

INFORMATION SHEET

WHO Global Clinical Platform for clinical characterization and management of hospitalized patients with suspected, probable or confirmed Cholera

To help with disease characterization, WHO has created a Global Clinical Platform of patient-level anonymized clinical data. It is a secure, limited-access, password-protected platform hosted on REDCap.

The objectives of the Platform are to:

1. Describe the clinical characterization of disease, its natural history and severity;
2. Identify the association of clinical characteristics of Cholera with outcomes.
3. Enable an understanding of the clinical resource-use when providing high-quality supportive care

WHO invites Member States, health facilities and other entities to participate in the global effort to collect anonymized clinical data relating to suspected, probable or confirmed cases of cholera and contribute data to the WHO Global Clinical Platform.

WHO has developed a clinical characterization case report form (CRF) to standardize data collection of clinical features among hospitalized cases at baseline (admission), during treatment, and at discharge or death. These three modules may be completed prospectively or retrospectively.

Global Clinical Platform for clinical characterization and management of hospitalized patients with suspected, probable or confirmed cholera

The web-based electronic [WHO Global Clinical Platform for Cholera](#) enables rapid and systematic collection of anonymized clinical data, and facilitate aggregation, tabulation and data analysis across different settings and sub-populations globally.

Hosted on REDCap, the WHO platform is a secure, limited-access, password-protected platform. WHO will:

- protect the confidentiality and prevent unauthorized disclosure of submitted data; and
- implement and maintain appropriate technical and organizational security measures to protect data stored on the WHO platform.

Note: Upon submission of their data to WHO, contributors will have access to their dataset in an analysable format.

Entities wishing to contribute anonymized (i.e. stripped of all personal identifiers) clinical data to the WHO Global Clinical Platform for Cholera should email:
globalclinicaldataplatfom@who.int

Provided they agree to the Terms of Use, they will receive log-in credentials. Data contributors are respectfully requested to ensure that they obtain any consent or approval needed before collecting and contributing any data to the platform, and that they take all necessary measures to protect their platform log-in credentials and passwords. Data contributors will not have access to data from other facilities. The process for data sharing is further described in **Annex A**.

Data can be recorded directly into the electronic , or into the local database of a facility or network, or on printed paper CRFs, with data entered into WHO Platform thereafter.

What if clinical data of hospitalized patients with cholera have been already collected using local databases?

If clinical data have already been entered in local databases, the relevant datasets can be aligned and pooled with the WHO global dataset. WHO can work with data contributors from individual entities to transfer relevant variables from individual patients (i.e. not in aggregated fashion) from local databases to the Global Clinical Platform for Cholera.

Clinical characterization case report form

The CRF is designed to collect data obtained direct from patient examination and interview, and from review of hospital or clinical notes of people with suspected, probable or confirmed Cholera.

This CRF has three modules:

- Module 1: To be completed on the first day of presentation or admission to the cholera treatment unit, centre or ward.
- Module 2: Daily Form: To be completed on inpatient days.
- Module 3: To be completed at last visit, either hospital discharge, transfer, last outpatient follow-up or death.

The CRFs should be completed and updated throughout the outpatient management or stay in the health facility– including if the patient is transferred from one ward to another, i.e. from the date of admission to the hospital, until the date of death or discharge from the hospital, or transfer to another hospital.

Data may be collected prospectively or retrospectively through examination and review of medical records. To ensure the high value of information generated by the WHO Global Platform, it is critical that contributors ensure the completeness and quality of reported data.

Clinical Advisory Group

WHO has established an independent Clinical Advisory Group (CAG) who meets regularly to advise WHO on global reporting and analysis of anonymized cholera data.

Statistical analysis plan

- Data will be pooled and presented as aggregated global figures. Pending data availability, subnational, national or larger regional statistics may be reported.
- Descriptive analysis will be performed on clinical characteristics at hospital admission, during hospitalization, and on interventions and clinical outcomes (mortality, length of stay) at discharge.
- Analysis by subpopulations will be performed where possible (e.g. children, pregnant women, populations with co-infection).
- Other analysis will be guided by the CAG and data contributors.

Reporting and publication

WHO will analyse the data regularly and share a summary report with all contributors. The report will subsequently be made publicly available on the WHO website.

Where possible and appropriate, data will be reported in an aggregated fashion with other data provided to WHO by third parties. As such, facility-level information will not be identifiable, meaning that data contributors will still be able to publish their data elsewhere. Indeed, while publication in a peer-reviewed scientific journal is not the primary purpose of WHO repository, data contributors are encouraged to analyse and publish results from their own datasets.

Data contributors of cholera data will be acknowledged in the reports, as appropriate.

To contribute anonymized patient data to Global Clinical Platform for Cholera, there are 3 simple steps to follow:

STEP 1. CREATE YOUR PROFILE clicking the following web link:

STEP 2. REVIEW TERM OF USE and submit the form

STEP 3. After 1-2 days, you'll receive an email with log-in credentials for accessing the Global Clinical Data Platform for cholera or, if you have an established database, other instructions for sharing data.

For more information on the Global Clinical Data Platform for Cholera, visit the webpage: <https://www.who.int/tools/global-clinical-platform/cholera>

If you have any questions, please contact WHO at: globalclinicaldataplatfom@who.int

Annex A – Data sharing with WHO

World Health Organization has launched a Global Clinical Platform for Cholera, (the “Cholera Data Platform”) to enable State Parties to the International Health Regulations (IHR) (2005) and other entities to share with WHO anonymized clinical data and information relating to patients suspected or confirmed to have cholera (collectively, the “Anonymized Cholera Data”).

State Parties to the IHR are invited to contribute Anonymized Cholera Data collected by such State Parties (including, without limitation, by their ministries of health or public health agencies or institutions) through the WHO Cholera Clinical Data Platform, pursuant to and in line with the requirements of the IHR (2005). Other entities (such as healthcare facilities, universities, research networks) are invited to contribute their anonymized Cholera data to the WHO Clinical Data Platform for Cholera subject to and in accordance with the Terms of Use.

The Anonymized cholera data received from State Parties to the IHR and/or entities through the cholera Data Platform will remain property of the contributing State Party or entity, as applicable, and will be used by WHO to inform appropriate public health response and the development of clinical guidance concerning Cholera.

State Parties to the IHR and/or other entities wishing to contribute Anonymized Cholera Data to the WHO Cholera Platform should email globalclinicaldataplatfom@who.int to view the Terms of Use and obtain log-in credentials for the Cholera Platform.

In accordance with Article 11(4) of the IHR (2005), WHO will not make the individual dataset of Anonymized Cholera Data generally available to other State Parties or third parties until such time as any of the conditions set forth in paragraph 2 of such Article 11 are first met and following consultation with the affected countries.

Pursuant to that same Article 11, WHO will not make Anonymized Cholera data available to the public, unless and until Anonymized Cholera data has already been made available to State Parties, and provided that other information about the Cholera epidemic has already become publicly available and there is a need for the dissemination of authoritative and independent information.