

Ethical Framework for WHO's work in the ACT-Accelerator

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Background

The Access to COVID-19 Tools (ACT) Accelerator was formed in 2020 by the World Health Organization (WHO) and partners, under the guiding principle that “No one is safe until everyone is safe.” To this end, the ACT-Accelerator has brought together numerous stakeholders to end the pandemic as soon as possible. Four pillars form the foundation of the ACT Accelerator’s efforts, corresponding to particular categories of ‘COVID-19 tools’: diagnostics, therapeutics, vaccines and health systems.

Ending the pandemic is not simply a public health goal. Obligations to end the pandemic are underpinned by and in some cases turn on crucial considerations of ethics. For example, under the vaccines pillar, what is the fairest way to determine which subpopulations should receive vaccines first? Under the therapeutics pillar, how much risk is acceptable in accelerated authorization pathways for novel therapeutics? Under the diagnostics pillar, how should diagnostic tools be distributed across countries in light of vulnerabilities and epidemiology? And under the health systems pillar, to what extent should health systems resources be diverted from other priority areas in order to address this pandemic?

Purpose

This framework has been developed in order to assist stakeholders in navigating ethical issues and dilemmas, and more broadly make value-informed decisions, arising from efforts to respond to the pandemic through the use of COVID-19 tools.

Audience

The framework is intended to be of use both to ACT-Accelerator partner organizations, as well as key stakeholders in countries (i.e., those responsible for prioritizing populations and deploying COVID-19 tools, particularly governments, policy makers and civil society organizations).

Content Summary

The framework identifies seven overarching values that should guide decision-making. Four of these are substantive values: human well-being; respect for persons and communities; fairness; and solidarity. These values address the substance of what policies should do. By contrast, governance values – transparency, participation and accountability – address how decisions should be made and monitored. The three governance values taken together should be seen as advancing legitimate and trustworthy decision-making. These governance values are not meant to be exhaustive of all values potentially relevant to COVID-19 decision-making. They are, however, the governance values identified by the Working Group (in light of prior work by WHO, per the Sources section below) as the most essential and relevant to deploy for both ACT-Accelerator partner organization and key stakeholders in countries.

The Table offers principles for the realization of each value, as well as illustrations for how each value may be applied in each of the four ACT-Accelerator pillars. These illustrations are not meant to be comprehensive, but indicative of the way in which a given value intersects with some particular issues facing the development and deployment of COVID-19 tools.

Substantive values

Value	Principle(s)	Illustrative considerations
Human well-being	<ul style="list-style-type: none"> Protect and promote human well-being, including physical and mental health, social and economic security, human rights, and child development, through the effective, coordinated development, manufacturing and deployment of COVID-19 tools, while minimizing the harmful effects (e.g. adverse reactions to drugs, side-effects of vaccines or false positives of diagnostics) of those tools and/or their deployment. 	<p>What standard of evidence is acceptable for accelerated development, authorization and distribution, given the scale of the pandemic?</p> <p>Are there trade-offs during distribution between different aspects of well-being (e.g. health vs. economy), and the well-being of certain subpopulations prioritised to receive the tools? (e.g. essential workers vs elderly individuals)?</p> <p>Does the response to COVID-19 conflict with or threaten any human rights?</p> <p>How might different tools, e.g. diagnostics and therapeutics, be allocated together to promote human well-being?</p> <p>Are there mechanisms to report and evaluate potential harmful effects of COVID-19 tools? (including physical, psychosocial, and informational harms)</p>
Respect for persons and communities	<ul style="list-style-type: none"> Recognize the equal moral status, interests and rights of those who will benefit from COVID-19 tools (including individuals' interest in self-governance), as well as the status and interests of the communities of which they are a part. 	<p>To what extent do individuals receiving the tools have control over the disposition of information gathered/generated?</p> <p>Are tools being provided on a voluntary or mandatory/coercive basis?</p> <p>Is the agreement of relevant communities sought prior to deployment of tools amongst them?</p> <p>Are relevant cultural norms identified and appropriately taken into account?</p>
Fairness	<ul style="list-style-type: none"> Ensure equitable access to and benefit from COVID-19 tools globally and within countries, prioritising those disadvantaged due to biological, social or other factors, honoring obligations while avoiding unjust discrimination, compounding disadvantage, exploitation of vulnerable parties, or the blocking of access to other essential care. 	<p>Are tools being deployed/distributed to countries and contexts based on appropriate prioritisation schemas?</p> <p>Do plans for distribution explicitly or implicitly discriminate against or privilege certain groups, and for what reason? For example, if politicians are being prioritized, is this adequately justified?</p> <p>Are special obligations owed by some entities towards particular groups?</p> <p>Might the distribution of tools create or exacerbate disparities in illness and death related to COVID-19, including disparities in the social determinants of health?</p> <p>Are tools available to the vulnerable populations in countries (e.g. migrants, refugees, etc.)?</p> <p>How is the continuity of essential health services maintained, including for persons with non-COVID-19 health issues?</p>

		To what extent should countries reasonably prioritise the needs of their own residents over those in other countries in deployment of COVID-19 tools?
Solidarity	Act in a manner that acknowledges the interdependence of countries and populations and that individual well-being is dependent on the control and suppression of the virus across the world through COVID-19 tools.	Are tools developed for a wide array of contexts (e.g. different public health and tool delivery capacities)? Are members of the international community devoting sufficient resources to support the development and equitable global distribution of tools?

Governance values - promoting legitimacy and trustworthiness

Value	Definition	Illustrative considerations
Transparency	The underlying rationale (including relevant risks/benefits), decision-making processes, and decisions related to the coordination, development, manufacturing, and deployment of COVID-19 tools should be communicated publicly in an honest, straightforward manner and made available for public review.	Is information on how decisions are reached publicly available, including justifications for decisions? Is information about the risk/benefit of the tools provided in an appropriate way to communities and individuals?
Participation and Inclusion	Decisions should be made with the opportunity for input from relevant stakeholders such as civil society and community organisations, to the extent practicable and appropriate for a given context.	To what extent do decision-making bodies include input from affected parties, including those historically under-represented and representatives of civil society and community organisations? Is attention given to potential power imbalances between those included in the decision-making process? What are the mechanisms to engage people in decision making processes?
Accountability	Decisions should be made with clearly defined objectives, targets, processes, roles, responsibilities and decisions, supported by mechanisms to enable decision-makers to be held to account and mitigate conflicts of interest.	Is it clear to the public who is responsible and answerable when a decision is made? Are mechanisms in place to evaluate whether stated values and objectives are being promoted or achieved?

Sources

This framework was developed by the WHO ACT-Accelerator Ethics and Governance Working Group. The values were selected to be consonant with existing COVID-19 values frameworks developed by the WHO, particularly the WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination; (1) the WHO Concept for fair access and equitable allocation of COVID-19 health products; (2) and the Framework for the Governance of Personal Data for the Access to COVID Tools Accelerator (3). Each of those are specific to particular COVID-19 tools; the present document takes a broader approach, laying out a set of values that can be applied in different contexts.

How to use the framework

What should be done in a given circumstance cannot simply be read off from a value's definition, or even its application in context. Rather, the values provide a frame by which stakeholders can identify and articulate different, potentially competing ethical considerations raised in relation to a particular question.

More systematically, stakeholders could consider taking the following steps in order to apply the framework:

1. Clarify the context, and the question, dilemma or decision to be addressed. This step may be provisional, and subject to revision at Step 3, but an initial identification of scope will aid in identifying and applying appropriate processes in Step 2.
2. Reflect on the process of decision-making (including who is responsible for contributing towards and ultimately making a decision), to ensure adequate accountability. In well-established systems, such as with many government agencies, existing accountability structures may be apparent and this step proceed without difficulty. In other more novel contexts, such as with ACT Accelerator, this step may require more careful consideration and stakeholder consultation (further aligning with the procedural values of participation and transparency). If the process has deficiencies, these should be refined as soon as possible, ideally before proceeding with the below. Inadequate accountability of decision-making could threaten the legitimacy of decisions that are made, even if the decision is ethically defensible on its merits.
3. Consider the way in which the decision intersects with each of the substantive values, identifying relevant consequences of each option in light of available empirical evidence and specifying the application of a given value in context. A given decision might promote certain values at the expense of others; moreover, there may be tensions within a given value. For instance, a policy might advance the well-being of one subgroup at the expense of the other, or respect individuals' right against discrimination at the expense of some individuals' right to self-determination. This application of values will vary depending on the context under consideration. It may also involve returning to Step 1, potentially clarifying or revising the objectives of a given decision in light of attention to the values.
4. Weigh up or balance the comparative tradeoffs within and between values that a given decision represents, to ensure proportionality and arrive at a determination of the course of action that is most ethically defensible. This requires careful, considered judgment. There is no set formula; no value generally trumps or takes precedence over another, though in some contexts certain considerations may be more salient, relevant or pressing than another. It is unlikely that a given policy position will equally promote all values, but it is crucial that value trade-offs are explicitly evaluated and justified by transparent reasoning. This could involve showing how one value is of overriding importance in a given context, or demonstrating that certain options overall better satisfy the demands of conflicting values than others.

The governance value of participation, by consulting key stakeholders affected by a decision, may assist in weighing values for particularly contentious issues. This process should also not be considered one-off, but

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