

Ethical questions about vaccination against COVID-19

Opinion of the Bioethics Commission

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Contents

Preamble	5
1 Current situation	5
2 Allocation of a COVID-19 vaccine in a situation of (temporary) shortage	7
a. Medical-epidemiological and pharmacological principles and other conditions relating to prioritization.....	8
b. Legal aspects of prioritization.....	9
c. Ethical aspects of prioritization.....	11
d. Conclusions.....	15
3 COVID-19 vaccination—voluntary choice and its limits	16
a. General observations on “mandatory vaccination”.....	16
b. Vaccination against COVID-19 as a prerequisite for carrying out specific professional activities.....	16
c. Mandatory vaccinations against COVID-19?.....	17
4 Free vaccination and state monitoring of distribution	18
5 Impact of individual vaccination status on the exercising of fundamental rights during the pandemic	18
6 Supporting measures	19
a. Information, transparency, motivation—vaccination campaign.....	19
b. Recording of side effects.....	20
7 Recommendations of the Bioethics Commission	20
Members of the Bioethics Commission for the 2017 to 2020 term	23

Preamble

The COVID-19 pandemic is probably the greatest challenge to our healthcare system, our economy and our society since the founding of the Second Republic. Hopes for rapid, natural community immunity, as was viewed by some even as a primary strategy for combating the pandemic, have now been largely dashed. For some time, hopes have therefore been placed on the development of an effective medication that reduces the need for hospitalization and, in particular, intensive care or on the creation of an effective vaccine against COVID-19. The latter now appears to be within reach. The Bioethics Commission at the Federal Chancellery therefore considers it necessary to issue an opinion addressing some of the questions arising around the introduction of vaccines against COVID-19.

This Opinion is understood as a consistent continuation of a series of Opinions issued by the Bioethics Commission on similar topics, specifically in June 2015 on ethical aspects of vaccination in general,¹ in May 2019 on mandatory vaccinations against measles,² in March 2020 on the allocation of scarce resources during the COVID-19 pandemic,³ in June 2020 on promoting active prophylactic vaccination against specific diseases correlating with COVID-19,⁴ and again in October 2020 on supplying the influenza vaccine to the public.⁵

1 Current situation

Of the current 260 vaccine candidates, 56 are in clinical testing, 24 of these are in Phase I, 17 in Phase I/II, 4 in Phase II and 11 in Phase III.⁶ Among the vaccines that have already been tested in Phase III, three candidates are being evaluated in the accelerated rolling review process, in which the Committee for Human Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) is assessing the study data provided with regard to the quality, effectiveness and safety of the products.

1 Bioethics Commission, Vaccination—Ethical Aspects, June 1, 2015, this and the documents mentioned in footnotes 3 to 5 can be downloaded from <https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html>.

2 Bioethics Commission, <https://www.bundeskanzleramt.gv.at/themen/bioethikkommission/pressemitteilungen-bioethik/stellungnahme-der-bioethikkommission-zum-impfen.html>, May 19, 2019.

3 Bioethics Commission, Management of scarce resources in healthcare in the context of the COVID-19 pandemic, March 31, 2020.

4 Bioethics Commission, Vaccination against diseases for which there are approved vaccines in times of the COVID-19 pandemic, June 8, 2020.

5 Bioethics Commission, Influenza vaccine supply for the Austrian population in the 2020/21 season, October 19, 2020.

6 As of November 16, 2020, according to Covid vaccine landscape, London School of Hygiene & Tropical Medicine, https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ (accessed on November 19, 2020).

The associated regulatory and documentation steps (but not including the clinical trial phases) have been accelerated to require only 150 days instead of the usual 210 days.⁷ As such, the approval of the first vaccines is expected toward the end of the year. Four of the most successful producers thus far published their study protocols in September to comply with the call for maximum transparency.⁸ A number of questions remain open, such as that the current trial procedure cannot say anything about protection against severe progressions during an infection. On the other hand, this early opening of the study protocols is unprecedented and creates an opportunity to bring external expertise into the vaccine development process at an earlier point in time rather than only after publication of the study results.⁹

Women are still underrepresented in clinical studies in general, with the consequence that gender-specific reactions to medical interventions often remain unknown and/or are not systematically investigated. The share of women among the trial subjects for the new vaccines against COVID-19 cannot be determined from the sparse information currently available, and the few smaller studies that have been published to date provide no data disaggregated by gender. However, it appears that the research institutions carrying out the work are striving to include a representative cross-section of the population in the Phase III clinical trials. (According to Pfizer,¹⁰ at the 150 trial locations to date, 42% of the global participants and 30% of the US participants have been ethnically mixed, while about 41% and 42%, respectively, were in the age group of 56–85 years).

The vaccines farthest along in the approval process are BNT162b2 (Pfizer / Biontech), mRNA-1273 (Moderna) and ChAdOx1-Sars-CoV-2 (Astra Zeneca / University of Oxford). The first two products use a concept originally developed for cancer immune therapy but also for other vaccines. In contrast to typical vaccines, which make use of inactivated or weakened living viruses, for example, RNA vaccines utilize messenger RNA molecules (mRNA), embedded in lipid nanoparticles that code for Sars-Cov-2 surface proteins. In the body of the vaccinated individual, these mRNA sequences are translated into the corresponding protein, which the immune system recognizes as an antigen and forms antibodies against it.¹¹ This concept relies on the assumption that the vaccinated

7 Interview with Christa Wirthumer-Hoche, Der Standard, November 18, 2020, p. 4; Covid-19 Guidance for medicine developers and other stakeholders on COVID-19, EMA, at: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirusdisease-covid-19/guidance-medicine-developers-other-stakeholders-covid-19#acceleratedprocedures-for-covid-19-treatments-and-vaccines-section> (accessed on November 19, 2020).

8 Doshi P, Covid-19 vaccine trial protocols released, BMJ 2020;371:m4058, doi: <https://doi.org/10.1136/bmj.m4058> (Published October 21, 2020) (accessed on November 19, 2020).

9 Doshi P, Covid-19 vaccine trial protocols released, BMJ 2020;371:m4058, doi: <https://doi.org/10.1136/bmj.m4058> (Published October 21, 2020) (accessed on November 19, 2020).

10 <https://www.pfizer.com/science/coronavirus/vaccine>

11 Walsh EE et al., Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates, N Engl J Med 2020 Oct 14; <https://doi.org/10.1056/NEJMoa2027906>; Jackson LA et al. An mRNA Vaccine against SARS-CoV-2—Preliminary Report. N Engl J Med 2020; 383:1920-1931 (Nov 12, 2020); <https://doi.org/10.1056/NEJMoa2022483>.

mRNA itself is then decomposed like other endogenous mRNA and does not remain within the body or become integrated as genome. On the other hand, the vaccine being developed by the University of Oxford in cooperation with Astra Zeneca is known as a viral vector vaccine. This means an adenovirus vector that is incapable of replication is used as a vehicle for the Sars-Cov-2 spike protein.¹² The European Commission has signed purchase agreements for the vaccines from Astra Zeneca / University of Oxford, Pfizer / Biontech, Janssen (Ad26.COVS, adenovirus vector vaccine, Phase III) and Sanofi / Glaxo Smith Kline (consisting of a viral S-protein in a baculovirus expression system, which has been used successfully in the production of influenza vaccines, Phase I/II) and is in negotiations with CureVac (CVnCoV, mRNA, Phase II) and Moderna.¹³ Other vaccine candidates in Phase III trials are using selected antigens of the Sars-Cov-2 spike protein, inactivated Sars-Cov-2 viruses and other adenovirus vectors. In addition, a number of other vaccine candidates are in testing that make use of, for example, replicating viral vectors, virus-like particles or DNA (virus protein-encoding sequences that are translated into mRNA in the cell nucleus).¹⁴

2 Allocation of a COVID-19 vaccine in a situation of (temporary) shortage

Upon availability of a vaccine (or multiple vaccines) against COVID-19, a situation could arise in which demand for the vaccine at least temporarily exceeds the supply of available vaccine. Such a situation is conceivable even if the total number of vaccine doses secured by the Republic of Austria exceeds the number of persons willing to be vaccinated. Both the simultaneous procurement of several million doses of vaccine and the thorough vaccination of the willing population pose tremendous logistical challenges, and delays are to be expected.

In such a situation of at least temporary shortage, clear standards must exist for prioritizing specific people and groups of people that are based on medical, ethical and legal considerations.

12 Van Doremalen N et al., ChAdOx1 nCoV-19 vaccine prevents SARS-CoV-2 pneumonia in rhesus macaques. *Nature* 586, 578–582 (2020). <https://doi.org/10.1038/s41586-020-2608-y>.

13 Press release of the European Commission, November 11, 2020, Coronavirus: Commission approves contract with BioNTech-Pfizer alliance to ensure access to a potential vaccine, https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2081 (accessed on November 19, 2020).

14 Covid vaccine landscape, London School of Hygiene & Tropical Medicine, https://vacshtm.shinyapps.io/ncov_vaccine_landscape/; summary in Fischer L et al. Zwei moderne Impfstoffe sind fast am Ziel [Two modern vaccines are almost ready], *Zeit online*, 17 Nov 2020, <https://www.zeit.de/wissen/gesundheit/2020-08/impfstoffentwicklung-corona-impfstoff-klinische-phasen-forschung> (accessed on November 19, 2020).

a. Medical-epidemiological and pharmacological principles and other conditions relating to prioritization

The ethical and legal evaluation of prioritization decisions depends significantly on the underlying medical-epidemiological framework. One particular difficulty in this regard lies in the fact that it is not yet clear which vaccines will be available when and what properties they will have. Another difficulty is that when the first vaccine or vaccines become available, there will not yet be a long-term history of experience with them. The latter issue applies to the applications covered by the approval decision but even more so in the area of off-label use that goes beyond the usage envisaged by the approval.

From a medical-epidemiological perspective, it is therefore initially important to assess the impacts of a vaccination for a specific person willing to be vaccinated and that person's environment. Above all, the following factors must be considered:

- the extent to which the person will be protected by a vaccination against subsequent infection;
- whether the vaccine actively protects the person against contracting the disease and simultaneously hinders the spread of the pathogen or whether it merely prevents the vaccinated person from suffering a severe case of the disease;
- the severity of the risks that the person in question and third parties would face from an infection with COVID-19;
- the severity of the risks and side effects (vaccine complications) for the person in question that may be associated with the vaccination against COVID-19.

In general, a medical-epidemiological perspective calls, firstly, for weighing the benefits and risks to the person in question and, secondly, for weighing the risks to the person in question against the epidemiological benefits for third parties and the overall population.

Because of the extent to which a prioritization depends on the pharmacological properties of the vaccines (which are not yet fully known at this time) and other still unknown framework conditions, prioritization strategies formulated at the current time are either necessarily vague,¹⁵ highly simplified¹⁶ or extremely differentiated and complex in

15 Examples include the previous recommendations of the European Commission; see for instance European Commission, Communication of 15 October 2020 from the Commission to the European Parliament and to the Council, Preparedness for COVID-19 vaccination strategies and vaccine deployment, COM(2020) 680 final (accessible at https://ec.europa.eu/health/sites/health/files/vaccination/docs/2020_strategies_deployment_en.pdf); European Commission, Coronavirus vaccines strategy (accessible at https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/coronavirus-vaccines-strategy_en#possible-priority-groups, accessed on November 22, 2020) or the US Centers for Disease Control and Prevention, see CDC, How CDC Is Making COVID-19 Vaccine Recommendations, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html> (accessed on November 22, 2020).

16 One example would be the joint position paper of the Standing Committee on Vaccination, the German Ethics Council and the German National Academy of Sciences Leopoldina on

how they take the various scenarios into account.¹⁷ In order to present a prioritization strategy with an absolutely sound ethical foundation, one would have to follow the example of the WHO and proceed in three steps by initially identifying the key criteria and value weightings and abstractly weighing these against each other,¹⁸ then developing a more specific prioritization strategy in a second step,¹⁹ followed by a third step of issuing final recommendations concerning each approved vaccine separately, taking into account its specific pharmacological properties.

As can be seen in the work of the WHO presented to date, prioritization decisions based on pharmacological properties of the vaccines (in particular whether vaccinations prevent the infection of others or which groups of people are covered by the approval) and other conditions (in particular: actual vaccination capacities, the epidemiological situation, willingness to be vaccinated) are quite complex since they need to differentiate between the many different constellations. While the Bioethics Commission certainly recognizes the need for careful differentiation, it also sees the need for the Republic of Austria to already have relatively simple, communicable and also rapidly implementable recommendations. In particular, the Bioethics Commission will require that the available vaccines lead to at least a significant reduction in the risk of vaccinated persons infecting others (even if this cannot be entirely ruled out).

b. Legal aspects of prioritization

Any prioritization in the distribution of scarce vaccination capacities must first of all be in accordance with applicable legislation. Where measures require a legal basis, such a legal basis must be established in good time.

the ethical, legal and practical framework from November 9, 2020, accessible at <https://www.ethikrat.org/en/press-releases/2020/recommendations-for-fair-and-regulated-access-to-a-covid-19-vaccine/?cookieLevel=accept-all&cHash=f2351a17f4a87c493d98f6e46824b770>.

- 17 Another example is from the National Academies of Sciences, Engineering, and Medicine. 2020. Framework for Equitable Allocation of COVID-19 Vaccine. Washington (DC): The National Academies Press. Accessible at <https://doi.org/10.17226/25917> or <https://www.nap.edu/catalog/25917/framework-for-equitable-allocation-of-covid-19-vaccine>; Toner E, Barnill A, Krubiner C, et al. Interim Framework for COVID-19 Vaccine Allocation and Distribution in the United States. Baltimore, MD: Johns Hopkins Center for Health Security; 2020, accessible at https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200819-vaccine-allocation.pdf.
- 18 WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination (14.09.2020), accessible at https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?sequence=1&isAllowed=y.
- 19 WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply (November 13, 2020), accessible at https://www.who.int/docs/default-source/immunization/sage/covid/sage-prioritization-roadmap-covid19-vaccines.pdf?Status=Temp&fvrsn=bf227443_2&ua=1.

Importance of the scope of a vaccine's approval with respect to its application

From a legal perspective, the specific content and scope of a vaccine's approval according to the EU Medicinal Products Regulation (EC) 726/2004 is of initial relevance to the prioritization. The approval is issued under the prerequisite that the quality, safety and efficacy of the vaccine have been sufficiently demonstrated. However, it generally does not apply universally. Depending in particular on the groups of persons included in the three phases of clinical studies prior to the approval process, it generally contains conditions and restrictions on the use of the vaccine (Art. 9 (4)(b) and (c) of the EU Medicinal Products Regulation). The Bioethics Commission is not currently in a position to foresee which groups of persons the approval may be restricted to.

Use of the vaccine beyond the scope of the approval cannot be fundamentally ruled out. In fact, Section 7 (1) Austrian Medicines Act (AMG), Federal Law Gazette 185/1983, as amended by Federal Law Gazette I 110/2012, only permits the sale of medicines (including vaccines) if they have an Austrian approval or an approval according to the EU Medicinal Products Regulation. According to the letter and the objective of the AMG, however, this is relevant only for the sale or provision of medicines as covered by the AMG; the administration to an individual as such (by a physician) does not require approval.²⁰ From the outset, however, off-label use should only be considered with a secure scientific basis and after appropriate clarification.²¹

Fundamental rights and equal treatment

If vaccines are allocated by the regional authorities (or their agencies and other institutions) (see in particular Section 57 (1) clauses (5a) and (5c) and clauses (6), (6a), (7) and (8) AMG), any prioritization requires a substantive legal justification—if for no other reason than the principle of equality (Art. 7 (1) Federal Constitutional Law). The fundamental right to life (Art. 2 ECHR) means a positive obligation on the part of public stakeholders to ensure balanced allocation of scarce medical resources.²² The organization of the allocation and prioritization by the state must have a corresponding legal basis—at least when non-state entities are to be involved in the distribution. In that case the Federal Minister of Health would need to issue an ordinance based on Section 94d AMG or on an explicit legal basis yet to be established.

20 See Kopetzki C, Off-label-use von Arzneimitteln [Off-label use of medicines], in FS B. Raschauer [2008] 73 [76 ff]; also Mayrhofer M, Off label use von Analgetika in der perioperativen Kinderschmerztherapie aus rechtlicher Sicht [Off-label use of analgesics in perioperative pediatric pain therapy from a legal perspective], *Der Schmerz* 2014, 65 (65).

21 For more on these prerequisites, see Kopetzki C, Off-label-use, 92 ff; Mayrhofer M, Off label use, 66.

22 See Kopetzki C in Korinek K, Holoubek M et al, Commentary on Austrian Federal Constitutional Law II/1 (5th supplement 2020) Art. 2 ECHR marginal note 76; Kneihls B in Kneihls B / Lienbacher G, Rill-Schäffer Commentary on Federal Constitutional Law IX (8th supplement 2011) Art. 2 ECHR marginal note 19.

The necessity of differentiated and appropriate prioritization based exclusively on substantive criteria applies to any vaccination measures carried out by public authorities or within companies (Section 57 (1)(5)(a) AMG) pursuant to the applicable laws on equal treatment, in particular the Federal Equal Treatment Act (B-GlBG) for federal employees, the regional government equal treatment laws for regional government employees and the Equal Treatment Act (GlBG) for the private sector. In the case of any prioritization of older public and private employees in connection with vaccination against COVID-19, this does not constitute a prohibited form of discrimination because there is a substantive legal justification for the unequal treatment in consideration of the increased age-related vulnerability.

Legal approaches to prioritization

Specific legal approaches to prioritization arise from Section 17 (3) and (4) Austrian Epidemics Act 1950 (EpidemieG), Federal Law Gazette 156/1950 (WV) as amended by Federal Law Gazette I 104/2020. According to these laws, mandatory protective vaccinations can be ordered by public authorities, especially for members of healthcare professions (and, in individual cases, for certain vulnerable persons). On the basis of this it can be concluded that prophylactic vaccination is of particular relevance in connection with such persons, even if no such order is issued in this specific case.

c. Ethical aspects of prioritization

The ethical perspective, which is in this respect not dissimilar to the medical-epidemiological perspective, focuses primarily on multiple principles that must be brought into balance:

- autonomy;
- principle of doing no harm and of doing good with respect to the individual person willing to be vaccinated;
- principle of the duty of care with respect to third persons who come into contact with the person willing to be vaccinated and therefore participate in the protection of their immune status (if this is provided by the specific vaccine); and
- principle of responsibility with respect to the entire population and the community, including economic structures and social institutions.

The principle of justice is to be applied in the vaccine distribution and generally calls for the equal treatment of identical situations and different treatment of situations that are not identical. From the perspective of human dignity and the resulting entitlement to healthcare resources, all people are considered equal. However, special circumstances can arise that make it necessary to prioritize specific groups from an ethical perspective.

In view of the high value assigned to the legally protected rights to life and health, ethical considerations must be oriented primarily towards the goal of preventing deaths and severe disease courses (with potentially lasting consequences).

Vulnerable persons

This principle generally leads to the “rule of thumb” that prioritization must take place based on the degree of vulnerability to COVID-19, which can result from a variety of factors (age, specific prior medical conditions, general health condition, psychosocial situation, etc.). This “rule of thumb” is naturally subject to limitations if the person in question would in fact be subject to elevated risk in the event of contracting COVID-19 but application of the vaccine to members of the respective risk group would be associated with an elevated or at least an indeterminate risk. In particular, this can be the case for any off-label uses.

In this context, reference should be made to the situation of pregnant and nursing women, who are explicitly excluded from clinical studies, meaning that neither an approval nor practical experience exist. This widespread form of “protection exclusion” is justified by the necessary protection of the expectant mother and the fetus. Although the risk to pregnant women from severe courses of COVID-19 has not been conclusively established, considerations of vaccination against COVID-19 should include the possible impact on pregnant women, especially those with known risk factors, although the benefit / risk assessment can only take place separately for each individual case.²³

With regard to persons who have already had COVID-19, further scientific evaluation of the immunity situation is required to determine whether they would have to be included in the vaccine distribution in the case of limited vaccination capacities.

Medical and healthcare personnel

Medical and healthcare personnel require special prioritization. This is supported by a variety of considerations. Firstly, experience with the COVID-19 pandemic has shown that medical and healthcare personnel are themselves vulnerable based on their work (due to exposure to increased viral loads).²⁴ Moreover, medical and care personnel typically work

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- 23 Adhikari EH et al., Pregnancy Outcomes Among Women With and Without Severe Acute Respiratory Syndrome Coronavirus 2 Infection. *JAMA Netw Open* 2020;3(11). <https://doi.org/10.1001/jamanetworkopen.2020.29256>; Akhtar H et al., COVID-19 (SARS-CoV-2) Infection in Pregnancy: A Systematic Review. *Gynecol Obstet Invest* 2020;85(4):295306. <https://doi.org/10.1159/000509290>; Zambrano LD et al., Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status—United States, January 22–October 3, 2020. *MMWR Morb Mortal Wkly Rep* 2020 Nov 6;69(44):1641-1647. <https://doi.org/10.15585/mmwr.mm6944e3>; Khalil, A., Kalafat, E., Benlioglu, C., O'Brien, P., Morris, E., Draycott, T., ... & von Dadelszen, P. (2020). SARS-CoV-2 infection in pregnancy: a systematic review and meta-analysis of clinical features and pregnancy outcomes. *EClinicalMedicine*, 25, 100446.
- 24 Karlsson U, Fraenkel C-J, Covid-19: risks to healthcare workers and their families, *BMJ* 2020;371:m3944 doi: <https://doi.org/10.1136/bmj.m3944> (Published 28 October 2020); WHO, Keep health workers safe to keep patients safe, <https://www.who.int/news/item/17-09-2020-keep-health-workers-safe-to-keep-patients-safe-who>; <https://www.statista.com/statistics/1110950/coronavirus-covid-19-cases-among-medical-staff-italy-as-of-april/>: “As of November 11, 2020, the number of coronavirus cases recorded among medical staff in Italy reached approximately 53.3 thousand.”

in close physical contact with a large number of people, many of which are typically very vulnerable. Secondly, medical and care personnel carry out an exceptionally important function during the pandemic, especially since the possibility of healthcare capacity bottlenecks is one of the particular dangers of the COVID-19 pandemic.

For example, if only 30 vaccine doses are available to a nursing home with 30 caretakers and 200 residents, it would make more sense to vaccinate the caretakers than to vaccinate 30 of the 200 residents based on who is the oldest or has the most severe preexisting conditions. This prioritization is justified for two reasons: firstly, because it eliminates the possibility of residents being infected by the care personnel, thereby protecting the 200 residents from the most likely source of infection. Secondly, because the absence of care personnel would also endanger the care of the residents—including in the case of an infection. This does not involve weighing the lives of the residents against those of the care personnel; rather, it involves a determination of which measures will be most effective at preventing the most deaths and severe cases among a specific and individual group of vulnerable persons.

In practice, however, if such an extreme shortage did not apply, it may be best, if only for logistical reasons, to vaccinate both residents and healthcare workers in a nursing home at the same time, meaning that the prioritization of the staff over the residents will not make a difference in practice. In the described scenario, one would strive to obtain 230 vaccine doses for a vaccination programme at the nursing home rather than carrying out the vaccination in various stages. In the interest of efficiently implementing such vaccinations, it is recommended to contact the legal guardians and other persons authorized to make care decisions on behalf of patients incapable of consenting themselves in good time before the intervention. This would ensure that decisions on who can get vaccinated have been made on time.

The prioritization of medical and healthcare personnel applies in principle even for unspecified groups of people. For example, if 30 vaccine doses are available that could, in principle, be used to vaccinate a registered physician and her four employees as well as the 25 most vulnerable of the total 500 patients or to vaccinate the 30 most vulnerable patients, it will still be right to prioritize the physician and her staff. It is a fundamental consideration here again that it is better to offer indirect protection to 475 patients for whom vaccination is not initially available while also securing their medical care than to offer neither direct nor indirect protection to 470 patients while also endangering the medical care of all 500.

“Multipliers” outside of medical and healthcare personnel

Weighing the prioritization of vulnerable persons themselves against a prioritization of persons who are in contact with many others and can therefore be potentially considered “multipliers” becomes more difficult the harder it is to identify the individual third parties with whom the multipliers come into contact and the lower the share of vulnerable persons among these third parties is.

For instance, teachers come into contact with a large group of people (children) who are, however, typically less vulnerable (although they could naturally infect vulnerable persons in their families whose make-up is not necessarily known). Likewise, certain professions, such as hairdressers or sales personnel, come into contact with many people who cannot be individually identified in advance and whose vulnerability is unknown.

The vaccination of such people who are multipliers of lesser degree than medical and healthcare personnel must generally give way to the vaccination of individual, particularly vulnerable persons, especially if the latter actively demand vaccination. In other words, if a dose of vaccine could be given either to a specific 75-year-old person or to a 35-year-old teacher without preexisting conditions, the decision from an ethical perspective would normally have to be made in favor of the specific 75-year-old despite the high number of persons who may be indirectly impacted by the teacher (namely his students and their family members). This is based on the consideration that the responsibility toward the specific 75-year-old person would be violated by denying a vaccination to this person despite recognition of a higher vulnerability and therefore a higher concrete danger to life and health only because it might be possible to indirectly protect a larger number of persons against an abstract risk by vaccinating someone else.

However, the ethical deliberations must also consider the systemic relevance of the activity of specific multipliers (more on this below), meaning that a certain modification of the weighting can result from the perspective of systemic relevance.

Workers in critical infrastructure and professions with comparable significance

While the considerations in the case of medical and healthcare personnel as well as other multipliers are ultimately focused on the question of which decision (including based on type-specific analysis) could best prevent deaths and severe cases, factors beyond direct protection against COVID-19 and individual health outcomes cannot be entirely ignored. Preserving functions that are particularly important for the community also is an objective that is worthy of ethical weighting in prioritization decisions. It is not easy to delineate which persons fall under consideration here. In addition to the aforementioned medical and healthcare personnel, this could be expected to include employees of public health agencies, the police, the fire department and utility companies as well as teachers and educators.

In the evaluation of which priority should be assigned to workers in critical infrastructure and similarly important professions in comparison with particularly vulnerable persons, it is necessary to consider, on the one hand, the significance of the respective infrastructure for preserving the community and, on the other hand, the danger that the infrastructure in question could actually fail due to COVID-19 clusters among the relevant workers. Only when these criteria apply to a high degree it is justifiable, as an exceptional case, that groups of outstanding societal relevance in the current situation will be prioritized over the group of vulnerable persons.

d. Conclusions

From medical-epidemiological, legal and ethical perspectives, the most important criterion for prioritization in the event of a temporary shortage of vaccination capacities is vulnerability. Whether and to what extent a person is considered particularly vulnerable must be defined by virtue of evidence-based characterization (e.g. determination of age classes, lists of relevant prior medical conditions or relevant social circumstances). If a specific, particularly vulnerable person desires vaccination, this person may only be refused a vaccination if this is justified by exceptionally strong reasons. Such exceptionally strong reasons normally apply only in the case of medical and healthcare personnel. If there is a shortage of vaccine doses, therefore, the healthcare personnel at a nursing home may be given priority for vaccination in order to protect all residents before individual residents are vaccinated (if it is not possible to procure sufficient doses for the residents and healthcare personnel at the same time).

When it comes to proactively addressing specific groups of the population, prioritization should again take place primarily based on the level of vulnerability. However, the goal of preventing a maximum number of severe cases or deaths or comparably severe impairments of legally protected fundamental rights could lead to exceptional prioritization of other groups of persons, specifically based on a weighted assessment of the following:

- their role as “multipliers” in the epidemiological sense; in other words, the risk that they could infect others despite taking reasonable protection measures, whereby the number and expected vulnerability of these others must in turn be taken into account; and
- the importance of their function for the community; in other words, the risk that their infection would endanger functions that are particularly important to the general public and thereby indirectly endanger the life and health of many people, if only potentially in the future.

These considerations can lead to giving vaccination priority to members of certain professional groups. In addition to medical and healthcare personnel, who are to be given first priority regardless, this includes persons who play a special role in infection processes despite all reasonable protection measures (e.g. teachers and educators) and / or who are otherwise essential for guarding the legally protected rights to life, health and other fundamental rights (e.g. fire department, police, essential public services). To justify a departure from the general rule of prioritization by vulnerability, however, these criteria must be met to a very high degree.

3 COVID-19 vaccination—voluntary choice and its limits

The discussion concerning medically, ethically or legally supportable prioritization always assumes that more people desire vaccination than can be supplied with available doses at a given time. However, it is also possible to conceive of a scenario in which either more vaccine doses are available than people willing to be vaccinated or in which persons afforded a higher priority for vaccination according to the above considerations are not at all willing to be vaccinated. In this case, the question arises whether participation in vaccination programmes can be entirely voluntarily.

a. General observations on “mandatory vaccination”

For some time already, the topic of mandatory vaccinations has been discussed very emotionally. It is important to distinguish between different terms here. Those who demand that vaccinations should be voluntary typically oppose vaccination enforced by the state. This stance must be kept apart from vaccination requirements for specific activities that pose particular dangers to third parties. Just as no one speaks of a “mandatory driver’s license” when obtaining a driver’s license is made a precondition for operating a motor vehicle on the road, the term “mandatory vaccination” should not be employed when, for instance, medical personnel are required to have proof of vaccination in order to do their work. To make this difference clear, it is better to speak of a “prerequisite for practicing the profession” when a vaccination is mandatory in order to engage in certain activities.

b. Vaccination against COVID-19 as a prerequisite for carrying out specific professional activities

This terminological clarification cannot of course obscure the fact that a situation of “limited voluntariness” can arise for persons who belong to such a profession, perform such an activity or strive to enter into such a career or activity. From an ethical perspective, however, it is necessary to weigh any hardships and burdens that arise against the dangers that would occur for third parties without a corresponding vaccination.

In the case of vaccines that have been tested over many years (such as the measles vaccine), vaccination should be made a prerequisite for people in medical or healthcare professions who come into contact with patient groups (especially vulnerable ones).²⁵ This generally follows from the existing protection and organizational requirements of the institutions that are responsible for ensuring that patients or people in need of care are not subjected to health risks from the medical or care personnel. If there are unassailable individual reasons against the vaccination of specific members of

25 Bioethics Commission, Vaccination – Ethical Aspects, June 1, 2015, accessible at <https://www.bundeskanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html>.

the medical and healthcare personnel, such persons may be deployed by the institutions in question in activities that do not include physical proximity with patients. Individual practicing physicians and independently operating members of other legally regulated healthcare professions are also subject to contractual and statutory obligations to protect their patients, which must have been known to such persons upon selection of their profession. A corresponding obligation can arise within the purview of the Hospitals and Health Resorts Act (KAKuG) due to the required treatment level according to Section 8 (2) KAKuG (and the corresponding state implementation regulations) if and insofar as this corresponds to the current state of medical sciences. Section 17 (3) Austrian Epidemics Act (EpidemieG) would also enable the introduction of a vaccination requirement for these medical personnel.

With regard to COVID-19 vaccination, the situation differs from the situation of measles vaccination, for instance, in that no long-term experience is available that could illuminate the risks and side effects associated with the vaccination. However, it must be considered, firstly, that vaccines made available in the Republic of Austria have passed through a strict approval process, and secondly, that the COVID-19 pandemic poses challenges to the whole of society and has ushered in massive restrictions of everyone's fundamental rights that are without historical precedent within the Second Republic. All things considered, it appears to be justified from this perspective that apart from acute emergency situations only medical personnel who have acquired a COVID-19 vaccination may be permitted to carry out their work in proximity of patients. In consideration of the high levels of uncertainties associated with the COVID-19 vaccination, however, it will be necessary to take a very cautious approach when it comes to legal consequences for medical and healthcare personnel.

The same principles that apply to medical personnel also apply to other professions in the service sector with close physical contact with people insofar as these professions come into contact with persons of various levels (i.e. including high levels) of vulnerability. This applies, for instance, to hairdressers, massage therapists, pedicurists and the like.

c. Mandatory vaccinations against COVID-19?

In previous Opinions, the Bioethics Commission has taken the position that mandatory vaccinations are ethically justified under certain conditions. The decisive factor for mandatory vaccinations is proportionality: the less potential for harm the intervention carries for the individual person, the greater risk the disease presents for the health of the population and the greater the benefit of mandatory vaccination is as a whole, the more it appears that an intervention in the physical integrity of the individual is justified.²⁶

26 Bioethics Commission, Vaccination– Ethical Aspects, June 1, 2015, accessible at <https://www.bundestkanzleramt.gv.at/en/topics/bioethics-commission/publications-bioethics.html>.

Without entering again²⁷ into the ethical justifiability of a general requirement of measles vaccination, it appears to the Bioethics Commission that—considering the lack of long-term experience with COVID-19 vaccinations—a general requirement to be vaccinated against COVID-19 cannot be justified from the perspective of proportionality. Moreover, empirical research shows that mandatory vaccination is in many contexts less effective when it comes to the willingness of people to be vaccinated than other measures, such as information and discussion initiatives and easy access to vaccinations.

4 Free vaccination and state monitoring of distribution

During the pandemic itself, there is certainly not only a tremendous health risk to individual persons but also a considerable public interest in having as many people vaccinated as possible. Free vaccinations against COVID-19 should therefore definitely be offered for the duration of the pandemic.

Since the distribution of the vaccine represents an enormous logistical challenge, the state may be forced to make use of private agents for the distribution process. Even in this case, however, compliance with the prioritization criteria must be guaranteed and also monitored. In particular, the establishment of a “gray” or “black” market for vaccinations must be avoided.

5 Impact of individual vaccination status on the exercising of fundamental rights during the pandemic

From a perspective of fundamental rights, the question arises of whether—assuming a very high level of vaccine protection—restrictions to the fundamental rights of vaccinated persons (e.g. freedom of movement or respect for the private sphere) are still “necessary” for the protection of health and the healthcare system and therefore proportional. This question is not about whether or not to establish a “reward” for vaccination. It is solely about whether the prerequisites for an otherwise constitutional curtailing of fundamental rights are eliminated by vaccination.

If a vaccine also prevents vaccinated persons from infecting others, the answer to this question will almost certainly be yes, but the practicability of such a restriction as well as its indirect consequences on the effectiveness of general protection measures are also important considerations. A person’s vaccination status is not visually apparent, meaning that it is practically impossible to determine why, for instance, a person on the

27 Bioethics Commission, <https://www.bundeskanzleramt.gv.at/themen/bioethikkommission/pressemitteilungen-bioethik/stellungnahme-der-bioethikkommission-zum-impfen.html>, May 19, 2019.

subway is not wearing a face mask. This could be related to vaccination status, if such an exemption to the mask requirement existed, but it could also be due to a refusal to comply with statutory requirements. For the enforcement authorities who are ultimately responsible for assessing compliance with statutory obligations, considerable effort is associated with checking the vaccination status of a specific person, and this effort could also tie up important resources that are urgently needed elsewhere. It must also be considered that the presence of many people not wearing face masks in the subway, for example, will almost necessarily contribute to a general “demoralization” since it must be realistically expected that many other people, who are not vaccinated, would be willing to accept the very low risk of a police check. All of these considerations can lead to the need for certain particularly minor curtailments of fundamental rights (in particular: face mask, distancing, hygiene rules) to be complied with regardless of vaccination status since it can be assumed that these protection measures will not become immediately superfluous when the first vaccines become available.

However, when it comes to more severe curtailments of fundamental rights as well as situations in which a check of vaccination status can be accomplished 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) and in which the visual separation of such persons avoids the risk of a wide-ranging “demoralization” that could occur because passers-by cannot determine the reason for failure to comply with a measure in a public space, it appears necessary to exempt vaccinated persons from the curtailment of fundamental rights.

6 Supporting measures

The Bioethics Commission would like to refer once again—partially as a repetition of earlier published Opinions—to some supporting measures that should be taken in connection with the introduction of vaccines against COVID-19.

a. Information, transparency, motivation—vaccination campaign

In view of the special importance of a sufficiently high vaccination rate within the population in order to achieve community immunity, it is very important to transparently inform the population of the significance and availability of the vaccination. This corresponds to a recommendation already made by the Bioethics Commission in 2015 in its first published Opinion on one of the key topics. Such information should be provided, for example, by the Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK)²⁸, by the health authorities of the states, and by the media. The Austrian

28 BMSGPK, FAQs about influenza vaccination, accessible at [https://www.sozialministerium.at/Themen/Gesundheit/Impfen/Impfempfehlungen-Allgemein/Empfehlung-Influenza-Impfung-\(-Grippeimpfung\)-Saison-2020-2021.html](https://www.sozialministerium.at/Themen/Gesundheit/Impfen/Impfempfehlungen-Allgemein/Empfehlung-Influenza-Impfung-(-Grippeimpfung)-Saison-2020-2021.html).

Broadcasting Corporation (ORF) in particular can make a significant contribution in the context of its specific legal mandate to provide comprehensive information to the general public, especially on health issues (Section 4 (1) clause (1)(14) in conjunction with Section 4c ORF Act).

b. Recording of side effects

The Bioethics Commission would also like to underscore the necessity of establishing generally accessible documentation (database) on the benefits and any occurring side effects of the vaccination against COVID-19. This documentation should appropriately cover the various approved vaccines that will be available against COVID-19 in the future and should be established in addition to the pharmacovigilance required by law. The Bioethics Commission also recommends documenting complications and long-term consequences of cases occurring in unvaccinated persons (quality of life, long-term disabilities, costs and burdens arising from care services).

7 Recommendations of the Bioethics Commission

In consideration of the fact that many aspects have not yet been fully clarified and in the assumption that vaccination provides at least significant protection against spreading the virus to others, the Bioethics Commission makes the following recommendations to the Austrian Federal Government in connection with vaccination against COVID-19:

1. Due to the logistical and practical difficulties involved in making an approved vaccine available to all persons in Austria willing to be vaccinated at more or less the same time, a temporary shortage of vaccination capacities is to be expected. Ethically sound principles for prioritization are therefore required. Primarily the following three criteria apply here: (a) the particular vulnerability of a person (e.g. due to age or preexisting conditions, social situation or profession), (b) status as a particular multiplier of the virus despite reasonable protection measures and (c) particular importance to the maintenance of public life.
2. The Bioethics Commission is of the view that, in consideration of these criteria, medical and healthcare personnel (including care-giving family members) have the highest priority because they (a) typically also represent a risk for particularly vulnerable persons and are also generally themselves particularly vulnerable due to their exposure to higher viral loads, (b) act as significant “multipliers” in an epidemiological sense and (c) are of extreme importance to maintaining public life, especially during a pandemic. Together with medical and healthcare personnel, extremely vulnerable persons in high-risk situations (e.g. persons in nursing homes and residential facilities for the elderly or in home care) should receive early vaccinations.

3. In the view of the Bioethics Commission, the second-highest priority belongs to individual persons of high vulnerability (e.g. due to preexisting conditions with a risk of complications associated with COVID-19) who actively desire a vaccination out of concern for their health. After the vaccination of medical and healthcare personnel and extremely vulnerable persons in high-risk situations, every person with elevated vulnerability should be offered vaccination if they so desire.
4. The next step, according to the view of the Bioethics Commission, is to evaluate whether groups of people exist who, in the interests of the legally protected rights to life, health and other important legally protected fundamental rights, should be given the third-highest priority for vaccination due to their status as “multipliers” in the epidemiological sense (despite reasonable protection measures) and/or due to their exceptional importance to the maintenance of public life and public order. Strict standards are to be applied here. If the prioritization is founded in relevance to maintaining public life and public order (e.g. police, fire department), it will normally suffice to initially vaccinate only those persons in such groups who actively wish to receive a COVID-19 vaccination. If the prioritization is founded in epidemiological importance (e.g. teachers and educators), proactive and thorough vaccination is indicated.
5. The fourth-highest priority should then be systematically given to thorough vaccination of all persons of above-average vulnerability (e.g. all persons in a specific age class), and with the fifth highest priority any remaining groups.
6. For medical and healthcare personnel as well as similar professional groups that come into intensive physical contact with other people of various levels of vulnerability (hairdressers, massage therapists, etc.), a COVID-19 vaccination should apply as a prerequisite for practicing such professions at least for the duration of the pandemic. Once a vaccination against COVID-19 is available, the failure to obtain a vaccination by members of such professional groups should be viewed as a violation of the obligation to provide suitable protection for others and be associated with various legal consequences. Anyone who cannot be vaccinated for valid, objective medical reasons should be utilized in other ways for the duration of the pandemic and as far as possible only come into contact with vaccinated persons.
7. Vaccination against COVID-19 should definitely be offered free of charge for the duration of the pandemic. The distribution of the vaccine should be planned and monitored by the government to ensure compliance with the prioritization criteria and prevent the establishment of a “gray” or “black” market for vaccinations.
8. In view of the absence of long-term experience with the vaccines and as long as no situation of absolute emergency arises, a general mandatory vaccination against COVID-19 should not be considered at this time. However, clear recommendations should be issued in favor of the vaccination. An objective and transparent dialog with the population is essential in this regard, including concerning any occurrence or non-occurrence of side effects, which requires careful, database-supported recording of the side effects.

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.
10. The Bioethics Commission recalls its recommendations from 2015 concerning increased transparency in order to strengthen public trust in vaccination programmes. An effective strategy to counteract expected disinformation campaigns is therefore essential in the given situation.
11. In view of the increased relevance to fundamental rights of many decisions associated with introducing vaccines against COVID-19, it can be advisable that certain key aspects of the allocation and prioritization as well as prerequisites for practicing certain professions be regulated by law.

One cannot have individual freedom without also bearing responsibility for oneself and one’s fellow human beings. From an ethical perspective, the Bioethics Commission recommends keeping this in mind when making decisions on whether to be vaccinated against COVID-19.

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