

Developing global norms for sharing data and results during public health emergencies

Statement arising from a WHO Consultation held on 1-2 September 2015

Leading international stakeholders from multiple sectors convened at a WHO consultation in September 2015, where they affirmed that timely and transparent pre-publication sharing of data and results during public health emergencies must become the global norm.

The following summary points represent WHO's position with regard to data and results sharing in public health emergencies, having taken into account the perspectives of those who attended the meeting.

Summary Points

1. Research is essential in the context of public health emergencies. The primary purpose of such research is to advance public health, prevent illness and save lives. Researchers should always weigh the public health consequences of their actions in withholding and sharing results.
2. Every researcher that engages in generation of information related to a public health emergency or acute public health event with the potential to progress to an emergency has the fundamental moral obligation to share preliminary results once they are adequately quality controlled for release. The onus is on the researcher, and the funder supporting the work, to disseminate information through pre-publication mechanisms, unless publication can occur immediately using post-publication peer review processes.
3. WHO seeks a paradigm shift in the approach to information sharing in emergencies, from one limited by embargoes set for publication timelines, to open sharing using modern fit-for-purpose pre-publication platforms. Researchers, journals and funders will need to engage fully for this paradigm shift to occur.
4. Representatives from major biomedical journals who attended the meeting agreed that public disclosure of information of relevance to public health emergencies should not be delayed by publication timelines and that early disclosure should not and will not prejudice later journal publication¹. WHO calls on all journals to follow this example, and help to be an important part of the solution of information sharing in public health emergencies, and to never be a hindrance when timelines for information sharing are critical.
5. Researchers should be responsible for the accuracy of shared preliminary results, ensuring that they have been subjected to sufficient quality control before public dissemination. Opting in to data and results sharing should be the default practice and the onus should be placed on data generators and stewards at the local, national and international level to explain any decision to opt out from sharing data and results during public health emergencies
6. Incentives for sharing data and results should be created and tailored for each type of data generator and steward.
7. The origin of data on an emerging pathogen is frequently obtained from biomedical samples. The ethical requirements of informed consent must be respected. The legitimate needs of the originating country must be taken into account. These include acknowledgement in future research reporting, inclusion in decision-making before any next steps are taken with information arising from samples (including with regard to intellectual property, access to knowledge and benefits), and a commitment from the international community to capacity development in settings with less experience in clinical research, pathogen genome sequencing and evaluation of diagnostics and experimental products.
8. Patents on natural genome sequences could be inhibitory for further research and product development. Research entities should exercise discretion in patenting and licensing genome-related inventions so as not to inhibit product development and to ensure appropriate benefit sharing.
9. The following critical ethical perspective must be borne in mind in the context of public health emergencies: there are very great risks in withholding data and results arising from analyses of that data, and these risks are to both the individual and community from which the data arises, and for nations, regions and the globe. The risks of withholding data and results must always be taken into account in the context of emergencies.
10. A critical point is to clearly distinguish between different issues related to individual participant level data sharing (where there are legitimate concerns about privacy) and sharing of results arising from analyses of those data which does not hold the same privacy concerns.

11. WHO considers that the principles outlined in this document should be considered during the current review of the International Health Regulations, and that sharing of epidemiological and population-based data should be strongly encouraged

¹ The group of journals that attended the meeting agreed a consensus statement which is appendix 1 below.

Appendix 1

A Consensus statement made by (in alphabetical order) British Medical Journal, the Nature Journals, the New England Journal of Medicine, and the 7 PLoS Journals is published here by WHO. Italics have been added for emphasis by WHO.

Public health emergencies of global significance constitute compelling examples of the importance of sharing data. Journals should not hinder the sharing of data that could help mitigate the impact of such emergencies.

In such scenarios, journals should not penalize, and, indeed, *should encourage or mandate public sharing of relevant data, which may include results of laboratory studies (for example, genomic and immunological data), demographic data, results of animal studies, and de-identified clinical data from individual study participants*. Data sharing should occur *no later than the time of publication of the related article, and earlier in the evaluation process if the situation warrants*.

Journals should *not penalize authors who, prior to manuscript submission, share data in the interest of resolving an urgent situation, for example with public health authorities or more broadly when warranted*.