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Allocation Framework for Equitable Access to COVID-19 Vaccine(s)

Introduction

The development of a vaccine for COVID-19 is the subject of an unprecedented global effort. Vaccines are critical public health interventions as they mitigate disease at the population level by both offering protection to individuals and curbing community transmission. If and when an effective vaccine with an acceptable safety profile becomes available, it will be a vital additional tool in controlling the pandemic and, over time, will contribute to reducing the health burden of the disease and the restoration of social and economic activity. While the goal is to offer the vaccine to those for whom it is indicated, given the global demand, it is likely that supply of any authorised COVID-19 vaccine will be limited initially, and will not be sufficient to vaccinate the entire population. Likewise, any vaccine will take time to distribute and administer. Determining who should be given priority for vaccination during this period of scarcity will require careful deliberation and informed planning. Identifying priority groups for COVID-19 vaccination is an essential element of planning a successful population-wide vaccination programme.

While a significant body of knowledge has been accumulated since the start of the pandemic, there remain a number of gaps in our knowledge regarding potential COVID-vaccines, as well as our understanding of the disease. Prioritisation strategies depend upon a number of factors including vaccine efficacy in different age/risk groups, vaccine characteristics, availability of effective therapeutics, as well as the epidemiological situation at the time the vaccine becomes available. Changing conditions, therefore, can lead to changing priorities. Any allocation framework, therefore, needs to be adaptable to the particular set of circumstances that may pertain at the time of vaccine distribution. Moreover, there should be continuous assessment of allocation priorities as new data becomes available. Vaccine prioritisation also needs to be seen within the broader context of the national pandemic plan. It is useful to consider allocation priorities in conjunction with other possible measures capable of protecting individuals such as ease of social isolation, modifications to the workplace, and/or provision of personal protective equipment.

The Allocation Framework provides four core ethical principles which should be used to guide prioritisation of various groups for vaccination, namely: the **moral equality of all persons**, **minimisation of harm**, **fairness**, and **reciprocity** (see page 7 for further details of these principles). The Framework also points to the importance of the procedural values of **transparency**, **inclusiveness**, **responsiveness**, reasonableness and accountability in reaching decisions regarding the allocation of a COVID-19 vaccine. The principles and procedural values which underpin this framework are grounded in the Department of Health *Ethical Framework for Decision Making in a Pandemic*¹. Ethical principles, objectives and available scientific evidence, once integrated, can identify an ethically defensible list of candidate priority groups for COVID-19 vaccination.

The Allocation Framework is designed to address the ethical issues pertaining to prioritisation of COVID-19 vaccine allocation. Equity is a critical consideration in the context of the distribution and administration of the vaccine to ensure that existing health inequalities are not perpetuated or exacerbated. Other ethical issues related to COVID-19 vaccines, including vaccine trial design, vaccination consent requirements, vaccine damage, origin of cell lines used in vaccine production, and global equity obligations, are outside the scope of this Framework.

Purpose of the Allocation Framework

Decisions about how to prioritise limited supplies of COVID-19 vaccines should not be based on public health considerations alone. To set priorities implies making a conscious decision or choice. The priority-setting process has tangible consequences for people's health and quality of life which requires that the values and principles which underpin choices regarding prioritisation should be made explicit. Using ethical principles to guide decision-making can enhance trust and solidarity and can strengthen the legitimacy and acceptability of the decisions reached. Using the Allocation Framework can assist decision-makers in assessing which populations have the strongest claims to limited vaccine supplies and can make value trade-offs transparent in situations in which there are multiple strong claims to a vaccine(s).

¹ Dept. of Health Ethical Framework for Decision Making in a Pandemic, available at <https://www.gov.ie/en/publication/dbf3fb-ethical-framework-for-decision-making-in-a-pandemic/>

Objective of Vaccination

The pandemic has cost lives and health, as well as incurring substantial socio-economic costs, often disproportionately affecting the marginalised and most vulnerable in our society. The aim of vaccination for SARS CoV-2 is to **ensure equitable access to a safe and effective vaccine with the goal of limiting mortality and morbidity from COVID-19, protecting healthcare capacity and enabling social and economic activity.**

Underlying Assumptions

A number of assumptions regarding putative COVID-19 vaccine(s) have been made which have informed the development of the allocation framework and are detailed below:

- The majority of the population remains susceptible to COVID-19² and prior infection is not necessarily proof of immunity³
- Surveillance and epidemiological research have identified certain groups in society who are particularly vulnerable to SARS-CoV-2 because of age, pre-existing medical conditions, social disadvantage or living circumstances⁴
- Vaccine supply will be highly constrained for the first several months of the vaccination campaign and may have different logistical requirements
- The number of doses of vaccine available may not be sufficient to vaccinate everyone in the priority groups identified and further prioritisation within these groups may be required
- It is unlikely that one vaccine will be equally effective in all populations⁵
- A proportion of the population may be hesitant to receive a novel COVID-19 vaccine.

² The estimated national prevalence rate of COVID-19 was 1.7% in July of 2020. See <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/scopi/SCOPI%20report%20preliminary%20results%20final%20version.pdf>

³ Iwasaki A. What reinfections mean for COVID-19. *The Lancet Infectious Diseases*. 2020 [https://doi.org/10.1016/S1473-3099\(20\)30783-0](https://doi.org/10.1016/S1473-3099(20)30783-0)

⁴ Williamson EJ, Walker AJ, Bhaskaran K *et al*. *Nature* 2020;584(7821):430-436

⁵ It is common for vaccines to be less effective in older adults and different types of vaccines may induce different kinds of immunity

Multi-Value Allocation Framework

The WHO has recommended that in allocating scarce resources such as a vaccine during a public health emergency, a balance needs to be struck between utility and equality and fairness⁶. This approach broadly reflects the ethics literature⁷, and existing plans for allocating vaccines in a pandemic^{8,9,10}. The Allocation Framework combines ethical principles for the stewardship of scarce resources as well as equitable access with prioritisation for those most in need¹¹. The Framework is also rooted in human rights law and standards¹² of which equality and non-discrimination are core principles, recognises the right of everyone to the enjoyment of the highest attainable standard of health, and precludes allocation of vaccine on arbitrary or discriminatory grounds¹³.

There is a range of different values which can be taken into consideration when setting priorities for access to a vaccine in the context of a pandemic. Fair allocation of limited vaccine supplies requires an adaptable multi-value ethical framework where principles are combined and balanced. The importance assigned to a particular ethical principle can vary, depending on contextual features including the epidemiology of the disease and the characteristics of

⁶ WHO 2016 Guidance for Managing Ethical Issues in Infectious Disease Outbreaks

⁷ Williams JH, Dawson A. BMC Medical Ethics 2020;21:40-48

⁸ World Health Organization. (2020). WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination, 14 September 2020. World Health Organization

⁹ National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC

¹⁰ The National Academies Press; Toner E, Barnill A, Krubiner C, et al. Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States. Baltimore, MD: Johns Hopkins Center for Health Security; 2020

¹¹ Historically, a solely utilitarian approach to managing scarce resources in a pandemic has been adopted which focusses on outcomes and is usually articulated as maximising benefits and minimising harm, e.g. saving the most lives and limiting morbidity and social and economic disruption. However, utility cannot be the sole determinant of who receives priority vaccination. Egalitarian considerations regarding which groups in the population will secure what share of the benefits and direct consideration of the worst-off is also required. Maximising utility may well justify deploying vaccines to urban centres with high population density rather than to rural areas but, if done in a systematic manner, this would be inequitable and could exclude some at risk populations

¹² Relevant provisions in International Human Rights instruments includes but is not limited to Article 2 of the European Convention on Human Rights which enshrines the right to life; Article 25 of the Universal Declaration of Human Rights, Article 12 of the International Covenant on Economic, Social and Cultural Rights, Article 11 of the European Social Charter which recognise the right to health; Article 3 of the Oviedo Convention which enshrines the principle of equitable access to healthcare; Article 15 of the International Covenant on Economic, Social and Cultural Rights which encompasses the right to benefit from scientific progress and its application; Article 2 of the Universal Declaration of Human Rights and Article 14 of the European Convention on Human Rights which guarantee protection from discrimination

¹³ Refusing priority vaccination to marginalised or stigmatised groups in society would violate considerations of equality and would likely fail to promote the common good

the available vaccine(s). Weighting and balancing the four principles must, therefore, be done with a full appreciation of the context of their application. In the likely event that vaccine supply will not be immediately sufficient to vaccinate all members of a prioritised group, relevant considerations include which sub-groups are at risk of the worst outcomes, e.g. over 85's are at significantly higher risk of dying than those in their 60's; whether a sub-group can be protected by means other than vaccination, e.g. social distancing or availability of PPE; how essential is the role of the sub-group in responding to the pandemic, and how easily would it be to restaff the role.

Procedural Values

Even where there is broad agreement about the relevant considerations or ethical principles at issue, reasonable, well-informed people may disagree about their application because of different value-commitments or because available evidence may be interpreted in conflicting ways. Accepting that there may be more than one justifiable approach to vaccine prioritisation i.e. *the who* gets priority, serves to emphasise the central importance of process followed i.e. *the how* such decisions are reached. A robust, inclusive and deliberative decision-making process not only demonstrates respect for people but will also promote procedural fairness, thereby conferring legitimacy on the decisions made.

The Ethical Framework for Decision-Making in a Pandemic describes five procedural values which are intended to guide and inform the process of making ethically sound decisions during a pandemic. The values are 'procedural' because reasonableness, transparency, inclusiveness, responsiveness and accountability are features of any decision-making process which claims to be publicly justifiable. **Transparency, Inclusiveness and Responsiveness** are particularly important in the context of vaccine allocation decisions. Communicating decisions and the rationale behind them in an open and transparent way is one of the crucial factors in increasing the acceptance and cooperation of those who will be affected by these decisions.

Transparency is vital for ensuring that all aspects of the vaccination programme are worthy of trust and can promote the necessary solidarity and mutual responsibility needed for a

successful strategy¹⁴. This is especially relevant in the context of potential public concern regarding vaccine safety and efficacy which could have broader implications for vaccine confidence.

The procedural value of **inclusiveness** requires that those affected by the decision are consulted and their views are taken into account, and any disproportionate impact on particular groups is considered. Timely public and stakeholder engagement can provide feedback on the goals, values and allocation strategy for a COVID-19 vaccine.

Responsiveness requires that decisions about who receives the vaccine and when, is based on the best available evidence, e.g. who are the populations most at risk of getting seriously ill or dying from COVID-19. Evolving evidence needs to be taken into account and this may impact on groups prioritised at different time points¹⁵.

Reasonableness requires that decisions reached on prioritisation are the result of an appropriate process and based on the best available evidence at the time. Documenting and allowing public scrutiny of the objectives, principles and evidence base underpinning those decisions will contribute to holding decision makers accountable.

Principles Underpinning Vaccine Allocation

Moral Equality

Human beings have equal worth and an equal right to respect and dignity. Human dignity is not contingent on people's personal qualities or on their status or function in the community, and no one person is more valuable or worthy of consideration for priority than another. Equal moral concern requires treating similar individuals similarly and not discriminating on the basis of morally irrelevant differences such as ability, social status, income, etc. This does not mean that differential treatment is precluded, rather, people should be treated in accordance with their specific needs and/or circumstances. Everyone who meets the criteria

¹⁴ DeBruin D, Leider JP. J of Public Health Manag Pract. 2020;26(4):306-309

¹⁵ For example, if it became evident that older persons could not mount a sufficiently robust immune response to the vaccine available, consideration would have to be given to reprioritising other groups and finding alternative methods of protecting older persons

for inclusion into a priority group should be provided with the opportunity to be vaccinated. Moral equality requires that the interests of all be taken into equal account, with meaningful consideration of the most marginalised and vulnerable in society. Moral equality serves as a fundamental precondition for fair and equitable treatment.

Minimising Harm

A foundational principle of public health ethics is the obligation to protect the public from serious harm. Harm is a broad concept and includes physical, psychological, social and economic harm. Harm is most obviously observed as COVID-related mortality and morbidity. The effects of the pandemic, however, extend beyond COVID-related deaths and illnesses. The pandemic has had damaging effects on societal and individual wellbeing, with many experiencing isolation from friends and family¹⁶ and has resulted in serious economic hardship for many¹⁷. The principle of minimising harm would justify prioritising groups with a significantly elevated risk of death or severe disease including (i) older persons and those with comorbidities which put them at risk of more severe disease (ii) groups with a significantly elevated risk of being infected such as healthcare workers and those living in congregated settings, e.g. long-term residential care, direct provision centres, prisons (iii) groups necessary to provide essential services including healthcare workers and essential workers outside the healthcare sector, e.g. Gardaí, teachers, transportation and food workers.

When considering the various dimensions of harm, the severity and irreversibility of the harm is particularly pertinent. Death, for example, is a devastating and irreversible harm. Moreover, long-term health effects from COVID-19 can compromise physical and mental wellbeing as well as educational and employment opportunities that can impose irreversible significant harm. Thus, an initial focus on preventing mortality and morbidity caused by COVID-19 is justified. This also offers the indirect benefit of protecting the health service from being overwhelmed and facilitates non-COVID emergency and non-scheduled care.

¹⁶ Department of An Taoiseach. Report on the Social Implications of COVID-19 in Ireland, update June 2020

¹⁷ ESRI, Quarterly Economic Commentary, Autumn 2020, <https://doi.org/10.26504/qec2020aut>

Fairness

The principle of fairness is related to distributive justice and equity concerns. Fairness requires that those with relevantly similar interests are treated similarly, and that no individual or group should shoulder a disproportionate burden or benefit relative to others. A fair decision is one that gives people with an equal chance of benefiting from a vaccine an equal chance of receiving it. While we are all vulnerable in the context of a pandemic, it is increasingly clear that certain populations are experiencing a disproportionate burden due to underlying biological, geographical and societal factors. Promoting fairness requires addressing inequities between social groups, especially those rooted in structural inequalities, and giving priority to the worst off¹⁸. There are many senses in which someone can be worse off than another person, e.g. in terms of health, resources and opportunities. Those at the highest risk of death or serious disease would have a strong claim to being worst off, as would those who, through their professional activity, are at higher risk of contracting SARS-Cov-2. The worst off could also include systematically disadvantaged and marginalised populations who often reside in higher risk living conditions, e.g. crowded accommodation, are economically vulnerable due to precarious employment and face challenges to accessing healthcare which is associated with a higher prevalence of health problems.

The principle of fairness also encompasses procedural justice which requires impartiality, consistency in implementation of vaccine prioritisation, and which seeks the participation of affected populations, especially those disproportionately affected, in determining allocation criteria and identifying priority groups.

¹⁸ It is widely acknowledged in the literature on health-related priority-setting that benefits to the worse off should be given some priority; Parfait D. Ratio 1997;10(3):202-221; Brock D. Health care and social justice. New York: Oxford University Press; 2001; Herlitz A, Horan D. Social Science & Medicine. 2016;157:96-102

Reciprocity

Reciprocity, although important, is somewhat more marginal than moral equality, minimising harm and fairness. The principle of reciprocity requires that special consideration be given to those groups who play an essential role in responding to the pandemic and, in doing so, place themselves at greater risk of being infected than the general population, e.g. healthcare workers, other essential workers outside the health sector, and those participating in vaccine clinical trials. Obligations of reciprocity do not apply evenly to all healthcare and other essential workers, but rather depend upon the degree of risk their job entails. For example, those healthcare staff directly caring for patients with COVID-19 have a greater claim to prioritisation than healthcare workers delivering care through telemedicine. Reciprocity is associated with fairness and solidarity in that it involves offering a level of protection to those who are assuming risks on behalf of the general population and setting aside personal claims to prioritisation in order to protect those on whom the general population depends.