

# How should access to a COVID-19 vaccine be regulated?

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## Summary

The rapid international development of effective vaccines against COVID-19, which will not be available initially in sufficient quantities to vaccinate everyone willing to undergo vaccination, necessitates the drawing up of a distribution plan and prioritisation. The population must be able to trust in the safety, efficacy and proper rollout of vaccination in order to maintain and increase their willingness to be vaccinated. This will require considerable efforts and level-headedness in the upcoming decisions on vaccination recommendations and prioritisation, in the practical roll-out of vaccination, in the timely recording of vaccination coverage rates, in the avoidance of vaccination complications and also in the ongoing education of the public regarding the efficacy and safety of vaccination.

- Prioritisation must comply with medical, ethical and legal principles. These are to be presented to the population in an understandable way so that prioritisation can be perceived as fair.
- Vaccine distribution is to be organised in such a way as to ensure the achievement of the vaccination goals. This requires suitable new structures.
- A self-determined decision about vaccination is dependent on ongoing, transparent information and education of the population regarding both the efficacy of vaccination and the associated risks.
- In order to identify and minimise vaccination risks at an early stage, a system for the timely recording and evaluation of adverse events must be established in parallel to vaccination.

This paper touches on and combines the main medical aspects of infection epidemiology and vaccination with ethical, legal and practical reflections, and develops a framework for action for vaccination measures against COVID-19.

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## 1. Preamble

More than 200 candidate vaccines to protect against COVID-19 are currently in the development phase, several of which have already been admitted to phase 3 clinical trials. If these trials were to confirm the efficacy and safety of the vaccines, the first COVID-19 vaccines could possibly be authorised as early as the start of 2021. However, it is to be assumed that, at least in the beginning, not enough vaccine doses will be available for all the people willing to undergo vaccination. This is when *prioritisation* becomes necessary. This process serves to decide which persons or groups of persons should have priority access to which vaccines. However, prioritisation should not be based on medical-epidemiological findings alone. It is rather the case that ethical and legal considerations should play a decisive role, too. With this in mind, the Federal Ministry of Health (Bundesministerium für Gesundheit) asked the Standing Committee on Vaccination (Ständige Impfkommision, STIKO), together with experts from the National Academy of Sciences Leopoldina (Nationale Akademie der Wissenschaften Leopoldina) and the German Ethics Council (Deutscher Ethikrat), to suggest criteria for the fair prioritisation of access to COVID-19 vaccines.

This document is intended as a guide for STIKO to develop a detailed COVID-19 vaccination recommendation. It should also show policy makers and other stakeholders which structures

should be established in order to be able to implement the recommendation. For it to have binding force, this prioritisation must – on ethical and constitutional grounds – be anchored in sufficiently precise statutory regulations. This position paper also aims to provide information for the public and thus help to make decision-making processes more transparent.

## 2. Background

Just a few days after publication of the genome sequence of SARS-CoV-2 in January 2020, the first groups began the preparations for the development of a vaccine. Since then (as per October 2020), the first authorisation procedures have been launched at the European Medicines Agency (EMA) in line with all customary clinical trials and evaluations. The vaccines that are expected to be rolled out first will be based on novel vaccine technologies. To date, no published phase 3 clinical trial results on efficacy and safety are available. There are also still many unanswered questions regarding individual aspects of the pathogen and the immunity it mediates. For example, it is still unclear how pronounced and how long immunity will last after recovery from the disease, what factors encourage or prevent it, and whether the immunity acquired through infection differs from immunity after vaccination. Nor is it clear what role is played by certain groups

in the population (for instance children) in pathogen transmission. Furthermore, when the first vaccines are authorised, only limited data will be available regarding their efficacy in specific risk groups (e.g. the elderly, people with serious diseases and children) and regarding the question whether the vaccines will not only prevent disease onset in but also virus transmission by infected individuals. Finally, new vaccines will continue to enter the authorisation procedure which means that, in the course of 2021, an increasing availability of vaccines is expected but also new challenges arising from the use of these products (e.g. interchangeability, preferential use). It is currently assumed that for numerous vaccines two vaccine doses with a minimum interval of three to four weeks will be required for effective vaccination; this will exacerbate any vaccine shortage.

### 3. Ethical foundations for prioritisation decisions

The initial short supply of COVID-19 vaccines will necessitate decisions about who should be vaccinated first. Prioritisation decisions therefore touch on elementary ethical and legal issues, in particular the protection of the health and life of each individual as well as justice and solidarity amongst all affected members of a society.

The starting point is the *self-determination* ('autonomy') of each individual. In principle, informed, voluntary consent is required for vaccination. Undifferentiated, general compulsory vaccination can therefore be ruled out. If at all, compulsory vaccination could only be justified on serious grounds and for a clearly defined group of persons. This would apply in particular to employees who, as potential multipliers, are in constant contact with members of a high-risk group if serious harm to this group of people could only be prevented by vaccination. The necessary legislative provisions and their practical application would also have to be implemented and reviewed in the light of emerging findings on the efficacy and risk profiles of the new vaccines. Consequently, compulsory vaccination limited to a specific area in the context of vaccines against COVID-19 would only be considered if the mode of action of the vaccine had been observed over a sufficiently long period of time. At the same time, this touches on the ethical principle of *non-maleficence* or *protection of integrity*. All prioritisation decisions must be measured in terms of whether they help to prevent serious harm – harm that can be avoided by means of self-protection of persons to be vaccinated through immunity, but also harm that results from a lack of protection for others and can therefore be averted by preventing pathogen transmission. Furthermore, harm can impact not only health but also basic interpersonal relationships of care or the organisational and supply structures of a society that are vital for its survival. It is, therefore, essential that prioritisation decisions also take these potential sources of harm into account. In contrast, the ethical principle of *beneficence*, particularly in the sense of the individual doctor's duty of care, must take a back seat in the case of prioritisation decisions in cases of conflict. Normally, medicine sees itself as duty bound to promote the well-being of its patients

in the best possible way. This is scarcely possible if there is a severe shortage of suitable resources. The aim here is to provide sufficient basic care for as many people as possible and not just the best possible care for only a few.

The ethical principle of *justice* and basic *equality before the law* are of key importance for prioritisation decisions. Not only do they prohibit certain unacceptable differentiation criteria, but they also require in principle that (substantial) equals be treated equally and (substantial) unequals unequally. The same risk situation therefore gives rise to the same right to care. Conversely, the following applies: an unequal risk situation justifies and necessitates unequal care. If a person has a significantly higher risk than the general population of contracting a serious or even a fatal disease due to his personal condition or through his professional activity or of exposing other people to such increased risks through transmission, then it is appropriate on the grounds of justice to give this person preferential treatment, i.e. to assign him priority for vaccination. This aspect of justice is closely linked to the ethical principle of solidarity: People who subscribe to *solidarity*, demonstrate responsibility towards people who are more at risk. In return, they put aside their own claim to speedy health protection – at least temporarily.

Fair prioritisation decisions are therefore based on the *urgency* of preventive health protection. This urgency may result on the one hand from the persons to be vaccinated – for instance due to age-related higher vulnerability, underlying health problems or social circumstances that make access to health care more difficult (homelessness, living in shared accommodation, etc.). The decisive factor is a significantly increased probability of the need for intensive medical care, of sustaining permanent serious harm or of dying after contracting the disease. On the other hand, this urgency may also result from the fact that certain (groups of) people live in physically dense professional or private quarters and are therefore either themselves exposed to an increased risk of illness or even mortality – for example due to intensive contact with COVID-19 patients – or represent an increased risk of transmission and therefore a risk for particularly vulnerable persons. Such urgencies are usually determined individually, i.e. in relation to each individual person. People's age or their physical or cognitive impairment alone does not automatically make them members of a high-risk group. However, under the conditions of a pandemic that spreads rapidly in terms of time and space, prioritisation decisions must necessarily be made on a generalised basis, i.e. for clustered groups of people, if they are to have the hoped-for positive effect. Consequently, there is not generally any need for proof of individual urgency. In any case, every individual has the right to refuse the offer of prioritised delivery of a vaccine. The chances of success of a vaccination measure only come into play in this prioritisation process if insufficient effectiveness can be expected for a person or group of persons and therefore their urgent risk situation cannot be averted by vaccination.

Ethically and legally admissible prioritisation decisions must also meet minimum formal and procedural requirements. They must be based on the latest and continuously updated medical and scientific facts. They must be convincingly substantiated

both in accordance with the Basic Law and in application of the ethical principles outlined above. They must draw on the broadest possible consensus involving all relevant stakeholders, must be publicly communicated in transparent procedures and must be anchored in law.

#### **4. Application of the ethical framework conditions to the STIKO prioritisation recommendation**

The ethical and legal principles outlined above as well as the following concrete vaccination goals constitute guiding principles for the future detailed prioritisation recommendation:

- Prevention of severe courses of COVID-19 (hospitalisation) and deaths
- Protection of persons with an especially high work-related risk of exposure to SARS-CoV-2 (occupational indication)
- Prevention of transmission and protection in environments with a high proportion of vulnerable individuals and in those with a high outbreak potential
- Maintenance of essential state functions and public life

Ideally, a COVID-19 vaccination will contribute to the achievement of all vaccination goals. However, the contribution to the vaccination goals varies significantly between different groups of people. The contribution to the respective vaccination goal also varies markedly depending on the vaccine's characteristics: a vaccine that completely prevents transmission can achieve all vaccination goals. A vaccine that prevents only severe courses of a disease meets in particular the requirements of vaccination goal 1. In this respect, the vaccines that will soon become available will most likely be situated between these extremes. Nevertheless, it seems possible already now to basically identify groups of persons who should be invited to undergo vaccination first on the basis of the principles described above.

In the context of the principle of urgency outlined above, vaccination goal 1 is the decisive one in the case of a disease such as COVID-19 with a high risk of death and serious illness. Non-maleficence and justice point in the same direction. As a result, priority should be given to those individuals at the highest risk of death and serious illness from a disease such as COVID-19. STIKO carries out systematic literature analyses in order to undertake a hierarchical classification of the relevant risk groups. It is already evident that old age is by far the most pronounced and most easily identifiable generic risk factor. However, even regardless of age, some underlying medical conditions can significantly increase the risk of a severe course of COVID-19. For a finer subdivision into smaller priority groups (with these maximum risks), vaccine characteristics and risk constellations in different groups must be taken into account, among other things. Statistical analyses of empirical data are used for this purpose. The groups of persons to be given priority therefore include:

- persons (groups of persons) who have a significantly increased risk of serious or fatal disease progression due to their age or underlying medical condition, especially in the case of

increased contact density (for example in nursing homes and other long-term care facilities)

The second priority group encompasses those who assist COVID-19 patients and who may themselves be exposed to increased risks. Health care professionals are exposed to the risk of transmission and increased exposure to the virus through regular contact with patients. Conversely, in the case of a non-occupational primary infection of this group of people, multiplier effects put patients at risk. In turn, this can lead to the infection of people who are particularly vulnerable to COVID-19. Alongside aspects of urgency, considerations of solidarity come into play here. Here, too, the details need to be modelled more precisely to ensure that the people in this group who are actually most at risk and who constitute the greatest risk to other people if they become infected themselves, are vaccinated first. This second group includes:

- employees of inpatient or outpatient health care and geriatric facilities who, due to their close and frequent professional contacts with persons suffering from COVID-19, have a significantly increased risk of infection and, perhaps in addition, a risk of a serious or fatal course of the disease, or who, as multipliers, can carry the virus into the facilities and out into other areas of society.

In addition, protection must be afforded to persons who fulfil functions that are particularly relevant to the community and cannot be easily replaced. The assignment of people to this third priority group can only be done correctly when the relevant epidemiological data are available. They include:

- persons (groups of persons) who hold key positions in basic areas of services of general interest and are responsible for maintaining central state functions (e.g. employees of local health authorities, police and security agencies, fire brigades, teachers and educators), especially if they have direct, risk-increasing contact with patients, members of risk groups or potentially infected persons.

Before the end of the year, STIKO will present a matrix based on scientific data, which may require fine-tuning, in which different groups of persons will be arranged more precisely in a hierarchy, bearing in mind the framework set out here. An evidence-based rationale will explain in a transparent manner why a certain priority level is initially assigned to which group of people. Further adjustments may be necessary during the epidemic if new scientific evidence emerges or new vaccines become available. They will comply with the ethical principles presented here. Given their considerable impact on relevant ethical values and values pertaining to basic rights, the rollout of the vaccination distribution recommendations formulated on this basis will have to be anchored in clear regulations drawn up by parliament. The Protection against Infection Act and the Basic Law only contain rather brief statements on the topic of distribution. The legislator is therefore responsible for putting in place precise statutory foundations. It would be conceivable for instance to have a provision comparable to Swiss law (Article 61 Epidemics Ordinance [Epidemienverordnung]) which, under the conditions of an epidemic on a national scale (section 5 (1) sentence 1 IfSG), would standardise the above-mentioned prioritisation criteria

## Consideration of ethical criteria in the work of STIKO

In accordance with the Protection against Infection Act (Infektionsschutzgesetz), STIKO makes recommendations for carrying out vaccinations. The highest federal state health authorities have been tasked with formulating public vaccination recommendations based on the respective STIKO recommendations.

The internal regulations and a standard operating procedure (SOP) freely accessible on the Internet ensure that STIKO complies with conditions of procedural fairness when drawing up vaccination recommendations. According to its internal regulations, STIKO has to provide comprehensive justification for recommendations and draft recommendations. The internal regulations also help to minimise conflicts of interest by means of exclusion from the discussion and the decision-making process. Transparency is guaranteed both by publication of the SOP, self-declarations by members and minutes of STIKO meetings on the STIKO website ([www.stiko.de](http://www.stiko.de)) and by the use of what are known as 'evidence-to-decision' tables. In these tables the evidence and reflections on criteria such as the benefits and risks of vaccination, cost-effectiveness or even justice and expected acceptance are likewise recorded in writing. The standard procedure described in the SOP ensures that STIKO systematically refers to a set of key questions and uses methods of evidence-based medicine for the scientific processing and evaluation of the quality of evidence. In accordance with the internal regulations, draft recommendations go through a six-week procedure to ensure participation in and openness for revision, during which the highest federal state health authorities, the Joint Federal Committee and professional stakeholders may comment. In the case of an urgent new recommendation which may be deemed necessary in the context of a pandemic, the cut-off date for the submission of comments may be reduced to two weeks.

As a consequence of the described dynamics in data availability and the successive authorisation of several new COVID-19 vaccines over a period of one year and longer, STIKO must – from the methodological angle – conduct what is known as a 'living systematic review' of the efficacy and safety of the vaccines authorised in Europe. The results are continuously updated and factored into a mathematical transmission model. The model simulates the population in Germany, and contains components of the natural course of the disease as well as relevant infection epidemiology behavioural and vaccination parameters. The updates of the review and the modelling then lead to a 'living guideline' which continuously takes on board new scientific findings. This means that the STIKO recommendation is constantly updated and adapted where necessary.

and groups of persons. More concrete details could be set out in an ordinance (perhaps with Bundestag participation, for instance through the approval of the Committee on Health) and/or a STIKO recommendation (with the approval of the Federal Ministry of Health).

## 5. Implementation of the vaccination recommendation and conduct of the vaccination campaigns

The consistent and transparent implementation of the prioritisation criteria for the fair distribution of scarce vaccine doses are crucial for acceptance and trust. They are in conformity with ethical principles of public health care.

How the above-mentioned prioritisation specifications are complied with and implemented will very much depend on the environment in which vaccination is rolled out. Although this is not a classical state task in Germany, it does seem appropriate on the basis of reflections linked to the welfare state and duty of protection – and given the risks associated with COVID-19 not only for the individuals concerned but also for society as a whole – not to surrender distribution specifications for vaccines to the usual market rules of supply and demand. More particularly, a person's insured status must not be the determining factor for their access to vaccination. For fundamental ethical and legal but also for pragmatic reasons, distribution should be as uniform and transparent as possible. This will inspire confidence and ensure acceptance of distribution. This argues in favour of a vaccination

strategy that does not rely on individual general practitioners but on vaccination centres mandated by the state (such as local health authorities, etc.). For the rest, the following applies: the more decentralised the rollout is, the more important binding prioritisation rules become. However, the prerequisite for binding rules is a sufficiently clear legal basis, possibly combined with the power to issue ordinances. The Federal Ministry of Health has already submitted a draft along those lines.

It is also crucial that policy makers and the scientific community take steps to adequately address fears around vaccination. Here, too, trust and acceptance are dependent on transparency, information and communication. Vaccinations can be reactogenic; a significant proportion of vaccinated individuals may experience temporary reactions at the vaccination site (e.g. redness, swelling, pain) or transient fever or discomfort. Very rarely, more serious adverse events occur after vaccination such as the onset of a new, serious disease. In most cases, the adverse event is coincidental, i.e. random. In order to comply with the ethical principle of non-maleficence, a prompt distinction must be made between a random coincidence and a possible signal of a causal relationship. Fears when using a vaccine developed with new technologies can only be credibly assuaged if any signals of vaccination complications can be detected early on and distinguished from random associations in a timely manner. This is the only way of avoiding harm caused by the unfounded rejection of a potentially life-saving vaccination. An indispensable prerequisite for the differentiation between signal and chance is the timely and product-specific recording of COVID-19 vaccination coverage rates in a central database. This is also necessary to determine the efficacy of the various vaccines.

## 6. Communication and transparency in prioritisation and rollout

Social acceptance of the prioritised distribution of vaccines depends above all on it being communicated clearly and implemented consistently and transparently. Independent of prioritisation, the following applies in general: If a vaccine against COVID-19 is to be widely and successfully used in future to contain the pandemic, public confidence in its safety and efficacy must be gained, increased and maintained. According to surveys, the willingness to be vaccinated against COVID-19 is currently less than 60 percent.<sup>[1]</sup> There is, therefore, a need for action.

### *Building confidence*

The overall communication goal is to behave in a way that builds, maintains or restores confidence. Key aspects that increase confidence are the use of clear, understandable and non-technical language;<sup>[2]</sup> the ability to respond to people's concerns<sup>[3]</sup> and the regular provision and repetition of information even when there is no new scientific evidence.

### *Providing customised information*

Everyone must be able to retrieve and understand messages about COVID-19 vaccination. This means that the language and communication formats used must be barrier-free and should be suitable for groups with different levels of education, for people with disabilities or communication difficulties and for all other groups with special communication needs.

### *Identifying, acknowledging and responding to concerns*

The following questions could arise in connection with the authorisation of a COVID-19 vaccine: How effective is the vaccine? What side effects does it have? How was its safety tested and what steps were taken to ensure that the relevant requirements were not compromised by the pressure of the crisis? How do the risks of side effects and unknown long-term effects compare to the risks of the disease?

Public concerns must be addressed in a respectful manner. This also means that questions and concerns must be taken seriously. This also means not playing down the importance of questions, even if they are based on incomplete or incorrect information or convictions from a scientific point of view.

### *Transparency*

Transparency is essential to maintain public confidence. It enables the general public to understand the information gathering, the risk assessment and the decision-making processes in conjunction with COVID-19.<sup>[4]</sup> There should also be transparent communication of the fact that the respective decisions are based on the currently available data and that recommendations will have to be adjusted in the light of any new findings.

### *Obtaining feedback, monitoring acceptance*

The acceptability of vaccines against COVID-19 is likely to change over time. For this reason, the aspects that influence

people's behaviour in relation to vaccination (including confidence in the efficacy and safety of vaccination, risk perception of the disease, practical barriers or a sense of community responsibility) should continue to undergo regular review with the help of validated surveys.

Health communication should continue to find ways of integrating new technologies into communication strategies as the public increasingly seeks relevant information from online and other electronic sources. If positive findings on the safety and efficacy of a vaccine are available, they should also be specifically publicised on social media. The Federal Centre for Health Education (Bundeszentrale für gesundheitliche Aufklärung, BZgA) and the Federal Ministry of Health, among others, can play a central role here. It is also important to prepare the public for the ongoing systematic adoption of the familiar protection and hygiene measures even when COVID-19 vaccines are available. The availability of vaccines is no substitute for prevention through hygiene measures, especially as long as vaccination coverage rates remain low and data on the scale and duration of protection after vaccination are unavailable. Ultimately, what is needed is an integrated communication approach that encompasses diverse areas of action and involves the main interest groups.

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## References

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