Research ethics preparedness: Lessons for the next pandemic

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AABHL

Susan Bull

Epidemic Ethics
https://epidemicethics.tghn.org/

EPIDEMIC ETHICS
Research, Preparedness & Response

Mission: develop a credible, reliable, timely, and accessible global community which provides high-quality advice, support, resources, and capacity strengthening to help respond to ethical issues as they arise and to support ethical decision-making in the context of public health emergencies.

Key objectives:

- To support the identification and evaluation of ethical issues arising in policy development, practice, and research.
- To help leverage, coordinate and support real-time, contextual ethical decision-making in public health emergencies.
- To build capacity globally and locally to embed ethics in public health preparedness and response to public health emergencies.
- To conduct empirical and normative research that addresses ethical issues from outbreaks and emergencies outbreaks and promotes preparedness for future public health emergencies.
- To support the work of the WHO Emergencies Programme and WHO R&D Blueprint for Action to Prevent Epidemics.

Led by Katherine Littler – WHO Health Ethics and Governance Unit

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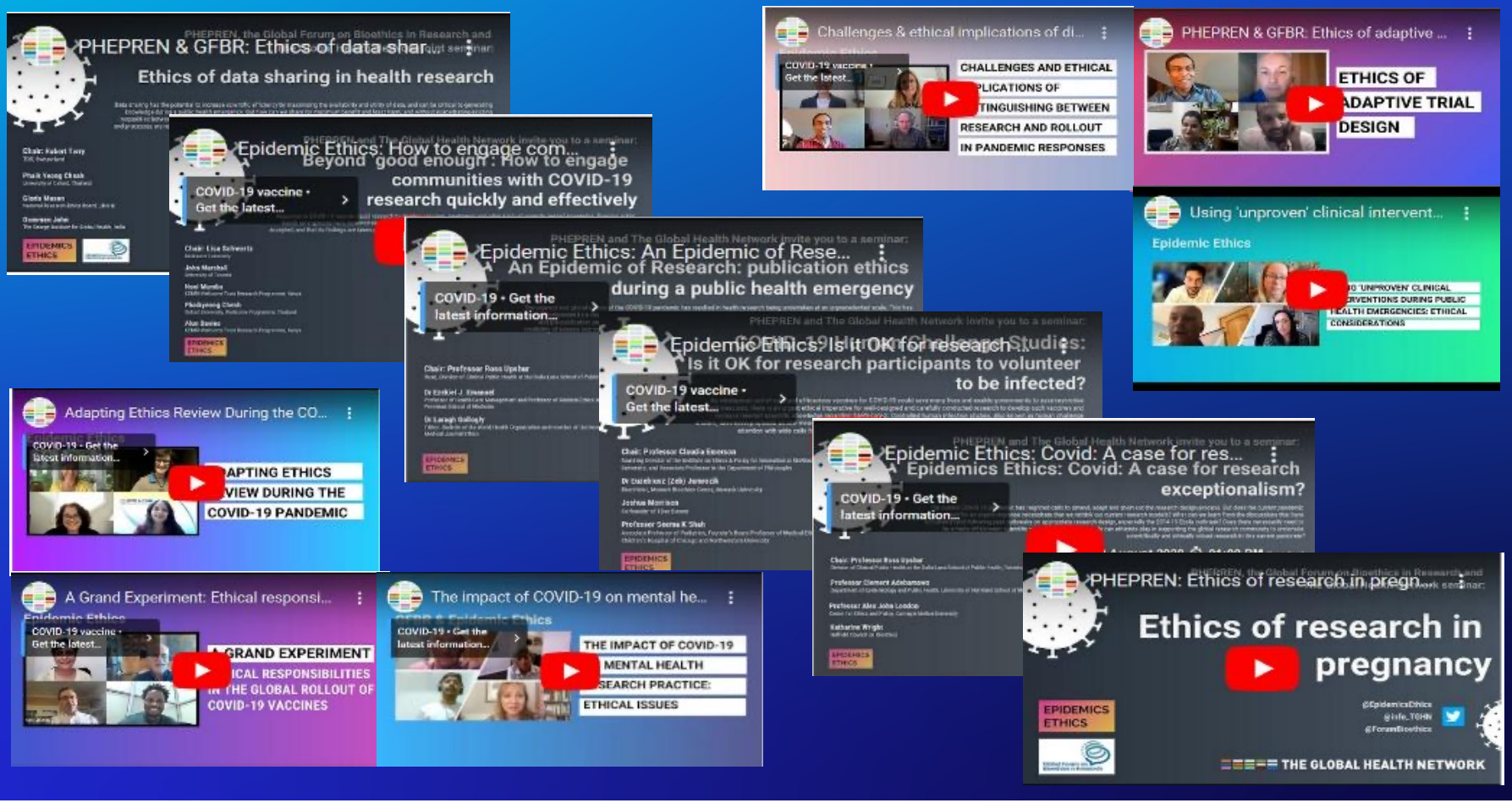
Seminars – rapid responses & global perspectives

https://epidemicethics.tghn.org/seminars/



Public Health Ethics Analysis 8
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Research Ethics in Epidemics and Pandemics: A Casebook

Springer

44 complex cases and nine thematic commentaries

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Casebook themes

- Complex interactions between researchers, reviewers and policy makers
- Research prioritisation and de-prioritisation
- Research quality and dissemination
- Boundaries between research, surveillance and monitored emergency use
- Adapting and adaptive research
- Ethical review challenges
- Data curation and sharing
- Inclusion and vulnerability
- Participant protections: recruitment and responsibilities

Parties shall be guided by ‘the best available science and evidence as the basis for public health decisions for pandemic prevention, preparedness and response.’
(WHO Pandemic Agreement 2025)

However:

Pandemics are also radically non-ideal research environments, characterised by:

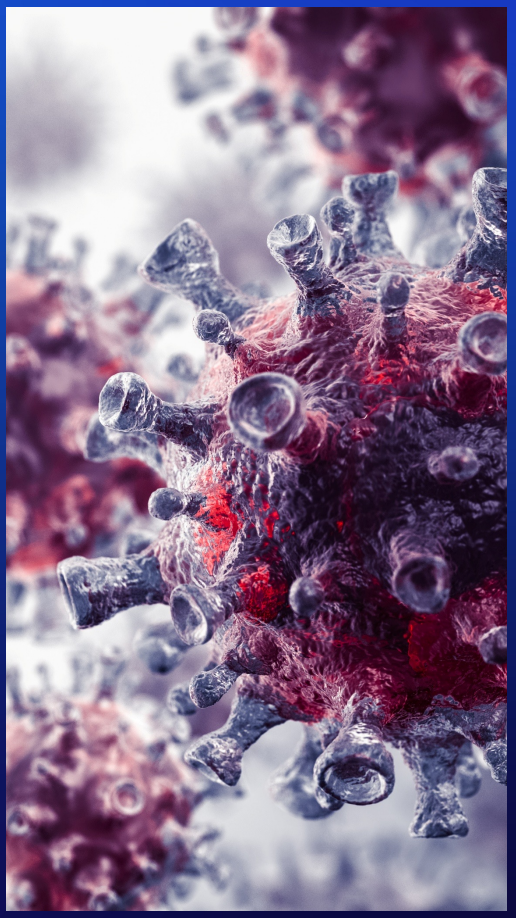
- Urgency
- Complex whole of society impacts
  - Overburdened health systems
- Challenging evidentiary landscapes
  - Uncertain, rapidly evolving, contested, infodemics

Responding to rapidly evolving pandemic landscapes

- Changing / competing obligations, values and priorities of researchers, reviewers and policy-makers
  - What constitutes sufficient evidence to inform policy changes and early implementation?
  - What responsibilities arise to implement novel policies in ways that can be evaluated?
  - What responsibilities do researchers have when involved in policy-making processes?
- Case study examples
  - Early implementation of innovative telemonitoring approaches
  - Controlled human infection studies

What counts as research?
Research, surveillance and monitored emergency use

- **Challenges with distinguishing between research and non-research responses**
- **Case study examples**
  - When are antibody testing and systematic data collection surveillance or research activities?
  - Following emergency authorisation –
    - Should the initial administration of vaccines be considered research or rollout?
    - Should vaccine trials be unblinded?
  - When is use of unproven interventions outside clinical trials justifiable?



Waipapa Taumata Rau, University of Auckland

Policy responses: Declaration of Helsinki 2024

*"The workgroup proposes a rewritten paragraph 37 because of substantial feedback at multiple regional and topical meetings about the paragraph's misuse during COVID-19. The 2013 language "may use" was previously inappropriately relied on to justify use of therapies proven **in**effective. "*

General Principles (2024)

8. While new knowledge and interventions may be urgently needed during public health emergencies, it remains essential to uphold the ethical principles in this Declaration during such emergencies.

Unproven Interventions in Clinical Practice (2024)

37. When an unproven intervention is utilized in an attempt to restore health or alleviate suffering for an individual patient because approved options are inadequate or ineffective and enrollment in a clinical trial is not possible, it should subsequently be made the object of research designed to evaluate safety and efficacy. Physicians participating in such interventions must first seek expert advice, weigh possible risks, burdens, and benefits, and obtain informed consent. They must also record and share data when appropriate and avoid compromising clinical trials. These interventions must never be undertaken to circumvent the protections for research participants set forth in this Declaration.

Prioritising and deprioritising research: competing considerations

- How should decisions about reprioritising research in response to outbreaks be reached?
- Complexities include:
  - Health system burdens and constraints on research capacity
  - Changing funding priorities
  - Implications of de-prioritising existing research
  - Breadth of research required
  - Emerging (non-evidence based) practices
- Case study examples
  - Balancing priorities: clinical & social science research
  - Reprioritising research into community priority areas
  - Responding to widespread off-label use of medication

Adapting and adaptive research

- Adapting research methods and designs to constraints and contexts
  - What is required, desirable or unjustified?
- Adaptive research designs
  - Managing modifications in outbreak contexts
  - Treatments, doses, sample sizes, interim data analysis
- Case study examples
  - RECOVERY
  - Suspending participation
  - Moving from in-person to remote designs
  - Responding to emerging evidence

Looking forward: 100 days missions

‘Reducing the impact of future pandemics by making diagnostics, therapeutics, and vaccines available within 100 days’
(International Pandemic Preparedness Secretariat 2025)

100DM Framework Outputs, Outcomes, and Impact

VISION: within 100 days of a recognised international trigger (e.g. WHO PHEIC), diagnostics, therapeutics and vaccines are approved* and ready to be produced at scale for global deployment

SPHERE OF CONTROL	SPHERE OF INFLUENCE		SPHERE OF INTEREST
IPPS activities	100DM 2025 outputs	100DM long term outcomes	Impact
Facilitating and convening multisectoral collaborations	**DIAGNOSTICS R&D** • Publish 100DM diagnostics roadmap • Develop rapid point-of-care tests for at least two priority viral families • Reduce complexity of diagnostic regulatory pathways	• Diagnostics R&D is coordinated in a sustainable ecosystem • Development of diagnostics libraries provides broad coverage for priority viral families • Diagnostics routinely linked to testing and treatment	✓ DTVs are rapidly developed, and equitably distributed based on greatest impact and need, in the event of a pandemic threat
	THERAPEUTICS R&D • Therapeutics Development Coalition launched and operationalised • Coalition is supported to take de-risked candidates through preclinical and early clinical development, bringing assets to phase 2 for at least two viral families	• Prototype therapeutics libraries developed, supported by pre-agreed procedures in place for therapeutic repurposing and equitable access • At least two therapeutics products for the WHO viral families with high pathogen potential, ideally with different mechanisms of action	
	VACCINES R&D • Progress vaccine candidates for priority viral families to clinical stages • Establish economic risk-sharing models to enable development of diverse platform technologies	• Continued work on vaccine libraries covering WHO priority pathogen families • Rapidly programmable platform technologies available • Vaccine platforms optimised for large-scale production	
Providing technical expertise (STEG, implementation reports)	**CLINICAL TRIALS AND REGULATORY PROCESSES** • Global emergency use clinical trial guidance finalised and adopted, utilising regional networks • Regulators coordinate to adopt preparatory regulatory approaches • Regional reliance models adopted, enabled by an appropriate number of globally recognised regulatory authorities in each region	• Clinical trial sites are sustained between pandemics • Best practices on clinical trial design and innovative and adaptive trial designs utilised • Master trial protocols pre-agreed for use in emergencies, emphasising real-world evidence for product licensure • Preparatory and harmonised regulatory frameworks adopted by regulators for pathogens where traditional randomised controlled trials are unfeasible • Strengthened and aligned regulatory capacity in all regions with pharmacovigilance enabled from the outset	✓ Products authorised for use in humans (e.g. EUA) within 100 days due to pre-emptive data generation and high-quality clinical trials mobilised rapidly utilising existing infrastructure
	SURVEILLANCE • Collaborative surveillance enhanced through international networks • National capacities for data collection and early warning systems strengthened • Digitally connected diagnostics feed into the surveillance system	• International network(s) of global/regional/local surveillance systems identifies outbreaks and enables trusted data sharing • Reliable, fair, safe, and fit-for-purpose mechanisms for rapid exchange of pathogen samples enable equitable R&D efforts for DTVs	✓ Pathogens are characterised using genomic sequencing and other integrated approaches, with surveillance data shared to prevent outbreaks from escalating into pandemics
Influencing global political agendas	**SUSTAINABLE AND GEO-DIVERSIFIED MANUFACTURING** • Regional authorities supported to implement sustainable manufacturing capacities • Continued strengthening of public-private partnerships within regional manufacturing strategies for drug substances, drug products and intermediaries • Preparatory voluntary licensing systems expanded on a case-by-case basis and as appropriate	• There is capacity and capability to produce DTVs in each region • The ecosystem supports voluntary licensing, technology transfer, supply-side incentives for investment and demand-side procurement mechanisms • Developers and manufacturers align on platforms that can be adapted to produce both routine and pandemic products	✓ Each region produces technologies, pivoting its manufacturing sites along the value chain in response to threats, ensuring equitable and timely access to critical inputs
	SUSTAINED PANDEMIC FINANCING AND EQUITABLE PROCUREMENT • Global recommendations set on surge financing, stockpiling strategy, and advanced market commitments • Procurement agreements prioritise equitable access	• Mechanisms enable the automatic release of funding (e.g., for procurement) tied to globally agreed trigger points • LMICs can purchase and distribute DTVs through equitable allocation and procurement of supplies	✓ Countries have access to and mobilise funding to reduce pandemic threat escalation

Looking forward: 100 days missions

Embedding ethics in pandemic

- prevention,
- preparedness, and
- response …

Thank you!

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