Recommendations for fair and regulated access to a COVID-19 vaccine

Joint position paper of the Standing Committee on Vaccination (STIKO), the German Ethics Council and the National Academy of Sciences Leopoldina on ethical, legal and practical framework conditions

The first COVID-19 vaccines could be authorised as early as the start of 2021. However, in all likelihood, there will not be sufficient vaccine doses in the beginning for all the people willing to undergo vaccination. This is why prioritisation will be necessary. In the position paper published today, medical-epidemiological aspects of infection prevention are presented alongside ethical, legal and practical considerations. On this basis, the authors develop a framework for action for the initial prioritisation of vaccination measures against COVID-19.

Prioritisation helps with decisions on who should receive which vaccine first. 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.

According to the experts, decisive results on the characteristics of the vaccines from the ongoing clinical trials (phase 3) are not yet available. Consequently, a detailed recommendation by STIKO concerning priority groups for vaccination is still not possible at the present time. However, the ethical and legal principles according to which prioritisation is to be undertaken have already been established. In addition to self-determination, they are non-maleficence and protection of integrity, justice, fundamental equality of rights, solidarity and urgency.

These ethical and legal principles are reflected in concrete 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.

The paper points out that the distribution of the initially scarce vaccines touches on relevant ethical values and values pertaining to basic rights, and therefore necessitates clear legal regulation. Furthermore, vaccine distribution is to be organised in such a way as to ensure that the vaccination goals are achieved. This requires suitable new structures. Uniform, transparent distribution is needed that inspires confidence and ensures acceptance. This argues in favour of a vaccination strategy that relies not on individual general practitioners but on vaccination centres mandated by the state.

In principle, informed, voluntary consent is required for vaccination. Therefore, prioritisation criteria must be presented to the population in a comprehensible way. Furthermore, the authors of this position paper also rule out undifferentiated, general compulsory vaccination.

Experts are of the opinion that 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, the timely nationwide recording of all vaccinations and an evaluation of adverse events must be established in parallel to vaccination. To this end, the authors call for the product-based recording of COVID-19 vaccinations in a central database, also for the purpose of exactly determining vaccination coverage rates. Standing Committee on Vaccination (STIKO) at the Robert Koch Institute Seestraße 10 13353 Berlin www.stiko.de

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