Exemptions from ethics reviews – comparing Australia to the UK, USA and the Netherlands

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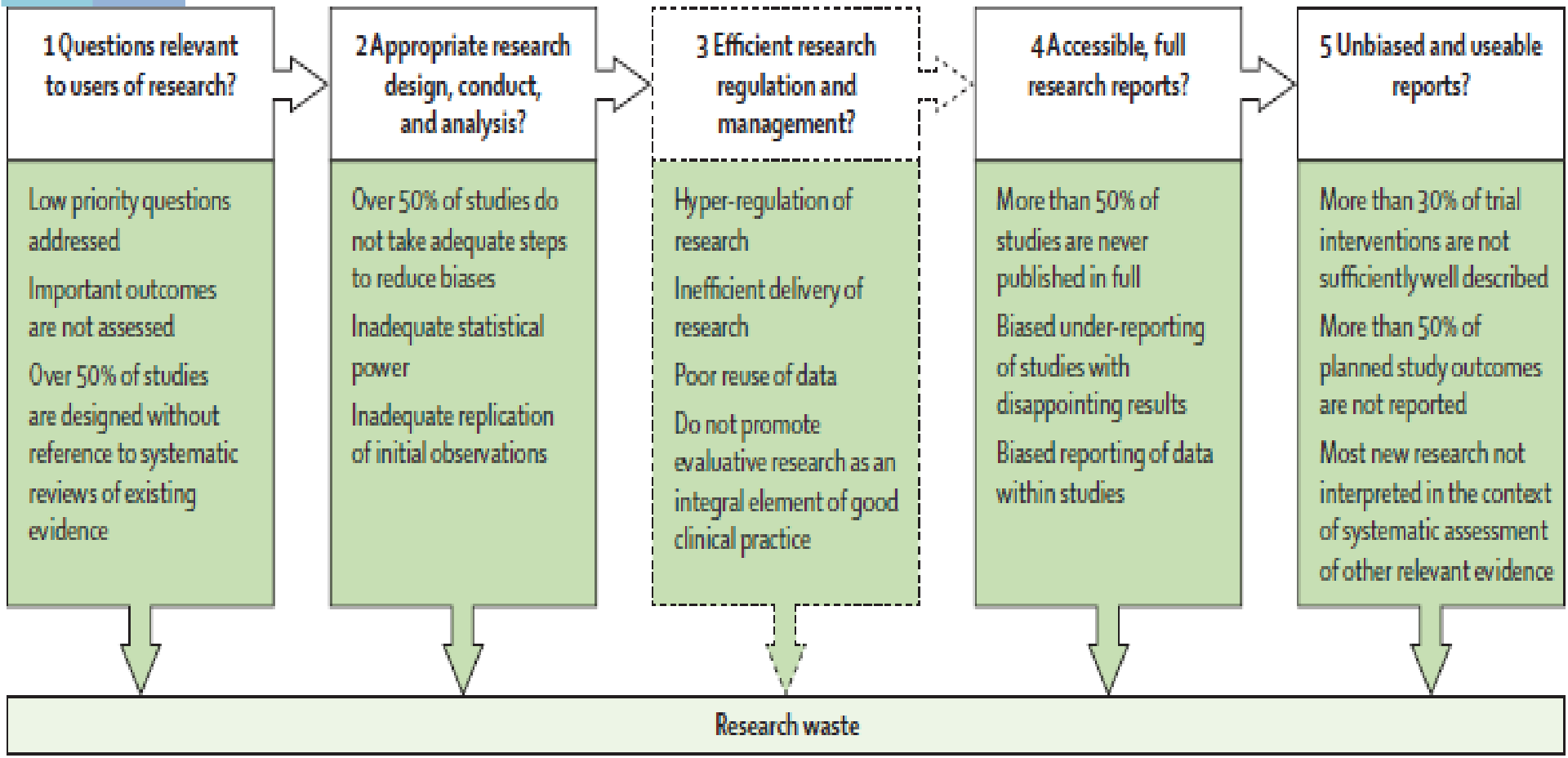
The issue: research waste



Research regulation in Australia - is there a problem?

- We don't know

- Our objectives:
  - To generate empirical evidence on the proportionality of ethics reviews to research risk
  - And, if required, to offer rationales for bringing the level of ethics review in Australia, into closer alignment with the level of research risk

Ethics reviews in Australian health/medical research – the approach

A two-part project

PART 1:

- **Identify what health/medical research is EXEMPT from ethics reviews in similar jurisdictions**
- **Compare to Australia**

PART 2:

- **Generate scenarios corresponding to exemptions**
- **Survey Australian researchers & ethics committees on their views and rationales for agreement/disagreement**

Methods

- Analysed documents from national-level agencies
  - UK: NHS's National Research Ethics Service
  - USA: Dept. of HHS, Office for Human Research Protections
  - Netherlands: Organisation for Health Research & Development (ZonMw), Central Committee on Research Involving Humans (CCMO)
  - Australia: NHMRC

- Identified the types/examples of health/medical research that is EXEMPT from ethics review

Exemptions from ethics reviews: UK

Exemption	UK	USA	Netherlands	Australia
Existing data / specimen				
Questionnaire or survey				
Interview				
Post-marketing studies				
Eval of public benefit or service programme				
RCTs				
Research w/ staff in their professional role				
Other				

Exemptions from ethics reviews: USA

Exemption	UK	USA	Netherlands	Australia
Existing data / specimen				
Questionnaire or survey				
Interview				
Post-marketing studies				
Eval of public benefit or service programme				
RCTs				
Research w/ staff in their professional role				
Other				

Exemptions from ethics reviews: Netherlands

Exemption	UK	USA	Netherlands	Australia
Existing data / specimen				
Questionnaire or survey				
Interview				
Post-marketing studies				
Eval of public benefit or service programme				
RCTs			*some	
Research w/ staff in their professional role				
Other				

Exemptions from ethics reviews: Australia

Exemption	UK	USA	Netherlands	Australia
Existing data / specimen				
Questionnaire or survey				
Interview				
Post-marketing studies				
Eval of public benefit or service programme				
RCTs			*some	
Research w/ staff in their professional role				
Other				lacks foreseeable risk of harm (no more than inconvenience)

Summary

- All 4 jurisdictions exempt research on existing specimens/data from ethics review
- Other jurisdictions also have a few other exemptions…
- … but not Australia – fewest exemptions from ethics reviews
- Is this a GOOD thing or a BAD thing?
  - Burden on researchers & research waste issues vs. issues around protecting the subjects who assume personal risks of research

Next steps…

PART 2 of the project:

- **Generate scenarios corresponding to the exemptions identified above**
- **Survey Australian researchers & ethics committee members**
  - **whether those scenarios should also be considered exempt in Australia**
  - **their rationales**
- **Identify whether there may be rationales for broadening (or perhaps narrowing?) the existing ethics exemptions in Australia**

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Thank you.

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Possible discussion points

- Why those jurisdictions: convenience sample, breadth of approaches
- Why those bodies: national-level bodies (rules may differ at sub-national level, admittedly) - but we wanted an "apples to apples" comparison
- What the statement says (exclude) vs. what happens at institutional level (gets reviewed) – yes, but cannot control for this
- Why look at what's excluded from ethics rather than what's included: admittedly, it's a shift in thinking (we are trained to think what DOES trigger an ethics review rather than what doesn't)
- Interestingly enough, broadest exemptions in the US, despite its reputation for litigiousness – not sure what to make of t his
- Focus on the health/med research in human: even more differences possible re: animal studies, e.g.
- Rules that underpin the exclusions/rationale for exclusions (what is excluded is clear; WHY it's excluded is not always clear – though note the nice example of Netherlands / RCT exemptions)
- I haven't defined EXEMPT FROM ETHICS REVIEW:
  - a broad and vague concept – meaning 'something less than full IRB review' (e.g. brief/short app, self-testifying that exempt, somewhere in between…)
  - E.g. US: studies are called "exempt" for falling outside the federal regulation 45 C.F.R. 46,
- I haven't defined "ethics review"
  - process of evaluation by a full ethics committee
- "Middle ground" review: US "expedited review", UK "proportionate review": <full committee (e.g. 1-3 members) reviews the application.
  - Netherlands may be implementing this in the next couple years.

Possible rationales for exemptions

- By risk level (e.g. physically invasive vs. non-invasive)
- By whether or not personal medical info is being used (e.g. community jury or Delphi vs. survey on personal health)
- By study design type (RCTs vs. observational)
- By level of burden on participant (a la Netherlands/RCT)
- By activity type (quality assurance vs. research vs. surveillance…)
- By activity purpose (aim to create generalisable knowledge applicable to others, vs. not)
- By severity of anticipated consequences (can kill or maim vs. can make subject uncomfortable vs. minimal/no discomfort)
- By identifiability of the information obtained (identifiable/personal vs. not)
- Etc.

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