



RAPID ETHICS REVIEW

THE ETHICS OF PANDEMIC VACCINE PRIORITISATION

Jonathan Pugh, Dominic Wilkinson and Julian Savulescu
University of Oxford

On 2nd December 2020, the UK government announced that it had accepted the Medicines and Healthcare products Regulatory Agency's recommendation to approve the use of Pfizer/BioNTech's BNT162b2 mRNA vaccine against covid-19.¹ By the end of July 2021, the UK had approved a total of 4 covid-19 vaccines, and had delivered over 84 million vaccine doses, 126.5 doses per 100 people.²

The UK compares favourably with other developed nations with respect to the speed of its vaccine roll-out. However, in the early months of 2021, there were a number of questions about how the vaccine roll out should proceed, and which groups should be prioritised for vaccination. This is a review of the ethics literature regarding the prioritisation of vaccines in a pandemic, which will serve to contextualise the UK's approach. The present review draws particularly on Williams and Dawson's review on vaccine

prioritisation for pandemic influenza.³ The literature identified in William's and Dawson's review is supplemented here with review of the ethics literature that is specific to the prioritisation of vaccines for covid-19.

We shall begin by outlining the Phase 3 vaccine trial data published in late 2020, with a particular focus on what these trials told us about the efficacy of the vaccines in different groups. With this data in mind, we shall then outline moral considerations that might inform vaccine prioritisation strategies, including considerations of fairness, as well as the various kinds of benefits that a prioritisation strategy might aim to achieve. We shall then use this moral analysis to contextualise the UK's two-phased approach to vaccine prioritisation, outlining some alternative strategies that could have been adopted, and the moral justification for these alternative strategies.

OVERVIEW

- In view of the initial scarcity of vaccine doses following the approval of covid-19 vaccines, countries around the world adopted prioritisation strategies for their vaccine roll-outs. This review surveys the ethics literature regarding the prioritisation of vaccines in a pandemic.
- Having briefly outlined the vaccine efficacy data available in late 2020, the review identifies 'fairness' and 'benefit' as two core values that vaccine prioritisation strategies must strive to balance.
- It outlines the various benefits that a prioritisation strategy could seek to achieve (including, but not limited to 'number of lives saved') and explains how different benefits could be invoked to justify affording priority to different groups.
- On the basis of these theoretical considerations, the review then outlines the JCVI's two-phased prioritisation strategy in the UK and compares it to other national approaches.
- It is concluded that the UK vaccine roll-out has had considerable public health benefit, but that there is a need for greater transparency about the moral reasoning underlying policy decisions determining the population's access to crucial medical resources in a pandemic.

THE PFIZER AND ASTRA ZENECA VACCINE TRIALS

In December 2020, the UK government approved two covid-19 vaccines on the basis of Phase 3 trial results. The Pfizer/BioNTech vaccine was approved on 2nd December, whilst the Astra Zeneca vaccine was approved on the 30th December.

(i) The Pfizer Trial

A Phase 3 trial of the Pfizer vaccine showed that it is 95% efficacious in preventing covid-19, and that its safety profile over the observed period is similar to other viral vaccines.⁴ The study included 43,448 participants; 15,921 of them were aged over 55 (roughly 42%). However, it is important to acknowledge that this trial was not sufficiently powered to determine the vaccine's efficacy in particular sub-groups. Furthermore, some high-risk groups were excluded from this initial trial, including pregnant women, and immuno-compromised persons. The trial also did not include children under 16, and it was not designed to provide evidence of the efficacy of the vaccine in reducing viral transmission.

(ii) The Astra Zeneca Trials

The interim analysis of the Astra-Zeneca vaccines pooled efficacy data from two different trials (COV002 and COV003).⁵

There were well-documented issues with how the efficacy results of the Astra-Zeneca COV002 and COV003 trials were reported, due to differences in the dosing regimens between the trials, and also within COV002 itself.⁶ With that caveat in mind, the COV-003 trial suggested a vaccine efficacy of 64.2% in preventing the primary outcome (confirmed, symptomatic covid-19). Overall, primary outcome efficacy in COV-002 was 73.5%; however, there

were two different efficacy rates in sub-groups with different dosing regimens. The vaccine had a primary outcome efficacy of 90% in a sub-group who received a low dose followed by a standard dose, but only an outcome efficacy of 60.3% in the sub-group that received two standard doses.

Concerns were also raised about the paucity of elderly participants across these studies. Only 1,418 of the 11,636 participants were aged over 55 (roughly 12%). Further reports suggested that there were only 660 participants aged over 65, and that there were only 2 cases of covid-19 in this subgroup.⁷ Due to the lack of elderly participants in these initial efficacy trials, a number of European countries issued recommendations not to use this vaccine in the elderly⁸. Nonetheless, other published evidence at the time suggested that the vaccine had an important effect in the elderly. A later study analysed whether the vaccine provoked an immune response in 560 participants, including 400 participants over the age of 55.⁹ This trial found that the vaccine elicited a similar immune response across all age groups after the second dose.

Although the prevention of asymptomatic infections was not the primary endpoint of COV002, this trial also provided some data in this regard. However, this data was subject to the same limitations as the primary outcome efficacy data (due to inter-group differences in dosing regimens), and the confidence intervals around this data are wide. That said, the data suggested an overall vaccine efficacy in preventing asymptomatic infections of 27.3%. Again though, there were two different efficacy rates in sub-groups with different dosing regimens. The data suggests an efficacy of 58.9% in a sub-group who received a low dose followed by a standard dose, but only an outcome efficacy of 3.8% in the sub-group who received two standard doses.

PRIORITISATION – THEORETICAL CONSIDERATIONS

In view of the initial scarcity of these novel vaccines, the Joint Committee on Vaccinations and Immunisations (JCVI) and other organisations published advice on prioritisation for vaccination.¹⁰ The JCVI serves in an advisory capacity to the UK government.

The UK ultimately proceeded with two phases of prioritisation as we shall detail below. First though, we outline some of the ethical values that can be used to justify different approaches to vaccine prioritisation.

Fairness vs Benefit

A wide array of ethical values are apparent in the published vaccine prioritisation guidelines. However, analysis of these guidelines suggests that 'fairness' and 'benefit' are two key values that feature across different guidelines.¹¹

In prioritisation decisions these values can conflict. To illustrate, some have argued that vaccines in a pandemic situation should be allocated on a lottery

basis.¹² This would be fair, in the sense that it would give everyone an equal chance of receiving a vaccine. However, a lottery allocation would also be highly inefficient in reducing mortality. Accordingly, published vaccine prioritisation guidelines uniformly identified priority groups for vaccination, in order to maximise the benefit that can be obtained with this scarce resource.¹³ Allocation within each priority group can be carried out in accordance with a procedure that ensures fairness within that group, such as a lottery.

Which Benefits? Saving The Most Lives

The nature of the benefits that we hope to maximise with a vaccination prioritisation strategy can help to determine which groups should feature in a priority ranking, whilst still allowing some scope for individual judgment calls. One frequently invoked benefit that we might seek to maximize is ‘the number of lives saved’.

One strategy for maximizing the number of lives saved by a distribution policy is to first prioritise healthcare professionals.¹⁴ Safeguarding the functional capacity of the healthcare system is necessary for any plan to save lives during a pandemic. For this reason, there is widespread recognition across national prioritisation recommendations that health and social care staff should be prioritised. Such an approach is also supported by considerations of just desert and reciprocity¹⁵ given the high risk of exposure that such professionals face (Williams and Dawson, 2020). Nonetheless, some ethicists have challenged the claim that healthcare workers should be given priority.¹⁶ In any case though, a prioritisation policy might also give the highest priority to those healthcare workers who are also members of one of the other high-risk groups detailed below.

Beyond healthcare professionals, there are two factors that will significantly influence how many lives we can expect to save by prioritising different groups for vaccination. The first is the *direct* protection that a vaccine provides to the recipient herself. In order to maximise the benefit of such protection, policies should prioritise individuals who are most at risk of developing severe covid-19, and for whom the vaccine is most likely to work. In early 2021, the available data suggested that the Pfizer vaccine worked well across different demographic groups, and there was already a considerable amount of data identifying various groups that were at particularly high risk of developing severe covid-19.¹⁷ Indeed, most prioritisation recommendations (including those of the JCVI, which we detail below) prioritised groups that were most clearly at risk, such as the elderly and those suffering from certain co-morbidities.¹⁸ However, other high risk

groups such as Black, Asian, Minority Ethnic (BAME) groups, individuals living in conditions of social deprivation, and individuals who have high exposure to the disease by virtue of a profession outside of health or social care have only seldom been included for prioritisation, as an international comparison of the different prioritisation strategies makes clear.¹⁹

The second factor that influences how many lives we can expect to save with a vaccine prioritisation strategy is the extent of the *indirect* benefit that a vaccine may provide to others by preventing the recipient from transmitting the virus. Indeed, some have argued that children should be prioritised for vaccination because they are most likely to transmit the virus, even if they themselves are at low risk of developing severe covid-19.²⁰ Other groups that might be prioritised on this basis include the homeless, due to the fact that these individuals move through populated urban spaces.²¹ However, in early 2021, there was very limited data about the efficacy of the vaccine in preventing infections and onward transmission, as opposed to covid-19 symptoms. As such, it was not clear that an approach based on putative indirect benefits would have been empirically justified when decisions about prioritisation were being made in early 2021.

Other Benefits?

The relevant benefits that a vaccine distribution policy could potentially aim to achieve go beyond merely the number of lives that we can expect a particular policy to save. For instance, it has been argued that the length and/or quality of lives that we expect a distribution policy to save should have some bearing on prioritisation.²² Prioritising life-years might conflict with the goal of saving the most lives overall when there is disproportionate mortality amongst the elderly. Indeed, an approach that seeks to minimize years of life lost might favour prioritising children who have many more life-years to gain from early immunity.²³ However, the covid-19 vaccines were not initially approved for use in these under-18, limiting the applicability of this prioritisation approach in this context.

Other approaches support prioritising those in middle age, on the basis of the amount that they have invested in their life, balanced by their expected amount of life remaining.²⁴ Finally, the Quality-Adjusted Life Year (QALY) and Disability Adjusted Life Year (DALY) metrics that are used to guide resource allocation decisions elsewhere in healthcare could potentially be invoked in prioritisation decisions.²⁵ Notably, prioritizing QALYs, or even simply life years would plausibly conflict with

the aim of saving the most lives overall, given the high covid-19 mortality rates in the elderly.

Incorporating considerations of length and/or quality of life into prioritisation is highly controversial. In addition to practical issues concerning the assessment of these factors, it has been argued that they introduce the possibility of bias and unjust discrimination.²⁶ However, the mere fact that a policy is discriminatory in some sense does not entail that it would be unethical or illegal.²⁷ Indeed, most published prioritisation guidelines positively discriminate in favour of the elderly by prioritising older age groups for vaccination.

The key question is whether the discrimination can be justified as a proportionate means to achieving a legitimate aim.

It is also possible that vaccination prioritisation could be used to safeguard other social goods. For instance, some countries included professionals who are central to critical infrastructure or security in their prioritisation groups.²⁸ Such policies may be viewed as seeking to ensure key social goods such as social order, security and justice.²⁹ Others have argued that one of the aims of prioritisation should be to minimise the pandemic's effects on societal infrastructure and the economy.³⁰

Table 1 – Summary of How Different Benefits Justify Different Priority Groups

BENEFIT TO BE MAXIMIZED	GROUPS THAT MIGHT JUSTIFIABLY BE PRIORITIZED
Direct Benefit (confer protection)	Healthcare workers (take priority for all direct benefit strategies)
Number of Lives	Groups at highest risk of mortality –will likely include The Elderly; Those with certain co-morbidities; BAME groups; Other groups at relatively higher risk may be included depending on threshold of risk employed (including high exposure professionals, those living in conditions of social deprivation)
Life-years	Younger age groups.
Life-Investment	Adolescents – Middle Age [Those with the optimal balance between years of life remaining and amount already invested]
QALYs/DALYs	Younger age groups; Those who are not living with health conditions that decrease well-being.
Social/ Economic Benefits	Professionals in critical infrastructure Individuals central to economic revival
Indirect Benefit (reduce transmission)	Groups potentially at high risk of high viral transmission. These may include: Children; The homeless Professionals with high exposure to others, including healthcare professionals

Fairness & Social Justice

The different mortality risks faced by some demographic groups is at least partly explained by pre-existing inequalities.³¹ For this reason, many prioritisation recommendations suggested that one of the key aims of prioritisation must be to mitigate these inequalities.³² One way in which they could be mitigated is by prioritising regions within priority groups, in accordance with metrics of social inequality.

For instance, the US National Academies of Sciences, Engineering, and Medicine has outlined such an approach. They recommend four phases of vaccine roll-out, and suggest that vaccine access in each phase “should be prioritized for geographic areas identified as vulnerable through the Social Vulnerability Index [SVI] or another more specific index”. In this way, the NASEM strategy may be understood as forging a stronger balance between benefits and fairness construed as social justice.

THE UK APPROACH IN CONTEXT

The JCVI recommended that vaccine prioritisation should proceed in the UK in two stages. We outline each in turn.

Phase One

In the first stage of prioritisation announced on 2nd December (and updated on 30th December 2020), the JCVI claimed that the goal of prioritisation should be the prevention of mortality and the maintenance of the health and social care systems. In order to achieve this aim, they outlined 9 priority groups, which were to receive the vaccine in descending order. The groups are detailed below.

JCVI Priority Groups – Phase One

1. residents in a care home for older adults and their carers
2. all those 80 years of age and over and frontline health and social care workers
3. all those 75 years of age and over
4. all those 70 years of age and over and clinically extremely vulnerable individuals
5. all those 65 years of age and over
6. all individuals aged 16 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality
7. all those 60 years of age and over
8. all those 55 years of age and over
9. all those 50 years of age and over

The JCVI claimed that this age-based programme would likely result in faster delivery and better uptake in those at the highest risk, and that age represented the single greatest mortality risk factor for covid-19. They also noted that the 9 priority groups represented 99% of preventable mortality from covid-19.³³

Notably, not all countries adopted the UK’s approach of prioritising the vaccine in a way that would serve to simply maximise the expected number of lives saved. Rather than prioritising on the basis of age, China prioritised key occupations for vaccination first, including police officers, firefighters, and customs officers.³⁴ Some EU countries, such as Germany, prioritised in accordance with age, but also included key occupations for infrastructure in their prioritisation plans.³⁵ In fact, the UK was something of an outlier in stratifying priority groups by age to the degree that it did in Phase One. A survey of vaccine priority guidance performed by the European Centre for Disease Control and Protection suggests that the published guidance in many EU countries incorporated less stratified age prioritisation. For instance, in the Netherlands, residents of nursing homes and institutions for people with intellectual disabilities, and those over the age of 85 received top priority amongst non-healthcare workers (Zaken, 2021). However, the next priority group in the Dutch approach included all those over the age of 60.³⁶ In this system then, a 60-year old had the same priority as an 84 year old, even though the latter has a far higher mortality risk. In the UK, the latter would have been eligible to receive a vaccine long before the former.

The Dutch strategy represented a way in which considerations of fairness as well as mortality can inform prioritisation decisions – this strategy gave more people who passed a certain threshold of risk an equal chance or a ‘fair go’ at accessing a vaccine.

Phase Two

In their initial guidance for Phase One, the JCVI suggested that a key focus for the second phase of vaccination should be on further preventing hospitalisation, and that this may require prioritising those in certain occupations, given differences in occupational risk of exposure to the virus.³⁷ However, they also noted that the occupations that should be prioritised for vaccination on this basis is an issue of policy, rather than an issue that the JCVI should advise upon.

Yet, the UK did not adopt this approach in the second phase. Instead, once all of those in the Phase One priority groups had been offered a vaccine, the JCVI guidance for Phase Two issued in April 2021 suggested that prioritisation should continue to proceed in accordance with age. The JCVI justified this strategy by claiming that rapid vaccine deployment was the most important means to maximise public health benefits against severe outcomes from covid-19, and that prioritising in accordance with occupational risk would be complex to deliver and potentially slow vaccine delivery.³⁸ Moreover, they noted that a strategy aimed primarily at reducing transmission of infection would take longer to achieve reductions in hospitalisations.

Phase Two – Alternatives to Minimising Mortality With An Age-Base Approach?

In this regard, the JCVI's approach in phase two represented a pragmatic approach for minimising overall mortality. However, as we have outlined above, minimising mortality is not the only salient moral value in the context of vaccine prioritisation. Indeed, since Phase One of the vaccine prioritisation targeted 99% of preventable mortality, it might be argued that other moral values ought to have had greater recognition in the second phase. There are other moral reasons to prioritise certain groups for vaccination besides their increased risk of death or severe disease.

For instance, in addition to the higher mortality risk faced by some essential workers, prioritising certain occupations could have served a number of other moral values. First, it may have served to ensure that prioritisation achieved key social goods (such as social order, security, and justice) as well as reducing mortality. As detailed above, a number of EU countries included professionals who maintained critical infrastructure or security in their first phase of prioritisation, in addition to the elderly and healthcare worker.³⁹

Prioritising certain occupations sooner might also have made it possible to relieve certain public health restrictions. For instance, prioritising teachers for vaccination might potentially have enabled schools to re-open sooner; this would not only have the significant benefit of enabling children to access education facilities, it would also have relieved the significant childcare burden faced by parents during lockdown. It may also have served to mitigate inequalities associated with parents' ability to provide adequate home schooling. Some alternative prioritisation strategies may have thus enabled greater societal freedoms and equality, even if they would not have been the most effective way to minimize mortality.

One challenge for this alternative strategy of prioritising to achieve societal benefits is that it is difficult to compare the very different kinds of societal goods that different occupations aim to achieve. Moreover, prioritisation decisions can have an expressive function:⁴⁰ a strategy that prioritises certain occupations for vaccination may be construed as sending a message that people in some occupations are more valued members of society than others. Any such strategy must carefully attend to the potential effects of that decision on overall social solidarity,⁴¹ a key element in a successful pandemic response.

However, there were other moral arguments in favour of prioritising essential workers in the second phase. Many essential workers in the pandemic have continually put themselves at risk of exposure in order to perform vital societal roles. It could therefore be argued that these workers deserved priority for the vaccine, in recognition of the role they had already played in the pandemic.

Alternatively, the second phase could have aimed to prioritise fairness by seeking to mitigate inequalities that have become starkly apparent in the pandemic. For instance, on such an approach, rather than targeting groups in accordance with their age-based absolute mortality risk, the second phase could have targeted groups with higher relative risk discrepancies compared to relevant comparator groups. For instance, on the data available, this might have involved prioritising BAME groups, those in socially deprived areas, men, and/or those in occupations at much higher risk of exposure.

Ultimately though, despite the moral reasons to pursue alternative approaches, the UK vaccine roll-out has had considerable public health benefit. Of course, the success of the vaccine roll-out is not solely attributable to the prioritisation strategy that the UK adopted. Its success also depended on its

ability to overcome the various logistical challenges involved in deploying the vaccine in accordance with this prioritisation strategy. Nonetheless, this strategy helped to ensure that by July 23rd 2021, Public Health England estimated that the vaccines had prevented 60,000 deaths and 22,057,000 infections (Public Health England 2021).

Yet, there are some important lessons to be drawn from the vaccine roll-out. In particular, in future emergencies, it is crucial that there is greater transparency about the moral reasoning underlying policy decisions determining the population's access to crucial medical resources. Whilst the speed of the Covid-19 vaccine roll-out in the UK was an admirable success, we should also acknowledge that there was also limited opportunity for societal input into discussion about alternative vaccine prioritisation strategies, and the moral objectives that prioritisation should aim to achieve.

About this submission

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This submission was compiled by the Prioritisation workstream. For further details about this submission contact Jonathan Pugh at the Oxford Uehiro Centre for Practical Ethics. Suite 8, Littlegate House St Ebbes Street, Oxford OX1 1PT
Email jonathan.pugh@philosophy.ox.ac.uk.

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About the UK Pandemic Ethics Accelerator

The UK Ethics Accelerator is a UKRI/AHRC-funded initiative that aims to bring UK ethics research expertise to bear on the multiple, ongoing ethical challenges arising during a pandemic emergency. We provide rapid evidence, guidance, and critical analysis to decision-makers across science, medicine, government, and public health. We also facilitate public stakeholder deliberation around key ethical challenges.

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