Ethics of surgical and device innovation during a crisis

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This presentation includes new research undertaken with Dr Jane Johnson, Professor Wendy Rogers, A/Prof Bernadette Richards, Dr Robyn Clay-Williams, Professor Guy Maddern, Dr Quinn Grundy and Dr Brette Blakely, for Australian Research Council Discovery Project DP200100883 “Support or Sales? Medical device representatives in Australian hospitals”.
It also builds on past research with Professor Wendy Rogers and Mr Angus McNair (2019).

Background: three theoretical approaches to ethics

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Principle-based ethics

- Focus on **right action**, guided by (universal) rules or principles
- A widely accepted approach in bioethics
- Four principles: **Autonomy**, **Justice**, **Beneficence** and **Non-Maleficence** (Beauchamp & Childress, 2001)

Consequentialist approaches

- Focus on **outcomes** – maximizing good consequences
- **Relevant to public health** (**maximising justice, efficiency**)
- Consequentialist calculations can be involved in applying principles (e.g. minimising harm)

Virtue ethics

- Focus on **character** – what traits do ethical people have?
- Virtues might include humility, honesty, trustworthiness, compassion, empathy, courage, self-reflexivity

Principle-based framework for analysing ethical issues in surgical innovation

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Ethical Issue	Medical Ethics Principles	Description
Minimising harm	Principle of non-maleficence; Principle of beneficence	• Minimise **harm to patients** • In pre-IDEAL studies, **harm to animals** may be relevant. • Minimise risk of **harm to clinicians**, e.g. reputational and psychological
Autonomy and consent	Principle of autonomy	• Rigorous **patient consent** processes • Explain the **innovative nature** of the procedure • Transparency about **limits of existing knowledge**
Justice issues	Principle of justice	• Ensure **fair distribution of risks and benefits** • Avoid targeting **vulnerable patient groups** • **Maximise access** to successful innovations
Conflicts of interest	Principle of beneficence; Principle of justice	• Clinical decisions should reflect **clinical considerations** • Financial and other incentives can risk **harm to patients** • Fair access can be stymied by profit motive

Adapted from: Johnson & Rogers (2012) and Rogers, Hutchison, & McNair (2019).

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Applying the ethics framework and guidelines in a crisis

SURGICAL PERSPECTIVE

Ethical Issues Across the IDEAL Stages of Surgical Innovation

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(*Ann Surg* 2019;269:229–233)

Innovation is essential for progress in surgery, yet surgical innovations may be risky for patients, fail to improve outcomes, and increase healthcare costs.[1] The IDEAL Framework seeks to mini-

PRE-IDEAL STUDIES: (PRECLINICAL)

Animal and laboratory based pre-IDEAL studies can give rise to distinctive ethical issues, principally concerned with minimizing harm and conflicts of interest.

Minimizing Harm

Future harms to humans may arise if relevant animal studies of

TABLE 3. Summary of IDEAL Ethical Guidance

IDEAL Stage	Guidance and Strategies
Pre-IDEAL: Preclinical research	• Use relevant and well-established science to inform preclinical studies • Reduce, refine, and replace animals to extent possible • Ensure relevance and validity of animal studies • Avoid assumptions and bias in design and use of simulators • Identify potential conflicts of interest
Stage 1: Idea (first in human)	• Obtain formal research ethics approval for planned first in human trials • Develop appropriate and tailored oversight for supporting and reviewing incremental innovations • Develop mechanisms to identify when innovations are introduced (eg, use of innovation checklist) • Prioritize patient welfare over knowledge generation and avoid "heroic" individual cure attempts • Develop comprehensive consent mechanisms with disclosure of experience with innovation, any known risks, and likelihood of unknown risks • Foster excellent communication including with all colleagues whose work may be affected by the innovation • Manage conflicts of interest by limiting control of commercial funders over study design and data uses and avoiding individual decision making by surgeons with financial or reputational interests in the innovation • Report all results, positive or negative • Plan for care of patients who receive an innovation that may be abandoned
Stages 2a: Development and 2b: Exploration	• Obtain formal human research ethics approval, using modified processes if appropriate such as appointment of surgeon onto review committee or use of an oversight committee • Use supported training to minimize learning curve harms • Recruit diverse patients to ensure justice across different subgroups and maximize utility of results • Report all outcomes, including patient-reported outcomes, in accessible ways to inform future research and practice • Identify and manage conflicts of interest (as per Stage 1)
Stage 3: Assessment	• Obtain formal human research ethics approval and register all trials • Use supported training to minimize learning curve harms • Consider need for and acceptability of placebo-controlled trials • Use fair inclusion and exclusion criteria and ensure equitable access to trial participation • Include outcomes relevant to patients • Identify and manage conflicts of interest (as per stage 1)
Stage 4: Long-term monitoring	• Create sustainable registers for long term outcome studies • Resolve issues of consent for longitudinal data use and including for nested RCTs • Address access and equity issues caused by factors such as financial and geographic barriers • Identify and manage conflicts of interest (as per stage 1)

How might these highlighted ethical recommendations (from Rogers, Hutchison & McNair 2019) apply across the IDEAL stages in a crisis?

What about during a crisis?

Three take-home messages:

#1 Bifurcation of ethical considerations, depending on whether it is a crisis-related versus a business-as-usual innovation

#2 Transitioning out of crisis contexts and into a “new normal” raises unique ethical challenges

#3 Staged approaches – like IDEAL – have natural advantages in dealing with these unique ethical challenges

Paradigm cases / examples for highlighting ethical considerations will be different during a crisis…

… and relevant examples depend on the nature of the crisis

Case studies for "normal" times from Rogers, Hutchison & McNair (2019:230)

Box 1 The Artificial Trachea

In 2011, a team of clinicians and researchers led by Paolo Macchiarini from Sweden's Karolinska Institute (KI) implanted the world's first synthetic trachea into a patient. The trachea was made of a tailored bioartificial

Box 2 Minimally Invasive Oesophagectomy (MIO)

Laparoscopically assisted oesophagectomy (LAO) and minimally invasive oesophagectomy (MIO) are innovative surgical procedures that aim to improve oesophagectomy outcomes for cancer patients. In 2005, a team of surgeons and researchers in Bristol, the United Kingdom, introduced these procedures and formally evaluated the extent to which IDEAL recommendations for stages 1–2a and 2b were followed.[11]
National ethics committee approval was not sought, but the techniques

Note also, bifurcation and different ethical considerations

Innovations **unrelated** to the crisis

Innovations **focused on the crisis***

*E.g. COVID- 19: test kits, PPE, ventilators, lung transplants

Applying the ethical framework in a crisis

Minimising harm

"Prioritize patient welfare over knowledge generation and avoid "heroic" individual cure attempts"

- Ethical assessments of patient welfare may be different in a crisis
- How urgently is new knowledge needed? What are the potential opportunity costs?
- Example: ethical analysis of COVID-19 test kits in early 2020 might accept a different threshold for how accurate is accurate enough to minimise harm than would normally apply for diagnostic tests.
- In contrast, continuing 'business-as-usual' research or innovation may give rise to unacceptable risks of harm – e.g. health system overload and infection considerations during pandemic

"Obtain relevant ethics approvals / oversight"

- Expedited ethics review and oversight processes (or exemptions) might apply in a crisis,
- … but compliance with ethics policy should never be a substitute for ethical analysis.

"Use supported training to minimize learning curve harms"

- How do ethical considerations related to learning curves change in a crisis?
- What is regarded as an acceptable level of training? Who provides it and how?
- Example: impact of COVID-19 changes to hospital access on training and support provided by manufacturer employees

Applying the ethical framework in a crisis

Autonomy and consent

"Develop comprehensive consent mechanisms with disclosure of experience with innovation, any known risks and likelihood of unknown risks"

- How might consent processes be affected by a crisis?
- Availability of information
- Availability of personnel
- Availability of time

"Resolve issues of consent for longitudinal data use and including for nested RCTs"

- How might crisis factors affect downstream data use?
- Note possible impacts on crisis-related longitudinal data, and business-as-usual data (e.g. will the crisis disrupt collection/consent for registries etc?)

Applying the ethical framework in a crisis

Justice issues

"Recruit diverse patients to ensure justice across different subgroups and maximise utility of results"

And

"Address access and equity issues caused by factors such as financial and geographic barriers"

- What is the impact of the crisis on recruitment processes and fairness?
- On equitable access to innovations?
- Does the crisis itself disproportionately impact some groups?

"Report all results/outcomes in accessible ways to inform future research and practice"

- Example: COVID-19 research – *benefits* to transparency and information sharing might need to be weighted against *decrease* in quality.

Applying the ethical framework in a crisis

Conflicts of interest

"Identify and manage conflict of interest"

- Risk that exemptions and expedited approvals processes will be exploited by unethical players
- Especially in grey area between crisis-related and business-as-usual innovations

The ethics of transitioning to a 'new normal'

- So far, I have concentrated on ethical issues during the crisis period.
- However, from an ethical perspective the challenges associated with transitioning out of a crisis are just as significant… if not more significant.
- All sort of things *that matter, ethically speaking* will be different during a crisis.
    - Weighing of individual patient welfare vs need for knowledge
    - Formal ethics oversight processes and regulatory approval processes
    - Training in new techniques and management of learning curves
    - Informed consent expectations and processes
    - Research methodology, including recruitment of participants
    - Publication and peer review of evidence
- Any IDEAL framework for evaluating innovations in crisis contexts must offer guidance, *including ethical guidance*, for transitioning out of the crisis.

The need for a staged framework

- Crisis contexts are temporary
- Indeed, it is appropriate to think of them as having stages. The nature and duration of these stages depend on the sort of crisis
- When it comes to evaluating innovations during a crisis, there are ethical issues associated with *transitioning* between these different stages
- Including
  - *The transition into a crisis context*, which changes the ethical considerations pertaining to evaluation of "business-as-usual" innovations
  - And the *transition to a 'new normal'*
  - When it is ethically critical to ensure that exemptions, expedited processes, and crisis-time ethical weightings do not continue to apply to post-crisis use of innovative procedures and devices.

- The IDEAL framework already recognises stages of surgical innovation
- Any process for evaluating innovations during a crisis needs to recognise the stages of a crisis, too
- And recognise that ethical issues arise at each stage, but also when *transitioning between stages*

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Thank you.

Questions and discussion?