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Ethical reflections on Covid-19 vaccines
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ABSTRACT

Objectives: More than 1 year after the start of the Covid-19 pandemic it is becoming increasingly clear that vaccines will prove to be essential in combating this global pandemic. The demand for such vaccines is great (since nearly everyone is a candidate for vaccination) yet supplies are currently limited. This raises clear ethical questions regarding the current and future Covid-19 vaccines.

Methods: In this paper we highlight the several ethical questions that are raised using a threefold categorization. We will discuss questions concerning: (1) the design and testing of vaccines; (2) who gets the vaccines; and (3) the tensions between public health and individual interest/autonomy. Each of these three more broad categories encompasses many different and concrete ethical questions.

Results: We argue that different ethical frameworks apply both across these three categories, but also within these categories.

Conclusion: Despite the fact that ethical conflict might not completely disappear, we argue that distinguishing and discussing separate questions from an ethical perspective can help create the necessary clarity and provide an ethical justification in favour of particular vaccination issues.

Introduction

Vaccines for Covid-19 have been developed, tested and approved in record speed and are now being used for a vaccination campaign on a global and unprecedented scale. There seems to be little doubt that vaccines will prove to be essential in combating the worldwide Covid-19 pandemic. For one, herd immunity achieved through infection is unlikely as is exhibited, for example, by the resurgence of Covid-19 in Manaus, Brazil in January 2021 despite a study of blood donors indicating that 76% of the population had been infected with SARS CoV-2 by October 2020 [1]. Second, as regards non-pharmaceutical interventions, strict measures have been implemented globally, but have failed to prevent new waves of the pandemic. A recent review of such non-pharmaceutical interventions in 130 countries and territories indicated that the effectiveness of some interventions is relatively proven empirically, but that this is less so for a series of other interventions [2]. Third, as far as pharmaceutical treatment is concerned, there have been both anecdotal reports of therapeutic success [3] as well as more large-scale studies [4]. However, although such treatments or interventions are important in mitigating the effect of moderate or severe clinical manifestations of Covid-19, they will not suffice to halt the Covid-19 pandemic. It is now clear that patients that survive Covid-19 can have long-term aversive health effects [5], making prevention a clinically and ethically superior option to treating and/or reducing mortality.

Categorizing the issues

As such, ethical debates surrounding Covid-19 vaccines and vaccine strategy are both timely and extremely relevant. Ethical issues are often taken together in one big ethical question, but a more fruitful approach is to divide the issue into different ethical questions or categories. Based on a publication by Macklin et al. one could (roughly) divide them into three categories [6] (Table 1).

There is a common aphorism in statistics that says that ‘all models are wrong, but some are useful’. This can also apply in this case where we do not claim that the categorization is exhaustive. Nevertheless, we believe this distinction to be useful because:

1. It does capture the majority of ethical questions.
2. It helps disentangle the complex web of ethical issues that surround Covid-19 vaccination (or any other large-scale vaccination campaign for that matter)
Table 1.

<table>
<thead>
<tr>
<th>Categories about design and testing of vaccines</th>
<th>Most relevant ethical framework</th>
<th>Examples of specific ethical questions</th>
</tr>
</thead>
</table>
| Concerns about design and testing of vaccines  | Research ethics                 | -What research standards should vaccines meet?  
|                                               |                                 | -Is it justified to do placebo studies once good working vaccines are available? |
| Concerns about who gets vaccine               | Distributive justice            | -Who should be prioritised in vaccine strategies?  
|                                               | Public health ethics            | -How can we guarantee equal access to vaccines?  
|                                               |                                 | -Can more freedoms be granted to those who are vaccinated? |
| Concerns about the tension between public health and individual interests/autonomy | Clinical ethics                  | -Is it justified to make vaccination compulsory under certain conditions or for certain citizens?  
|                                               | Public health ethics            | -What degree of side-effects for some individual patients are we willing to accept for the group benefits?  
|                                               |                                 | -Can certain freedoms be granted to those who chose to be vaccinated and (consequently) refused to those who refuse? |

(3) It shows why ethical dilemmas are so rampant as various questions might require the use of different ethical frameworks that provide conflicting answers.

Based on this categorization, we briefly explore some ethical questions.

**Concern about design and testing**

One large category of questions relates to the concern about the design and the testing of such vaccines. The ethical framework most relevant for these questions is, of course, the research ethical framework that has been applied to this category in a number of publications [7,8].

As concerns the vaccines that are currently on the market or for which market approval is pending, there is no reason to assume that the speed at which they were developed in any way negatively affected the degree to which they were tested for safety, tolerability and immunogenicity. Large-scale phase III study results were published in high ranking international journals [9–11] and the FDA and EMA did not lower their standards for market approval. These studies all indicate that the current vaccines are both safe and efficacious. For this paper, we would like to highlight two other issues.

**Post-licensure evaluation**

Despite the safety of the vaccines demonstrated in trials there is of course also the issue of a good post-licensure evaluation for real-world safety and effectiveness. There is an ethical need to do a successful evaluation (e.g. via test-negative design) and to create a good system for reporting adverse events. What constitutes the best way to do such evaluation is, of course, a mainly scientific question [12]. What should happen when moderate or side-effects do show up, however, is a political and ethical question.

**Ethics of placebo trials for new vaccines**

Finally, there is an interesting research ethical question that is gaining traction. It concerns the design and testing of new Covid-19 vaccines that are being developed. Although various vaccines have gained market approval, dozens of vaccines are still in the process of (pre)clinical testing. Classically these go through a final large-scale phase 3 trial where the vaccine is compared to a placebo. However, in light of the fact that we now have a working vaccine that is becoming available and being administered to an increasing number of people, the scientific feasibility and ethical justification of such a placebo controlled vaccine trial has been questioned [13]. Normally a placebo controlled trial is justified by reference to clinical equipoise (i.e. when there is genuine uncertainty whether a certain treatment or intervention is superior). With a safe and efficacious vaccine on the market, the presence of clinical equipoise could be questioned and thereby also the ethical justifiability of a placebo trial. Although the relevance of clinical equipoise has been questioned [14], the fact remains that a placebo controlled trial for a new vaccine would involve a control group (with a considerable number of patients) who are not vaccinated despite there being safe and efficacious vaccines available.

An alternative to a placebo controlled trial is a non-inferiority study where the vaccine would be compared not to a placebo but rather to the best available alternative. Of course, if we set the threshold on Moderna or Pfizer vaccines which can show a 95% efficacy and new SARS CoV-2 strains developing, showing non-inferiority will be very hard for new vaccines. Another alternative could be to set the bar lower, for example, by requiring new vaccines to be non-inferior to any currently approved vaccine. Although new vaccines would then not be tested compared to the best alternative, this would allow new vaccines to more efficiently reach the market and that market would not have to lower its bar concerning efficacy.
Concerns about who gets vaccine

A concern for any vaccine is the question of who gets the vaccine and the corresponding ethical question of who should get the vaccine. As we are dealing with the distribution of vaccines either globally or on a more local level, the ethical frameworks most relevant here are those of distributive justice [15] and public health ethics [16].

Such questions are even more pressing where the price for a vaccine is high (and it is thus a question of justice and affordability) or when there is a large gap between supply and demand (and there is thus the issue of scarcity). For a Covid-19 vaccine where just about anyone is a vaccine candidate and current supplies are limited, the latter is definitely the case. This makes the issue of an ethical distribution particularly pressing. There is, of course, also the issue of the distribution of vaccines between countries with most vaccines currently going to more wealthy countries. Key here is, for example the COVID-19 Vaccines Global Access (COVAX) initiative to guarantee equitable access to vaccines worldwide. However, as this is a matter of international distributive justice but equally politics, it will as such not be dealt with in this shorter paper. Our focus lies on distribution within a certain country or region.

Ethical justification for vaccine strategies

The question is thus what the best and most ethical approach is to distributing vaccines. When it comes to the ethical justification for vaccination strategies there seem to be roughly two approaches. One is a more consequentialist or utilitarian reasoning that believes that the ethical justification of actions or policies depend mainly or solely on the outcomes or consequences of those actions or policies (hence the name ‘consequentialism’). When a certain outcome is agreed upon to be good, the ethical option is that which maximizes that outcome. Taking, for example, the reduction of mortality or Covid-19 patients in ICU as the morally relevant aim, the most ethical approach is that which overall best reduces mortality or ICU admissions. The advantage of such an approach is that once the relevant aim is agreed upon, it turns various ethical questions into more practical scientific questions. A recent modelling study, for example, used various simulations to determine which vaccination prioritization is best at minimizing mortality [17].

This could then also be coupled with serological testing so that those with sufficient antibodies (e.g. due to previous PCR confirmed Covid-19 episodes) are deprioritized in order to maximize the effects of vaccination. The drawback of such an approach is that it looks mainly towards the most efficient way to obtain a certain outcome, thereby often minimizing or ignoring questions of fairness or distributive justice.

Another approach would be more deontological and would work to allocate vaccines based on, for example, good principles, rules and/or some form of merit (i.e. who rightfully deserves or merits priority). From a deontological perspective it would be crucial that vaccines are distributed in a way that is most just, equitable and/or fair, even if this means that vaccines are then distributed somewhat less efficiently. Vaccination could, from this perspective, be used not just to minimize suffering, but, for example, also to compensate those who were most at risk during the pandemic (e.g. health care workers) or to promote equity following a pandemic. We know, for example, that not everyone was hit as hard by the pandemic [18] and vaccination strategies could thus also aim at promoting equity as a form of compensatory justice. One drawback of such a strategy is that, unlike the more utilitarian strategy, it cannot deflect the ethical issues but has to tackle complex value based questions (who is most vulnerable, who was hit the hardest, who is most at risk, etc.) head-on.

In the public debate, both justificatory perspectives are used. Strict non-pharmaceutical interventions such as lockdowns have, for example, been justified based on the death and suffering they prevent. Other authors have raised the issue of fairness in access to vaccines [19]. Ideally an approach would combine these approaches. One example is a recent paper by Persad et al. (2020) that looked at three guiding values for prioritizing access to Covid-19 vaccines [20]. The first of the values they propose is consequentialist (maximizing benefits and limiting harm) but the other two are more deontological (prioritizing disadvantaged populations and equal concern). Such a combination of both perspective has also been used in other recent papers [21].

In our view such an incorporation of consequentialist concern (namely that good action or policy should not get caught up in good intention but also change things for the better) within a deontological framework is the most fruitful approach. That good outcomes should be maximized is an important principle, but it cannot be the only one since this could involve under-emphasising the societal inequality and injustice that may follow as a result. However, we do recognize that although it is definitely crucial to have both perspectives and to combine them, they do remain fundamentally at odds and will therefore continue to generate ethical conflict and dilemma.

Granting freedoms to those who are vaccinated

With an increasing number of people worldwide being vaccinated, the question naturally arises whether particular freedoms could be granted to those who have been vaccinated or whether different rules (e.g.
concerning number of contacts or quarantine rules) could apply for this group.

As regards this question, we believe it is crucial to distinguish between the situation where not everyone has had the chance of being vaccinated and the (currently hypothetical) situation where this would be the case. When not everyone has been vaccinated the question of whether freedoms can be granted is inherently tied to the question of who gets the vaccines, and thus fits best within this category of ethical issues. Concerns that are raised regard distributive and compensatory justice. Once everyone has been given the opportunity to be vaccinated the issue, we argue, shifts somewhat and the conflict between people’s individual autonomy and public health comes into focus. This question thus falls within the next category that is discussed below.

As regards the first issue of whether freedoms can be granted to those who have been vaccinated when not everyone has had the chance, we believe this is a highly sensitive debate but that there are some arguments supporting its justifiability. There have been criticisms of a so-called ‘immunity passport’ [22,23], but many of the ethical concerns here related to the fact that such an immunity passport could be granted after Covid-19 infection. This could put those who were careful not to get infected at disadvantage (a deontological concern) and, more importantly, could incentivise risky behaviour and attempting to get infected in order to obtain a passport (a consequentialist concern). However, many of these concerns do not apply when it comes to vaccines since here the strategy and prioritisation can be done according to agreed upon and transparent ethical principles.

One fear could be that allowing some freedom for those who are vaccinated would be discriminatory or unjust. In this respect, a basic principle of justice is that ‘like cases are treated alike and different cases are treated differently’. Here we argue that it would not automatically be the case that by allowing some freedom to those who vaccinated we are treating like cases differently (thus violating the justice principle). If it turns out that those who are vaccinated have very little or no risk of being infected or of transmitting the SARS CoV-2 virus, this could be deemed a relevant difference between those who are vaccinated and those who are not. Basic freedoms, such as freedom of movement, are not ‘privileges’ but, instead, are basic human rights whose infringement requires strong justification. Reducing these rights for people who have no risk of being infected nor of infecting others might not meet an ethical (or even legal) test of proportionality.

That being said, there is an important caveat to mention. Although we believe granting freedoms based on vaccination status might not automatically be discriminatory or unjust, there are certainly situations in which it would be discriminatory or unjust. This is the case when *ab origine* the criteria on the basis of which vaccines are distributed are unjust. If, for example, people would be able to buy vaccines, then vaccination status would be a surrogate for socio-economic status (i.e. those who can afford it buy the vaccine first). In such a scenario this would thus amount to giving certain freedoms based on ability to afford it, which is definitely unfair. Thus whether or not granting freedoms to those who are vaccinated hinges upon the criteria that are used for distributing vaccines. A distribution that mimics pre-existing inequalities would only enforce these inequalities while a distribution based on fair and transparent principles could actually promote equity.

That being said, it is unclear whether these conditions are currently met. We do not know, for example, to what degree current vaccines protect against asymptomatic Covid-19 and to what degree they protect against transmission of the virus. These questions are, as we argue, nevertheless crucial. Overall, there are reasons to suspect that vaccination status will at some point become relevant (e.g. the debates about a ‘vaccination passport’ on a European level). In view of what we discussed above, we think this pleads for a more deontological approach and a careful assessment of the principles and criteria on which vaccines are distributed. If this is not done properly there is a risk that not only vaccines are distributed unequally, but that these inequalities are further enlarged through the granting of certain freedoms to those who are vaccinated.

**Concerns about the tension between public health and individual interests/autonomy**

A final category of ethical issues concerns the tension between individual interest and public interests. This is a broad category that focuses less on distributive policies, but more on what degree of freedom should be granted to individuals when it comes to refusing or accepting a vaccine. From an ethical perspective, the frameworks most relevant here are clinical ethics [24] and public health ethics [16].

For example, a question that has arisen is whether or not countries should (temporarily) stop vaccinating with the AstraZeneca vaccine based on suspicions that the vaccine may cause thrombosis in otherwise healthy young individuals. What arises here is a conflict between individual interests (i.e. not to get injected with a vaccine that is potentially harmful) and the public interest of speedily vaccinating as many as possible. Interestingly, there are two different positions in this debate that can be traced back to the consequentialist-deontology distinction drawn earlier. From a consequentialist perspective, for example, one could argue that the potential harmful side effects of the AstraZeneca vaccine (1) are not yet proven and (2)
even if this would be the case, they would not outweigh the benefits of continuing to vaccinate. Belgium took this line of reasoning. Other countries (e.g. France, Germany, the Netherlands, etc.) have instead opted for a temporary vaccination stop based on more deontological rights and duties. This could include a principle of precaution (namely that even in absence of hard proof policies should always err on the side of caution) or the moral duty of governments not to administer to its population substances that might be harmful. The consequentialist-deontology distinction can thus help to make clear precisely why different countries believe a different approach is justified.

**Herd immunity and vaccination as a common good**

There is a second important debate namely that while vaccines will have to play an important role if we want a short term exit out of this global pandemic, the herd immunity that could be achieved through Covid-19 vaccines is a classic example of a collective good. This means that it is a good that can only be achieved through the cooperation of a large number of people where each of these people’s individual contribution is (in itself) minimal [25]. This generates a fundamental conflict as patient autonomy is a key ethical value, but this opens up the option that not enough people will choose vaccination in which case the collective good is not achieved [26]. There seem to be, roughly, three ways to deal with this issue.

**Options 1 or 2: mandatory or autonomous choice**

A first way is to prioritise autonomy and to accept that people are free to choose and therefore also free to refuse. One can attempt to persuade those who refuse or create a system of nudging by, for example, displaying vaccination as the default option and request that people opt-out. The drawback of such a strategy is that herd immunity might not be reached. Another drawback might be that people will attempt to free-ride by not getting vaccinated while hoping that a sufficient number of other people will get vaccinated. They can then refuse vaccination and still reap the benefits of herd immunity. The paradox is that if too many people follow such a strategy that herd immunity will not be reached and there is nothing to free ride on. Such a fear that an insufficient amount of people will opt for vaccination is not just purely theoretical when we know that a considerable anti-vaccine movement exists in the context of Covid-19 [27].

The second way of dealing with this conflict is by prioritising public health and making vaccines mandatory for the entire population or a part of it (e.g. certain professions such as the health care profession or police force). Such a strategy would guarantee that the vaccination strategy reaches a critical uptake and herd immunity is reached. The drawback here is evident as this involves a breach of an important *prima facie* ethical principle, namely that people have the right to autonomous choice when their health is concerned. It is also unclear to what extent there is public support for such a measure. In the early 1900’s Rio de Janeiro mandated a smallpox vaccine for its population which subsequently led to the 1904’s Brazilian Vaccine Revolt and the subsequent abandonment of the mandated vaccine program [28]. This is a painful reminder of what can happen when mandated medical measures fail to find public support.

Which of these two strategies is superior depends on many factors, most importantly perhaps on how many people are willing to be vaccinated. However, the difficulty seems to be that the choice between these strategies has to be made before it is clear how many people will choose to be vaccinated. Starting with autonomous choice and then switching to a mandatory vaccination once it is clear that uptake is insufficient might be hard to justify socially, legally, and ethically.

**Option 3: granting freedoms to those who are vaccinated**

There is of course a third way to balance autonomy and public health, which involves coupling vaccination status to certain rights. In such a scenario vaccination would not be obligatory, but being vaccinated could be a requirement in certain situations (e.g. international traveling or attending mass events) or people who aren’t vaccinated could be asked to meet certain extra requirements (e.g. being able to present a recent negative Covid-19 PCR test). Here, so the idea goes, autonomous choice is guaranteed as well as public health. In this scenario, of course, everyone would have had the opportunity to be vaccinated.

The ethical issue with this scenario would, of course, be the risk of coercion where people are at first sight given a free choice, but end up feeling excessive pressure to choose vaccination. Naturally, this would still be less pressure than in a mandatory vaccination scenario, but the ethical problem here would be that this third scheme would potentially be deceptive (by framing coerced choice as free choice). Also, the coercive pressure would not be felt in equal degrees by anyone. Some people, e.g. socio-economically disadvantages populations, may experience more pressure, thereby creating a certain inequality and potentially also injustice.

**Conclusions**

It is evident that the Covid-19 pandemic has raised several ethical issues. Often these ethical issues are lumped together in major ethical questions. In this paper we have made use of three categories in order
to distinguish various questions. For each category we have identified the relevant ethical framework needed to tackle those questions, but have also provided examples of currently highly relevant questions in each category.

Distinguishing and categorizing ethical questions lays bare the enormous complexity of ethical questions and the source of many conflicts. There is often a conflict between ethical frameworks, for example a conflict between research ethics (the need for ethical trials) and public health ethics (the rapid need of vaccines for battling the pandemic). There might also be conflict between consequentialist justifications (the need for the most efficient distribution of vaccines) and deontological ones (the need for a fair distribution of vaccines).

In short, based on our analysis we have identified the most pressing ethical questions and possible ways of answering those questions.

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