

Special Rules for Vaccinated People?

AD HOC RECOMMENDATION

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Since the beginning of the vaccination programme at the latest, the question of whether vaccination against Covid-19 should or even must lead to special rules for vaccinated people has become the subject of controversial public discussion. Such rules might affect the withdrawal of state restrictions on civil liberties, the access to goods or services of private providers, or the duty to perform occupation-related or public welfare activities.

In order to adequately evaluate special rules of this kind, it is necessary to establish with certainty, to what extent Covid-19 protective vaccinations will be sufficiently safe and effective in suppressing (i) the outbreak or a severe to fatal progression of Covid-19 and (ii) the transmission of the SARS-CoV-2 pathogen. Such an evaluation presupposes a valid assessment of relevant empirical data from a medical and scientific perspective (under (1)).

In the ensuing ethical as well as legal evaluation, the following differentiation must be made:

- With regard to state restrictions on civil liberties on the grounds of infection control, it must be clarified to what extent the general continuation of such restrictions can still be justified as the vaccination programme progresses, whether it is permissible to discriminate between vaccinated persons and non-vaccinated persons, or whether such distinctions may even be necessary for certain events or areas (under (2) and (4)).
- With regard to distinctions between vaccinated persons and non-vaccinated persons by private providers, the question arises to what extent these are covered by private autonomy or whether they also require justification, and how this should be assessed from an ethical point of view (under (3)).

In both cases it must be considered (a) whether all those wishing to get vaccinated have access to vaccinations, (b) what criteria shall apply to determine the “sufficient effectiveness” mentioned above, and (c) what consequences the progress of the vaccination programme has on the legitimacy of state restrictions on civil liberties. It must be said that from a legitimacy point of view, it is not the spreading of the virus as such that is decisive. In the opinion of the German Ethics Council, the far-reaching restrictions on civil liberties as well as their social, economic and cultural consequential damages may only be justified by severe negative consequences such as high mortality, long-term health problems of significant parts of the population or the impending collapse of the health system.¹ This is why all persons with a very high personal risk for a severe or even fatal course of the Covid-19 disease should get priority access to the vaccination, i.e. not only the elderly, but also young people with severe pre-existing medical conditions (also by way of hardship provisions, if required). Prioritisation along these lines has been widely included in the recommendation on vaccination prioritisation by the German Ethics Council, the Ständige Impfkommission (STIKO, Standing Committee on Vaccination) housed by the Robert Koch Institute, and the Nationale Akademie der Wissenschaften Leopoldina (National Academy of Sciences Leopoldina), and is stated there as an overriding vaccination goal.²

Whether and to what extent being vaccinated may also bring about special *obligations*, would need to be discussed separately. The same applies to the possibility of a mandatory vaccination policy for specific events and areas.³ In the opinion of the German Ethics Council, persons who have been vaccinated on a voluntary basis should currently not be obliged to fulfil additional duties in combatting the pandemic, neither by the government nor by their employers. A strong argument against such an approach is that it is currently not sufficiently clear whether being vaccinated also effectively reduces the risk of transmitting the virus. This is also the reason why a mandatory vaccination policy must be rejected at this point. The joint recommendation on vaccination prioritisation mentioned above sets conditions to this end which are not fulfilled at the moment.

1 Scientific and medical fundamentals

The vaccination strategy has two main goals: firstly, to prevent the development of severe symptoms, particularly symptoms that lead to hospitalisation and/or are life-threatening, and secondly, to interrupt the chain of infection. These two goals do not necessarily coincide, even if the World Health Organisation (WHO) considers both of them to be requirements in the development of Covid-19 vaccines.⁴ SARS-CoV-2 first infects and replicates in cells in the upper respiratory tract, which means that to avert the initial infection a local mucosal immunity, induced by secreted antibodies, would be required.⁵ However, the vaccines against SARS-CoV-2 that have been developed so far, are based on an injection into the muscle and trigger the formation of neutralising antibodies circulating in the blood, thus preventing the virus from spreading further within the body. Virus replication in the cells of the upper respiratory tract, and therefore transmission after exposure to the virus, remains possible.⁶

The relationship between suppression of symptoms and suppression of the infection is not yet known for the existing Covid-19 vaccines, it will only become apparent in long-term follow-up studies.⁷ A faster, systematic way to answer this question would only be feasible by means of so-called challenge studies involving the deliberate infection of participants after they have received the vaccination. However, such an approach must be ruled out for ethical reasons.⁸

Up until now, we can only draw analogies to previous vaccination programmes against other pathogens. Studies on chicken-pox and pneumococcal vaccination in children have shown that the transmission rate among family members could be reduced by about half for families with vaccinated children, compared to families with non-vaccinated children.⁹

In the development of the vaccines against SARS-CoV-2 that have been approved so far, only the clinical immunity has been examined, i.e. the absence of symptoms in the vaccinated persons themselves, but not a possible effect on the spread of the infection within families or groups.¹⁰ The neutralising antibody titers¹¹ observed in vaccinated persons were in some cases even higher than the levels observed in convalescent patients, which means that a reduction of virus production due to vaccination is likely.

However, no systematic trial data on its extent and its effects on the infectiousness of vaccinated people with asymptomatic infections are available as yet.¹² Moreover, the reduction of virus production due to vaccination might be curbed by the appearance of virus variants. Immunity is not achieved immediately after the first vaccination, but develops over several weeks. In addition, in the case of the first vaccines against Covid-19 with approval for Germany, those by BioNTech/Pfizer and Moderna, two doses of vaccine need to be given at an interval of 21 or 28 days respectively, in order to trigger the protective immune response.¹³ As far as hitherto known, one single dose of vaccine does not lead to long-term protection against SARS-CoV-2. Even after the second dose of vaccine and notwithstanding the 95 percent efficacy claimed by some vaccine producers, it cannot be ruled out that some vaccinated persons remain unprotected and are potentially infectious. This means that at least in the period between the first vaccination and the onset of the effect of the second vaccination – and maybe even longer – there is still a risk of infection for that individual person, as well as a risk of transmission from that person to others. There is, therefore, every indication that it is necessary to achieve a high vaccination coverage¹⁴ and also to maintain further protective measures after the vaccination, at least for a limited period of time.

With all due caution it may thus be assumed in a normative analysis that the vaccination programmes against Covid-19 will bring down the hospitalisation and mortality rates among vaccinated persons considerably. In addition, it may be expected that with the increase in vaccination coverage, the risk of infection and disease for non-vaccinated persons will continue to decrease, because the vaccination should reduce the risk of transmission, at least to some extent. To what extent exactly cannot be estimated with certainty at this point.

2 Withdrawal of state restrictions on civil liberties

Infection control measures include restrictions on civil liberties that need to be ethically and legally justified. It must therefore be verified in each case whether for protection reasons the burdens are necessary, effective, efficient and reasonable, in view of the targets pursued, and which impairments to the social, economic and cultural life go along with them – also in the long-term.¹⁵ In addition to, and apart from the state's task of protecting the health of its citizens, it is essential to bear in mind the issues of a just distribution of advantages, solidarity obligations, burdens and restrictions, as well as of potential exclusion and problematic discrimination, and to adequately take into account their significance.

General withdrawal for vaccinated and non-vaccinated persons

The massive threat for life and health of many people resulting from a possible exponential increase in infection rates, in severe courses of disease and – as a consequence – from an excessive strain on the health system in principle justifies the current measures, even if they are very far-reaching. Should there be any more specific and more effective means available to achieve these aims, then the general restrictions on civil liberties that have applied

up until now must be lifted in favour of more specific protective measures. Since the corresponding assessments are inevitably subject to epistemic uncertainty, it is necessary to draw normative limits.

In all probability, the vaccination is a more specific and more effective means as described above to contain the pandemic and its consequences, even if it probably does not reliably prevent the spread of the pathogen through persons who get infected despite being vaccinated. The more people are vaccinated, the larger the share of the population who is protected from developing the disease. Correspondingly, the number of deaths and of severe courses of disease and consequently the threat of an excessive strain on the health system with all its consequences should gradually recede as the vaccination programme progresses. This is all the more true as initially those groups of persons get vaccinated who are at a particularly high risk of suffering from a severe and potentially life-threatening course of disease in case of an infection. The vaccination programme should therefore lead to a drop in the number of severe and fatal cases relatively quickly. To the extent that this overriding target of the vaccination strategy will be achieved, the decisive ethical and legal grounds to justify state restrictions on civil liberties gradually cease to apply.

However, the normatively relevant relation of the probability of infection on the one hand and the burden of protective measures on the other hand must be taken into consideration: While social distancing and wearing a face mask as comparatively minor restrictions on civil liberties should be deemed reasonable in public transport and in the public sphere for quite some time, restrictions of the social, economic and cultural life as well as restrictions of contacts and curfews are far-reaching. They go along with an exacerbation of social inequality and tensions within society, and they bring considerable burdens and disadvantages for individual groups of people ((school) children, students, creative artists, solo self-employed persons, employees in the event, hospitality or travel business and in retail, etc.). They can thus no longer be ethically and legally justified once the primary target of the vaccination strategy has been achieved. This is why these restrictions should be lifted step by step in the same pace as the risk of a collapse of the health system through a large number of severe and potentially life-threatening cases decreases. It must be ensured that groups of persons with a high risk of a severe or fatal course of disease – also younger ones – will already have received a vaccination offer by that time. Also, the level of infection rates must be considered in weighing the risk of future, potentially dangerous mutations.

Individual withdrawal for vaccinated persons

For as long as not all people can get vaccinated, part of the population would perceive as unjust an individual withdrawal of state restrictions on civil liberties for vaccinated people only. This perception might reduce the citizens' solidarity and their willingness to comply with the rules, and consequently undermine the measures taken to contain the pandemic that are intended to protect the health of all people. The ethically and legally difficult question whether and to what extent these indirect consequences justify that the far-reaching restrictions on civil liberties, also of

vaccinated persons, be maintained, does not have to be answered right now. Such a decision should only be taken when reliable estimates can be made about the degree by which vaccinations against Covid-19 reduce the infectiousness of vaccinated people. As even contacts among vaccinated persons might lead to a transmission of the virus and indirectly to the infection of persons that have not yet been vaccinated, the individual withdrawal of state restrictions on civil liberties for vaccinated persons is currently out of the question.

Given the uncertainty regarding the infectiousness of vaccinated people, the general restrictions of freedom currently continue to apply to them. However, as the vaccination programme unfolds and to the extent that the particularly severe risks are being reduced and better insights on non-infectiousness become available, individual revocations of restrictions on civil liberties for vaccinated persons become more plausible and maybe even imperative. In this process, controversial issues of justice and of the consequences for the acceptance of the vaccination strategy must be duly considered. Measures interfering comparatively little with people's lives, like social distancing or wearing a face mask, which might lead to insecurity and unrest if exceptions were granted, may be maintained without exception even if it must be assumed with great probability that vaccinated people are no longer or only slightly infectious.

3 Access restrictions by private providers

Whether and to what extent it should be or can be denied to private providers to restrict access to their goods and services to vaccinated persons only has recently been publicly discussed at great length. The issue was brought up by the Australian airline Qantas with the announcement that they would only allow vaccinated passengers on board in the near future – at least on their international flights. However, international flights are a special case, since access to them requires the authorisation to enter the country of the flight's destination. It is quite feasible that, as the vaccination programme progresses, countries will grant entry to persons only upon proof that they are vaccinated. This is currently being discussed even within the European Union. In this case, also other airlines could probably not avoid requiring their passengers to provide proof of vaccination for flights to such countries.

Access restrictions to goods and services offered by private providers are also considered in other areas, where they are likewise the subject of heated public debate. Especially if the far-reaching state restrictions on civil liberties that are currently required to prevent a collapse of the health system will be lifted and it turns out in the further development of the pandemic that vaccinated persons are clearly less infectious than non-vaccinated persons, private providers might consider restricting their offer to vaccinated people. They might then advertise by pointing out that the threat of getting infected with Covid-19 is reduced if customers choose their offer, because vaccinated persons are amongst themselves.

In the ethical and legal evaluation, it must be taken into account that for private individuals and private companies the principle of contractual freedom applies, which means that they are essentially free in deciding with whom they want to conclude

a contract. This basically includes the possibility to differentiate according to people's vaccination status. Evaluating access restrictions of private providers thus starts from a different basis than the evaluation of state restrictions on civil liberties. While state restrictions on civil liberties always require a justification, private providers basically have the option of regulating access to their offer at their own discretion. It is rather the restriction of that freedom which requires a justification.

Restricting the contractual freedom of private providers may be justified if the access to their offer is indispensable for a generally equal, basic participation in social life. However, applicable law is rather cautious here. Even in the few cases where it provides for a so-called obligation to contract, restrictions can be included in the general terms of contract. The same applies to cases where jurisdiction has derived an obligation to contract from the general principles of law. The vaccination status is not included in the grounds for discrimination prohibited by the Allgemeines Gleichbehandlungsgesetz (General Act on Equal Treatment). Therefore, apart from data protection requirements, no provisions must be complied with on a regular basis. For any further restriction of the private providers' private autonomy new legal regulations would be required, e.g. to counter concerns that "vaccinated persons are privileged" or that an "indirect duty to vaccinate" could be installed. Whether such new legal regulations would make sense and could be designed to be constitutional, cannot be conclusively discussed in the context of an Ad hoc Recommendation.

4 Restrictions on civil liberties in nursing homes, facilities for the elderly and the disabled, and hospices

Restrictions on civil liberties in nursing homes, facilities for the elderly or disabled, or hospices are a major challenge.¹⁶ Since the beginning of the pandemic, their residents have been affected particularly severely by infection control measures in the form of limitation of contact. These include prohibitions or restrictions to go out, visiting restrictions even for close relatives and contact restrictions within the facilities implying, for instance, that communal meals and group activities are cancelled. Due to isolation measures, the residents in nursing homes, facilities for the elderly or disabled, or hospices are still suffering under great strain that goes far beyond the burdens that other citizens have to bear. Keeping up this extra burden can only be justified as long as the residents of such facilities have not been vaccinated. This is one of the reasons why they belong to the first group that is currently being vaccinated.

However, there will be individuals in almost every facility who do not want to be vaccinated or who cannot be vaccinated because of pre-existing medical conditions. Since it is not clear to what extent vaccinated people can continue to transmit the virus, it cannot be excluded that non-vaccinated residents living in such facilities might get infected and develop severe symptoms if the existing contact restrictions were lifted, even if such a withdrawal only applies selectively for vaccinated persons. Nevertheless, this risk should be reduced due to the vaccination of the other residents. This is why a general continuation of comprehensive contact restrictions for all people living in such facilities in order to

protect those persons who cannot be vaccinated would no longer be appropriate in view of the particular burden that these contact restrictions present for residents, and because of all their negative consequences (depressions, worsening of dementia symptoms, loss of the will to live, etc.). Instead, non-vaccinated residents must be especially protected by means of other measures (FFP2 masks, protective clothing for nursing staff, rapid tests, etc.), apart from maintaining the general infection control measures.

5 Recommendations

In its Ad hoc Recommendation “Solidarity and Responsibility during the Coronavirus Crisis” (March 2020), the German Ethics Council has tied the ethical and legal legitimacy of far-reaching restrictions of fundamental rights as well as severe further damages to the necessity of protecting the health system from collapse due to a high number of severe or fatal courses of Covid-19, but not to combatting the pandemic as such. To the extent that this target is achieved, the restrictions shall be lifted for everybody, irrespective of their vaccination status. Complete eradication of SARS-CoV-2 is neither a realistic nor a necessary target of a successful vaccination strategy.

In assessing the question whether vaccination against Covid-19 should or must lead to a withdrawal of the restrictions justified by reasons of infection control, a differentiation must be made between state restrictions on civil liberties on the one hand and limitations to social life through access restrictions to the offer of private providers that are no requirement by the state on the other hand.

1. At this point in time there should be no individual withdrawal of state restrictions on civil liberties for vaccinated persons, because their infectiousness cannot be reliably estimated as yet.

2. As the vaccination programme progresses, the general state restrictions on civil liberties should be lifted step by step for all citizens. Hospitalisation rates and the number of severe or fatal courses of disease shall be the primary benchmarks for the withdrawal of these restrictions, and not the mere infection rates. As a precondition, all people with a very high personal risk of developing a severe course of the Covid-19 disease must first have had access to the vaccination.
3. The withdrawal of the general state restrictions on civil liberties should be accompanied by support measures for the further self-isolation of persons with a high personal risk for a severe course of the Covid-19 disease, which is necessary if these people do not (yet) have access to the vaccination, for example children with severe pre-existing medical conditions. Examples of such measures are a right to distance learning, easier access to corona rapid tests, extension of the claim to sickness benefit and dismissal protection for the persons concerned or for their parents.
4. The obligation to wear a face mask and to keep a distance may be maintained for a longer period of time, because they present a relatively minor burden. Due to the threat that the practical enforceability and the acceptance of these rules might suffer if vaccinated persons were granted exceptions, these measures should be lifted for all people at the same time.
5. The substantial isolation measures that are still in place in nursing homes, facilities for the elderly or disabled, and hospices should be lifted for vaccinated persons as soon as possible as the vaccination programme progresses.
6. Only insofar as the access to offers of private providers is indispensable for a generally equal, basic social participation, is it illegitimate to restrict access to such offers in favour of vaccinated persons.

¹ Cf. Deutscher Ethikrat (ed.) (2020): *Solidarity and Responsibility during the Coronavirus Crisis*. Berlin, 2.

² Cf. Ständige Impfkommission beim Robert Koch-Institut; Deutscher Ethikrat; Nationale Akademie der Wissenschaften Leopoldina (eds.) (2020): *How Should Access to a COVID-19 Vaccine Be Regulated?* Berlin, 2. This joint position paper does not correspond in all details to the Federal Ministry of Health's ordinance on vaccination prioritisation.

³ See in this context with regard to measles: Deutscher Ethikrat (ed.) (2019): *Vaccination as a Duty?* Berlin.

⁴ Cf. World Health Organisation (ed.) (2020): *WHO Target Product Profiles for COVID-19 Vaccines*. <https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines> [2021-01-25].

⁵ Cf. Russell, M. W. et al. (2020): *Mucosal immunity in COVID-19: a neglected but critical aspect of SARS-CoV-2 infection*. In: *Frontiers in Immunology*, doi:10.3389/fimmu.2020.611337.

⁶ Cf. van Doremalen, N. et al. (2020): *ChAdOx1 nCoV-19 vaccine prevents SARS-CoV-2 pneumonia in rhesus macaques*. In: *Nature*, 586 (7830), 578–582.

⁷ Public Health England (ed.) (2021): *COVID-19 Vaccine Surveillance Strategy*. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/951189/COVID-19_vaccine_surveillance_strategy.pdf [2021-01-25], 13 f.

⁸ Cf. O'Neill McPartlin, S. et al. (2020): *Covid-19 vaccines: should we allow human challenge studies to infect healthy volunteers with SARS-CoV-2?* In: *BMJ*, doi:10.1136/bmj.m4258.

⁹ Cf. on chicken-pox: Seward, J. F. et al. (2004): *Contagiousness of varicella in vaccinated cases: a household contact study*. In: *JAMA*, 292 (6), 704–708. It could be proved for pneumococci as bacterial pathogens in 2005 that in the context of vaccination programmes for children the incidence of infection with the specific pneumococcal serotypes covered by the paediatric vaccination was reduced by about half in older people, too, while the incidence for other serotypes was not affected. Cf. Lexau, C. A. et al. (2005): *Changing*

epidemiology of invasive pneumococcal disease among older adults in the era of pediatric pneumococcal conjugate vaccine. In: *JAMA*, 294 (16), 2043–2051.

¹⁰ Cf. for the vaccine by BioNTech/Pfizer: Polack, F. P. et al. (2020): *Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine*. In: *New England Journal of Medicine*, 383 (27), 2603–2615; for the vaccine by Moderna: Baden, L. R. et al. (2020): *Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine*. In: *New England Journal of Medicine*, doi:10.1056/NEJMoa2035389; and for the vaccine of AstraZeneca: Voysey, M. et al. (2021): *Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK*. In: *Lancet*, 397 (10269), 99–111.

¹¹ The key indicator that shows whether a person has acquired vaccine-induced protection or not.

¹² Since the vaccination programme in Israel progresses very rapidly, it might be possible to get initial valid results for these issues there. Cf. <https://inews.co.uk/news/world/covid-vaccine-israel-vaccination-roll-out-transmissibility-programme-palestine-834999> [2021-01-25].

¹³ Cf. Polack, F. P. et al. (2020): *Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine*. In: *New England Journal of Medicine*, 383 (27), 2603; Baden, L. R. et al. (2020): *Efficacy and safety of the mRNA-1273 SARS-CoV-2 vaccine*. In: *New England Journal of Medicine*, doi:10.1056/NEJMoa2035389, 9.

¹⁴ Since no Covid-19 vaccines have been approved for children or adolescents under 16 years of age yet, and individual contraindications might exist, it is currently impossible to achieve a complete vaccination coverage of the population wishing to be vaccinated, quite independent of the actual availability of vaccines.

¹⁵ Cf. Deutscher Ethikrat (ed.) (2020): *Solidarity and Responsibility during the Coronavirus Crisis*. Berlin.

¹⁶ See on this already Deutscher Ethikrat (ed.) (2020): *A Modicum of Social Contact in Long-term Care during the Covid-19 Pandemic*. Berlin.

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