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Ethics Matters

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COVID-19 Vaccine Rationing and Mass Immunisation — Challenges and Solutions

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The clinical trials of a COVID-19 vaccine are a beacon of hope for governments seeking a definitive exit strategy from the COVID-19 pandemic. Should an effective vaccine become available, we may no longer need to rely on burdensome public health measures like lock-downs and border restrictions to avoid future COVID-19 outbreaks. This article looks specifically at the ethical issues attendant to the widespread distribution and administration of a COVID-19 vaccine. We believe that there are major ethical questions that are likely to arise as state and federal governments seek to distribute a vaccine among the Australian population. It is crucial that all stakeholders – including public health authorities and members of the general public – are aware of these issues and engaged in a discussion of how to effectively, and ethically, achieve a goal of widespread vaccination.

I begin this report with a brief overview of COVID-19 trials and government plans for vaccine manufacturing and distribution. We also discuss safety and efficacy concerns associated with "fast-tracked" vaccine trials. Section one considers how we should allocate vaccines when we do not have enough vaccine units to immunise the whole population. It is likely that governments will have to deal with problems of scarcity, at least in the early stages of the pandemic. We consider how governments might navigate the ethical complexities of vaccine scarcity. Section two discusses different approaches to mass vaccination and the ethics of coercive vaccination policies. The government will need to consider different means of encouraging vaccination, some more aggressive than others. We explore the ethics of coercive measures, and argue in favour of less restrictive means to promote vaccination among the community.

RECOMMENDATIONS

1. **State and Federal Governments should work to develop a national COVID-19 vaccine distribution plan.**
2. **This distribution plan should ensure that healthcare workers and essential service workers have priority access to a vaccine. Authorities must not repeat the PPE distribution errors that occurred in the early stages of the pandemic.**
3. **The distribution plan should also prioritise vulnerable groups, including people experiencing homelessness, people with comorbidities, ethnic and indigenous minorities, and prison populations.**
4. **The Australian Federal Government should explore less restrictive alternatives to compulsory vaccination before countenancing coercive vaccination measures. Restrictive vaccination policies may hinder, rather than promote, widespread vaccination.**
5. **The Government should utilise data on COVID-19 scepticism and develop targeted public health campaigns to combat COVID-19 misinformation and vaccine hesitancy.**
6. **Governments should have a strategy for dealing with conscientious objection to COVID-19 vaccines. This may involve making multiple vaccine candidates available so as to accommodate for moral objections to ethically contentious vaccines.**

Preliminaries: The development and widespread distribution of a COVID-19 vaccine

A large number of COVID-19 clinical trials are currently underway, with many more vaccine candidates due to begin trials shortly. At the time of the publication of this report, clinical trials had commenced for 32 vaccine candidates worldwide. Importantly, vaccine development is not just concentrated in the US and Europe. Russia, China, Japan and India have COVID-19 vaccine trials that are rapidly progressing, while trials are beginning in countries such as South Korea and Singapore.

Many experts are confident that a COVID-19 vaccine will be available by the end of 2020, though some believe that this prediction is optimistic. Certainly, the positive results of several clinical trials for a COVID-19 vaccine give hope that we will have a vaccine within the next twelve months.[1,2] Indeed, Pfizer and AstraZeneca believe they can deliver the first units of the vaccine by the end of 2020.[3]

Governments will need to produce a COVID-19 vaccine in large numbers for it to be accessible to the general public, and -- even with increased production capacity – it may take some time to produce vaccine units in sufficient quantities to vaccinate the entire population.[4] As a group of ethicists and health researchers from Johns Hopkins University recently observed in a report on US vaccine distribution, "it may take many months before most US residents have access to vaccination; bottlenecks at various stages of the vaccine manufacturing process (e.g., supply of vials or syringes, fill and finish process) could cause further delays in vaccine availability".[5] This is one reason why it is important to consider the resource allocation challenges involved in the distribution of a coronavirus vaccine.

The eventual vaccines produced for COVID-19 may also be of varied safety and efficacy. Some vaccines may trigger an immunological response in almost all recipients, though experts suggest that COVID-19 vaccines will probably have certain limitations, particularly when they are administered to vulnerable population groups.[6] Certainly, a substantial majority of the population would need to be immunised for there to be any semblance of herd immunity. The less effective the vaccine, the higher the proportion of the population that would need to be vaccinated to allow life to return to normal in countries affected by the pandemic.[7]

Some vaccines currently being trialled have had serious side effects on a small number of study participants. It will be important to monitor, therefore, if these vaccines produce similar side-effects when trialled on a large portion of the population. Unfortunately, accelerated trials do not give us data on whether vaccines have long-term side effects, such as whether a vaccine increases one's risk of developing cancer or infertility or other serious side effect. This is not to say that there is evidence of a link between other vaccines and cancer or infertility; it is merely to identify a shortcoming of accelerated trials.[8] Large scale clinical trials will, however, give us a reasonably reliable picture of whether COVID-19 vaccines produce serious, rapid-onset side-effects in recipients.

1 Lisa Jackson *et al*. "An mRNA Vaccine against SARS-CoV-2 — Preliminary Report". *New England Journal of Medicine* 2020 DOI: 10.1056/NEJMoa2022483.

2 Pedro Follegati *et al*. "Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial". *The Lancet* 2020;396(10249): 467-468.

3 John Cohen. "Doubts greet $1.2 billion bet by United States on a coronavirus vaccine by October". *Science* May 22 2020.

4 UK Department for Business, Energy and Industrial Strategy. "Press release: Over £100m cash boost to manufacture millions of doses of COVID-19 vaccine". London: UK Government, 23rd July 2020.

5 Eric Toner, Anne Barnill, Carleigh Krubiner *et al*. *Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States*. Baltimore, MD: Johns Hopkins Center for Health Security, 2020.

6 Sarah M Bartsch, Bruce Y. Lee, Kelly J. O'Shea *et al*. "Vaccine efficacy needed for a COVID-19 coronavirus vaccine to prevent or stop an epidemic as the sole intervention". *American Journal of Preventive Medicine* 2020 DOI: https://doi.org/10.1016/j.amepre.2020.06.011.

7 Bruce Y. Lee. "How effective does a COVID-19 coronavirus vaccine need to be to stop the pandemic? A new study has answers". *The Conversation* July 15th 2020.

8 Cf. Centers for Disease Control and Prevention. "Historical vaccine safety concerns". Atlanta, GA: Centers for Disease Control and Prevention, 2020.

1. Resource allocation and vaccine scarcity

One ethical issue that has achieved significant attention in the COVID-19 pandemic is healthcare resource allocation. Prior to the pandemic, there was already a substantial literature discussing the ethics of vaccine allocation in a pandemic. This literature has burgeoned considerably in the last six months as ethicists seek to offer guidance for the impending challenges of distributing vaccines among a population with diverse needs.

Importantly, vaccine distribution is different to how one might approach saving lives in a critical care setting, though for many ethicists the primary goal is still the same -- to save the most lives.[9] If our primary aim in vaccination is indeed to save as many lives as possible, or to protect people from the risk of a fatal COVID-19 infection, then we should give priority to older members of the community (who have a much higher risk of death from COVID-19) over younger persons, other things being equal.[10]

It could be argued that certain vulnerable groups in society – such as prisoners or people with so-called lifestyle illnesses -- are in fact not deserving of priority.[11,12] Our assessments of priority, however, should not be based on morally contentious ascriptions of responsibility and desert, but rather should focus primarily on people's health. People with comorbidities related to lifestyle factors should receive priority access to vaccination on account of their vulnerable state.[13] Their claim on resources is not weakened by the fact that they have made imprudent lifestyle choices in the past. Similarly, prisoners should receive priority because they are at greater risk of contracting the virus; their criminal record is irrelevant to their claim on healthcare.

Ethicists agree that frontline healthcare workers should receive priority access to a COVID-19 vaccine.[14] I would argue, however, that it is ethically problematic to focus specifically on frontline healthcare workers while not prioritising other essential service workers. If our concern is that healthcare workers have a higher risk of contracting the virus (and also pose a risk to others), then the same concern should apply to other essential service providers. Health authorities should prioritise all individuals who are heavily involved in the government's pandemic response, be they healthcare staff or members of other professions. I also wish to stress that priority should be afforded to aged care staff in addition to healthcare workers employed in hospitals and clinics. One of the most serious errors made by health authorities in the COVID-19 pandemic has been to neglect the needs of aged-care residents and staff.[15]

Much more could be said about specific social groups and the ethical justification for giving them priority access to a COVID-19 vaccine. In lieu of further discussion, we draw readers' attention to the model vaccine allocation framework at the end of this report. There I have attempted to arrange social groups in order of priority based on points of convergence between different ethical principles.

9 Lisa Rosenbaum. "Facing Covid-19 in Italy — Ethics, Logistics, and Therapeutics on the Epidemic's Front Line". *New England Journal of Medicine* 2020;382: 1873-1875.

10 Ezekiel Emanuel *et al*. "Fair allocation of scarce medical resources in the time of covid-19". *New England Journal of Medicine* 2020;382: 2049-2055.

11 Chris Kaposy, Natalie Bandrauk. "Prioritizing vaccine access for vulnerable but stigmatized groups". *Public Health Ethics* 2012;5(3): 283-295.

12 Ibid.

13 Cf. Kristy Buccieri, Stephen Gaetz. "Ethical Vaccine Distribution Planning for Pandemic Influenza: Prioritizing Homeless and Hard-to-Reach Populations". *Public Health Ethics* 2013;6(2): 185–196.

14 By essential service workers, I have in mind people who are responsible for ensuring that basic goods and services remain available to the community throughout the pandemic. There is debate, however, about what should be considered an essential service. Though for the sake of brevity I will not engage with this debate in my report.

15 Xavier Symons. "Care homes and older members of the community". *Anscombe Bioethics Centre COVID-19 Briefing Paper No. 4*. Published 23rd May 2020.

2. Ethics of mass vaccination and public health policies to increase vaccination rates

The remainder of this report discusses what we take to be the most serious and ethically complex problem that Australia would face in the event that a COVID-19 vaccine became available. This is, namely, vaccine hesitancy. To motivate this section, it is worth remembering that some people are unable to receive vaccines for medical reasons. One way to protect these individuals is to achieve herd immunity among the Australian population. The task of increasing vaccination rates, then, is inextricably linked to the protection of vulnerable populations. We need a strategy to address vaccine hesitancy among Australians. Herd immunity requires high rates of vaccination, and this means overcoming vaccine resistance.

Recent overseas polls might be thought to suggest that resistance to a COVID-19 vaccine may be more intense than usual. There is a small group of anti-vaxxers who one might naturally expect resistance from. International data suggests, however, that a group much larger than this may refuse a safe and effective COVID-19 vaccine. One recent poll found that 25% of American adults were either "not so likely" or "not likely at all" to use a COVID-19 vaccine. A different poll found that 27% of American adults claimed they would refuse a COVID-19 vaccine. The sentiment isn't just restricted to the United States. In France, 26% said they would refuse a COVID-19 vaccine. In the UK, 1 in 6 adults said they will refuse a coronavirus vaccine.

Fortunately, Australia is a relatively vaccine-friendly society. A Roy Morgan study conducted in April found that 86% of Australians were likely to get the COVID-19 vaccine, and only 4% strongly disagreed with getting vaccinated.[16] Similarly, a study conducted by healthcare literacy experts from the University of Sydney found that 86% of participants would get a coronavirus vaccine if it became available, with only 5% saying that they would not get the vaccine.[17]

There is a substantial amount of quantitative and qualitative data available on the likely reasons for COVID-19 vaccine hesitancy among the Australian population.18 Two related issues are poor health literacy and a distrust of scientific institutions. Preliminary data suggests that individuals who say they would not get a COVID-19 vaccine are more likely to believe the threat of COVID-19 has been exaggerated.19 That is to say, vaccine-hesitant individuals may simply not think that coronavirus is of serious risk to them or to the community. Rather, they may believe that the virus only affects people over a certain age or people who are immuno-supressed.20

There are also widespread safety concerns about the COVID-19 currently under development. Policy makers need to be careful about having a premature discussion concerning the vaccination policies. Considering the manner in which COVID-19 vaccines have been manufactured, it is conceivable that there will be some degree of concern on the part of the public about the safety of the eventual vaccine candidate that is rolled out by the government. It may be the case that members of the public are concerned about the possibility of having an adverse reaction to a COVID-19 vaccine, and as a result may choose not to avail themselves of the vaccine. It is important that we do not conflate the debate about COVID-19 vaccine safety with debates about the safety of childhood vaccines for which we have abundant evidence of safety. We need a different paradigm than the stigmatisation paradigm employed for childhood vaccination.

A final concern would be that members of the public may have objections to the way in which vaccines were produced. Christian leaders have expressed concern that several of the COVID-19 vaccines currently under trial were manufactured using the fetal cell lines derived from aborted fetuses. According to an Anscombe Bioethics Centre briefing paper, one cell-line used in COVID-19 vaccine research (including a project of the University of Oxford) is the HEK 293 cell-line modified from tissue taken from the kidney of an unborn child aborted probably in 1972, while another (used in Johnson & Johnson's coronavirus vaccine) is the PER C6 cell-line from the retinal tissue of an 18-week baby aborted in 1985.[21] People with an objection to abortion may see this kind of research as a form of complicity in wrongdoing, and may be reluctant to avail themselves of a COVID-19 vaccine. To be clear, the Pontifical Academy for Life has stated that Catholics can in good conscience receive a tainted vaccine where there is no alternative and there would be grave consequences if one did not take the vaccine.[22]

16 Roy Morgan. "Nearly two-thirds of Australians (65%) now say Australian Government is handling COVID-19 well – up 22% in a week". *Roy Morgan* April 7th 2020.

17 Rachael H. Dodd, Carissa Bonner, Kirsten J McCaffery *et al*. "Willingness to vaccinate against COVID-19 in Australia". *The Lancet* 2020 DOI: https://doi.org/10.1016/ S1473-3099(20)30559-4.

18 Ibid.; Kristen Pickles, Kristen McCaffery, Erin Cvejic *et al*. "COVID-19: Beliefs in misinformation in the Australian community". *Medrxiv* August 6th 2020; Jessica Kaufman, Margie Danchin. "5 ways we can prepare the public to accept a COVID-19 vaccine (saying it will be 'mandatory' isn't one)". *The Conversation* August 21st 2020.

19 Ibid.

20 Cf. Polly Toynbee. "A coronavirus vaccine would be a triumph, but the worst human impulses threaten its success". *The Guardian* July 21st 2020.

21 Dr Helen Watt. "COVID-19 vaccines and the use of foetal cell lines". *Anscombe Bioethics Centre COVID-19 Briefing Paper 2* 27th April 2020.

22 Pontifical Academy for Life. *Moral Reflections on Vaccines Prepared from Cells Derived from Aborted Human Foetuses.* Vatican City: Libreria Editrice Vaticana, 2005.

This should suffice to provide a brief overview of the potential objection to a COVID-19 vaccine. Ethically speaking, how should the government handle these concerns?

First, it is vitally important that scientists and the government ensure that the vaccines for coronavirus have indeed been shown to be safe, and that this information be conveyed to the public. To address safety concerns, scientists should ensure that solid phase three safety data is available for the coronavirus vaccines that will be produced on a large scale.[23] A good way to demonstrate the safety of vaccines will be through open data. That is, we should work to make all the data from all the pharmaceutical trials available for public scrutiny.

We also know from the example of the MMR vaccine that good information can help, and that misinformation can be very damaging. It will be important that governments and health authorities run a well-coordinated and effective campaign to inform the public of the data on the safety and efficacy of a COVID-19 vaccine. They must also have strategies to effectively manage misinformation from the anti-vaxxing movement. It would be vital that we do not experience a Wakefield moment -- as occurred in the late 1990s with the MMR vaccine -- just when the COVID-19 vaccine is ready to be rolled out.[24]

Some people believe that the government should seriously consider mandatory vaccination as a policy to ensure that vaccination rates for COVID-19 are sufficiently high. Yet mandatory vaccination is unnecessary given current attitudes to vaccination in Australia. Australian health authorities should be able to achieve sufficient rates of vaccination through non-coercive measures. Furthermore, governments should always use the least invasive alternative to achieve their goals. This a basic principle in social ethics, and we certainly believe that it applies to vaccination policy. Data would suggest that the government could achieve sufficient rates of vaccination if they simply make an effort to run effective advertising and social media campaigns and marshall the support of community organisations. To the extent that is necessary, the provision of incentives for vaccination, or perhaps a nudging campaign, could be used to great effect to achieve higher vaccination rates.[25] We should bear in mind, however, as a baseline indication, Australians clearly have a greater receptivity to vaccination than citizens of other nations. This is encouraging, and gives us reason to think that non-coercive vaccination promotion policies could be used to great effect.

Finally, it is vitally important to consider the issue of conscientious objection to "ethically compromised" COVID-19 vaccines. As mentioned earlier, several of the leading COVID-19 vaccines currently being trialled use viral vectors that have been produced using the fetal cell line HEK-293, which comes from the kidney of a fetus aborted in the early 1970s. There are many persons and families across Christian denominations who would not access vaccines developed with the use of aborted fetal cell lines. This will be problematic if the vaccine becomes mandatory, as these individuals will be forced to engage in civil disobedience. If there is no ethically derived COVID-19 vaccine, we expect a portion of the community will yield and access the unethically derived vaccine, but there will also be a portion who do not, and this could lead to reduced population vaccine coverage at a time when coverage is critical.

The Federal Government should – as far as possible – consider making multiple vaccines available, or choose among the less ethically contentious vaccines under development. This will address the concerns of people with an ethical objection to certain vaccine candidates. The availability of multiple vaccine candidates may also give people with safety concerns different options, some more safe than others. This will be important, as assuaging the concerns of the general public may make the difference between reaching the level of vaccination necessary to achieve herd immunity and falling short of this level.

23 Brit Trogen *et al*. "Adverse consequences of rushing a SARS-Cov-2 vaccine: implications for public trust". *JAMA*. 2020;323(24):2460-2461.

24 Andrew Wakefield is a discredited and deregistered medical doctor who in 1997 published a paper in The Lancet claiming to have discovered a link between the childhood MMR vaccine and autism. Wakefield's paper was subsequently retracted after it was found to contain insufficient data to establish a causal link between the MMR vaccine and autism. The paper nevertheless appears to have caused childhood vaccination rates to plummet in the UK. It has taken health authorities many years to undo the damage of Wakefield's discredited research.

25 Julian Savulescu. "Good reasons to vaccine: COVID-19 vaccine, mandatory or payment model". *Journal of Medical Ethics* July 29th 2020.

Conclusion

This report has discussed the ethics of vaccination, with a particular focus on vaccine allocation under scarcity and measures to increase vaccination rates among the population. I considered how the government might go about distributing vaccine units among the general population once a vaccine becomes available, as well as how the government might seek to ensure that a sufficient number of Australians are eventually vaccinated so as to achieve herd immunity.

Government vaccination policy should seek to engage the general public to the extent that this is possible. Indeed, early on in the pandemic Prime Minister Scott Morrison described the government's COVID-19 restrictions as being based on a "social contract".[26] This social contract should also be reflected in the manner in which vaccines are selected and distributed among the general population. I would strongly recommend that further research be conducted on the public's views with respect to the allocation of scarce vaccine resources as well as coercive vaccination policies.

Appendix 1: A tiered ethical framework for COVID-19 vaccine distribution

Tier 1: Healthcare and essential service providers - civic leaders and public health response personnel

- Frontline healthcare workers and aged-care staff
- Essential service workers
- Public health experts and civil leaders coordinating the coronavirus response

Tier 2: Most vulnerable populations

- Immunosuppressed individuals; people with blood cancer
- People over the age of 80
- Prison populations; people experiencing homelessness
- Ethnic and indigenous minorities

Tier 3: At-risk groups

- People with comorbidities -- diabetes; lung disease; heart disease; those suffering from severe obesity; individuals with blood pressure problems; individuals with a neurological condition
- People over the age of 50
- Other at-risk groups

• Tier 4: general population

- People aged 2 to 50

26 Scott Morrison and Leigh Sales. *ABC 7:30 Report* April 16th.

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Xavier has taught bioethics for several years, and has worked with Catholic healthcare providers on several projects related to ethics education including coordination of the joint BBI-CHA course Decoding the Code. In 2020, Xavier was awarded a Fulbright Future Postdoctoral Scholarship, and he will be a scholar in residence at Georgetown University's Kennedy Institute of Ethics from January to July 2021.

Recent publications:

With Reginald Chua. "Rationing, responsibility and blameworthiness: an ethical evaluation of responsibility-sensitive policies for healthcare rationing". Kennedy Institute of Ethics Journal (forthcoming in March 2021 edition).

"Conscientious objection -- why the professional duty argument is unconvincing". Journal of Medicine and Philosophy (forthcoming)

With Reginald Chua. "'Alive by default': An exploration of Velleman's unfair burdens argument against state sanctioned euthanasia". Bioethics 34;3 (2020): 288-294.

“This essay represents the views of the author and not Catholic Health Australia. Readers should not rely on the essay if they are seeking specific ethical advice and should consult an expert in the field.”

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