Australian Government

National Health and Medical Research Council

NHMRC

National COVID-19 Health and Research Advisory Committee

Date of report: 12 May 2020

Ethical issues arising from the COVID-19 pandemic

Focus:

A workshop with members of the Australian Health Ethics Committee and representatives of the Consumers Health Forum, the Council of the Ageing, members of the NCHRAC, and other experts, identified a range of ethical issues related to the COVID-19 pandemic and prioritised the need for an ethics framework to address the needs of vulnerable people in the community.

In the first instance, this ethical framework was envisaged as a short document to guide the decision-making process of Government as it develops policy during the stages of the pandemic. A number of longer-term policy issues were identified that overlap with other areas of NCHRAC work, or may be issues on their own for future work. These include the need for:

- well-coordinated and clear messaging to build public confidence and ensure that those in need of critical health care services (including mental health) know that they are available and how to obtain them
- planning that does not reinforce, and helps to alleviate, existing systemic inequities, especially those affecting indigenous communities, rural and remote communities, people with special needs and older persons
- resolution of inconsistencies in jurisdictional and local frameworks and policies on allocation of scarce resources
- segmented communication and health promotion strategies to encourage return-to-normal use of health care services (including mental health), including by leveraging organisations with trusted relationships with target groups
- assessment of the extent of under-use of health care services (including mental health) by regular users of these services and the reasons for reduction in service use.

Conclusions:

NCHRAC conclusion 1: There are a range of ethical issues that need to be addressed to support government decision-making during and after the pandemic.

Despite the wide range of ethical issues arising from the COVID-19 pandemic that were considered by workshop participants, there was common ground on the set of issues that should be addressed first by government. These are described above and focus on planning, coordination and effective communication to ensure that the needs of people who are at greater risk of disadvantage as a result of the pandemic, for example through difficulties in accessing services and through economic disadvantage, are met.

Particular concern was expressed that those requiring services to support basic functioning during this crisis, such as primary health care and counselling, psychological care, allied health care, education and information support are not accessing those services due to fear, lack of confidence and confusion. This deficit will have inevitable detrimental flow on effects as we emerge from the pandemic. Addressing this requires careful planning, coordination between jurisdictions and effective communication strategies to promote available services and facilitate uptake of these services by those most in need of them.

In drawing this conclusion, NCHRAC considered:

- Input from consumer representatives from states and territories and Consumers Health Forum executive officers.

- Input from the Australian Health Ethics Committee.

- International guidance (e.g. World Health Organisation).

NCHRAC conclusion 2: Engaging with and promoting the active participation of those most affected by systemic inequities is critical to avoid reinforcing these inequities as we emerge from the pandemic.

For any steps taken by government to address the identified priority ethical issues to be effective, genuine engagement with and the active participation of those who are the intended beneficiaries of these actions should occur. The ethical framework should identify strategies for engagement and active participation both during and following the pandemic.

NCHRAC conclusion 3: Further consultation with the Australian Health Ethics Committee (AHEC) and key consumer groups is required to develop this framework and to identify and prioritise other ethical issues.

Discussion of the ethical implications of the COVID-19 pandemic, Australia's responses to it and our emergence from it focused on its impact on the members of the community in the most vulnerable circumstances. While this focus is appropriate, other key issues, such as the impact on the health, well-being, training and support of health care professionals, first responders and other frontline workers and the ethical conduct of socially necessary research and evaluation activities also merit investigation and, potentially, recommendation to government for action. Further, the COVID-19 pandemic has caused significant economic disruption, which is having inequitable impacts in the community raising a range of ethical issues.

Accordingly, the NCHRAC recommends that further concentrated deliberations by AHEC and others be supported by the CMO, with a full report to be provided as expeditiously as possible.

Background

Significant efforts have been made nationally and internationally to identify and analyse the ethical implications of people's experiences of the COVID-19 pandemic and the impact of responses to the pandemic, including necessary public health measures and other government policy decisions. These analyses draw on well-articulated considerations of common ethical concerns such as allocation of scarce healthcare resources, the impact of social, health and economic policy on disadvantaged populations and the responsible conduct of research.

Workshop participants considered a number of themes outlined in an issues paper (Attachment 1) including resource allocation, the impact of public health measures, issues specific to Aboriginal and Torres Strait Islanders, and those affecting health care professionals, research ethics issues and planning for the emergence from the pandemic.

Other considerations

In the course of developing this advice, NCHRAC identified the following ethical considerations that were out of scope for this current advice, but are important and related considerations and could form the basis for further advice to be developed over time:

- Ethical concerns about the conduct of vaccine research and the use of 'compassionate use' mechanisms to provide unproven drugs or other therapies to those with COVID-19 or associated symptoms.

- The detrimental impact of 'freezing' or de-emphasising non-COVID-19 related research, particularly research into life-threatening health conditions, infectious diseases and critical mental health research.

- The development of a national ethics framework for access to and allocation of ICU beds and other critical care resources.

Attachments

Attachment 1: Issues paper: Ethical issues arising from the COVID-19 pandemic (provided to all workshop participants)

ETHICAL ISSUES ARISING FROM THE COVID-19 PANDEMIC

BACKGROUND

The advice you provide today will be considered by NCHRAC and will help shape its considerations of advice on the following questions:

1.   What are the key ethical issues that require specific consideration by the Australian Government in relation to the COVID-19 pandemic?

2.   What next steps should the Australian Government take to consider these issues?

DISCUSSION

The COVID-19 pandemic, and responses to it, present existential, health, social, political and economic challenges, both on a societal and individual level. All of these challenges have an ethical dimension and there are numerous organisations, academic centres and others around the globe who have been active in scanning the landscape and scoping these issues. Some of these resources are included in the list provided at Appendix A to this document.

For the purposes of considering the ethical issues and the development of advice for the NCHRAC and the CMO, the following themes below are proposed as a way to structure the discussion at this workshop.

Community engagement and support is critical to the successful implementation of measures to contain the pandemic. Population groups and sectors of the Australian community are affected by the pandemic in different ways and will have varying responses to it. The ethical issues raised by the pandemic will also express themselves differently within Australian communities and it is important to understand the ways that these issues manifest themselves. The aim of the workshop is to provide a forum for sharing a broad spectrum of views on a range of ethical issues in order to inform the Government's response.

Each of the topics outlined below aims to start a conversation on a range of ethical issues. Participants will be asked to identify key areas for prioritising and what actions they would like to see taken by government and to raise any other issues they would like included in the advice presented to the CMO.

1. Resource allocation
2. Implementation of public health measures
3. Issues faced by health care providers
4. Impact on Aboriginal and Torres Strait Islander peoples and communities
5. Research ethics
6. Emerging from the pandemic and future planning

It is further proposed that the issues above are considered through the lens of what Australia's unique contribution to the ethics landscape can be and that we identify the top three priorities for consideration by the CMO and the Australian Health Protection Principal Committee.

1. Resource allocation

Health resource allocation in the pandemic operates on multiple levels:

- deciding who receives specific interventions and care options when they become limited
- funding public health resources more broadly (such as increased testing and surveillance), and
- balancing the allocation of public health resources versus equally important resources for general health care provision.

There is a rough consensus in the literature and in practice that allocation of scarce resources should be guided by efforts to balance considerations of utility and equity; however formulas, criteria and application vary, resulting in inconsistent processes and outcomes. Another key principle is reciprocity; that is, prioritising provision of or access to services and resources for those individuals (health care professionals or others), who contribute directly to the pandemic response.

Consequently, much guidance on the ethics of resource allocation emphasises the importance of transparency and consistency in decision-making processes, both on the individual case level and with respect to policy development and implementation.

> For an overview of these issues, see:
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> - Guidance For Managing Ethical Issues In Infectious Disease Outbreaks (WHO), Chapter 4: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y

2. Implementation of public health measures

Ethical issues arise in both the implementation and lifting of public health measures required to manage the pandemic. These include:

- restrictions on human activity and movement,
- specific quarantining measures,
- requirements for testing, contact tracing and surveillance,
- decisions to lift some, but not other restrictions and the need to balance competing priorities (such as reducing economic and psychological burdens by loosening some restrictions, which may ultimately lead to new outbreaks).

In each of these instances, key ethical considerations might include efficacy, proportionality, equity, transparency, protecting confidentiality and limits on disclosure of information, the potential for coercion in the interest of universal participation and ensuring adequate oversight.

An obvious single-issue focus could be on surveillance technology and its implications for privacy and community trust in government as well as broader risk/benefit assessments.

Focus could also be put on the differential impact of public health measures on individuals and communities who are both disproportionately impacted by them and less able or willing to comply with them due to systemic inequity and consequent distrust of authority.

An issue related to surveillance is ethical issues associated with the development of registries of people who have had, or been treated for, COVID-19 for the purposes of tracking, follow-up or development of reliable and complete data sets.

For an overview of these issues, see:

- Guidance For Managing Ethical Issues In Infectious Disease Outbreaks (WHO), Chapters 5 & 6: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y

3. Issues faced by health care providers

Frontline health care workers and other health professionals and emergency responders are challenged by the parameters of their duty-of-care to those whom they treat and care for and balancing this with their own safety and, potentially, that of their families.

Key issues are the extent to which health care providers are obliged to secure access to resources on behalf of their patients/clients, what resources are within their duty-of-care to provide and what their obligations are if the most effective resources are not available.

Another critical issue, related to the above, is the extent to which health care providers are expected to risk their own health and well-being in order to provide treatment and care to those who have COVID-19 in the absence of adequate and sufficient personal protective equipment.

For an overview of these issues see:

- Guidance For Managing Ethical Issues In Infectious Disease Outbreaks (WHO), Chapter 13: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y

4. Impact on Aboriginal and Torres Strait Islander peoples and communities

As we have seen throughout the world, the pandemic and governments' responses to it, have highlighted existing inequalities in society and prompted different ways of thinking about and managing these inequalities. In Australia, Aboriginal and Torres Strait Islander communities face greater inequalities and lower health outcomes than many other non-indigenous Australians. In addition, public health measures such as social distancing, the requirement to 'stay home' and closing borders in the Northern Territory may have a disproportionately greater impact on indigenous communities than other Australians. This is due to cultural practices that require social interaction, the fact that it is more difficult to self-isolate in poorer quality housing and the fear that those with underlying health issues may be more badly affected by COVID-19.

The increased attention to health during the pandemic presents an opportunity to tailor our responses as a nation to those whose overall health is poorer and for whom access to treatment and other health care resources is more difficult. This could take the form of recommending that more specific resources are made available to people who have been and continue to be subjected to systemic inequity, and/or live in more remote or isolated environments. It could also generate a recommendation that the perspectives of Aboriginal and Torres Strait Islander peoples and other disadvantaged groups should be explicitly sought and taken into account in the development of ethical responses to the pandemic.

5. Research ethics

There are a range of issues that merit consideration in the area of research ethics. These relate primarily to the fact that there is an urgent need to find an effective vaccine and treatments for COVID-19 and also to measure our response to interventions in order to most effectively manage the pandemic.

Issues that have been identified include:

- The use of unproven interventions as treatment outside of the usual clinical trial process. The use of mechanisms to get experimental therapies or treatments to those with COVID-19 without subjecting them to the rigour of the clinical trial process may be increasing. In Australia, this would come under the TGA's special access scheme (SAS) or its authorised prescriber (AP) scheme. Common language for these schemes is 'compassionate use'. In the international literature, these mechanisms are referred to as "monitored emergency use of unregistered and experimental interventions" (MEURI).

- Ethical issues associated with the pressure to introduce interventions with an insufficient (in normal times) evidence base and the need to collect and share data on their efficacy whether or not they are introduced 'prematurely' and whether or not they are the subject of defined research.

- Proposals to vary the standard process for development of a new vaccine to accelerate its development. One popular proposal is to bypass Phase 2 clinical trials and go directly from Phase 1 studies to Phase 3 randomised clinical trials.

- The need for modifications to research design, development, review and conduct during the pandemic to enable important COVID-19 research to commence and to provide for the safe continuation of existing non-COVID-19 research.

- The ethical conduct of rapid research into the impact of the pandemic and responses to the pandemic, and

- Considerations around the prioritisation of research; specifically, the impact of de-emphasising and discontinuing non-COVID-19 research.

For an overview of these issues see:

Guidance for Managing Ethical Issues in Infectious Disease Outbreaks (WHO), Chapter 9: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y

See Guidance for Managing Ethical Issues in Infectious Disease Outbreaks (WHO), Chapter 8: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y

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6. Emerging from the pandemic and future planning

In the event that a SARS-CoV-2 vaccine does not emerge in the short to medium term, or even in the long-term, consideration will need to be given to how to emerge from the pandemic and to safely restart social and economic activity.

Australia's apparent success in containing the spread of the virus could serve to position us at the forefront of global initiatives to advise on emerging from the first phase of the pandemic and research evaluating those initiatives.

We could, for example, lead consideration of the ethical issues arising from widespread testing, the impact of relaxed travel and trade and associated routine quarantining and other initiatives, as well as the psychological, and socio-economic impact of (a) emergence from the first phase (b) potential management of any second phase (second wave / new cluster/s) of virus spread and (c) ongoing adjustment to the 'new normal' at the individual and societal levels.

Appendix A – Pandemic ethics resources

General

WHO Guidance on Management Ethical Issues in Infectious Disease Outbreaks: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y

Nuffield Council on Bioethics: https://www.nuffieldbioethics.org/topics/health-and-society/covid-19

Hastings Center Ethics Resources on the Coronavirus (Covid-19): https://www.thehastingscenter.org/ethics-resources-on-the-coronavirus/

Bioethics.net and the American Journal of Bioethics: http://www.bioethics.net/2020/03/bioethics-toolkit-resources-for-covid-19/

AG Ethik Public Health Ethics and COVID-19: https://www.public-health-covid19.de/images/2020/Ergebnisse/Policy_Brief_Pandemic_Ethics_GeneralF.pdf

Public Health Emergency Preparedness and Response Ethics Network: https://epidemicethics.tghn.org/

Group of Eight COVID-19 Roadmap to Recovery – A Report for the Nation: https://go8.edu.au/research/roadmap-to-recovery

Resource allocation issues

WHO Ethics and COVID-19: resource allocation and priority setting: http://origin.who.int/blueprint/priority-diseases/key-action/EthicsCOVID-19resourceallocation.pdf

Australasian Association of Bioethics & Health Law resources: https://aabhl.org/allocating-scarce-healthcare-resources-during-the-covid-19-pandemic/

Sydney Health Ethics Clinical Resource Allocation framework: https://www.sydney.edu.au/content/dam/corporate/documents/faculty-of-medicine-and-health/research/centres-institutes-groups/she.-clinical-ethics.-resource-allocation-framework.-version-1.-2-april-2020.pdf

Implementation of public health measures

WHO Ethics & SARS-CoV-2 – Restrictive Measures and Physical Distancing: https://media.tghn.org/articles/Ethics__COVID-19__Restrictive_Measures_-_Apr_14.pdf

WHO Guidelines on ethical issues in public health surveillance: https://apps.who.int/iris/bitstream/handle/10665/255721/9789241512657-eng.pdf?sequence=1

Issues faced by health care providers

Not yet identified

Impact on Aboriginal and Torres Strait Islander peoples and communities

News article (Croakey): https://croakey.org/urgent-calls-for-more-resources-to-protect-aboriginal-and-torres-strait-islander-communities-from-covid-19/

Research ethics

WHO Ethical standards for research during public health emergencies: http://origin.who.int/blueprint/priority-diseases/key-action/liverecovery-save-of-ethical-standards-for-research-during-public-health-emergencies.pdf

Guidance on clinical trials for institutions, HRECs, researchers and sponsors (CTPRG Joint Statement of the Commonwealth and state and territory Departments of Health, NHMRC and TGA): https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials

Emerging from the pandemic and future planning

Not yet identified

Other

Queensland Health ethical framework to guide clinical decision making in the COVID-19 pandemic: https://www.health.qld.gov.au/__data/assets/pdf_file/0025/955303/covid-19-ethical-framework.pdf