


Key Ethical Concepts and Their Application to COVID-19 Research

Angus Dawson*, Sydney Health Ethics, University of Sydney

Ezekiel J. Emanuel, Department of Medical Ethics and Health Policy, University of Pennsylvania

Michael Parker, The Ethos Centre, University of Oxford

Maxwell J. Smith , School of Health Studies, Faculty of Health Sciences, Western University

Teck Chuan Voo, Center for Biomedical Ethics, Yong Loo Lin School of Medicine, National University of Singapore

*Corresponding author: Angus Dawson, Sydney Health Ethics, University of Sydney, Sydney, NSW, Australia. Email: angus.dawson@sydney.edu.au

During the WHO-GloPID COVID-19 Global Research and Innovation Forum meeting held in Geneva on the 11th and 12th of February 2020 a number of different ethical concepts were used. This paper briefly states what a number of these concepts mean and how they might be applied to discussions about research during the COVID-19 pandemic and related outbreaks. This paper does not seek to be exhaustive and other ethical concepts are, of course, relevant and important.

Ethics is integral to research conducted in response to a public health emergency, including the current outbreak of COVID-19. One of the ways that ethics supports the conduct of research in these settings is via the identification of key values or considerations that should guide research design, implementation and the sharing of benefits. Yet, when values are invoked it is not always appreciated that they are fundamentally of an *ethical* nature and that they are imbued with certain ethical commitments. As ethicists and invited experts to the 11–12 February WHO-GloPID-R COVID-19 Global Research and Innovation Forum, [https://www.who.int/blueprint/priority-diseases/key-action/Global_Research_Forum_FINAL_VERSION_for_web_14_feb_2020.pdf?ua=1], we were struck by the frequency with which values or ethical considerations were invoked throughout discussions, including solidarity, equity, trust, autonomy, equal moral respect and vulnerability. Consequently, we felt it necessary to produce very brief discussions that aim to (i) define these key ethical concepts and (ii) guide their

application to COVID-19 research efforts. It is our overarching aim to emphasize the ethical nature of these terms and ensure that, when invoked, they carry the ethical force they are intended to have. A few caveats are necessary. First, justice cannot be done to the theoretical and conceptual complexity of these concepts in the space required to achieve our practical objectives. The result is that nuance and philosophical debate are largely eschewed in favour of clarity and being useful for practice. Second, that there are multiple relevant ethical values will sometimes mean that there will be overlap or conflict in how they are applied and what they require for research. It is not our intention to explain exactly how these values or considerations ought to be weighted or balanced in decision-making, as this should be done with full appreciation of the context of their application. Third, we do not mean to suggest that these are the only relevant values. We focus on these six, just because they were the ones appealed to at the WHO-GloPID meeting. Finally, given a lack of clarity with respect to precisely how these concepts should be balanced and applied, we

note that fair processes for deliberations regarding their relevance and application are necessary.

Solidarity

Solidarity is, in brief, the practice of standing up together and acting in common. Solidarity can provide both an explanation for behaviour ('they acted in solidarity against the bushfire') and also a justification for action. It is the latter that is more important here. How solidarity is justified will be contentious, but the concept has been linked to ideas of justice, mutuality, compassion, empathy, the valuing of equal worth of all, the recognition of need in others and even self-interest in the face of a joint threat of harm. Whatever the basis of justification, solidarity should be seen to be at the heart of the way that we do and should think about much of our ethics. Human beings, whatever they want to choose to achieve, have various interests in common. They are interconnected, dependent on others and necessarily relational. This is, hopefully, of obvious relevance to infectious diseases. Just as infection spreads through connection, our ethical response requires us to act together to ensure recognition of our common nature, needs and value.

How Is Solidarity Relevant to COVID-19 Research?

Research and public health action. COVID-19 requires a collaborative, community response and part of that response involves research. Research can contribute to protecting us all, through better understanding of the virus, how it is transmitted, who is most at risk and contribute to the production of new vaccines and treatments. Such action can be justified through an appeal to solidarity. COVID-19 will result in research not just into new therapeutics, but also into the effectiveness of social distancing measures from the acceptance (or not) of minor inconveniences such as more frequent and thorough hand washing to restrictions on our freedoms through social distancing. Mutual social bonds are weak in some societies, but many have strong community attachments through common geographical location or commitments of politics and faith, as well as recognizing a shared interest in responding to threats to health in an emergency. Such commitments, through an appeal to solidarity, may result in participation in research for the public good.

Prioritizing those who are vulnerable. Not every individual is equally able to look after their own interests,

and thereby protect themselves. Surveillance and epidemiological research can identify vulnerable groups in society, because of pre-existing chronic disease, age, living circumstances (e.g. prison, nursing home, etc.) or patterns of social disadvantage. Solidarity with those in need can be used as an appeal for participation in research. For example, to what extent does social distancing protect those most vulnerable through reducing the chances of them encountering the virus? What impact do such measures have not just on individuals but also on the resilience of health systems? Such research is vitally important and seeks to ensure that those most in need have the best possible chance of access to care and treatment when needed.

Research as a societal good. Research on diagnostics, vaccines and treatments in response to COVID-19 and other outbreaks will benefit us all, not only through direct health improvements, but also through increased knowledge in general. Increasing knowledge is a public good that can be supported through an appeal to solidarity. Research has other benefits for society including positive impact on economic and more general well-being.

Equal Moral Respect

Equal moral respect means treating others as moral equals, which includes respecting their dignity, humanity and autonomy.¹ This is an obligation shared *by* everyone, which in turn must be afforded *to* everyone. Unless there are good ethical reasons that justify differential treatment between persons or populations, equal moral respect requires that the interests of all be taken into equal account. Irrelevant characteristics of individuals, population groups and countries such as race, ethnicity, creed, ability or gender should not arbitrarily serve as the basis for differential treatment. Equal moral respect also requires being sensitive to cultural diversity and plurality, which in turn requires a willingness to engage in dialogue and deliberation on terms of equal standing and recognition. Importantly, while it is expected that substantive disagreement will invariably exist about how the benefits and burdens should be distributed in society, there can be no room for disagreement regarding the equal moral respect that is owed to every individual. In short, equal moral respect serves as a fundamental precondition for fair and equitable treatment.

How Is Equal Moral Respect Relevant to COVID-19 Research?

Community engagement. Equal moral respect requires meaningful engagement with and involvement of those whose lives are affected by public health emergencies and/or the research conducted in response. Many of the precise requirements for ethical research in the context of public health emergencies are contingent upon respectful and inclusive engagement of affected individuals and populations. In practice, this means that those affected should be informed about what is being done and why, and that they should be able to exert some influence over decision-making processes as well as decisions themselves. Critically, equal moral respect requires meaningful consideration of, and engagement with, those most marginalized and vulnerable.

Respect for cultural norms. Treating people with equal moral respect means being sensitive to cultural plurality and diversity. It is important that researchers respect cultural norms. In practice, this means ensuring that potential participants are empowered to reach their own decision regarding whether they would like to participate, ensuring that consent is sought in a culturally appropriate manner, and addressing participants' perspectives or concerns about the research, including information about how their data and samples will be handled, and so forth.

Collaborative partnership. Equal moral respect means recognizing the contribution that is made by all those involved in the research process, including research participants, research collaborators, research institutions, partner organizations and affected communities. It requires respectful partnerships between researchers and research participants throughout the entire trajectory of the research process. It also requires fair research collaborations.

Welfare and fair treatment of front-line workers. The successful conduct of research depends upon the work undertaken every day by front-line workers. In addition to the dangers and practical challenges they face in their work, this work requires great skill, expertise and ethical sensitivity. Equal moral respect requires that research institutions take action to mitigate the foreseeable risks of this important work. It also requires them to treat local and international workers fairly and to be transparent about the basis for any differential treatment.

Equity

Equity means treating people fairly. This requires *acknowledging the equal moral standing of all persons*. Unless there are good reasons that justify treating people differently, the interests of all individuals and population groups should be taken into equal account. Irrelevant characteristics of individuals or population groups such as age, race, ethnicity, creed, ability or gender should not arbitrarily serve as the basis for differential treatment. But, this does not require that everyone be treated the same. Rather, treating people equitably means treating *like cases alike*, e.g. treating people in accordance with their unique needs. When considering the unique and diverse needs of individuals and population groups, it is important to account for their physical, mental and social needs, as well as the structural and social drivers that create or perpetuate those needs, and address those wherever possible. Finally, fair treatment will to some extent depend on contextual factors, including the values of those affected by that treatment. As a result, for people to be treated equitably, they should be able to exert at least some influence over the decision-making process as well as the decision itself, i.e. *procedural fairness*.

How Is Equity Relevant to COVID-19 Research?

Fair selection of research participants. Individuals and communities participating in COVID-19 research will be exposed to potential risks (e.g. experimental vaccines or therapeutics) in service of advancing our knowledge about the virus and the potential countermeasures we could deploy to address it. Additionally, where individuals or communities participate in research with positive results, this may mean earlier access to effective therapies. For both of these reasons, it is imperative that mechanisms be put in place to ensure that research participants are selected in accordance with the standards of equity noted above. Criteria for inclusion can justifiably result in some being selected and others not, but these criteria should minimize risk, protect vulnerable populations and maximize social value and scientific validity of the research. Exclusion from participation should be justified by robust and updated scientific evidence, such as unfavourable benefit–risk ratios. Pregnant women, minorities, children and others should not be routinely excluded from research participation without a reasonable scientific and ethical justification.

Equitable access to the benefits of research. Equity requires that researchers, research funders and host

countries provide individuals and communities who participate in research with access to any benefits that result from their participation. Where interventions are found to be safe and effective, equity requires that those interventions be made available to local populations as soon as possible, in accordance with standards of equity, including via monitored emergency use of unregistered and investigational interventions (MEURI) when appropriate. Once research is completed, all efforts should be made to provide everyone with equitable access to its benefits.

Setting priorities for prophylaxis and treatment. Where capacity to respond to COVID-19 is overwhelmed, priorities must be set for accessing scarce resources, like vaccines, hospital beds, ventilators and therapeutics. Equity permits differential treatment, but requires that these priorities be set in a principled and accountable manner, with explicit consideration of the fair distribution of benefits and burdens. Given the fact that there is likely to be disagreement about how priorities should be set, it is imperative that this be accomplished through fair processes that meaningfully involve or reflect community perspectives.

Autonomy

Autonomy is often linked to the idea of control over what happens to you as an individual. It can be thought of as a key aspect of the *choices* that we make (e.g. choices free of the influence of others and based on relevant information, etc.) or the kind of *agent* that we are (e.g. we have the capacity and opportunity to reflect upon our choices and preferences and either endorse or change them). An autonomous individual is able to control what happens to their bodies and lives. Autonomous people may also forego making choices. They may, for instance, assign decision-making authority to family members or a personal physician, but that is their decision to make without manipulation or coercion. Autonomy is recognized universally as a core value in medical care and research. Hence, as some bioethicists argue: ‘Respect for autonomy is no mere ideal in health care; it is a professional obligation’.

How Is Autonomy Relevant to COVID-19 Research?

Consent to research. Respect for autonomy justifies several fundamental practices within research. One of the central issues is that of the necessity of informed consent prior to involvement in research. Informed consent

requires disclosing information about the nature of the research interventions, including risks, benefits, alternatives and the right of refusal or withdraw. The information must be understood by a competent person and a voluntary decision is made. Although the word ‘autonomy’ is not mentioned in the Nuremberg Code, it does capture well perhaps the most fundamental objection to medical experimentation proceeding without the free consent of patients, thereby violating their autonomy over their physical body and the direction of their life. The first principle of the Code, clearly appealing to the idea of autonomy, is:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

Respect for confidentiality. Research often involves the collection of health data about individuals. Researchers are under a general obligation of confidentiality to ensure that they only disclose such information where an individual has given permission to do so. Confidentiality can be respected by various means used to protect the data from disclosure such as coding or anonymizing the source. Identifying individuals or associating communities with an infectious disease can result in stigma and other harms. The requirement to seek advance and express permission to share data within research can be justified through an appeal to autonomy.

Vulnerability

When a person or group is regarded as vulnerable, it suggests that the person or group is thought to have a particular feature or be in a particular situation that exposes them to a threat, or an increased risk of harm or wrongful treatment (e.g. exploitation). To claim that someone is vulnerable is to imply that there is an ethical duty to protect their well-being or interests, perhaps because they are unable to do so adequately themselves. While ‘vulnerability’ has been defined in many ways, its core ethical function is to mark out the need for additional ethical consideration—or, heightened ethical scrutiny in the context of research—towards the risks and threats faced by a person or group regarded as

potentially vulnerable. This means that there is a need to understand just how and why they may be (more) susceptible to a risk or threat in a given context. This conceptualizing of vulnerability promotes an ethically justified response from others in terms of providing the safeguards a person or group needs.

How Is Vulnerability Relevant to COVID-19 Research?

Involving vulnerable participants in biomedical research. Certain groups (e.g. children, prisoners, etc.) have traditionally been categorized as vulnerable and are more likely to be excluded from biomedical research involving a pharmaceutical or medical intervention, due to concerns over their ability to provide an informed consent, or because they are held to be at higher risks of harm by the research than other potential participants. As mentioned, members of these groups should not be routinely excluded from research participation, because if, e.g. a novel treatment's effect on these groups remains unclear this only increases their vulnerability in the future. While not inherently vulnerable, pregnant women are importantly recognized as a population requiring special ethical consideration in research, given the potential risks to the developing foetus. When involving groups considered to be vulnerable, researchers must consider the factors that increase their risks of harm or wrongful treatment and propose appropriate safeguards. Research ethics committees may require additional protections. Representatives from these groups or relevant advocacy groups should also be engaged to review the protocol.

Mitigate the harms of research and response. In responding to the COVID-19 epidemic, research and other response measures (e.g. isolation, social distancing, quarantine) may result in inadvertent harm by diverting resources from and disrupting essential care and services in healthcare and community settings. Certain groups may be particularly vulnerable in the sense that they would be at increased risk of harm or be disproportionately burdened by the effects of the response measures. While it is important to conserve limited reserves given the uncertainties of the epidemic, it is equitable to provide greater resources to those at greater risk of serious harm or excessive burden to ensure that their essential needs are met.

Trust

Trust is a vital component of human interaction. When we trust, we rely on another to do the right thing; to act in

the appropriate way. This is true, whether we are talking about trust in providing a truthful answer to a question (e.g. is it raining?), we entrust someone with confidential information (e.g. in a medical consultation) or we entrust something of value (e.g. looking after my young child, whilst I take the dog to the vet). The person or institution that is or could be trusted can do various things to establish and seek to maintain their trustworthiness. Trustworthiness is the degree to which a party acts in ways that offer other people reason to trust that party. An institution, such as a Department of Public Health, can act in ways to try and ensure its trustworthiness. It should not expect to be trusted merely because it is an arm of government. Trustworthiness is built upon prior relations of trust, not such things as mere authority. You can compel action, but not trust. Common reasons for trustworthiness in institutions might include making sure that any spokesperson has the relevant professional expertise, that decisions are based upon sound reasons, a transparent and fair evaluation of the relevant evidence and that an opportunity is provided for questions, consultation and revisions to any policy, etc. There is a strong onus on persons and institutions that wish to be trusted to work to maintain trustworthiness, as once trust is lost in a person or an institution it is hard to re-establish.

How Is Trust Relevant to COVID-19 Research?

Trust in public health response, surveillance and research. Infectious diseases, by their nature, impact upon whole communities. However, in the early stages of an outbreak, much of the public health effort should go into detecting individuals (through testing) and the follow-up of possible contacts. Citizens must trust that any test is accurate and they must also trust public health departments to act appropriately with information disclosed about their activities and contacts. Surveillance, the routine detection and recording of disease, is an essential component of understanding the epidemiology of any outbreak. Trust is required for the disclosure of relevant information, so that patterns of infection can be understood and action taken in response as well as future planning (such as the allocation of resources). Finally, research is vital with a novel virus such as COVID-19 as we have, currently, no vaccine to prevent infection and no proven specific treatments. When individuals and communities are asked to be involved in research they depend upon the trustworthiness of researchers. Gaining consent, seeking research ethics review and ensuring confidentiality of data and the security of samples are all means for researchers to maintain trustworthiness in themselves and the results of their research.

Trust in expertise. During public health emergencies, such as COVID-19, action is required to ensure the maintenance of trustworthiness in those given responsibility for the response. Trust is more likely to be maintained where public health authorities are open and honest with the information that they have, they explain any limitations and uncertainties, and there is a clear link between the stage of an outbreak and any proposed action. For example, where action is taken to restrict the freedoms of people, such as the closing of schools, workplaces or parts of a country, this may be justified in some circumstances. However, trustworthiness is more likely to be maintained where reasons for such restrictions are given, impacts are mitigated (especially where some people are unfairly burdened), and the decision is time-limited, etc.

Note

1. This entry is largely informed by the recently published Nuffield Council on Bioethics Report on Research in Global Health Emergencies, of which one of the authors, Michael Parker, was an author. We would therefore like to acknowledge this Report and its authors.

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Conflict of Interest

None declared.

Additional Resources

Barrett et al. 2016, Council for International Organizations of Medical Science (CIOMS) 2017,

Nuffield Council on Bioethics 2020, and World Health Organization 2009, 2015, 2016.

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