

Joint Position Paper

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

- Paper commissioned by health secretary Jens Spahn on 21.9.
- Results of joint working group published on 9.11.





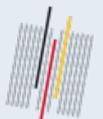
## Joint Working Group comprised of:

- Standing Committee on Vaccination (STIKO)
  - a scientific committee comprising 18 members that provides official recommendations for vaccination policies and schedules



## And delegates from:

- German National Academy of Natural Sciences Leopoldina
- German Ethics Council





## The situation

- Effective vaccines against Covid-19 will initially not be available in sufficient quantities to vaccinate everyone willing to undergo vaccination.
- This makes it necessary to prioritise initial access to vaccines and regulate their distribution in a fair and transparent way.
- Prioritisation should not be based on medical and epidemiological findings alone. Ethical and legal considerations should play a decisive role, too.



## Medical Uncertainties

- The novelty of the virus and the speedy vaccine development mean that some uncertainties will remain even when the first vaccines are authorised.
- For example, only limited data will be available regarding the efficacy of different vaccines in specific risk groups.
- We also do not know whether the vaccines will not only prevent disease but also virus transmission, or how long any protective effect will last.
- This makes it difficult to give detailed recommendations for allocating specific vaccines at this point in time.



## Ethical Constants

6 important ethical and legal principles for prioritising access to vaccines can be referred to independently of remaining medical uncertainties.





## **Self-determination / autonomy**

- Informed, voluntary consent is required for vaccination.
- If at all, compulsory vaccination could only be justified on serious grounds and for a clearly defined group of persons.

## **Non-maleficence / protection of integrity**

- All prioritisation decisions must be measured in terms of whether they help to prevent serious harm, e.g.:
  - by preventing infection of people who are vaccinated
  - by preventing them from infecting others
  - by preventing harm to basic interpersonal relationships of care or the organisational and supply structures of society



## **Beneficence**

- In the sense of individual doctors' duties of care, this principle must take a back seat during prioritisation decisions.
- The aim here is to provide sufficient basic care for as many vulnerable people as possible and not just the best possible care for a few.

## **Justice and basic equality before the law**

- Treat equals equally and unequals unequally.
- If a person has a significantly higher risk of contracting a serious disease or of exposing other people then it is appropriate on the grounds of justice to give this person priority access to vaccination.



## Solidarity

- Demonstrate responsibility towards people who are more at risk by putting aside own claims to vaccination - at least temporarily.

## Urgency

- How urgent is the need for protection?
  - Who is most at risk?
  - Who puts themselves – or others – most at risk?
- Clustering: OK to make group-based decisions about this – there is no need for proof of individual urgency.



## Results of applying the ethical framework

Priority should be given to reach 4 ‚vaccination goals‘:

- 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



## Implementing the recommendations

Consistent and transparent implementation of prioritisation criteria for the fair distribution of scarce vaccine doses is crucial for acceptance and trust, and in line with principles of public health ethics.

- Distribution specifications for vaccines should not be governed by market rules of supply and demand.
- A person's insurance status must not be a determining factor for access to vaccination.
- Distribution should be as uniform and transparent as possible to inspire confidence, e.g. through vaccination centres mandated by the state.



## Further important considerations for vaccination campaigns

Even beyond prioritisation, policy makers and the scientific community need to adequately address concerns about vaccination.

- There should be comprehensive documentation of efficacy and side-effects in a central database.
- Clear and respectful communication is key and should be guided by the following principles:
  - Build confidence
  - Provide customised information
  - Identify, acknowledge and respond to concerns
  - Transparency
  - Obtain feedback, monitor acceptance



# Thank you!

POSITION PAPER OF THE JOINT WORKING GROUP OF MEMBERS OF THE STANDING COMMITTEE ON VACCINATION, THE GERMAN ETHICS COUNCIL AND THE NATIONAL ACADEMY OF SCIENCES LEOPOLDINA

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

---

### 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.

---

The full paper is available in German and English at [www.ethikrat.org](http://www.ethikrat.org)