedical Framework of Ethics

Analysis: Conflict of interest?



As clinicians and researchers we have a responsibility to *BOTH* patient and population.

BUT… if there is true equipoise, a research study may directly benefit a patient as well as the population

Results:

Key challenges (3,4)

- High attrition rates
- Poor clinical condition of patients, exhaustion, depression, high stress
- Difficult to recruit representatively
- Impact of research on participant
- Vulnerability of participants
- Difficulty obtaining or maintaining informed consent
- Exposing staff to distress

Why we should research

- It *is* possible to design a feasible and elegant studies (5)
  - E.g. Temel's study of early palliative care v.s. standard oncological treatment
- Many patients *want* to take part in research (7)
  - E.g. Gysels *et al*. found widely different motivating factors: pure altruism, wanting to voice an opinion, wanting someone to talk to and seeking information.
- Patients may benefit from research (2, 6)
  1. Opportunity to contribute to *knowledge*
  2. Direct benefit from research,
  3. Avoidance of informal n=1 trials
  4. Opportunity to regain lost independence/identity
- Even those who are vulnerable have the right to participate in research (6, 8)
  - E.g. HIV-AIDS sufferers in the 1980s and 1990s were vulnerable. However, without their cooperation in, and indeed their *advocacy* for, research, HIV would not today be a largely treatable illness that it is today.

Conclusions:

- We have a moral imperative to improve the evidence base for palliative care thus:
  1. Preventing administration of inappropriate, useless or harmful treatments (non-malificence)
  2. Preventing informal n=1 trials without consent, thus avoiding assault (non-malificence)
  3. Promoting use of treatments which *do* work (beneficence)
  4. Ensuring all groups of patients, even vulnerable groups and those without the capacity to consent, have the same access to the fruits of research and evidence based treatment (justice).
  5. Respecting that some patients wish to take part in research, *even* if it is not of direct benefit to them (autonomy).
  6. Providing the utmost dignity and the highest levels for individuals (deontology) and concomitantly our population as a whole (utilitarianism).
- Research at the end of life is challenging. We must strive to safeguard vulnerable groups. That said, we should not seek to expose patients to our own sensitivities, rather we should seek to empower them and foster their autonomy
- We have a duty to design studies which do not negatively impact patient or researcher and which are adequately powered to account for attrition.

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