World Health Organization

# Frequently Asked Questions

# WHO policy on the use and sharing of data collected in Member States outside the context of public health emergencies

## Background

### When did this policy come into force?

The policy on the use and sharing of data collected in Member States by WHO outside the context of public health emergencies was introduced on 1 January 2018. The policy will be monitored and evaluated over a 12-month transition period (at least one data collection cycle for technical programmes in WHO). Subsequent modifications may be made taking into account the views of technical departments at WHO (compiling and analysing data), Member States (providing data) or third parties (receiving data). The policy will not be applied retrospectively to data already provided by Member States to WHO, and/or which have already been shared by WHO with third parties.

### Why did WHO adopt this policy?

The collection, analysis, publication and dissemination of data form a core part of WHO's mandate. Furthermore, WHO's functions include acting as the directing and coordinating authority on international health work within the United Nations system. Against this background, it was considered desirable to develop a policy setting out the terms and conditions of data transfer from Member States, in line with best practices. The policy aims to maximize the benefits of data-sharing, while safeguarding the privacy and interests of individuals, and the interests of Member States that provide data.

The benefits of data-sharing are also increasingly recognized by governments and intergovernmental organizations. Major research and funding agencies are publishing more open data-sharing policies and positions.

## Scope of the policy

### Which data are covered by the policy?

The policy applies to data collected by WHO in, and/or provided to WHO by Member States other than data which are published by Member States without any restrictions on their use.

**Table 1. List of data types (non-exhaustive)**

| Data types | Examples |
|---|---|
| WHO-supported household surveys | WHO Strategic Advisory Group of Experts (SAGE) on Immunization, WHO STEPwise approach to surveillance (STEPS), World Health Survey |
| Unit record mortality data | (Not currently collected by WHO headquarters, but by the WHO Regional Office for the Americas/Pan American Health Organization) |
| Aggregated mortality data | WHO Mortality Database |
| Aggregated health facility data | DHIS 2.0 data (not currently collected by WHO headquarters, but hospital data are collected by the WHO Regional Office for Europe) |
| Case-based health facility data | WHO Global Burn Registry data[a] |
| Health expenditure data | WHO Global Health Expenditure Database (National Health Account indicators) |
| Health facility surveys | Availability of medicines and diagnostics |
| Health research data (other than clinical trials)[b, c] | Case–control investigations, prospective cohort studies |
| Key informant surveys | Existence of national road traffic laws |
| National survey reports | Prevalence of hypertension or tobacco use |
| Disease surveillance data | HIV prevalence in pregnant women or tuberculosis treatment outcomes |
| Surveillance of notifiable diseases | Total number of cases of plague |

[a] Note: the collection of case-based data from health facilities, such as that in the WHO Global Burn Registry, does not require WHO Member State approval.
[b] The world health report 2013: research for universal coverage. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/85761/2/9789240690837_eng.pdf?ua=1, accessed 17 May 2018).
[c] WHO statement on public disclosure of clinical trial results: Geneva: World Health Organization; 2015 (https://www.who.int/ictrp/results/en/ , accessed 17 May 2018).

### Which data are excluded from the policy?

The policy excludes the following data types:

- data shared in the context of public health emergencies, including officially declared public health emergencies of international concern (PHEICs) under the International Health Regulations (2005);
- data and reports from clinical trials;[1]
- biological samples.

### For whom is the policy intended?

This policy is aimed at all stakeholders: Member States, WHO staff and interested third parties.

### To whom does the policy apply?

The policy applies to all WHO offices, i.e. WHO headquarters, regional offices and country offices, as well as partnerships hosted by the Organization. It also applies to consultants, volunteers and interns working for WHO.

### How does the policy change current practices with regard to data collection, use and sharing?

The policy seeks to establish a clear framework for data collection, use and sharing, including measures to ensure the ethical and secure use of data. The policy outlines the terms under which:

- Member States will provide data to WHO; and
- WHO will use the data and make them available on request to interested parties for non-commercial, not-for-profit use for public health purposes.

### Who is authorized to agree to the terms of data collection in a Member State?

This should be a duly authorized representative of the government with authority to release health data to WHO (i.e. the Ministry of Health or other responsible governmental entity).

### Please explain the text for inclusion in data collection forms

The Annex of the policy provides **mandatory** text for inclusion in data collection forms in all tools (paper-based, electronic or other) used by WHO to collect data from Member States. This text should be reproduced (verbatim). The form will not be signed by the Member State providing the data, unless the Member State wishes to opt out of the arrangement in respect of certain data (see What is the process for opting out of sharing data?).

[1] WHO's existing position is that: (i) all clinical trials are to be prospectively registered in a clinical trial registry meeting international standards (http://www.who.int/ictrp); and (ii) at a minimum, a summary of results from the clinical trial are to be made publicly available within 12 months of study completion (http://www.who.int/ictrp/results/reporting).

### What is the process for opting out of sharing data?

The ministry of health or other responsible governmental entity of a Member State may in respect of certain data opt out of (any part of) the terms of the data collection form, by notifying WHO thereof in writing, provided that it clearly identifies the data in question, indicates the scope of the opt-out and gives specific reasons for the opt-out. Such notifications should be addressed to Director SPI, World Health Organization, 20 avenue Appia, 1211 Geneva 27, Switzerland.

The opt-out is not possible for data that must be shared and published pursuant to legally binding instruments, such as the International Health Regulations (2005) or the WHO Nomenclature Regulations 1967.

### In what way can WHO use and share Member State data with third parties under the policy?

Subject to measures to ensure the ethical and secure use of the data, and an appropriate acknowledgement of the country, WHO can:

- publish the data, stripped of any personal identifiers (such data without personal identifiers being hereinafter referred to as "the Data");
- make the Data available to any interested party on request (to the extent they have not, or not yet, been published by WHO) on terms that allow non-commercial, not-for-profit use for public health purposes (provided always that publication of the Data shall remain under the control of WHO);
- use, compile, aggregate, evaluate and analyse the Data, and publish and disseminate the results thereof, in conjunction with WHO's work and in accordance with the Organization's policies and practices.

### The policy states that WHO may share the unpublished anonymized data with any interested party on request – what does this mean?

If an organization, such as an institution, wishes to conduct some research on the anonymized data from a particular country, it can make a request to WHO. If the proposed use is non-commercial, not-for-profit use for public health purposes, then WHO would sign a data-sharing agreement to ensure that the data remain under the control of WHO and that certain conditions are respected, including acknowledgement of the country concerned and inclusion of a disclaimer. The institution would not have the right to distribute or publish the data. Any findings and/or analyses arising from the use of the country data cannot be made public without the express written consent of WHO.

### What does anonymization of data involve?

Under the policy, WHO can only use, publish and share Member State data after the data have been anonymized (i.e. stripped of any personal identifiers). Data on individuals (e.g. patients, survey respondents) provided by Member States may contain information that identifies those individuals. In order to safeguard the privacy and anonymity of individuals, data on individuals, and other information deemed sensitive

(e.g. detailing specific locations or health facilities) will only be used, published and made available by WHO to third parties after the removal of identifying details following a formally verified anonymization procedure.

### What other ethical considerations apply to the collection, use and sharing of data?

In addition to the obligation to anonymize data (above), the policy includes measures to avoid stigmatization or exclusion of people or communities as a result of data collection. In cases where the compilation, analysis and sharing of aggregated data raise ethical concerns or present risks with regard to confidentiality, WHO will:

- comply with informed consent agreements where such consent is needed and respect assurances about ways in which the data (anonymized or otherwise) would be used, shared, stored or protected;[2] and
- adopt appropriate security measures to foster public trust.

In addition, any platforms established to share data should have an explicit ethical framework governing data collection and use.

### Does the policy feature any additional data security or confidentiality measures?

Measures to ensure the ethical and secure use of data are a key element of this policy. WHO's existing information security policies (and their respective implementation guidelines) will apply. These policies cover information security, access to information and systems, cloud computing, application security, information classification and related security standards. They are based on the ISO 27001 standard.

The policy foresees additional safeguards, including the establishment of an independent data review committee within WHO to consider, on a case-by-case basis and in consultation with other relevant departments in WHO, any instances where the policy provides inadequate guidance on data-sharing. In addition, data on individuals, and other information deemed sensitive will be made available by WHO to third parties only after the removal of identifying details following a formally verified anonymization procedure (see What does anonymization involve?)

### Why are data and reports from clinical trials excluded from the policy?

WHO's position with regard to the disclosure of data generated during clinical trials is reflected in its statement of 9 April 2015,[3] together with an accompanying article explaining the rationale for its position.[4]

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[2] WHO statement on public disclosure of clinical trial results: Geneva: World Health Organization; 2015 (http://www.who.int/ictrp/results/en/, accessed 17 May 2018).

[3] WHO statement on public disclosure of clinical trial results. Geneva: World Health Organization; 2015 (http://www.who.int/ictrp/results/reporting/en/, accessed 17 May 2018).

[4] Moorthy VS, Karam G, Vannice KS, Kieny MP. Rationale for WHO's new position calling for prompt reporting and public disclosure of interventional clinical trial results. PLoS Med 12(4): e1001819. https://doi.org/10.1371/journal.pmed.1001819

Pursuant to WHO's statement, it is expected that: (i) all clinical trials are to be prospectively registered in a clinical trial registry meeting international standards;[5] and (ii) at a minimum, a summary of results from the clinical trial are to be made publicly available within 12 months of study completion).

The registration of clinical trials with a clinical trial registry and the publication of clinical trial results should not prejudice the confidentiality of information, which is proprietary to WHO, parties collaborating with WHO and/or third parties. In the case of results that may be capable of industrial or commercial exploitation, confidentiality shall be maintained for a period of 12 months in order to enable patent rights to be safeguarded or to allow alternative forms of legal protection to be explored. Unless it is mutually agreed that confidentiality beyond a period of 12 months is necessary and consistent with the public interest, the parties shall not be bound by any obligation to keep the results confidential.

### Will the policy be applied retrospectively?

The policy will not be applied retrospectively to data already provided by Member States to WHO. It applies to data provided by Member States to WHO after the date of its entry into force, i.e. 1 January 2018. Furthermore, the policy places no obligation on WHO or Member States to collect, anonymize, analyse or share other health data than those already being collected, anonymized, analysed and shared.

### Is the new policy meant to be a completely "open" data-sharing policy?

No. The policy does not provide for open data-sharing without restrictions. Rather, it sets out specific conditions for data sharing with third parties.

5 International Clinical Trials Registry Platform (ICTRP). Geneva: World Health Organization (http://www.who.int/ictrp/en/, accessed 17 May 2018).