

University of Groningen

Vaccination Policy: Ethical perspectives on a future vaccination program against COVID-19 in Germany.

Schröder-Bäck , Peter; Wild , Verina; Heilinger, Jan-Christoph ; Buyx, Alena; Ehni, Hans-Jörg ; Hurst, Samia; Kuhn, Joseph ; Ludwig, Maria-Sabine; Maeckelberghe, E.L.M.; Martakis, Kyriakos

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version

Publisher's PDF, also known as Version of record

Publication date:

2020

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Schröder-Bäck , P., Wild , V., Heilinger, J-C., Buyx, A., Ehni, H-J., Hurst, S., Kuhn, J., Ludwig, M-S., Maeckelberghe, E. L. M., Martakis, K., Michelsen, K., & Ranisch, R. (2020, May 22). Vaccination Policy: Ethical perspectives on a future vaccination program against COVID-19 in Germany.

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

The publication may also be distributed here under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license. More information can be found on the University of Groningen website: <https://www.rug.nl/library/open-access/self-archiving-pure/taverne-amendment>.

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Vaccination Policy

Ethical perspectives on a future vaccination program against COVID-19 in Germany

Summary

This Policy Brief discusses several prominent ethical challenges of the administration of a COVID-19 vaccine that is expected to be available in the future – yet, will be scarce at first and its distribution will be introduced only stepwise. The Policy Brief reflects on pertinent ethical principles (Population Health Maximization, Justice, Autonomy, Harm Principle, Public Trust, Solidarity & Reciprocity), and provides ethical guidance on prioritization and distribution of vaccines by formulating a set of recommendations for the German context.

The Policy Brief aims at health policy advisors, public health institutions and health policy makers on different levels of governance within Germany.

Context

Currently, research institutes and pharmaceutical companies in different countries are researching and developing vaccines against COVID-19. First clinical trials on safety and effectiveness are taking place (WHO 2020). Most estimates do not expect a safe and effective vaccine before 2021, with some assuming the entire process might take many years. The availability of the vaccine will significantly change current public health policies and allow easing restrictive interventions regarding COVID-19. Ideally, the vaccine could be administered widely to quickly reach herd immunity.¹ However, during an initial, critical transition period of indeterminate duration vaccination doses will likely be scarce. The time *before* the vaccine becomes available should be used for ethical and public reflection on the distribution and prioritization of the (initially scarce) vaccine. Accordingly, the German Federal Minister of Health asked the German Standing Committee of Vaccination on April 17th 2020 to develop a risk-oriented vaccination strategy (BMG 2020).

¹ So-called “herd immunity” or “herd protection” is achieved once such a large part of the population is immune so that the virus does not spread anymore. Then, also people are better protected who cannot be vaccinated for medical reasons. N.B.: Here we refer to achieving herd immunity through vaccination; not, as was also discussed in the context of COVID-19, through (potential) immunity after recovering from the disease. In case the virus mutates, new vaccines are needed again to achieve herd immunity.

Goal of this Policy Brief

This Policy Brief (PB) reflects on priority setting and distribution of initially scarce COVID-19 vaccines from an ethical perspective. The focus of this PB is only the German context (for wider perspectives see e.g. the statement from this working group: Venkatapuram et al. 2020).

Method

This PB identifies ethical principles and discusses their normative scope within this context (cf. also Ontario Health 2020). Ultimately, some recommendations are proposed for the prioritization and distribution of vaccinations during the transition period.

Ethical Principles and Reflection

The field of Public Health Ethics discusses different normative principles to guide good and right public health actions (Heilinger et al. 2020). The principles mentioned below play a key role in the literature on pandemic ethics and the distribution of scarce resources. They are considered to be of particular pertinence to the current situation.² Interpretations of these *prima facie* principles are offered for the particular context of a COVID-19 vaccination program in Germany under conditions of scarcity. The principles are presented in no hierarchical order.

<i>Ethical Principle</i>	<i>Interpretation for this context</i>
Population Health Maximization	COVID-19 morbidity and mortality should be as low as possible. Epidemiological guidance on how to minimize overall morbidity and mortality through prioritizations in vaccination policy shall inform decision making.
Justice	Justice as fairness in the distribution of resources and opportunities reducing health inequalities, secures that everyone receives his or her due, according to health needs, and that no one is discriminated against due to personal characteristics such as gender, socio-economic status or age.
Autonomy	People have the right to make their own informed decisions, also in relation to voluntary vaccination programs, and are free to act according to their norms, wishes and beliefs. Out of respect for autonomy, mandatory vaccinations should be prevented whenever possible.

² Cf. Daniels 2009, DeBruin et al. 2012, Deutscher Ethikrat 2020, Gostin, Powers 2006, Heilinger et al. 2020, Holland 2019, Kotalik 2006, Prainsack/Buyx 2017, Schröder-Bäck/Martakis 2019, Schröder-Bäck et al. 2008, Smith/Upshur 2019, Thompson et al. 2006, Upshur et al. 2005, Uscher-Pines et al. 2007, William/Dawson 2020.

Harm Principle	Self-determination is acceptable as long as one does not harm others. Thus, given the potential impact immunization status can have on others, vaccination can also help to avoid harm to others.
Public Trust	Public institutions informing about, regulating and practicing vaccine distribution should be trustworthy, and decide and act according to shared moral and democratic values that are made transparent.
Solidarity & Reciprocity	Vaccine distribution should acknowledge our socio-economic interdependence at different levels (solidarity). Priority should be given to those who face a disproportionate burden in protecting the public good (reciprocity).

Table 1: Overview of relevant ethical principles

Recommendations

Consideration of these key principles for administering an expected vaccine can guide policy through the following recommendations:

- **Public, participatory and transparent clear communication with the public** is needed to secure, potentially even increase, public trust and justified acceptance of the vaccination strategy. It should include information and engagement about the current state of knowledge about the vaccine itself and about the political decision-making processes, including their underlying ethical arguments. Communicating these aspects transparently will help to discourage anti-vaxx campaigns (Deutsches Netzwerk Evidenzbasierte Medizin e.V. 2016) and support efforts to counter conspiracy theories about the vaccine and vaccination policy (Schaefer et al. 2020). Public health authorities (incl. Robert-Koch-Institut and Paul-Ehrlich-Institut, regional and local public health institutions) bear responsibility for clear communication with the public about
 - *the effectiveness and safety* of the vaccine, including information on potential risks and side-effects, or the expected, potentially limited effectiveness;
 - *the prioritization strategy* of the vaccination program;
 - *the opportunities to challenge and revise the strategy and decisions*;
 - *all stakeholders* involved in the process of developing and distributing vaccines, including those with financial interests;
 - *potential risks and side effects* of the vaccine, that should be closely monitored and registered (analogous to other types of vaccinations, compensatory justice demands that in case of side effects or injury from vaccination, financial and other support should be offered).
- Decisions about **prioritization of vaccination** must be based on
 - a) equal moral worth of every human being,
 - b) best available knowledge to maximize population health by preventing COVID-19 as well as prevention of discrimination and,



- c) democratic legitimation.
- Concretely, priority shall be given to *health care workers and key workers in other essential jobs* (from police, public administration, fire brigade, public transportation, public services to supermarket personnel). The three justifications of prioritizing key workers' groups are
 - a) to protect these population groups because they have a higher risk of infection,
 - b) to protect others from infections by these population groups,
 - c) to maintain the functioning of society.
- Specifications for prioritization: Key workers in essential jobs should be prioritized so that they can continue acting most effectively and thus contribute to overall population health.
 - Workers with specialist knowledge who cannot be replaced have, again, a higher priority within this group (Office fédéral de la santé publique, 2018).
 - Health care workers and other workers who come in contact with (medically) vulnerable groups and who refuse to be vaccinated should not be allowed to continue their work. This could also include informal caregivers.
 - Population health maximization requires considering a geographical dimension, as well. Key workers in regions a) with high incidence and prevalence rates, b) high day-to-day contacts (especially with high-risk groups) and c) high geographical mobility should be prioritized.
- Another priority group are *vulnerable people* incl. high-risk groups. These are:
 - People at higher risk of falling ill or dying from COVID-19. They should be prioritized in order to increase health for all. Among them are older adults and people with chronic illnesses.
 - Socio-economically vulnerable groups. These populations might have special needs, but less opportunity to voice them, and – due to structural disadvantages – limited opportunities and difficulties of accessing goods without additional interventions. Prioritization is needed to secure their fair chance of receiving a fair share of care.
- The distribution of the remaining available doses should be decided in a fair way, securing equal opportunities for everyone. A lottery would theoretically be better equipped to secure fairness than leaving distribution up to the forces of free markets (which would lead to a spike in prices) or a “first come first serve” principle (which would favor the already hospitalized irrespective of their health status, the better informed, often the socio-economically better off members of society). Yet, to employ a lottery or other ways of chance is practically challenging.
- Some people might **oppose being vaccinated** (for different reasons such as distrust in government, disbelief in medical effectiveness or fear of side effects).
 - While a (tiny) minority of persons not being immune does not overall endanger herd immunity against COVID-19, it is ethically difficult to deal with free-riders benefitting from herd immunity, but reluctant to get vaccinated themselves. While the German Infection Protection Act (IfSG) would allow for mandatory vaccination (IfSG § 20(6)), compulsion should only be considered a last resort measure, if no alternative measure to contain the virus is available or proportionate.
 - Considerations to make vaccination mandatory, if undertaken at all, have to take into account that compulsion might increase distrust and non-compliance in (other) public health measures (Betsch /Böhm 2016; Betsch et al. 2019).



- The SARS-CoV-2-vaccination shall be ***embedded into a comprehensive vaccination strategy and policy***, including targeted seasonal influenza and pneumococcus vaccinations (especially for the older adults), to protect vulnerable populations and decrease the burden of diseases that need ICU treatment overall. It is possible that the elderly are less well protected after immunization – they might show lower immune response. Thus, younger people, including children (although at lower risk), should be immunized to achieve herd immunity and also protect their contacts and carers (e.g. grandparents, teachers).

Implementation

Once a safe and effective vaccine is available, it will probably be jointly procured with other EU countries, the German Bund and Länder. (NB: This domestic focus of the present document must not lead to neglecting global coordination (cf. Venkatapuram et. al. 2020)). In the German multi-level health governance system, the states (“Länder”) are responsible for the distribution of the vaccine. They, again, have to coordinate – first, in some Länder, with the sub-regional level (Regierungsbezirke) and, second, with the local level (Public Health Services [Gesundheitsämter], local GP practices).

Pandemic planning in Germany outlines the mechanisms how to reach priority groups. High-risk groups for example can be reached through the established health care pathways. Workers in essential jobs and services can receive vaccination through their occupational physicians (cf. RKI 2017, Baden Württemberg 2020). After having secured access to the vaccination to these groups, Länder do have the discretion to further prioritize before approaching the general public (Baden Württemberg 2020).

The recommendations formulated above shall support the concrete decision making on all levels – from STIKO to local public health service – to make justified and ethically informed decisions. *Vaccination policies and their implementations shall be subject of ongoing ethical evaluation and other accompanying research, as well.*

References

- Baden Württemberg (2020) Influenzapandemieplan Baden-Württemberg. 2. März 2020. https://sozialministerium.baden-wuerttemberg.de/fileadmin/redaktion/m-sm/intern/downloads/Downloads_Gesundheitsschutz/Influenzapandemieplan-BW.pdf [accessed 13.5.20]
- Betsch C, Schmid P, Korn L et al. (2019) Impfverhalten psychologisch erklären, messen und verändern. Bundesgesundheitsbl 62:400-409
- Betsch C, Böhm R (2016) Detrimental effects of introducing partial compulsory vaccination: experimental evidence. Eur J Public Health 26:378–381.
- BMG (2020) Impfen als Lösung. Berlin, 17.4.2020. https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/C/Coronavirus/Faktenpapier_Impfen.pdf [accessed 13.5.20]
- Daniels N (2008) Just health: Meeting health needs fairly. Cambridge University Press, Cambridge.
- DeBruin D, Liaschenko J, Marshall MF (2012) Social Justice in Pandemic Preparedness. Am J Public Health 102(4):586–91.

- Deutscher Ethikrat (2020) Solidarität und Verantwortung in der Corona-Krise-Ad Hoc Empfehlung. Berlin.
- Deutsches Netzwerk Evidenzbasierte Medizin e.V. (2016) Gute Praxis Gesundheitsinformation. Ein Positionspapier des Deutschen Netzwerks Evidenzbasierte Medizin e.V. Version 2.0. https://www.ebm-netzwerk.de/de/medien/pdf/gpgi_2_20160721.pdf [accessed 13.5.20]
- Gostin LO, Powers M (2006) What does social justice require for the public's health? Public health ethics and policy imperatives. *Health Affairs* 25: 1053-1059.
- Heilinger J, Thompson A, Wild V (lead authors); Ballantyne A, Berlinger N, Chung R, Eckenwiler L, Ehni HJ, Ganguli Mitra A, Hurst S, Maeckelberghe E, Marckmann G, Munthe C, Rid A, Schröder-Bäck P, Strech D, Venkatapuram S (co-authors) [Working Group Ethics of "Public Health Covid-19"] (2020) Public Health Ethics and Covid-19. The ethical dimensions of public health decision-making during a pandemic (Policy Brief) https://www.public-health-covid19.de/images/2020/Ergebnisse/Policy_Brief_Pandemic_Ethics_GeneralF.pdf [accessed 13.5.20]
- Holland S (2019) Ethics and Governance of Public Health Information. Rowman and Littlefield, London.
- Kotalik J (2006) Preparing for an influenza pandemic: Ethical issues. In: Selgelid MJ, Battin MP, Smith CB (Hrsg.) Ethics and infectious disease. Malden, Blackwell Publishing: 95-104.
- Office fédéral de la santé publique (2018) Plan suisse de pandémie Influenza. Stratégies et mesures pour la préparation à une pandémie d'Influenza. 5ème édition, Questions éthiques. <https://www.bag.admin.ch/dam/bag/en/dokumente/mt/k-und-i/hygiene-pandemiefall/influenza-pandemieplan-ch.pdf.download.pdf/foph-swiss-influenza-pandemic-plan.pdf> [accessed 13.5.20]
- Ontario Health (2020) Ethics Table Policy Brief #3. Version date/time: 03-25-2020, 3:30 PM https://www.wrh.on.ca/uploads/Coronavirus/Ethics_Table_Policy_Brief_3_PPE_Within_Health_Care_Institutions_Community_Support_Services.pdf [accessed 13.5.20]
- Prainsack B, Buyx A (2017) Solidarity in Biomedicine and Beyond. Cambridge, Cambridge University Press.
- RKI (2017) Nationaler Pandemieplan Teil I. Strukturen und Maßnahmen. Berlin. https://www.gmkonline.de/documents/pandemieplan_teil-i_1510042222_1585228735.pdf [accessed 13.5.20]
- Schaefer, C; Bitzer, E-M; Okan, O; Ollenschläger, G (2020) Umgang mit Falschnachrichten in Medien. https://www.public-health-covid19.de/images/2020/Ergebnisse/2020_05_11_Factsheet_Fake_News-V1.pdf
- Schröder-Bäck, Peter; Martakis, Kyriakos (2019) Impfethik – Eine Skizze moralischer Herausforderungen und ethischer Kriterien. *Bundesgesundheitsbl* 62(4):472-478
- Schröder-Bäck, Peter; Sass, Hans-Martin; Brand, Helmut; Winter, Stefan (2008) Ethische Aspekte eines Influenzapandemiemanagements und Schlussfolgerungen für die Gesundheitspolitik – Ein Überblick. *Bundesgesundheitsbl* 51(2): 191-199.
- Smith M, Upshur R. (2019) Pandemic Disease, Public Health, and Ethics. In: Mastroianni AC, Kahn JP, Kass NE, editors. *The Oxford handbook of public health ethics*. New York, NY, Oxford University Press: 797–811.
- Thompson AK, Faith K, Gibson JL, Upshur RE. (2006) Pandemic influenza preparedness: an ethical

- framework to guide decision-making. *BMC Med Ethics* 7(1):12.
- Upshur R, Faith K, Gibson J et al. (2005) Stand on Guard for Thee. Ethical considerations in preparedness planning for pandemic influenza. University of Toronto, Joint Centre for Bioethics. http://www.jcb.utoronto.ca/people/documents/upshur_stand_guard.pdf [accessed 13.5.20]
- Uscher-Pines Lori, Duggan PS, Garoon JP, et al. (2007) Planning for an Influenza Pandemic: Social Justice and Disadvantaged Groups. *Hastings Cent Rep* 37(4):32–39.
- Venkatapuram S, Heilinger J.-C., Voss M, Wild V and members of the Ethics working group within the German Network Public Health COVID-19 (2020) Ethical principles for the Coronavirus Global Response: Ethical guidance for the development of fast and equitable access to safe, quality, effective and affordable diagnostics, therapeutics and vaccines against COVID-19. May 5, 2020 https://www.public-health-covid19.de/images/2020/Ergebnisse/Ethics_Global_Response.pdf [accessed 13.5.20]
- WHO (2020) DRAFT landscape of COVID-19 candidate vaccines – 20 April 2020. <https://www.who.int/blueprint/priority-diseases/key-action/novel-coronavirus-landscape-ncov.pdf> [accessed 13.5.20]
- Williams, J.H., Dawson (2020) A. Prioritising access to pandemic influenza vaccine: a review of the ethics literature. *BMC Med Ethics* 21: 40.

Authors / Reviewers

Lead authors: Peter Schröder-Bäck (Department of International Health, Maastricht University, peter.schroder@maastrichtuniversity.nl), Verina Wild (Institute of Ethics, History and Theory of Medicine, Ludwig-Maximilians-University Munich), Jan-Christoph Heilinger (Faculty of Philosophy, Ludwig-Maximilians-University Munich).

Contributing authors: Alena Buyx (TU Munich), Hans-Jörg Ehni (University of Tübingen), Samia Hurst (University of Geneva, Switzerland), Joseph Kuhn (Bayerische Landesamt für Gesundheit und Lebensmittelsicherheit), Maria-Sabine Ludwig (Bayerische Landesamt für Gesundheit und Lebensmittelsicherheit), Els Maeckelberghe (UMC Groningen), Kyriakos Martakis (JLU Giessen, Universität zu Köln), Kai Michelsen (HS Fulda), Robert Ranisch (University of Tübingen).

Reviewers: Christian Apfelbacher, Martin Härter, Thorsten Meyer

Disclaimer: Dieses Papier wurde im Rahmen des Kompetenznetzes Public Health zu COVID-19 erstellt. Die alleinige Verantwortung für die Inhalte dieses Papiers liegt bei den Autor*innen.

Das Kompetenznetz Public Health zu COVID-19 ist ein Ad hoc-Zusammenschluss von über 25 wissenschaftlichen Fachgesellschaften und Verbänden aus dem Bereich Public Health, die hier ihre methodische, epidemiologische, statistische, sozialwissenschaftliche sowie (bevölkerungs-)medizinische Fachkenntnis bündeln. Gemeinsam vertreten wir mehrere Tausend Wissenschaftler*innen aus Deutschland, Österreich und der Schweiz.