

Legal and ethical issues in connection with people who have been vaccinated or who have recovered from infection during the COVID-19 pandemic

Opinion of the Bioethics Commission

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1 Introduction

In an Opinion on “Ethical questions about vaccination against COVID-19,” dated November 25, 2020, the conclusions presented by the Bioethics Commission included the following Recommendation 9:

“It may be advisable to exclude vaccinated persons from specific restrictions that serve to prevent the spread of COVID-19. However, this applies only with regard to severe curtailments of fundamental rights or when the vaccination status can be checked with logistically reasonable means such as presentation of corresponding official verification (e. g. restaurant or concert visits, lodging, ski passes and similar cultural and recreational activities). It would also only apply in circumstances where there is no risk of wide-ranging “demoralization” that could occur if passers-by cannot determine the reason for failure to comply with a measure in a public space. On the other hand, vaccinated persons should continue to comply with measures such as distancing, face masks and hygiene practices in public.”

The Bioethics Commission has now been asked by the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK), in the light of recent developments (not least, the discussions at EU level about a “green pass”), to provide a separate Opinion specifically addressing this Recommendation 9, considering in detail a possible removal of current curtailments of fundamental rights for individuals on the basis of their vaccination status. The specific question is whether, and if so to what extent, restrictions introduced to contain the COVID-19 pandemic could or should be waived for people who have been vaccinated, who have recovered from infection, or who have tested negative.

2 Medical-epidemiological and pharmacological principles

The recommendation of the Bioethics Commission on the ethical aspects of vaccination against COVID-19 was adopted on November 25, 2020, when there was still significantly more uncertainty as to the effectiveness of the vaccines than is the case now, in April 2021, although there are still some questions to be answered (see section 5). There are now more results available from clinical studies, and very encouraging data from large vaccination programs involving millions of people.

These data come from Israel¹, Scotland² and England³. These countries all began their vaccination programs in December 2020 and have by now vaccinated a large proportion of the population. The data show that the vaccinations (using mRNA and vector vaccines) are highly effective in preventing hospitalization, severe cases and death, thus providing impressive evidence of the protection gained by people who have been vaccinated, as early as three weeks after the first dose of the vaccine. The data from Israel's vaccination program (using an mRNA vaccine) also showed evidence of protection against mild and asymptomatic cases.⁴

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- 1 Noa Dagan, M.D., Noam Barda, M.D., Eldad Kepten, Ph.D., Oren Miron, M.A., Shay Perchik, M.A., Mark A. Katz, M.D., Miguel A. Hernán, M.D., Marc Lipsitch, D.Phil., Ben Reis, Ph.D., and Ran D. Balicer, M.D. BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting, February 24, 2021, at [NEJM.org](https://www.nejm.org/doi/full/10.1056/NEJMoa2101765). DOI: 10.1056/NEJMoa2101765: <https://www.nejm.org/doi/full/10.1056/NEJMoa2101765> (accessed April 13, 2021)
 - 2 Vasileiou E, Simpson CR, Robertson C et al., Effectiveness of First Dose of COVID-19 Vaccines Against Hospital Admissions in Scotland: National Prospective Cohort Study of 5.4 Million People. Available at SSRN: <https://ssrn.com/abstract=3789264> or <http://dx.doi.org/10.2139/ssrn.3789264> (accessed April 13, 2021).
 - 3 Jamie Lopez Bernal, Nick Andrews, Charlotte Gower, Julia Stowe, Chris Robertson, Elise Tessier, Ruth Simmons, Simon Cottrell, Richard Roberts, Mark O'Doherty, Kevin Brown, Claire Cameron, Diane Stockton, Jim McMenamin, Mary Ramsay; Early effectiveness of COVID-19 vaccination with BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on symptomatic disease, hospitalisations and mortality in older adults in England (Preprint): <https://doi.org/10.1101/2021.03.01.21252652> (accessed April 13, 2021).
 - 4 Dagan et al., s. FN 1.

These findings have also been confirmed recently by data from a study group of 23,000 health workers in England who received the same mRNA vaccine.⁵ This is an encouraging indication that—at least in the case of mRNA vaccines—transmission of the virus by vaccinated persons can generally also be substantially reduced. Furthermore, it is now assumed that if an infection does occur, vaccinated people have a significantly lower viral load, regardless of the vaccine used,⁶ because they either do not become ill, or the disease is relatively mild, and they are therefore less likely to infect others.⁷ This correlates with findings that the viral load is linked to the severity of infection with SARS-CoV-2.⁸ Modeling for SARS-CoV-2 vaccines indicates that 70% efficacy is sufficient to prevent an epidemic, and that with 80% efficacy or more, the pandemic could be halted.⁹ However, the relationships between vaccine efficacy in clinical trials and effectiveness in real-world use against the pandemic are complex.¹⁰ Nevertheless, experience with other vaccines, such as those against influenza or pertussis, offers hope that even vaccines which do not completely stop a virus spreading will ultimately be very successful in combating a pandemic.¹¹

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- 5 Hall, Victoria Jane and Foulkes, Sarah and Saei, Ayoub and Andrews, Nick and Oguti, Blanche and Charlett, Andre and Wellington, Edgar and Stowe, Julia and Gillson, Natalie and Atti, Ana and Islam, Jasmin and Karagiannis, Ioannis and Munro, Katie and Khawam, Jameel and Group, The SIREN Study and Chand, Meera A. and Brown, Colin and Ramsay, Mary E. and Bernal, Jamie Lopez and Hopkins, Susan, Effectiveness of BNT162b2 mRNA Vaccine Against Infection and COVID-19 Vaccine Coverage in Healthcare Workers in England, Multicentre Prospective Cohort Study (the SIREN Study). Available at SSRN (Preprint): <https://ssrn.com/abstract=3790399> or <http://dx.doi.org/10.2139/ssrn.3790399> (accessed April 13, 2021).
 - 6 This refers to the mRNA and vector vaccines used in the studies cited here.
 - 7 For further references, see Malapaty S, Can COVID vaccines stop transmission? Scientists race to find answers, Nature News, 19 February 2021: <https://doi.org/10.1038/d41586-021-00450-z> (accessed April 13, 2021).
 - 8 Fajnzylber, J., Regan, J., Coxen, K. et al. SARS-CoV-2 viral load is associated with increased disease severity and mortality. *Nat Commun* 11, 5493 (2020): <https://doi.org/10.1038/s41467-020-19057-5> (accessed April 13, 2021).
 - 9 Bartsch SM, O'Shea KJ, Ferguson MC 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* 59(4), 493–503 (2020): <https://doi.org/10.1016/j.amepre.2020.06.011> (accessed April 13, 2021).
 - 10 Hodgson SH, Mansatta K, Mallet G et al. What defines an efficacious COVID-19 vaccine? A review of the challenges assessing the clinical efficacy of vaccines against SARS-CoV-2, *Lancet Infect Dis* 21: e26–35 (2021): [https://doi.org/10.1016/S1473-3099\(20\)30773-8](https://doi.org/10.1016/S1473-3099(20)30773-8) (accessed April 13, 2021).
 - 11 For further discussion see: Caddy SL, Coronavirus: few vaccines prevent infection—here's why that's not a problem, *The Conversation*, January 5, 2021: <https://theconversation.com/coronavirus-few-vaccines-prevent-infection-heres-why-thats-not-a-problem-152204> (accessed April 13, 2021); as well as: McKenna S, Vaccines need not completely stop COVID transmission to curb the pandemic, *Scientific American*, January 18, 2021: <https://www.scientificamerican.com/article/vaccines-need-not-completely-stop-covid-transmission-to-curb-the-pandemic1/> (accessed April 13, 2021).

In principle, there are two other factors that help to prevent infection in people who do not have vaccine protection (for instance because they have not yet been vaccinated or cannot be vaccinated). Firstly, previous infection gives protection to the affected person and, to an extent that is not yet clearly defined, also to other people.¹² So in terms of the current understanding, it is reasonable to assume that there is both self-protection and protection of others in this group of people as well. Secondly, a recent negative result from testing for SARS-CoV-2 also provides reasonable certainty that a person is not infectious at that specific time. So vaccinated, recovered and tested people are inherently less likely to infect others. Vaccinated and recovered people also have a smaller risk of becoming (re-)infected with SARS-CoV-2.

However, all three of these factors—vaccination, recovery from infection, and testing—are only relevant for a limited period of time, which is different in each case. According to current understanding, in the case of vaccination¹³ and past infection¹⁴, this lasts for several months. In the case of a negative test result, on the other hand, it is probably just one or two days.¹⁵ Expert evidence is needed to define what timeframes and test procedures are ultimately relevant here.

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- 12 Hall V, Foulkes S, Charlett A, et al. (2021), Do antibody positive healthcare workers have lower SARS-CoV-2 infection rates than antibody negative healthcare workers? Large multi-centre prospective cohort study (the SIREN study), England: June to November 2020, medRxiv 2021.01.13.21249642: <https://doi.org/10.1101/2021.01.13.21249642> (accessed April 13, 2021).
 - 13 Widge AT, Roupael NG, Jackson LA et al. (2021), Durability of Responses after SARS-CoV-2 mRNA-1273 Vaccination, *N Engl J Med* 384:80-82, DOI: 10.1056/NEJMc2032195: <https://www.nejm.org/doi/10.1056/NEJMc2032195> (accessed April 13, 2021).
 - 14 Rodda LB, Netland J, Shehata L et al. (2021), Functional SARS-CoV-2-Specific Immune Memory Persists after Mild COVID-19, *Cell* 184(1), 169-183.e17: <https://doi.org/10.1016/j.cell.2020.11.029> (accessed April 13, 2021); see also Hall et al. (2021), FN 12.
 - 15 Crozier A, Rajan S, Bucha Iain, McKee M (2021), Put to the test: use of rapid testing technologies for COVID-19, *British Medical Journal* 372 :n208: <https://doi.org/10.1136/bmj.n208> (accessed April 13, 2021).

3 Constitutional framework

The medical advances and insights described above call for a reassessment from constitutional and ethical perspectives of the government measures introduced to curb COVID-19, which impinge on fundamental rights, in some instances quite significantly. Assuming that—as the latest findings indicate is possible, although this is not yet conclusive—immunity acquired by vaccination or past infection with SARS-CoV-2 not only protects people from severe cases, but also significantly reduces the risk of transmitting the virus to other people, the question arises as to whether the measures introduced to prevent the spread of infection should continue to apply fully to people who have been vaccinated or who have recovered from infection.

The fundamental rights expressed in our European laws and values are based on the concept of individual liberties. The right to life, physical integrity, freedom of movement, freedom of expression, education, employment etc. is in each case primarily the right of an individual person, and not of a group, nor the whole of society. Restrictions on individual freedoms—such as those applied during the COVID-19 pandemic—are therefore justified first and foremost to protect the rights of others, specifically their right to life and physical integrity, and sometimes they are even required, based on the government's duty to protect its citizens. Where there is a conflict between constitutionally protected legal rights and a “practical concordance” needs to be agreed, then generally speaking, the factors to be considered are

- the value of the affected constitutionally protected rights,
- the degree to which they are affected and
- the number of people affected.

Protected collective assets—such as “the health system,” for example—may also need to be balanced against individual rights and freedoms. However, these other collective interests are often regarded as a symbol of the constitutionally protected rights of a particularly large number of unidentifiable affected people, such as “the population,” or all those who may need medical care of any kind in the future. The fact that some rights are also genuinely collective—such as for instance the people's right to self-determination or to indigenous data sovereignty—is not denied, but this has no specific relevance for the debate on COVID-19 restrictions.

It is consistent with the understanding of individual fundamental rights that restrictions of these fundamental rights during the COVID-19 pandemic must be justifiable with regard to each affected individual. This means that the restriction of individual freedom must comply with the principle of proportionality, i.e. it must be appropriate and necessary for a legitimate purpose, and strictly proportionate. Thus any restrictions of individual freedom to curb the spread of COVID-19 must in principle be appropriate

such that every affected person is helping to achieve this containment, there must be no equally effective but milder measure available, and the measure selected must also be proportionate from an overall perspective and with regard to the expected outcome and the interests of all those involved.

This would be based on the theoretical assumption that for each individual it is determined as precisely as possible what risk that individual poses in view of his/her immunological status, in terms of the current scientific understanding, and that freedoms are only restricted to an extent that is appropriate to this individualized risk analysis. However, in practice this kind of individualized risk analysis has its limitations, particularly due to

- difficulties in determining individual levels of risk with sufficient reliability,
- difficulties in monitoring compliance with individually adjusted rules of behavior, and
- negative effects on the willingness of the population as a whole to comply with behavior rules (“demoralizing” effect).

Considerations like these need to be taken into account in assessing proportionality in the constitutional sense, for the criterion of necessity, and affect the outcome of that assessment. Furthermore, individualized risk analysis may also have limitations if it includes a residual uncertainty, but the specific situation (e.g. dealing with extremely vulnerable groups of people) makes a residual uncertainty unacceptable.¹⁶

A logical outcome of these considerations is that restrictions to freedom that are intended to curb the spread of COVID-19 not only can be revoked by the legislature, but indeed must be revoked, as long as there are no compelling practical arguments against doing so. The freedom of the individual is not an asset at the disposition of lawmakers, but a constitutionally protected right, which may only be encroached on within the limits defined in the constitution. Where an encroachment is not admissible, particularly because it would be disproportionate, the legislature has no room to maneuver—it must refrain from the encroachment. If the restriction of fundamental rights is shown not (or no longer) to be appropriate or necessary in the case of vaccinated persons or those who have recovered from infection, but remains appropriate for other people, the constitutionally admissible question is not whether the restriction on fundamental rights should be continued for all individuals.

16 European Law Institute, *ELI Principles for the COVID-19 Crisis, 2021 Supplement*, https://europeanlawinstitute.eu/fileadmin/user_upload/p_eli/Publications/2021_Supplement_to_the_ELI_Principles_for_the_COVID-19_Crisis.pdf (accessed April 13, 2021). Council of Europe, Protection of human rights and the “vaccine pass.” 31 March 2021, SG/Inf(2021)11, [https://rm.coe.int/protection-of-human-rights-and-the-vaccine-pass/1680a1fac4SG%20Inf\(2020\)7](https://rm.coe.int/protection-of-human-rights-and-the-vaccine-pass/1680a1fac4SG%20Inf(2020)7) (accessed April 13, 2021).

The question is instead, considering the principle of equality, whether there is an objective reason for partial continuation of the restriction with regard to people who have neither been vaccinated nor recovered from infection, and thus require differentiated rules. This objective reason might be based on the lack of protection for these individuals and especially the concern for protecting others, depending on the extent of protection conferred by vaccination or past infection. However, another factor to consider here is the option to use a recent negative COVID-19 test to minimize the risk of transmission. Certainly until vaccinations are available to all, and while far-reaching measures are still necessary to curb the pandemic, there is a strong argument for regarding a test (carried out with the necessary expertise) as equal in validity to a vaccination or recovery from infection, within the parameters of what is epidemiologically justifiable in terms of objectivity, because it gives the individual a way to achieve this equality. For this reason, it is important to examine whether it is scientifically acceptable to include self-testing as part of the testing strategy and if appropriate, this should be supported.

It should be noted in this context that the law concerning COVID-19 measures currently assumes a slight epidemiological risk in the case of a negative test result or a past infection with SARS-CoV-2, but not in the case of vaccination. However, if these are to be considered as equal in validity the principle of equality requires that this must apply for each of these options. If the law on COVID-19 measures regards a negative test result as sufficient grounds to revoke a restriction, then vaccinated people should also have equal rights to tested people, providing the risk of infection is reduced by vaccination or recovery from infection to a comparable extent. As already established by the Bioethics Commission in its Opinion of November 25, 2020, this can mean for example that going to restaurants or concerts, or staying in overnight accommodation, the use of sports facilities etc. where there are individual entry checks or where these can be arranged, must be allowed for people who have been immunized. The comparatively minor general requirements to keep a minimum distance and wear a face covering of a specific quality should on the other hand continue to be observed also by people who have been immunized, until they are revoked for everyone. For instance it would not be feasible to determine or check whether certain people in public places are exempt from wearing a face covering and maintaining physical distancing because they are immunized. This might then give rise to a “demoralizing” impression of incomplete compliance with the rules. In this kind of context, given the progression of the COVID-19 pandemic to date, it is also advisable to preserve a subjective feeling of safety for individual people, at least until vaccinations are generally available to everyone. In the Opinion of November 25, 2020, the Bioethics Commission explored in detail the question of how to prioritize access to vaccines in short supply; this is not materially relevant to assessing the proportionality of a restrictive measure as far as fundamental rights are concerned. Clearly this does not mean that this prioritization itself does not have to satisfy constitutional requirements. On the contrary, the principle of equality demands an objectively justified allocation of vaccines. Even if this did not proceed properly in every respect, it would not legitimize disproportionate government restrictions of freedom.

4 Ethical aspects

4.1 Justice and solidarity

From an ethical standpoint, considerations of justice and solidarity must in any society be principles which are also reflected in the configuration of political instruments and institutions. A fundamental aspect of justice in the present context is that of identical treatment in cases of equality and different treatment in cases where equality does not apply. In the present circumstances, this demands an answer to the question of which differences between different people constitute an objective justification for unequal treatment of these people.

An inequality is not necessarily also an inequity. In the ethical sense, discrimination has only occurred if one person is treated worse than another in a certain situation where there is no objective reason for this, particularly if this happens because of characteristics that are associated with discrimination. The objective reason in the present context comes from the differing levels of risk to other people. As a result—providing the effectiveness of a vaccination or previous infection is considered to be equivalent—there is inequality, but not discrimination, because the unequal treatment is objectively justified.

Solidarity means behaviors and actions people take in support of others with whom they feel an affinity on an issue of relevance. It is often structurally vulnerable and disadvantaged groups who need such support; but it can also be people and groups who are not inherently vulnerable or disadvantaged, but who need solidarity and support in a particular situation. Solidarity can be manifested on an interpersonal level or on the level of groups or may be expressed in institutional form (e.g. a public health system, financed by contributions from the public according to their means, and used by the public according to their needs).¹⁷ Solidarity, in the words of Jürgen Habermas, is “the reverse side of justice” (Habermas 1991); it is the human practice which is necessary to make justice a reality. In practice, solidarity often seeks to compensate for social, economic and other inequalities by raising the people in the worst position up to the level where action is taken. Solidarity is largely based on voluntary commitment and—at least indirectly—on reciprocity. (Every individual is an other to others.) Similarly, the freedom of others also implies recognition of my own freedom. Policymakers are responsible for providing the regulatory frameworks that make this possible and ensuring compliance with them. The general ethical principle of solidarity can admittedly hardly be reflected

17 17 Prainsack, B. and Buyx, A., 2016. *Das Solidaritätsprinzip: Ein Plädoyer für eine Renaissance in Medizin und Bioethik.* (The solidarity principle: a call for its rediscovery in medicine and bioethics.) Campus Verlag.

in constitutional law, but it is an important aspect of the activities and aspirations of civil society. These might for instance be described as aiming to establish a “decent society”¹⁸, in which fairness, goodwill and altruism towards all others are important ethical criteria. However, the fundamental rights guaranteed in the constitution, like all legal norms, exist within a broader social context. Their validity is not dependent on it, but their effectiveness is materially affected by it. A contributing factor in this context is the ethos with regard to the law, i.e. people’s attitude towards the law. Since the system of laws in a liberal constitutional democracy is understood as a system of freedoms, the ethos towards the law is reflected in how people use the freedoms they are guaranteed by (constitutional) law. This cannot be conclusively prescribed by law, but demands a sufficient level of responsibility on the part of all those to whom the law applies.

This aspect has become abundantly clear over the past year: regulations to protect public health need this level of shared responsibility if they are to be sufficiently effective. Otherwise there is a risk not only of insufficient compliance, but also, as a consequence, an erosion of trust in legal certainty. For this reason, from an ethical standpoint it is to encourage a sense of responsibility towards legal regulations both when it comes to restrictions of fundamental rights and the restoration of fundamental rights and freedoms. To this end it is e.g. important to strengthen public understanding of health issues, so that people can take a differentiated approach towards risks; and to raise awareness of the requirements for solidarity within society.

Policymakers have a wide range of tools at their disposal to strengthen collective responsibility towards legal norms. Above all, during the pandemic, the government can encourage solidarity with individuals and groups which are particularly badly affected by the pandemic and the broadly-based efforts to curb it. In this context it is important to consider the wide-ranging social repercussions of the pandemic, which have affected different groups of people to a varying extent. Children, young people and young adults have frequently had to forgo contact with their peers, and have missed out on normal vocational, school or university education. People of all ages have experienced loneliness or anxieties about their livelihood.

Women are especially affected by multiple burdens during the pandemic; they do the majority of unpaid additional work and are more frequently affected by job losses. For people with disabilities, although specific programs and occupational support have been increased, they in particular have experienced the stresses of the pandemic. People who depend on direct or tactile forms of communication, and those living alone are particularly isolated during the pandemic, over what is now a very long period. Similarly, families living in confined apartments—and in general, people at the lower end of the income and wealth pyramids—are faced with particularly intense mental and social challenges. These and other effects of the COVID-19 pandemic should be given special attention, in the view of the Bioethics Commission. They should be minimized as much as possible, and counterbalanced by targeted positive measures. A list of measures devised

18 Avishai Margalit, *The Decent Society*, *Ethics* 107 (4):729-731 (1997).

to address these issues can be found in the recent report by Michael Marmot, “Build Back Fairer”¹⁹: they range from short-term immediate measures such as the expansion of free childcare, and medium-term measures such as the expansion of social housing, to long-term measures to combat poverty in a sustainable way.

However, it seems important to distinguish between actions taken in solidarity from those expressing a connection with other people without effectively improving their situation. If a person who has been vaccinated or who has recovered from infection consciously relinquishes their own freedom, this does not improve the situation of someone who has not yet been immunized. Since our actions are generally not purely one-dimensional in effect, the question is whether this denial of freedom might not even have negative consequences for others. From an ethical standpoint these may be particularly significant. For instance, if a vaccinated person does not visit his/her mother or grandmother in a care home and spend time with her, this has a negative consequence especially for the relative who remains isolated and continues to be deprived of the benefit of human contact and warmth, which is even more significant when there is a limited lifespan ahead. Here and in many other comparable instances, sacrificing that freedom might prolong loneliness and social isolation without this being epidemiologically necessary. Consideration should also be given in a general sense to business people and those working in the cultural and creative sector whose livelihood is endangered by this kind of restraint, or who will otherwise remain completely dependent on government support, with no epidemiological rationale for this.

4.2 The desire for “immunological equality”

It is in keeping with the constitutionally established principle of non-discrimination, and a general ethical principle, that society strives to counterbalance individual disadvantages – for instance as a result of individual health circumstances— as far as possible, and to enable as many members of society as possible to have access to essential resources and to be able to participate in key aspects of life. This idea is also the basis of all obligations for accessibility, according to which any obstacles to access for certain people, which could reasonably be avoided, should as far as possible be removed, even if this results in additional costs for the general public.

This leads—especially until vaccination against COVID-19 is generally available, and with regard to people who for health reasons cannot be vaccinated—effectively to both an ethical and a constitutional obligation, firstly to offer free and easily obtainable testing to those who are not yet immunized, and secondly, to revoke the restrictions for those with a recent negative test result, to a similar extent, although for a limited period

19 <http://www.instituteofhealthequity.org/resources-reports/build-back-fairer-the-covid-19-marmot-review/build-back-fairer-the-covid-19-marmot-review-executive-summary.pdf> (accessed April 13, 2021).

(e.g. for 24 hours), as for people who have been vaccinated or who have recovered from infection. It must also be ensured that no one—regardless of whether or not they are vaccinated, tested, or have recovered from infection—is prevented from meeting their basic needs. Targeted support may be needed for vulnerable groups (e.g. pregnant women, children and young people, people with disabilities and diseases which exclude them from immunization).

The Bioethics Commission therefore recommends that in addition to vaccination and recovery from infection, a negative test should be accepted as a reason for exemption from restrictions, at least until the point where vaccinations are generally available to all. Any deviation from this equal status of vaccination, recovery from infection and a negative test result should only be made for epidemiologically compelling reasons. It should also be kept in mind that there will probably still be no approved vaccine for children and young people under 16, even when vaccinations are freely available for other people. For young people in particular, an easily obtainable test, such as is currently in use in schools, should make it possible for them to be on an equal footing with vaccinated persons and those who have recovered from infection. This is even more important because the members of one family may have completely different immune status, depending on the government prioritization of vaccinations, the unpredictability of infection, and the availability of vaccinations to people under 16. The option of a test will therefore also be significant in enabling families to exercise their freedoms together (such as going to the theater or a restaurant).

In addition, it remains important to reconsider on an ongoing basis whether the vaccination coverage achieved has reduced the threat to the health system to a sufficient extent that certain restrictive measures can be lifted for everyone, or should be waived from time to time.

The earliest possible easing of restrictions for vaccinated persons and people who have recovered from infection, and—on a temporary basis—for people who have tested negative, is beneficial not only to those affected. It is also advantageous to society in general, because this allows the return to normal activity to be accelerated in many areas (including cultural activities, sport and restaurants), which has a positive impact and also reduces the need for government support measures in these areas.

4.3 Concerns about immunological discrimination or stigmatization

As already mentioned earlier, based on the assumptions of relevance here, unequal treatment of vaccinated persons or those who have recovered from infection on the one hand, and those who are not yet immune, on the other, does not constitute discrimination against the latter. Certainly from time to time—particularly in the public debate in Germany—there have been attempts not only to elevate a person's vaccination status to the same kind of level as gender or ethnic background, for instance, treating it as an

unacceptable basis for discrimination, but also even to establish a comprehensive rule that this factor may not be considered (similar to the principle that gender may not be considered when applying health insurance tariffs, even if one specific gender—e. g. in connection with pregnancy and childbirth—statistically speaking does in fact generate higher costs). This kind of exclusion above and beyond the principle of non-discrimination is however an absolute exception in our system of laws and values, because in itself it tends to lead to discrimination against the very group of people who—from an objective standpoint—would be in a better position without that exclusion. In other words, if the vaccination or recovery status of a person were subject to an exclusion rule, this would result in discrimination against vaccinated people and those who have recovered from the virus, as they would be subject to a restriction of their freedom, for no objective reason, which in this individual case goes far beyond what is specifically necessary. The price of disregarding this factor would be restriction of freedoms. The government certainly has no right to exact this price.

4.4 Concerns about indirectly mandatory vaccination

Naturally if restrictions are eased for people who have been vaccinated, this will create additional incentives for vaccination. Even if some individuals might feel they are being forced to be vaccinated in order to obtain exemption from restrictions themselves, this is not relevant to any evaluation in terms of fundamental rights or ethical considerations. The line beyond which vaccination is effectively compulsory would only be crossed if non-vaccinated people were prevented from meeting their fundamental basic needs, as they are typically defined for obligatory contracting, and which also have remained available even during “lockdown” (certain social contacts, public transport, supermarkets, pharmacies, outdoor exercise and more). Alternative pathways, such as the possibility of obtaining time-limited exemptions from restrictions with a negative test result for SARS-CoV-2 infection, must also be considered. Ultimately the situation for non-vaccinated people is not made any worse by the fact that other people are in a better position—at best they also benefit indirectly from the fact that increasing vaccination coverage in the population as a whole will (and must) result in earlier easing for all.

The Bioethics Commission also reiterates the position presented in its Opinion of November 25, 2020, to the effect that a general mandatory vaccination (currently) cannot yet be recommended, although in certain sensitive areas (e.g. hospitals, care homes) vaccination may be necessary as an occupational prerequisite in some professions, and should possibly also be introduced—on the basis of Section 17 (3) of the 1950 Epidemics Act.²⁰

20 Gazzetta Ufficiale della Repubblica Italiana, Anno 162° – Numero 79, Giovedì, 1° aprile 2021, <https://www.gazzettaufficiale.it/eli/gu/2021/04/01/79/sg/pdf>, pag. 3–4 (accessed April 13, 2021)

5 Dealing with uncertainty

In the light of the considerations above, the question arises as to how the existing medical uncertainty should be dealt with (see also Chapter 2, p. 5). We do know that all vaccines currently approved in the EU for use against COVID-19

- a. reduce the viral load, i.e. the lab parameter for the transmission capacity or infectiousness of a patient, and consequently
- b. can interrupt the spread, as well as
- c. prevent symptomatic and severe cases.

However, we do not yet know the specific extent and duration of this protection. Although we already know at what point in time protection commences after recovery from the disease or after vaccination (see Chapter 2, p. 5), the duration of this protection is not yet clear for any given case, or if this is different after

- a. vaccination or recovery from infection
- b. in turn for the original (“wild”) type of the SARS-CoV-2 virus or known virus mutations.

It is hoped that with regard to all these factors robust scientific results will be available in the foreseeable future (see also paragraph 2). These will come from further data gathering and evaluation of the global vaccination programs, and especially from the “human challenge” studies which began in the UK in March 2021, and which offer the prospect of fundamental information about the immune system and transmission of the virus.²¹ Nonetheless, uncertainties remain with regard to the emerging virus mutations. It should be also assumed that for every variant that evolves, we can only anticipate scenarios in terms of probabilities, such as for instance the assertion that a vaccinated person with specific characteristics or under specific conditions will no longer be able to transmit specific variants of the virus to other people, with a specific probability of X.

Because of the personal protection against severe cases which vaccination provides it will initially be necessary to revoke restrictions universally, i.e. for everyone, as soon as scientifically credible modeling of the cumulative effect of partial immunization indicates that there is no longer any danger that the health system will collapse. An argument for this is the fact that saving life is not absolute from either a constitutional standpoint or an ethical one, i.e. individual cases of the disease must be accepted, when a further reduction of disease figures can only be achieved at the cost of significant

21 Abi Rimmner, Sixty seconds on ... human challenge trials, *BMJ* 2021;372:n515 <http://dx.doi.org/10.1136/bmj.n515> (accessed April 13, 2021).

restrictions on freedom and risks to the mental health of additional segments of the population. This does not mean, however, as already mentioned (Chapter 2, p. 5) that an existing residual risk of infection of non-vaccinated people is acceptable in every case. For instance, in sensitive areas (e.g. hospitals and care homes), at least until vaccinations are generally available, restrictions will still be necessary if it can be assumed that vaccination gives a high but not complete protection against transmission of the virus. From an ethical perspective it also seems desirable to pay particular attention to protecting people who for health reasons cannot be vaccinated. This might be for example by taking appropriate organizational measures in the institutions concerned. The Bioethics Commission reiterates that this protection is assisted by the uptake of vaccination when offered amongst the staff of such institutions.

From the perspective of fundamental rights however, restrictions of freedoms should in any case be lifted sooner in those individual cases where, on the basis of available evidence (see paragraph 2), the probability can be assumed that there is a significantly reduced risk of further transmission of the virus by those people (who have been vaccinated or who have recovered from infection). General availability of vaccinations can in this context only be a relevant perspective if the (time-limited) exemption from restrictions of freedoms cannot be achieved on an equal basis by testing for infection with SARS-CoV-2. The Bioethics Commission has already emphasized the importance of keeping the test option in place, certainly at least until vaccinations are generally available.

6 Criteria for implementation (“green pass”)

Easing restrictions of freedom for immunized persons depends on a form of certification with which these people can verify their immunity on a case-by-case basis. In the view of the Bioethics Commission a simple system should be established for the specific form of this certification, which is easy to handle and avoids unnecessary obstacles—especially from a technical point of view—both for those needing to provide verification, and for the bodies or individuals with permission or obligations to check this verification, and which does not expose any personal details that are not necessary for these checks. The Bioethics Commission therefore recommends that in the case of a general digital implementation, there should also be an analog alternative. In the event, as currently proposed, that the European Union introduces an EU-wide form of verification (digital green certificate—a “green pass”),²² the forms of verification issued in Austria should be compatible with this. One crucial aspect, in view of potentially very dynamic medical and epidemiological developments, seems to be adequate flexibility in the system. For example, extending the validity of the verification as a result of new insights into the duration of vaccine protection should be as simple and automated as possible.

With regard to the evaluation of a digital system of verification and public debate on this topic, data protection considerations are regularly mentioned as foremost concerns. The details used to verify vaccination or past infection are health data as defined by Article 9 (1) of the General Data Protection Regulation (GDPR). The GDPR applies enhanced requirements to processing this kind of data. It will be necessary to establish the appropriate legal basis in compliance with Article 9(2)(i) of the GDPR. Compliance with data protection requirements, particularly the principle of data minimization, should already be largely ensured by the design of the verification system. Here it should also be considered whether a compulsory online check is necessary for every use of such verification certificates, or whether offline methods of verification— analog

22 Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate) (Text with EEA relevance), COM(2021) 130 final, dated March 17, 2021, EUR-Lex - 52021PC0130 - EN - EUR-Lex; Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate), COM/2021/140 final dated March 17, 2021, EUR-Lex - 52021PC0140 - EN - EUR-Lex (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/covid-19-digital-green-certificates_en) (accessed April 13, 2021).

or digital—are also an option, which in the view of the Bioethics Commission would clearly be preferable.

The requirement for implementation of a verification system which complies with data protection regulations does not however mean that—providing any questions with regard to preventing misuse of the data processed (e.g. for surveillance purposes) and to data security are resolved—a digital solution should be avoided for reasons of data protection. On the contrary, the Bioethics Commission assumes that the necessary flexibility of the system can be better achieved using a digital format.

7 Recommendations

In summary, the Bioethics Commission makes the following recommendations to the Austrian federal government:

1. Over the coming months, the highest policy priority should be making sufficient vaccine available as quickly as possible to enable anyone who wishes to be vaccinated to be offered a suitable vaccine free of charge as soon as possible. This requires—particularly in the light of previous experiences—finalizing the necessary contracts now to ensure that the EU and Austria will have sufficient access to modified vaccines as soon as there are indications that the vaccines currently on order are ineffective or significantly reduced in effectiveness against emerging mutations.
2. As soon as partial immunization of the population and the cumulative effect of vaccinated people (i.e. protection against infection or at least against severe cases) and a certain level of transmission prevention (i.e. protection against the capacity to infect others) together mean that there is no longer a risk that the health system could break down, the potential for infection of some individuals no longer justifies keeping measures in place that restrict their freedom.
3. To the extent that scientific analysis shows it is probable that one individual person cannot or can no longer transmit the COVID-19 virus on an epidemiologically significant scale, from a constitutional perspective any government measures which restrict the freedom of that person should in principle already be revoked before the point in time specified in recommendation 2. This results from the fundamental rights of the individual, which only allow restrictions with due regard to the principle of proportionality.
4. The constitutional obligation to revoke restrictive measures for individuals is necessarily limited by
 - a) practicability, particularly if an estimate of the specific epidemiological risk is either not possible with a reasonable effort, or if the circumstances in a specific situation cannot be controlled by reasonable effort;
 - b) by anticipated negative effects on compliance with the regulations by others (“demoralization”), particularly if the restrictions relate not to clearly definable activities and contexts, but to general rules of distancing or wearing a face covering; and
 - c) by a heightened need for protection, particularly where contact with highly vulnerable and non-immunized people is concerned.
5. There is also no compelling argument for the proposition that differentiation according to a person’s immunological status constitutes unacceptable discrimination, or that consideration of a person’s state of health to determine freedoms or

restrictions is not compatible with the principle of human dignity. This kind of strict exclusion of immunological status as a determining factor is foreign to our laws and values, which accept that objectively substantiated differentiations can also be linked to personal characteristics that individuals have not sought for themselves.

6. However, the effort to ensure equal access to essential resources and opportunities for participation is an expression of constitutionally established anti-discrimination rules and other provisions. Equal access in the present context means that
 - a) meeting basic needs and being able to access essential public services (e.g. certain social contacts, public transport, supermarkets, pharmacies, outdoor exercise) must not be dependent on immunological status; and
 - b) also that non-immunized people must as far as possible be given options for obtaining at least time-limited exemption from restrictions to a comparable extent as for immunized people. To make this possible, easy-access options for testing should be expanded further in both urban and rural areas.
7. Individual exemption from restrictive measures is simply a step on the way back to normal life, and not a “privilege” for immunized people, although it may be seen as such by some individuals due to the (as yet) limited availability of vaccinations. In our system of laws and values, freedom (of movement, to congregate, of employment etc.) is not a gift of the state, which would then need to allocate it to individuals according to aspects—however determined—of distributive justice. The fact is instead that the state may only restrict fundamental freedoms if and in so far as this is necessary to achieve a legitimate goal that is also (at least indirectly) constitutionally protected, and that it is proportionate in the narrower sense. Conversely, the continuance of restrictive measures for non-vaccinated people must be objectively justified and proportionate—particularly with due regard to the rate of vaccination coverage and the related positive consequences for protection of the health system. The possibility of obtaining parity with vaccinated people by using easily available tests is therefore particularly important until vaccinations are generally available for everyone.
8. This does not change the fact that here it is primarily the government that, by deciding priorities for the order in which vaccinations are given, also indirectly decides which individuals will be able to regain certain freedoms ahead of others. The fact that this prioritization must follow strictly objective criteria, as emphasized by the Bioethics Commission in its Opinion of November 25, 2020, is a separate issue. Regardless of whether previous prioritizing decisions or actual vaccinations carried out have satisfied all the requirements for objectivity in detail or not, it would be ethically unacceptable to keep restrictions in place for priority groups of people while recognizing severe personal disadvantages (e.g. loneliness in the last days of life, depression, loss of relationships, increased domestic violence), just in order to compensate for these groups’ advantages, which may perhaps not be entirely objective.

9. Solidarity and social justice are amongst the most important cornerstones of an ethically guided fight against the pandemic, and must be safeguarded and strengthened. Not every action which is intended by the person concerned as an expression of their solidarity with other people, leads to an actual improvement in the position of those other people. If for instance someone relinquishes their personal freedom as a way of expressing their solidarity with those who are not yet vaccinated, this does not solve the problem for the latter. Although such expressions of solidarity are important for the cohesiveness of a society, this problem can only be resolved by other strategies, such as a speedy vaccination program and an adequate supply of vaccine. Even if people cannot be forced into this kind of solidarity, any vaccinated or otherwise immunized person must of course be free to express their bond with other people by voluntarily relinquishing their freedom.
10. The earliest possible easing of restrictions for people who present only a slight epidemiological risk, is of benefit not only to these people themselves. It is also advantageous to society in general, and thus also indirectly for all other groups of people, because this accelerates the return to normality in many areas (culture, sport, restaurants). This has positive effects for the people affected by the restrictions and tends to reduce the economic stress for the general public, which in turn is in particular of benefit to socially disadvantaged groups.
11. It would be a mistake to only start easing restrictions for immunized people when it is shown without doubt that an immunized person cannot transmit the COVID-19 virus. This will never be possible as an absolute certainty, especially as every immunization only offers a certain probability of protection, and may depend on virus mutations. Generally speaking, in other contexts the absence of absolute proof that a person presents no risk to society cannot be used to justify drastic restrictions of this person's freedom.
12. In care homes in particular the drastic restrictions that are still in place with regard to visiting and participation in social life together are not justified and must be lifted as speedily as possible after vaccinations have been given, to ensure that people who over recent months have suffered particularly severely from isolation and separation, and generally speaking have a shorter lifespan ahead, are able again to join in social activities to the fullest possible extent.
13. A system for verification of vaccination or past infection should be simple—particularly from a technical point of view—and easy to use, both for those providing the verification and for the bodies and individuals authorized to check them, compatible with any system introduced at EU level, and have the capacity to respond to dynamic medical and epidemiological developments. As far as data protection is concerned, it will be necessary to establish the appropriate legal basis in compliance with Article 9(2)(i) of the GDPR. Compliance with data protection requirements, especially the principle of data minimization, the prevention of data misuse, and data security should already be largely ensured by the design

of the verification system, for example by ensuring priority is given to offline methods of verification. The requirement for a solution which complies with data protection regulations does not however preclude a digital verification system.

14. Verification of immunity conferred by vaccination or by past infection with SARS-CoV-2 should only be required for as long as this is justified by infection activity, and the risk to vulnerable people and the health system. Otherwise there is a danger that this kind of certification will become a permanent arrangement.

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