



PANDEMIC ETHICS ADVISORY GROUP

A subgroup of NPHET

Abstract

This document outlines the work of the Pandemic Ethics Advisory Group, including its publications, and provides details of the lessons learned that could inform future responses to public health crises.

Introduction

In December 2019, an epidemic of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) started in Wuhan and spread rapidly throughout the world. The World Health Organization (WHO) declared the 2019 coronavirus disease (Covid-19) a pandemic on March 11, 2020, and as of June 29th 2020, there are over 10 million cases confirmed worldwide with almost half a million deaths recorded globally. The COVID-19 pandemic is having unprecedented impacts on our healthcare systems, societies and economies, and poses numerous, and substantial, ethical challenges to health and social care. These challenges entail questions about how we balance different interests and risks, and who and what we should prioritise when responding to the pandemic. In order to answer such questions, careful reflection is required on the key ethical principles and values that should guide decision making in our health system.

The Pandemic Ethics Advisory Group (PEAG) was established as an expert subgroup of the NPHET in mid-March 2020 and met a total of 13 times (membership and terms of reference can be found in Appendix 1). The PEAG is multidisciplinary in composition so as to ensure a range of expertise and perspectives and includes members from the fields of ethics, medicine, law and patient advocacy. With its advice and collaboration, the Department of Health has published authoritative national ethics guidance to support healthcare workers, managers and policy makers in navigating the challenges that arise, and to bring consistency and fairness to the many difficult decisions that need to be made during the pandemic. In the development of the ethics guidance documents, the Department also consulted with a range of professional bodies including the Royal College of Physicians in Ireland, the Joint Faculty of the Intensive Care Society of Ireland, the College of Anaesthesiologists of Ireland, as well as a number of the HSE's National Clinical Programmes. All ethics guidance was reviewed and approved by NPHET.

Ethics Guidance

Ethical Framework for Decision-Making in a Pandemic

The Ethical Framework for Decision-Making in a Pandemic was published on 27 March 2020 and includes a number of substantive ethical principles and procedural values that can be applied to, and employed during, the decision-making process in a pandemic. Ethical principles apply to the decisions that are made, whereas procedural values relate to the manner in which those decisions are made.

The Framework is intended for policymakers, healthcare planners and providers in acute and community settings. It is also designed to assist clinicians in incorporating relevant ethical principles into their clinical practice. In recognition that every situation will be different, and that every patient is unique, the Ethical Framework is not prescriptive in approach, but provides general ethical orientation, in line with public health ethics principles. Each of the principles needs to be applied, reflected upon and balanced in individual and specific

contexts. The inclusion of procedural values should guide that process and support good decision-making. The Framework was drafted with reference to the WHO Guidance for Managing Ethical Issues in Infectious Disease Outbreaks¹.

Ireland's Ethical Framework was one of the first such documents to be published in the context of COVID-19. It is listed as a reference document by international organisations such as WHO, the Council of Europe, the International Network for Government Science Advice, American Journal of Bioethics, Alzheimer's Europe as well as a number of national bioethics committees.

Ethical Considerations relating to Critical Care in the Context of COVID-19

On Friday 3 April, the National Public Health Emergency Team (NPHET) approved the guidance document "Ethical Considerations Relating to Critical Care in the Context of COVID-19". The paper was subsequently published on 7 April 2020. Given reports relating to critical care triage emanating from other European countries, it was considered prudent, as part of the pandemic preparedness process, to formulate guidance to address a situation where healthcare resources, particularly in the context of intensive care, were likely to be severely limited and potentially overwhelmed. This situation would require healthcare professionals to make difficult choices regarding the prioritisation of critical care resources. The aim of the document is to support clinicians in this challenging role and to ensure that, in the event of a surge where critical care capacity was exceeded, decisions regarding the allocation of finite critical care resources are made in a consistent and fair way on the basis of clinical criteria and in a manner that avoids unfair discrimination.

Concerns were raised, both internationally and nationally about whether people with disabilities would be equitably cared for in the event that they contracted COVID-19 and became critically ill, due to the potential for value judgements being made regarding quality of life or social worth. A supplementary piece of guidance, published on 4 May 2020, states that safeguards against unfair discrimination are required to ensure that there will be no systematic de-prioritisation of any group, including those with a disability.

Ethical Considerations for PPE Use by Health Care Workers in a Pandemic

On Tuesday 14 April the National Public Health Emergency Team (NPHET) approved the guidance document "Ethical Considerations for PPE Use by Health Care Workers in a Pandemic". This paper was then published on 21 April 2020. It considers to what extent health care workers have an obligation to provide, or participate in the provision of, a medical intervention where there are constraints on supply of PPE.

The paper highlights that different procedures involve different levels of risk, and that risk will vary between healthcare workers depending on the nature and intensity of any exposure,

¹ Available at <https://www.who.int/tdr/news/2016/ethical-issues-in-inf-dis-outbreaks/en/#:~:text=New%20guidance%20on%20managing%20ethical%20issues%20in%20infectious,only%20focused%20on%20the%20specific%20pathogen%20in%20isolation.>

and on personal factors (for example, certain pre-existing conditions which put them at an increased risk of serious complications should they contract COVID-19). The guidance sets out specific factors for consideration when evaluating the risk of particular interventions.

Ethical Considerations Relating to Long-Term Residential Care Facilities

On 28 May the National Public Health Emergency Team (NPHE) approved the guidance document entitled “Ethical Considerations Relating to Long-Term Residential Care Facilities in the Context of COVID-19”. The paper was published on 4 June 2020. The purpose of this paper is to give ethical guidance for the provision of person-centred, rights-based care to people living in long-term residential care settings (LTRCS) during the COVID-19 pandemic. The guidance makes clear that the provision of health and social care during a pandemic should continue to be person-centred and follow a rights-based approach. While each individual has their own specific care needs and care settings differ, the paper highlights broad ethical considerations associated with congregated settings, such as increased vulnerability to infection and onward transmission within the residential community, difficulties with communication, testing and the implementation of physical distancing, the impact of isolation and restricted contact with family and loved ones, and the proportionate protection of rights in the context of supporting vulnerable persons.

Procedural Values for Decision-Making During a Pandemic

On 2 July the National Public Health Emergency Team (NPHE) approved the guidance document entitled “Procedural Values for Decision-Making During a Pandemic”. No ethical framework can offer a prescriptive solution to a clinical, organisational or policy dilemma. Even where there is broad agreement about the relevant considerations or ethical principles at issue, reasonable, well-informed people may disagree. This is due to individuals prioritising some ethical principles over others or because available evidence may be interpreted in conflicting ways. Depending on the context and circumstances, there may be more than one justifiable resolution to an ethically challenging situation. What is essential is that any resulting decision is reached using a process that is procedurally sound, acceptable to all stakeholders and is publicly defensible. The aim of the document is to elaborate on the role of the procedural values contained in the Ethical Framework, and to provide useful tools to guide the decision-making process and the application of the procedural values.

Dissemination of Guidance

The PEAG publishes all of its papers, its agendas and approved minutes to <https://www.gov.ie/en/collection/504017-nphet-covid-19-subgroup-pandemic-ethics-advisory-group-peag/> in accordance with the procedural value of openness and transparency. All of the guidance documents were published on the Department of Health website. The documents have also been added to the HSE COVID-19 Repository and the HSE communications team alerted staff to the guidance by email. Several professional and advocacy organisations both nationally and internationally have links to the documentation

on their websites. The guidance documents were also reported on by the media including RTE, national, regional and medical print media.

COVID Tracker APP

On the 19 May, the PEAG received a request from the COVID Tracker Ireland App Development Oversight Group to review the project from an ethics perspective. The PEAG opinion on the app was provided to the Oversight Group on 12 June and a copy was sent to NPHET for information. Issues covered included the effectiveness, transparency and trustworthiness of the App; privacy concerns, the importance of inclusiveness, equity and fairness and the importance of governance and accountability.

National Research Ethics Committee COVID-19

The Ethical Framework for Decision Making in a Pandemic recognises the need for mechanisms to allow for the accelerated review of research proposals in a pandemic, without undermining any of the substantive protections normally provided by ethics review. The Chair of the PEAG worked with colleagues in R&D and the Health Analytics Division to establish a temporary National Research Ethics Committee for COVID-19. The NREC COVID-19 reviews all COVID-19-related studies that fall under the definition of health research as set out in the Health Research Regulations 2018². The temporary National REC COVID-19 is designed to include structured and coordinated interaction with other bodies involved in regulation of health research including the Health Products Regulatory Authority (HPRA) and the Health Research Consent Declaration Committee (HRCDC). In this way, researchers and sponsors receive all the necessary decisions from appropriate parties within the same expedited timelines.

Reflections

The pandemic has brought into sharp relief questions regarding what we owe to each other and what values we wish to prioritise as a society. It has forced us to examine how and to what extent public goods are valued, as well as a re-evaluation of how we view, value, deliver and reward the act of caring in our society. The emphasis on solidarity during the pandemic has been a welcome one and has resulted in a collective commitment to carry the costs to support others and promote the common good. Our mutual inter-dependence means that solidarity must be conceptualised in the broadest possible terms. For it to be meaningful and effective, it must encompass all social groups, especially those who are already marginalised and disempowered. COVID-19 has exposed, and exacerbated, pre-existing health and social inequities, with a disproportionate burden falling on vulnerable and disadvantaged populations. Issues of social justice, human vulnerability and structural inequalities must be

² Includes the full spectrum of human health research including basic research, translational research, clinical research, diagnostics and treatment, population health research, social research, health services research and applied health policy research.

addressed, and care should be taken to ensure that decisions we make during and after, this pandemic do not deepen inequalities associated with age, disability, gender, ethnicity or socio-economic class.

While it is too early to engage in a comprehensive reflective exercise, as the public health crisis is still playing out both nationally and at the global level, there are some initial observations on the work of the PEAG, which should help us to be better prepared for a potential second wave of COVID-19. Some of the issues raised are procedural while others are more substantive in nature.

- In order to confer legitimacy on, and deepen understanding of, the values and choices being promulgated in the various guidance documents, significant efforts were made to engage with relevant stakeholders. PEAG endeavoured to listen, explain and respond openly and transparently to questions raised. Nonetheless, given the considerable pressures under which work was being completed, and in order to ensure that guidance was available to the healthcare system in a timely manner, it was not possible to be as inclusive as would have been wished. Revisions of the issued guidance, or elaboration of future guidance, should seek to engage with wider public groups in order to ensure that the different moral perspectives that the population may have on ethical questions can be more fully reflected.
- Another challenge encountered was the wide dissemination of the guidance produced to assist individual healthcare workers, healthcare providers and policy makers. The HSE and professional bodies greatly assisted in this task and thought needs to be given to how to facilitate the further dissemination of the documents to key audiences. This could include developing different formats, use of webinars other remote discussion/conferencing facilities to make the guidance easily accessible, all of which will require resources to achieve. Engagement with traditional media and newer social media is useful to stimulate broader public deliberation on ethics issues and it is considered that ethics should be part of any future COVID-19 communication strategy.
- There was a direct line of communication between the PEAG and NPHE. This could be enhanced by the establishment of a formal mechanism whereby the sub-group could identify, and raise ethical issues that arise with NPHE, for the purposes of suggesting that it be added to the Group's work programme.
- The PEAG was drawn together at short notice and worked in a highly collaborative and collegiate manner. Nonetheless it would be preferable to have a national, permanent, independent, multidisciplinary bioethics committee to provide oversight and high-level guidance in relation to ethical issues arising in the life sciences and in the provision of healthcare. Such a body would play a useful role in future public health emergency and pandemic planning. Ideally, this committee would have public visibility, and act as a forum to promote deliberative ethics discourse on biomedical issues or events considered to be of public interest.
- The ethics guidance published was, by necessity, formulated at a high-level, in order to be applicable across several settings. No Ethical Framework can offer a prescriptive solution to a specific clinical, organisational or policy question as individual decisions

are context dependent. This speaks to the need for a local clinical ethics committee infrastructure to support and empower health and social care staff to address specific ethical challenges in the provision of health and social care.

- More broadly, training and education in healthcare ethics, including public health as well as medical and nursing ethics could be more robustly addressed in both undergraduate and post-graduate training. The need for training extends to both research and clinical ethics committees.

There are many ethical questions in relation to COVID-19 that will require attention and further consideration including; the use of antibody testing and “immunity passports”; the prioritisation of certain groups for potential vaccination; the issue of whether such a vaccine should be mandatory; the impact of innovations such as telehealth on the professional-patient relationship; ethical issues related to research including study design, fast-tracking human trials, and the circulation of novel findings via pre-print prior to the completion of peer review; stigmatisation of those who contract COVID-19 and the healthcare workers who care for them; co-existence of COVID and non-COVID care; and the disruption of dying rituals. Having completed a significant programme of work, the PEAG proposes standing down for now with the proviso that it can be reconvened if necessary.

Appendix 1: Terms of Reference and Membership

Terms of reference:

To function as an expert sub-group of the National Public Health Emergency Team (NPHE) that will review and answer ethical questions relating to Covid-19 preparedness and response.

To provide expert ethical advice to the NPHE, the Department of Health, the HSE and others as appropriate.

Membership

Dr Siobhán O’Sullivan, Chief Bioethics Officer, DoH (Chair)

Dr Simon Mills SC, Law Library

Prof. David Smith, Healthcare Ethics and Law, RCSI

Dr Barry Lyons, Director of Patient Safety, College of Anaesthesiologists of Ireland, Consultant, Dept. of Anaesthesia & Critical Care Medicine, CHI Crumlin

Mr Stephen McMahon, Director, Irish Patients Association

Dr Joan McCarthy, Healthcare Ethics, School of Nursing and Midwifery, UCC

Dr Louise Campbell, Medical Ethics, School of Medicine, NUI Galway

Dr Andrea Mulligan BL, School of law, TCD

Mr Mervyn Taylor, Executive Director, Sage Advocacy