

Title Page

Title: Ethics of vaccination: measures used to inform SARS-CoV-2 vaccination priorities

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Abstract

Proposals for SARS-CoV-2 virus vaccination priorities in the UK and in many other countries are heavily influenced by epidemiological models, which use outcome measures such as deaths or hospitalisation. Limiting the values under consideration to those attributable to the direct effects of infection has the advantage of simplifying the models and the process of decision-making. However, the consequences of the pandemic extend beyond outcomes directly attributable to SARS-CoV-2 infection. The alternative to vaccination (in addition the threat of illness and death) is restrictions on educational and work opportunities, access to services, recreational activities, affiliations and relationships with others, freedom of movement (including escaping abusive relationships), and other determinants of human experience.

Capability theory gives emphasis to the freedoms that individuals have to express themselves (in doings and beings). Restrictions on freedoms restrict our capabilities. Capability theory has been used to provide a framework for the evaluation and comparison of international development approaches and in the evaluation of public health policy. There is a clustering of disadvantages associated with this pandemic that adds to pre-existing inequalities. Much of the disadvantage engendered in the SARS-CoV-2 pandemic is left out when public health policy is based on a limited range of metrics. Acknowledging the impact of policy across the range of human freedoms at both a national and international level has the potential to improve policy, facilitate the mitigation of direct and indirect adverse consequences, and improve public confidence in vaccine deployment strategies.

Word count **240** words

Introduction

There are an increasing number of vaccines available which have the potential to protect individuals against the SARS-CoV-2 virus.¹ What are the principles and values that should be used to determine the distribution of vaccines designed to mitigate the risks of SARS-CoV-2 virus infection? This question can be asked both from a national and international perspective. Many high-income nations have already purchased millions of doses of vaccine. Which groups within nations should be prioritised for vaccination when vaccines are relatively abundant? Many countries do not have the resources or infrastructure required to purchase and distribute vaccines without assistance. How do we assure vaccine distribution between competing nations? Do wealthier countries have responsibilities to assure vaccine distribution to and within those nations that are less well resourced?

The terms justice and fairness are often used interchangeably in popular as well as academic discourse. The definitions and meaning of the terms vary with context. John Rawls, perhaps the leading political philosopher of the 20th century, famously proposed 'Justice as Fairness'.² A just society gives every individual an equal right to basic liberties and opportunities. The terms justice and fairness share a common sentiment: that equal respect should be accorded to the rights and dignity of every individual, regardless of that individual's specific attributes or circumstances. This conceptualisation of inalienable individual rights has been most rigorously stated in the

Universal Declaration of Human Rights (1948).³ Justice and fairness become issues when interests conflict. Not everyone can be vaccinated immediately. In the long term, it is in the interests of all that disease caused by SARS-CoV-2 virus is controlled. In the short term, there are conflicts of interest entailed with distributing vaccines. The early distribution of the vaccine will potentially impact life expectancy, quality of life, risk, opportunity, security (financial and personal), and wellbeing of individuals unequally. Deciding on a fair distribution of a limited and potentially life-saving resource requires that we balance benefits and burdens. Whether individuals are happy to comply with the vaccination strategy will depend on the reasons given to support that strategy, and the underlying principles and values used to justify priorities.

What sorts of principles and values were used to support the current proposals for vaccine distribution?

In this section the principles and values underlying some of the proposals for prioritising recipients of SARS-CoV-2 vaccine are briefly overviewed.

Some of the proposals for vaccine allocation have taken a global perspective while others have focused on national priorities. Some have made ethical principles and values more explicit than others. Operation 'Warp Speed' in the USA⁴ prioritised vaccination in the USA (America First). By contrast a World Health Organisation proposal is that the vaccine should be distributed globally so that initially all countries would receive enough vaccine to immunise 3% of the population.⁵

Emmanuel et al. (2020)⁶ provide an ethical framework for global vaccine allocation focusing on three values. These are benefiting people and limiting harm, prioritising the disadvantaged, and giving an equal degree of moral concern to each person. Metrics are proposed that reflect these values and these include the Standard Expected Years of Life Lost that can be averted by use of the vaccine (SEYLL). Vaccines should be distributed in order of priority to 1. countries in which the vaccine would reduce more SEYLL per dose, and 2. to countries that would reduce more poverty, avert more loss of GNI (Gross National Income), and avert more SEYLL per dose, and 3. to countries with higher transmission rates.

The World Health Organisation has proposed an overarching goal that COVID-19 vaccines contribute significantly to the equitable protection and promotion of human well-being among all people of the world. The underlying values are human well-being, equal respect, global equity, national equity, reciprocity and legitimacy.⁵ Human well-being requires priority to the reduction of deaths and disease burden from the COVID-19 pandemic, reduction of societal and economic disruption (other than through reducing deaths and disease burden), and the protection of the functioning of essential services, including health services. Equal respect requires that the interests of all individuals and groups are treated with equal consideration as allocation and priority-setting decisions are being taken and implemented, and that there is a meaningful opportunity to be vaccinated for all individuals and groups who qualify under prioritisation criteria. National equity requires that countries take into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic, and that countries take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations. Priorities depend on national considerations, for example health workers in contexts with high levels of transmission would be given a high priority for vaccination.

The US National Academy of Sciences (NASEM)⁷ suggests a primary goal of maximising societal benefit by reducing morbidity and mortality caused by transmission of SARS-CoV-2, while also mitigating health inequities, ensuring individuals are shown equal regard and fairness, and that policies are evidence-based and transparent. As with the WHO framework the maintenance of health and emergency services is given a high priority in the early phase of vaccination in order to assure the maintenance of health and emergency services to aid prevention of morbidity and mortality.

The German Ethics council, Standing Committee on Vaccination, and the National Academy of Sciences Leopoldina joint position paper⁸ identifies three priority groups. These groups are those at a high risk of death and serious illness due to their age, those who assist COVID-19 in the course of their work (such as health and care workers who are both at increased personal risk and may also be responsible for multiplier effects), and those who perform roles in services of general interest and that maintain central state functions. This paper invokes a number of ethical principles, including that of solidarity (the responsibility of those who are less at risk to temporarily put aside their own health protection, for the needs of those who are more at risk). Secondly, prioritising those individuals (such as essential workers) who provide ‘instrumental value’ to society is consistent with the principle of reciprocity: recognising the additional personal risks and burdens assumed by keyworkers to maintain critical services for the benefit of society. By broadening this category to include service workers of general interest (such as supermarket staff & transportation workers), with some proposals extending this consideration to families of such workers, a form of recompense and reward for this service is put forward. Moreover, the reciprocity approach is linked to other relevant ethical objectives, such as advancing social equity.

The UK Joint Committee on Vaccination and Immunisation (JCVI) ‘advises that the first priorities for the COVID-19 vaccination programme should be the prevention of mortality and the maintenance of the health and social care systems. As the risk of mortality from COVID-19 increases with age, priorities are primarily based on age. The order of priority for each group in the population corresponds with data on the number of individuals who would need to be vaccinated to prevent one death, estimated from UK data’.⁹ Quality adjusted life years (QALYs) are used as a health measure by the National Institute for Clinical Excellence in the UK. The JCVI also state that mathematical modelling suggests that prioritising by age will save more QALYs than alternative strategies. This is particularly important to acknowledge in the context of the common misconception that many elderly patients who die of Covid-19 die “with Covid-19” rather than “of Covid-19” or that they would imminently had died “anyway” regardless of Covid-19 infection. This is not the case. For example, those over the age of 80 who contract Covid-19 have their lifespan curtailed by at least two years in the context of comorbidities and more than a decade in the absence of comorbidities.¹⁰

Justifying vaccination priorities

Priorities based on a dominant metric such as lives saved, years of life saved, Quality Adjusted Life Years (QALYs) saved, Standard Expected Years of Life Lost (SEYLL), societal benefit defined in terms of avoidable mortality and morbidity reflect what has been termed a ‘monotheism’ of values.¹¹ The JCVI advice is largely

based on epidemiology and mathematical modelling, and as such has attracted adverse criticism from ethicists. Giubilini et al. (2020)¹¹ argue that even when we accept that limited resources should be used to save the greatest number, and that the models are truly predictive, questions still remain with respect to the valuation placed on individual lives, and their quality. If the dominant principle is preventing loss of years of life, that would give different priorities to a principle based on preventing any death. SARS-CoV-2 is likely to be endemic in the world for many years to come. There are many uncertainties associated with modelling which should give rise to concerns about the use of models as a sufficient basis for the design of policy. In addition, there are profound philosophical issues such as the weight that should be given to saving lives in the future, when actions taken today will determine the impact of SARS-CoV-2 in the future. Insufficient consideration of global (as opposed to local) lives raises substantive moral questions and overlooks a continuing threat from new variants.

Extending considerations

Several of the proposals for vaccination priorities refer to other considerations such as the importance of health equity, even so, death and disease remain a dominant metric. By contrast Schmidt (2020)¹² argues that in a US context ‘Ethical, epidemiological, and economic reasons demand that rationing approaches give priority to groups who have been structurally and historically disadvantaged, even if this means that overall life years gained may be lower.’ He argues that essential workers (for example cleaners, supermarket workers, healthcare workers) should be given priority particularly when there is evidence of a heightened risk of infection and transmission associated with their roles. Schmidt draws attention to the fact that many of these essential workers come from deprived groups, adding to pragmatic arguments that emphasise the importance of maintaining essential services. Beyond these groups he argues that ‘When it comes to allocating vaccines among the general population, economic, ethical, and epidemiological considerations urge us to prioritise the worse off.’ For Schmidt ‘Reverting to “color blind” allocation models—ones that ignore the pandemic’s vastly disparate impact, especially on worse-off minorities—would be to risk becoming complicit in structures that, once again, systematically disadvantage worse-off populations.’

It is clearly important to consider the policies which will save the most lives, but this is insufficient as a standalone principle when it comes to the SARS-CoV-2 pandemic. Utilitarianism is the theory that we should try to maximise the overall good (utility). ‘Utilitarianism is highly dependent on accurate information about the world. It requires good evidence. Without good evidence, it is less likely that we would choose means that will bring about the most good.’¹³ A substantive criticism of utilitarianism is that it does not specifically take account of the fairness of actions. The ‘overall’ good may take little account of individual circumstances and the structural determinants of health driven by profoundly embedded racial, ethnic, and socioeconomic inequalities. Even if we accept some form of utilitarianism we still have to be able to describe the ‘good’. Accurate information about the pandemic requires that we look beyond ‘saving lives.’ The pandemic has widened disadvantage. Excess deaths are higher amongst disadvantaged households and has added other burdens to pre-existing inequalities.^{14,15,16,17,18} There is a clustering of disadvantage associated with this pandemic. For example, children from disadvantaged backgrounds have suffered disproportionately as a result of the restrictions.¹⁹ There is also evidence that systematic disadvantage is a factor in determining a reluctance to take up vaccination.^{20,21,22}

Attending to the intersection of these inequalities when making policy, whilst complex, is a key step in mitigating systematic disadvantages.

Saving the greatest number of lives takes no account of inequality. Limiting the values under consideration has the advantage of simplifying decision-making and the disadvantage of leaving out important dimensions of human experience. Restrictions on freedoms are potential burdens, in that individuals cannot pursue many of the activities that they value. The alternatives to vaccination are a continuing threat of avoidable disease or restrictions on educational and work opportunities, access to services, recreational activities, affiliations and relationships with others, freedom of movement (including escaping abusive relationships), and other determinants of the quality of human experience. These diverse domains are not commensurable or easily quantifiable, yet they remain important.²³ Lockdowns particularly have exacerbated social isolation, mental illness, unemployment, damage to education, and domestic abuse. The COVID-19 pandemic is estimated to increase the numbers of people in extreme poverty by between 88 million (baseline estimate) and 93 million (downside estimate) in 2020. Considering those who would have otherwise escaped extreme poverty but will not due to the pandemic (i.e. 31 million in 2020), the total COVID-19-induced new poor in 2020 is estimated to be between 119 and 124 million.²⁴ Extreme poverty is an indirect effect of SARS-CoV-2 that leads to blighted lives into the future, in addition to avoidable death. In the UK, the Office of National Statistics (ONS)²⁵ estimates that 14% of key workers are from black and minority ethnic (BAME) groups, and 18% are more likely to be born outside of the UK; thereby more likely to be disproportionately affected by COVID, and more likely to face structural barriers to accessing healthcare. Occupations with the highest number of COVID-19 deaths in the UK (taxi and cab drivers, security guards, and sales and retail workers), are those likely to fall under a 'services of general interest' and are comprised by 13% BAME workers. In the US context, Gupta and Morain (2020)²⁶ suggest this number may be as high as 45%.

A theoretical framework that focuses on human freedoms and inequalities is that derived from the work of Sen, Nussbaum, and others (for an overview see²⁷). Capabilities are the opportunities that people have to achieve 'doings and beings' (functionings), and as such are a measure of human wellbeing. Capability theory emphasises the freedoms that individuals have to express themselves. Every person is morally entitled to some level of a range of capabilities. Restrictions on freedoms restrict our capabilities. Capability theory has been used to provide a framework for the evaluation and comparison of international development²⁸ and in the evaluation and justification of public health policy.²⁹ Nussbaum has proposed a list of ten capabilities required (at some minimal level) for each to live a life with human dignity.³⁰ The capabilities listed by Nussbaum encompass life expectancy, bodily health & integrity, sense, imagination and thought, emotions, practical reason, affiliation, relations with other species, play and control over one's environment. By agreeing and specifying the capabilities at risk during the SARS-CoV-2 pandemic, and reporting relevant metrics the impact of relevant policies can be evaluated.³¹ Much of the disadvantage engendered in the SARS-CoV-2 pandemic is potentially overlooked when public health policy is based on minimising or maximising a limited range of metrics. The ten capabilities proposed by Nussbaum have been used to develop health outcome measures for example the OCAP-18,³² and to evaluate the possible use of antibiotics as a population intervention to prevent childhood growth stunting.³³ There is also increasing interest in the use of capability theory in the measurement of economic evaluations of health-related interventions.³⁴

The contribution of “lockdown” policies to the adverse effects on individual and societal capabilities does not necessarily entail a recommendation to lift restrictions. There are alternative strategies which could be deployed (with some political courage) that could allow for *more* lockdown measures alongside far-reaching and deep efforts to mitigate and alleviate the detrimental effects on individual capabilities. For example, mass provision of super-fast broadband and access to home computers for all, a fully-funded “Test, Trace, Isolate and Support” system, debt amnesties, commitments to increase income support, regulation and enforcement of workplace safety, the expansion of safe, low-cost, public transport systems, investment in the construction of bicycle lanes and other outdoor infrastructure. Indeed, in many regards, and in preparation of the post-pandemic landscape – it is entirely possible for the freedoms and capabilities of individuals to be expanded in the medium term - initially alongside the period of lockdown, and then transcending it.

Hesitancy, mandation and communication

Whilst anti-vaccine movements and outright *scepticism* are a real and increasing problem,³⁵ their impact on the present situation unclear. Vaccine *hesitancy* amongst historically disadvantaged and socially excluded groups²⁰ is likely to be a more significant problem in relative terms than ideologically driven scepticism. It has been argued that, for the foreseeable future at least, that vaccine demand will outstrip supply - “making the salient question not who must get them but who will be granted access to them”.³⁶ The possibility that vaccine skepticism and hesitancy will not be the main rate-limiting factor is one reason why mandatory vaccination (which has been mooted in some quarters) may not be an appropriate component of a successful and equitable vaccination program. It is also worth noting that penalties for vaccine-refusers have been trialed or considered in various settings abroad. These penalties have included: restriction of school access,³⁷ withholding of child benefit payments³⁸ and even employers taking on the right to refuse employment^{39,40} to those who are unvaccinated. Not only do these penalties have a distinctly regressive, class-discriminatory character but the evidence for the actual effectiveness of mandating vaccine (assuming a plentiful supply) is mixed; whilst it may have an effect on vaccine uptake overall it has little to no effect on those who are of a genuinely anti-vaccination persuasion.³⁵ Alternative strategies to mandation are more likely to safeguard individual capabilities, acknowledging uncertainty and ensuring transparency of regulatory decision making. Furthermore, as the recent controversy around the decision to extend the time-interval between the first and second dose of vaccine in the UK has shown: clear communication and an exposition of the ethical rationales for deviations from the evidence-base should be a must.

Global Perspective

There are disparities in the burden of vaccine-preventable disease around the world despite the widespread availability of effective vaccines. Poorer nations are impacted by increased disease burden, denser living conditions and lack of healthcare access, leading to increased transmission, treatment delay and a more severe

disease burden.⁴¹ These disparities exist for a wide range of different reasons.⁴² There are pragmatic arguments for the global control of the SARS-CoV-2 virus. SARS-CoV-2 has a high rate of mutation and new variants will emerge with varying degrees of virulence and transmissibility, and for which there will be variations in vaccine efficacy, unless there is global control of the virus. Deepening globalisation, increasing codependence, and travel developments require that assuring high levels of vaccination globally and minimizing disparities in vaccination rates for SARS-CoV-2 is in the interest of all. Recent examples of new variants have been reported from the UK, South Africa and Brazil.⁴³ Controlling SARS-CoV-2 globally minimises the possibility that new variants will emerge that escape the immune memory stimulated by existing vaccines.

Countries in which SARS-CoV-2 remains endemic are likely to carry burdens internally but also in their relationships with other nations. Covax is an initiative aimed at accelerating the development, manufacture, and fair and equitable distribution of SARS-CoV-2 vaccine globally.^{44,45,46} The short-term goal is to make 2 billion vaccine doses available for global distribution in 2021. This is sufficient for 20% of the populations of countries participating in the Covax initiative. The Director General of the WHO speaking in January 2021 noted that there were 44 deals between predominantly higher income countries and suppliers in 2020 and a further 12 in 2021. He went on to say that ‘this could delay COVAX deliveries and create exactly the scenario COVAX was designed to avoid, with hoarding, a chaotic market, an uncoordinated response and continued social and economic disruption.’ He pointed out the importance of global control of SARS-CoV-2 as the route to safety from this global threat but also warned that the world is on the brink of a ‘catastrophic moral failure’. A recent report from Duke University in January 2021 states that countries with 16% of the world's population had purchased 60% of the global vaccine supply.⁴⁷

The Alma Ata Declaration explicitly invoked an individual “right to health” and articulated the social and collective determinants that would allow the fulfillment of that individual right. These principles have been incorporated into the work of the World Health Organisation.⁴⁸ The WHO is an institution which has obligations to assure the fair distribution of vaccines across the countries of the world. There are strong moral arguments that we all have humanitarian reasons to assure an effective global vaccination programme. If we accept that everyone has an equal moral worth, then a just or fair distribution of vaccine extends beyond national boundaries. Historical relationships between nations (particularly when exploitative) can also justify responsibilities of richer countries to help low and/or middle-income countries (LMICs) ‘If the jointness of problems of justice is a global reality, interactive and informed reasoning is surely a global necessity’.⁴⁹ In addition to burdens already mentioned nations may suffer stigmatisation and isolation if SARS-CoV-2 remains uncontrolled, adding to existing disadvantages, by damaging travel, trade and educational opportunities. Again, these SARS-CoV-2 consequences are poorly captured when saving life is the dominant metric.

Wang et al. (2020)⁵⁰ takes existing ethical frameworks (including^{5,6} mentioned above) to estimate vaccine target population sizes if three objectives are to be achieved. These objectives are (a) to maintain core societal functions, (b) to minimise deaths, and (c) to reduce transmission. They add that ‘additional factors such as availability of vaccines for initial distribution, epidemiological situation, and vaccine hesitancy should be taken into account by individual countries to refine allocation plans.’ They report substantial variations in numbers of

essential workers and vulnerable populations in different regions. 2.2 billion people (27.7% of the global population) was found to be in a particularly vulnerable group, illustrating a substantial gap between projected Covax objectives and vaccine need. Inevitably there is currently competition for SARS-CoV-2 vaccines. The Covax initiative is unlikely to be successful without substantial commitments from higher income countries. Even if Covax achieves the target of 2 billion doses in 2021 that will still be grossly insufficient to achieve global herd immunity.⁵¹ Higher income countries have blocked a proposal put to the World Trade Organisation (WTO) by India and South Africa to waive intellectual property protections around vaccinations; which would have given lower income countries the freedom to manufacture and distribute vaccinations for a lower cost at the national level.⁵² Vaccine distribution acts as a locus of tension between national self-interest and global justice concerns. The term ‘vaccine sovereignty’ has been used to denote how access to vaccines are shaped by a nation’s wealth and power, and how non-state actors (pharmaceutical companies and research universities benefitting from public funding) reinforce these entrenched power imbalances between LMICs and high-income countries.⁵³

Conclusion

Important dimensions of human experience that have been severely compromised by the SARS-CoV-2 epidemic are not well-captured when emphasis in policy making is based on the output of mathematical models in which death and disease are the dominant metrics. Freedom from the burdens of SARS-CoV-2 can be better represented when we use metrics that capture relevant freedoms. Capability theory offers one such approach, and perhaps also offers the potential for a better society.⁵⁴

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