Ad hoc public health ethics consultation in response to the SARS-CoV-2 pandemic

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Ad hoc ethics consultation for the "Landesinstitut für Gesundheit, Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit" (State Institute for Health, Bavarian Health and Food Safety Authority) prepared by:

Verina Wild (LMU Munich), Alena Buyx (TU Munich), Samia Hurst (University of Geneva), Christian Munthe (University of Gothenburg), Annette Rid (NIH, USA), Daniel Strech (Charité Berlin), Alison Thompson (University of Toronto)

QUESTION 1: The document written by the Imperial College COVID-19 Response Team outlines two major strategies: The suppression strategy and the mitigation strategy. Should the number of deaths, years of life lost, or the like be the ethically dominant criterion in these two strategies? (How) can other ethical aspects, e.g. the higher degree of restrictions on freedom in the suppression strategy or unequal sacrifices in the mitigation strategy, be a) operationalized and b) weighed against the number of deaths? Or should all aspects aside from the number of deaths only be taken into discussion in individual deliberative processes?

Imperial College COVID-19 Response Team. Ferguson NM et al. March 16 2020 https://www.imperial.ac.uk/media/imperial-college/medicine/sph/ide/gida-fellowships/Imperial-College-COVID19-NPI-modelling-16-03-2020.pdf

ANSWER:

Weighing arguments:

- From an ethical point of view public health decisions should not exclusively be based on the number of averted deaths, or on the years of life lost. Other social goods or harmful effects have to be considered as well. Hence, the current situation - while unprecedented at least in recent times - must not lead to an exclusive focus on lives lost by death of COVID-19. States not only have an obligation to suppress and mitigate the pandemic (and avert deaths in this regard), but they also have an obligation to enable and maintain the general conditions for a healthy and flourishing life for the population. The first duty does not entirely cancel out the second.

Note: There is an ethically relevant difference between counting the number of averted deaths, life years gained or quality-adjusted life years gained.

- The ethical trade-offs (or weighing of sometimes competing ethical considerations) can change depending on the context, including the health status of the population and the degree of a health threat. Enabling both freedom and justice in a society depends on a certain level of health and social stability for all.
- A possible justification for restrictive public health measures (e.g. physical distancing) is the state's duty to save and protect bodily integrity and lives. This duty requires enabling equal access to health care, maintaining the health care system with safe working environments (including e.g. personnel, hospitals, equipment, respirators), and continuing to provide care for other diseases and accidents as well.
- The protection of life has to be weighed against infringements of individual rights as well as far-reaching, potentially harmful consequences for society through public health measures (e.g. economic losses, job insecurities and losses, restrictions on education and training, increase in domestic violence, increase in mental health problems, increase in social inequalities (including in the areas of class and gender)). The weighing of incommensurable social goods is certainly not straight-forward or simple, and results of such a process will vary according to the specific circumstances, context and level of evidence.
- Infringements on individual rights and far-reaching, potentially harmful social consequences weigh heavily. Restrictive measures may therefore only be used for as short a period as possible, and they must be compensated for as quickly and as far as possible (see below, listed separately). It must be explicitly guaranteed and ensured by established processes that the infringements on individual rights cease as soon as the state of emergency is over. Whether or not there is an emergency has to be justified.
- Any limitations of individual rights must be in conformity with the rule of law, including the right to appeal, to be heard by an impartial instance, etc. Since these are measures that make the infringement on individual rights and the harm to individuals smaller, implementing them will tend to make strict measures such as confinement more ethically acceptable on balance.
- Any infringements on individual rights will be more easily justified if all alternative measures that could have prevented these infringements have already been exhausted (principle of subsidiarity). This means, for example, increasing hospital and respiratory capacities, limiting the contagion through other means, increasing personnel, increased production of respiratory masks and disinfectants, etc., creating places outside the home environment to

which infected persons can be transferred. These measures may also include simplified production and certification processes for respirators, tests, ventilators, etc.

- Overall, the *simultaneous* pursuit of "containment" and "mitigation" strategies should operate at the same time. The leading norm for pandemics plans should consist of two components: Reduce mortality and morbidity while minimising societal disruption and restore normal social life as quickly as possible.
- Deliberative processes for these trade-offs are not the only way to make decisions in this situation. There are general public health ethics frameworks on which decisions can be based (see list of references). In emergency and disaster situations, the time for deliberative processes is limited. However, this underlines the need for transparent and reasoned decision-making and communication (see below). Nevertheless, deliberation is important and can and should be considered as a method, especially in pandemic planning.
- Operationalising the complex ethical considerations (including the vulnerabilities mentioned below) is difficult, but not always impossible. Scaling and quantifications can help bring about faster decisions and comparisons. For example, desired outcomes of Non-Pharmacological Interventions (NPIs) are to A) “flatten the curve” operationalized by e.g. the speed of increased/decreased infection rates etc., B) preparedness operationalized by e.g. the number of ICU beds, C) availability of effective and safe vaccines etc. Undesired outcomes are manifold, including health-related, economic, and social outcomes. Health-related outcomes might include overall mortality (e.g. does overall non-COVID-19 mortality increase?), morbidity (e.g. do rates of heart attacks, severe depression, domestic violence increase?), quality of care (e.g. does quality of care in nursing homes decrease substantially?). Economic outcomes include, for example, the rate of insolvencies, the rate/extent of liabilities etc. Social outcomes include measures for social inequality such as income inequality, rate of unemployment, gaps in education or instability in children, loneliness etc.

Social vulnerabilities/social justice

- The far-reaching, potentially harmful consequences of infringement of individual rights (including confinement) must be determined professionally and across sectors. Simply defining vulnerabilities in medical terms (e.g. age, comorbidities) is not enough for a comprehensive public health strategy. Other areas such as income, jobs, socio-economic status and inequalities, housing, education, personal safety, disabilities,

nationality/residence status/migration status, mental health, gender inequalities etc. must also be taken into account in the identification of vulnerabilities.

- It can be assumed that disadvantaged population groups will be burdened more by the pandemic itself, but also by restrictive measures. Social vulnerabilities can be reproduced and reinforced in pandemics. Pandemic planning must seek to maintain and stabilize social justice.

Reciprocal obligations/Reparations

- The public is asked to comply with potentially heavily restrictive public health measures, and some are asked to continue working during outbreaks at some personal risk. There is an obligation for the state to limit the potentially harmful effects of these measures to the greatest extent possible. The public obligations should thus be accompanied by a reciprocal duty to compensate for the multidimensional harms and losses incurred currently and to be incurred in the future. Reparations can be far-reaching, especially in wealthy states, e.g. improvement of unemployment insurance rights, debt relief (such as suspension of deadlines), protection against termination of tenancies, waiver of fees for credit card payments when buying food, provision of safe working environments for those who are required to continue working (again with special attention to social vulnerabilities as many workers who have to continue working tend to be from vulnerable groups).
- This obligation not only exists to prevent harm to individuals, but is also a condition for implementing public health strategies, also in the future. Rules of isolation and quarantine, for example, cannot be implemented equally for everyone: often they are more difficult to implement for disadvantaged groups. However, non-implementation threatens all, so social justice is of great importance for all.

Trust and communication:

- Public trust in political authorities and successful communication by the political authorities are particularly decisive to the implementation of restrictive measures. It is important to communicate the measures transparently and to justify them as fair, justified and oriented towards the welfare of the population (see below Ethical processes, Table 1). In particular, the recognition of social vulnerabilities (see above) must be taken into account and creative proposals and solutions for minimising vulnerabilities must be developed and presented quickly

- In the planning of measures as well as in communication, it must be recognised that, although decisions are made on the basis of increasing evidence, many decisions are made under conditions of uncertainty. In this context, it is necessary that public communications clearly relay what is known and evidence-based and what is not, otherwise public confidence may be damaged. Ethical justification must also be communicated transparently. Without justification, a strong emphasis on utilitarian objectives (such as maximising the benefits of limited resources, e.g. for ventilator beds, vaccines) may be considered inappropriate in the population (e.g. as distribution according to need or giving priority to the worst of might be more plausible).

Implementation

- When implementing restrictive public health measures, it must be taken into account that people may balance competing ethical considerations differently than authorities. This can affect adherence and make measures more difficult, more costly or less effective.
- The implementation of restrictive measures must be evaluated in accompanying research. Data collection is necessary both from an epidemiological point of view and from a broader social perspective (school closures, economic effects, class- or gender-related effects, etc.). The question here is not only what effectiveness the measures have or have had in direct relation to SARS-CoV-2/COVID-19, but also what positive and negative effects can be observed beyond that, and what will the long-term effects will be. In addition to economic factors, the consequences for mental health, social vulnerabilities and social justice must also be taken into account (see above).
- To the extent possible, implementation of restrictive measures should always be proportionate to the threat. The threat should be understood in a broader sense than just the impact of COVID-19, and include wider societal consequences mentioned above. The conditions of uncertainty and lack of evidence in relation to the threat while having to implement proportionate responses underscore the need for research.

Planning for the future

- Long-term pandemic planning (in relation to COVID-19) is necessary to ensure sustainable health and health care and to maintain other social goods that are necessary for a flourishing life. Ideally, these long-term aspects should be anticipated now and given the best possible consideration. In addition to economic factors, the consequences for mental health, social vulnerabilities and social justice should be taken into account.

- General pandemic planning should be included as an integral part of regional, national and international health policy, including the perspectives of global health (e.g. the situation of low- and low and middle income-countries, the situation of refugees in camps or transit, international collaboration and solidarity, role of WHO), one health (e.g. the connections between animals, human beings, environment) and the collaborative, international collection and sharing of good evidence. General pandemic planning should also include long-term stabilisation of health care systems and infrastructure, including adequate resources for staff (link to general pandemic planning, that include these aspects)

QUESTION 2: We do not yet have a reliable measurement of the effects of the measures that we are currently implementing (time horizon 2-3 weeks until full effectiveness). The effectiveness of the measure therefore seems rather limited as a decision-making criterion. Which additional ethical criteria should we consider, especially with regard to more than the existing social distancing measures (e.g. a general curfew)?

ANSWER:

- If too little data is available, every effort should be made to obtain **evidence** on the effectiveness of the measures (internationally coordinated, evaluation of existing data, immediate start of studies). These efforts must be maintained throughout the outbreak and beyond. We have the advantage that evidence from other countries is already available. As already mentioned, evidence must be collected in a broad sense, including effectiveness of measures on SARS-CoV-2/COVID-19-development but also on broader, societal effects. The collection and evaluation of international evidence accompanied by domestic research is absolutely necessary. Even if rapid data collection is urgently necessary, quality criteria for evaluating evidence are necessary too, otherwise there is a risk of momentous decision-making based on low-quality evidence.
- **Solidarity, responsibility** (including individual responsibility) and **reciprocity** are established as further ethical principles of public health measures and could be additionally considered.
- The above-mentioned circumstances regarding uncertainty, communication and trust also apply here:
    - **Uncertainty**: Decisions are being made under conditions of uncertainty. Preventive measures are being proposed in the face of uncertain and difficult to predict

developments (see above). If community transmission is to be assumed, measures should be strengthened to protect risk groups and the operative health care system (see above). This includes streamlining strategies (instead of inefficient or missing individual strategies for individual practices and hospitals), increasing efficiency with regard to tests, laboratory capacities, immediate isolation of risk groups, as well as all other measures to “flatten the curve” (e.g. social distancing) and, if necessary, curfews. The Precautionary Principle implies that measures are taken in order to gain time, obtain more evidence and avert catastrophic developments. The weighing, as described above, must be continued while taking broader, also serious consequences into consideration (economic, psychological and other medical, social and justice-relevant).

- **Communication**: Given the infringement on individual rights, other sacrifices that are being made by the public and in order to maintain solidarity, it is necessary to communicate why the a precautionary approach was applied, i.e. why individual responsibility is now necessary, how and why this decision was taken under conditions of uncertainty, when and how the effectiveness of the measures will be reviewed and when the probable end can be expected.

QUESTION 3: We are currently expanding testing in large magnitudes. Routine surveillance (according to the German law on infectious diseases) will now primarily measure test activity rather than the actual development of the number of cases. Would accompanying studies on the performance of the test (test metrics, e.g. sensitivity, specificity, positive/negative predictive values) also be ethically advisable?

ANSWER:

- Yes, such studies are very useful now and in the future.
- Ideally such studies should be internationally coordinated.
- Ideally, such studies should be repeated and conducted in cohorts in all regions. In particular, those persons who now have negative test results should be tested again to see whether the restrictive measures (social distancing, etc.) have any effect.
- However, the studies must fit well into the overall infection control strategy, e.g. resources must be used in a way that is compatible with the laboratory capacity and expertise currently required for acute infection control. If tests cannot collect much information outside of acute health care, it may make sense to use them only for symptomatic cases. It also depends

on whether community transmission is assumed. In the prevention phase or during interventions to reduce community transmission, the argument for extending testing may be stronger.

- Scenarios can also be considered in which all tests are included in studies through opt-out procedures or even compulsory provision of samples and data, provided that anonymisation is guaranteed. The risks to the individual study participant are low, the potential gain in knowledge for public health and decision-making could be very high.
- Rigorous study designs, cooperation and data exchange, and the fastest possible, peer-reviewed and open access publication of data are important.

QUESTION 4: Which ethically problematic issues could arise from a representative cohort study that examines the longitudinal serological activity and disease severity, possibly in subgroups? Which subgroups should be specifically studied?

ANSWER:

- Overall, this type of study is absolutely necessary not only to reduce current uncertainties e.g. regarding lack of evidence, but also to understand Covid-19 in the long term. This is a unique opportunity to gain insights into an emerging infectious disease.
- Study results can also lead to the identification of persons who are immune and no longer infectious, which can then be deployed into essential sectors of society (including health care). This would then no longer be part of the "study" in the strict sense, but it could be considered from the start of the study whether and how this could be done.
- During a pandemic, however, resources should be concentrated primarily on the management and containment of the pandemic. Tests can also be marked and prepared for retrospective cohort studies. If all Covid19 cases, documentation, test results, etc. are marked and prepared for such retrospective studies, subgroups can also be formed later.
- Study designs must meet recognized ethical standards for research despite all haste.
- Avoiding the stigmatisation of subgroups is an important point, but cannot be answered ad hoc in terms of content but rather in a process-oriented way: From the very beginning avoidance of stigmatisation should be taken into consideration, data should not be published unfiltered and thoughtlessly in a subgroup-specific manner. A coordinated strategy to avoid potential stigmatisation should be developed.
- Further study designs must now be planned and coordinated, for example, regarding vaccination and therapy.

- Study results must be processed in an internationally coordinated manner as quickly as possible and published in an open access format (see above).

Literature

COVID-19 Public Health Ethics resources (selection):

Deutscher Ethikrat. Solidarity and Responsibility in the Corona-Crisis. March 27, 2020 https://www.ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/deutsch/ad-hoc-empfehlung-corona-krise.pdf

Hastings Center provides a collection of COVID-19 related ethical resources: https://www.thehastingscenter.org/ethics-resources-on-the-coronavirus/

Human Rights Watch: Human Rights Dimensions of COVID-19 Response, March 19, 2020: https://www.hrw.org/news/2020/03/19/human-rights-dimensions-covid-19-response

Nuffield Council of Bioethics. New briefing: Responding to the COVID-19 pandemic - ethical considerations. March 17, 2020 https://www.nuffieldbioethics.org/news/responding-to-the-covid-19-pandemic-ethical-considerations

UNESCO. Ethics in research in times of pandemic COVID-19: https://en.unesco.org/news/ethics-research-times-pandemic-covid-19

General pandemic ethics and research ethics (selection):

Biddison et. al.: Ethical Considerations. Care of the Critically Ill and Injured During Pandemics and Disasters: CHEST Consensus Statement. 146(4_Suppl):e145S-e155S

Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector: https://www.canada.ca/en/public-health/services/flu-influenza/canadian-pandemic-influenza-preparedness-planning-guidance-health-sector.html

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects (see esp. Guideline 20): https://cioms.ch/wp-

content/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf

Ethical Guidance for Public Health Emergency Preparedness and Response: Highlighting Ethics and Values in a Vital Public Health Service: https://www.cdc.gov/od/science/integrity/phethics/docs/white_paper_final_for_website_2012_4_6_12_final_for_web_508_compliant.pdf

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WHO 2014: Ethical issues related to study design for trials on therapeutics for Ebola virus disease: https://www.who.int/csr/resources/publications/ebola/ethical-evd-therapeutics/en/

WHO Guidance For Managing Ethical Issues In Infectious Disease Outbreaks: https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf;jsessionid=90D397564B3996CA5B331D1F65F50E76?sequence=1

General Public health ethics frameworks (selection):

Childress, J. F., Faden, R. R., Gaare, R. D., Gostin, L. O., Kahn, J., Bonnie, R. J., ... Nieburg, P. (2002). Public health ethics: Mapping the terrain. Journal of Law, Medicine & Ethics, 30(2), 170–178;

Grill, K., & Dawson, A. (2017). Ethical frameworks in public health decision-making: Defending a value-based and pluralist approach. Health Care Analysis, 25(4), 291–307.

Kass, N. E. (2001). An ethics framework for public health. American Journal of Public Health, 91(11), 1776–1782;

Marckmann, G., Schmidt, H., Sofaer, N., & Strech, D. (2015). Putting public health ethics into practice: A systematic framework. Frontiers in Public Health, 6(3), 23;

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Willison, D.J., Ondrusek, N., Dawson, A., Emerson, C., Ferris, L.E., Saginur, R., Sampson, H., Upshur, R., 2014. „What makes public health studies ethical? Dissolving the boundary between research and practice“. BMC Medical Ethics