Policy Statement on Data Sharing by the World Health Organization in the Context of Public Health Emergencies

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The primary purpose of data sharing by WHO during a public health emergency is to permit analyses that allow the fullest possible understanding of the emergency, and to ensure that decisions are based on the best available evidence.

There are different considerations for data sharing in public health emergencies in each of the following three categories: (1) surveillance, epidemiology and emergency response, including health facilities, (2) genetic sequences, and (3) observational studies and clinical trials. This policy statement sets out to clarify WHO's position in providing access to data in these three categories.

This statement does not cover other kinds of data that could be useful but which are not typically provided to WHO, such as telephone Call Detail Records (CDR). Furthermore, this statement refers to the sharing of data only, not biological samples. The latter require a different set of considerations.

1. **Surveillance, epidemiology and emergency response**

It was recognized at the WHO R&D Blueprint consultation in September 2015 [1] that epidemiologic data belong to the countries where they are generated, but there was consensus that data should be shared by default, but with an opt-out policy, to ensure that the knowledge generated becomes a global public good.

Articles 6-11 of the International Health Regulations (IHR) are intended to encourage States Parties to share information with WHO before a Public Health Emergency of International Concern (PHEIC) is declared. The restrictions on when WHO can disclose that information publicly are in paragraph 4 of Article 11. Data can be made publicly available when both of the following apply:

(1) the requirements for making the information available to States parties are fulfilled, i.e. when (a) a PHEIC is declared or, (b) evidence indicates that there is, or will be, international spread of infections or other harmful agents or,(c) there is immediate need for international control measures, and

(2) other information about the event has already become publicly available and there is a need for the dissemination of authoritative information. In practical terms, this second requirement (information on the event is already public) is fulfilled in the earliest stages of

[1] www.who.int/medicines/ebola-treatment/data-sharing_phe/en/

an event, which permits disclosure to the public immediately following disclosure to States Parties.

Policy statement

Against this background, WHO makes the following the policy statement:

"*In accordance with Article 11 of the IHR (2005), WHO will disclose and publish information received under Part II of the IHR (Information and Public Health Response), when requirements for disclosure (paragraphs 2 and 4 of Article 11) are satisfied [i.e. under conditions (a)-(c) above]. Data will be anonymized to protect privacy and to ensure confidentiality. WHO will consult with affected countries to inform them prior to disclosing data. WHO underlines that countries should share benefits arising out of the utilization of the data received through WHO with the originating country in accordance with applicable international commitments."*

This data includes data from surveillance and monitoring (informing epidemiology), from the emergency response (e.g. contact tracing, vaccination, treatment), and data concerning health facilities (e.g. the numbers and locations of in-patient and out-patient centres, and the staff and medical facilities available at these centres).

Anonymisation will remove all personal identifiers and locators, and will comply with personal data protection requirements as laid out in Article 45 of the IHR. Efforts will be made to curate data so as to increase their utility, and further analysis and reporting of new data generated will be encouraged. In exceptional cases, where there is a compelling reason to opt out of sharing for subsets of data, this will be possible.

2. **Genetic sequence data / information**

The sharing of genetic sequence data / information is as important as the sharing of other event-related information under the conditions laid out in Article 11 of the IHR and restated above. Sharing data allows the better tracking of epidemics, and aids the development of diagnostic tests, therapeutics and vaccines.

It may be desirable to establish one or more consortia of public sector genome sequencers, who will provide a service to WHO in the context of a public health emergency.

Policy statement

WHO will advocate that pathogen genome sequences be made publicly available as rapidly as possible through relevant databases and that benefits arising out of the utilization of those sequences be shared equitably with the country from where the pathogen genome sequence originates. This refers only to the public sharing of sequences, not to biological samples, which will be subject to a separate WHO policy (in preparation).

3. **Observational studies and clinical trials**

Observational and clinical studies relate to data generated under research protocols. For scientific reasons, these protocols often preclude the disclosure of data before predefined interim or final assessments. Furthermore, the early sharing of primary data in emergencies is not important in the same way that it is for epidemiological and genetic sequence data. The critical need in emergencies is to ensure that there is transparency about which studies and trials are being carried out, to specify in advance the points at which preliminary findings will be made available, and to work with researchers, funders and journals to make preliminary results, and then final results, available without delay.

Policy statement

All interventional clinical trials must be prospectively registered in a primary clinical trials registry, conforming to standards agreed by WHO International Clinical Trials Registry Platform (who.int/ictrp).

During a public health emergency, before each trial begins each research protocol should make a specific commitment to share results in a pre-specified expedited timeline. WHO's position will be that the public disclosure of results will be the norm, in the expedited timeline as dictated by the research protocol. Outside public health emergencies the norm is for public disclosure of results within 12 months of completion of a trial.[2]

Transparency concerning the conduct of animal experiments is important for drug and vaccine development. WHO will communicate the importance of transparency and a public log of all animal models with key outcomes should be maintained and updated.

Security of Data Held at WHO

WHO has a formal and comprehensive policy for securely managing all data bases and information sources hosted by the Organization. The policy includes information security, technical and physical data security, data access and retention procedures, and confidentiality arrangements. As international civil servants, all WHO staff are required to adhere to the policy and its procedures (detailed under Staff Regulations), including with full respect to Article 45 of the IHR.

[2] The WHO position is outlined at www.who.int/ictrp/results/reporting.