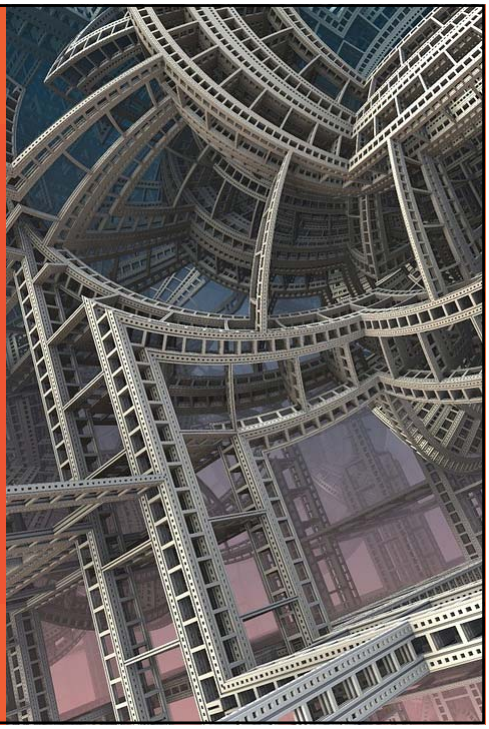
# Clinical Ethics Support:
A useful 'ethical scaffold' for innovation in health?



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## What can clinical ethics support offer when innovation in health is being implemented or contemplated?

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## Outline

1. Debates over distinction between research and clinical practice; and implications for innovation
2. Innovative treatment committees
3. Clinical ethics support (CES) and the innovation pathway



## Patients seeking innovation…

- Likely experiencing serious, potentially life-limiting illness
  …who may have few (or no) options
  … who may be keen to find options
- Strong autonomy rhetoric; 'information-armed'
- Culture of medicine "to fix"
- "Is it ethical not to…?"

## Innovation: points where ethical issues can arise

1. Should this innovation be introduced at all?
2. Should this innovation be used at this institution or with this patient?
3. Does the clinical team have any concerns regarding this treatment?
4. Does the patient (or family) have any concerns regarding this treatment?



**Part 1**

Research, Practice and Innovation

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## Research versus Treatment

| Research | Treatment/practice |
|---|---|
| Aims to generates knowledge<br>e.g. Does treatment X work? | Not aiming to generate knowledge<br>e.g. We have evidence treatment X works and it is indicated here |
| Formal protocol or study design to test a hypothesis | No protocol; no hypothesis |
| Externally regulated and overseen | Shared decision between professional and patient |
| No 'best interests' test | Aims (solely) to serve patient's interests |
| Benefit to patient not yet proven nor intended | Benefit to patient known and intended |
| Risk may be unknown | Risk more quantifiable |
| Prospective oversight | *Post hoc* oversight |

(Belmont Report, 1978; Lewens, 2006; Brierley & Larcher 2009; Beauchamp & Saghai 2012)

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## Innovation

- *Significant* departure from standard therapy
- Un-validated or not supported by evidence

- Aims to benefit patient
  - but can actually be more risky than research
- Risks akin to research; but ethical issues more patient-specific
- May not be exclusively therapeutic
  - can also generate new information
- May not fit a standard protocol

(Evans Chan 2013; Agich 2002)

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## So…

- If all **innovation** is classified as **research**, it can protect patients by not having bad innovation creep into standard treatment
- If all **innovation** is classified as **treatment**, there is flexibility to tailor interventions as they arise
- But also: innovation is not a uniform entity



## Part 2

Innovative treatment committees

## Innovative treatment Committees

- Can assist with the first two 'orange innovation questions'
  1. Should the innovation be introduced at all?
  2. Should the innovation be used at this institution or for this patient?

- These can utilise an over-arching framework:
  - "Bioethics of Innovation" (Axler & Lipworth 2016)
  - Responsible Research and Innovation
  - Specific innovation frameworks (e.g. Evans, 2002; Brierley & Larcher, 2009; Taylor, 2010; Sugarman 2012; NSW Health, 2016)



## New Zealand

- Remit of research ethics committees includes review of some innovative practices

- But: how often are they put forward?
  - Do they only tend to be submitted once the 'research threshold' has been crossed?


(http://www.ethicscommittees.health.govt.nz)

## New South Wales, Australia

- State-level Framework
  - Recommends Local Health Districts have their own policies and processes to review, assess, approve and oversee implementation of new health technologies
  - "May take the form of a specialised committee"
  - Specifies some parameters of review, including consideration of ethical factors and consent procedures
  - Ministry can engage bioethicists
  - Can also nominate technologies for state-wide assessment

NSW Framework for New Health Technologies and Specialised Services

NSW GOVERNMENT Health
GUIDELINE

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## Royal Prince Alfred Hospital, Sydney

- Innovative treatment committee for > 20 yrs
- Crossover of members with research ethics committee and clinical ethics committee
- Bespoke application paperwork

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## Innovative treatment committees

- Streamlined
- Address specific issues, e.g. conflict of interest; consent processes
- **BUT:** how know when innovation threshold triggered c.f. research paradigm?
- **BUT**: may be less able to consider and advise or support professionals regarding particular patient dilemmas



## Part 3

What role might CES play in health innovation?

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## My 'take' on CE support…

- Advisory/**supportive**
- CES provides **conceptual scaffolding** and framing
  - Ideal is to promote sound reasoning; no single framework or theory (Newson & McDougall 2016)
- Ideally available to **all stakeholders**, including patients
- Ultimate decision rests with **clinical team**



## What can clinical ethics support offer health innovation?

- Specific features:
  - Deliberative and partnership approach
  - Recognise contextual features
  - Flexible
- Can assist with 'orange questions' 3 & 4

## Counter-claims

- Knowing when to use a CES vs. a REC paradigm?
- CES not universally established or supported?
- Workforce/workload in CES (are we ready?)
- CES competence to respond to innovation?

These are considerations to overcome, not reasons not to use CES.



## Conclusions

- **Answer to initial question:**
  - Clinical ethics support offers mechanism to support health professionals and patients in their consideration of innovative treatment
    - Part of a suite of support and oversight
    - Need to engage with other mechanisms too

## References

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