WEBINAR SERIES

HEALTH THROUGH THE LIFE COURSE

Promoting health throughout the life-course during the COVID-19 pandemic

Webinar-1: COVID-19 in children

PEDIATRIC COVID19 REGISTRY

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KNOWLEDGE TO ACTION phfi
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CONTEXT

- Most of the published data is derived from adults with coronavirus disease 2019 (COVID-19)
- Our knowledge about clinical and laboratory characteristics as well as prognosis of COVID-19 in children is still limited
- Susceptibility of children and environmental factors different in LMICs like India, could affect the severity and course of COVID 19 disease

WHO COVID-19 CLINICAL DATA PLATFORM

WHO established the Global COVID-19 Clinical Data Platform to inform:

1. **Characterization of the key clinical features of hospitalized cases** of suspected or confirmed COVID-19, to increase understanding of the severity, spectrum, and impact of the disease in the hospitalized population globally, in different countries;
2. **Characterization of clinical interventions,** to assist WHO with operational planning during the COVID-19 pandemic.

World Health Organization

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Global COVID-19 Clinical Data Platform for clinical characterization and management of hospitalized patients with suspected or confirmed COVID-19

Global understanding of the severity, clinical features and prognostic factors of COVID-19 in different settings and populations remains incomplete. WHO therefore invites Member States, health facilities and other entities to participate in the global effort to collect anonymized clinical data relating to hospitalized suspected or confirmed cases of COVID-19 and contribute data to the Global COVID-19 Clinical Data Platform.

WHO will use the information to inform:

1. **Characterization of the key clinical features and prognostic factors** of hospitalized cases of suspected or confirmed COVID-19, thereby increase unders
of the disease in the hospitalized population globally, in diffe
2. **Characterization of clinical interventions**, thereby facilita planning during the COVID-19 pandemic.

About the Clinical Management team

Register to the platform

Link for registration to obtain log-in credentials for data input

Core CRF

HOW TO COLLABORATE AND CONTRIBUTE?

If you are working in any health facility setting anywhere across the World and are involved in management of COVID- patients , you can contribute to the database.

3 simple steps

- Create your profile
- Review Terms of Use
- After 1-2 day, you'll receive an email with the log in credential to access the Global COVID-19 Clinical Data Platform or, in case you have an established database, other instructions to share data.
- If you have any questions, please contact COVID_ClinPlatform@who.int

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Clinical characterization case report form (CRF)

To harmonize data collection across diverse global settings, WHO has developed a standard CRF. This contains a minimum set of key variables and forms the basis of three types of CRFs:

1. **Core CRF:** to record data relating to hospitalized adults and children with suspected or confirmed infection with COVID-19.
2. **Pregnancy CRF**: to record additional key information relating to the subgroup of hospitalized pregnant women with suspected or confirmed infection with COVID-19.
3. **Multisystem inflammatory syndrome (MIS) in children and adolescents temporally related to COVID-19 CRF:** to record data relating to suspected cases with this syndrome.

Links to standard case record forms

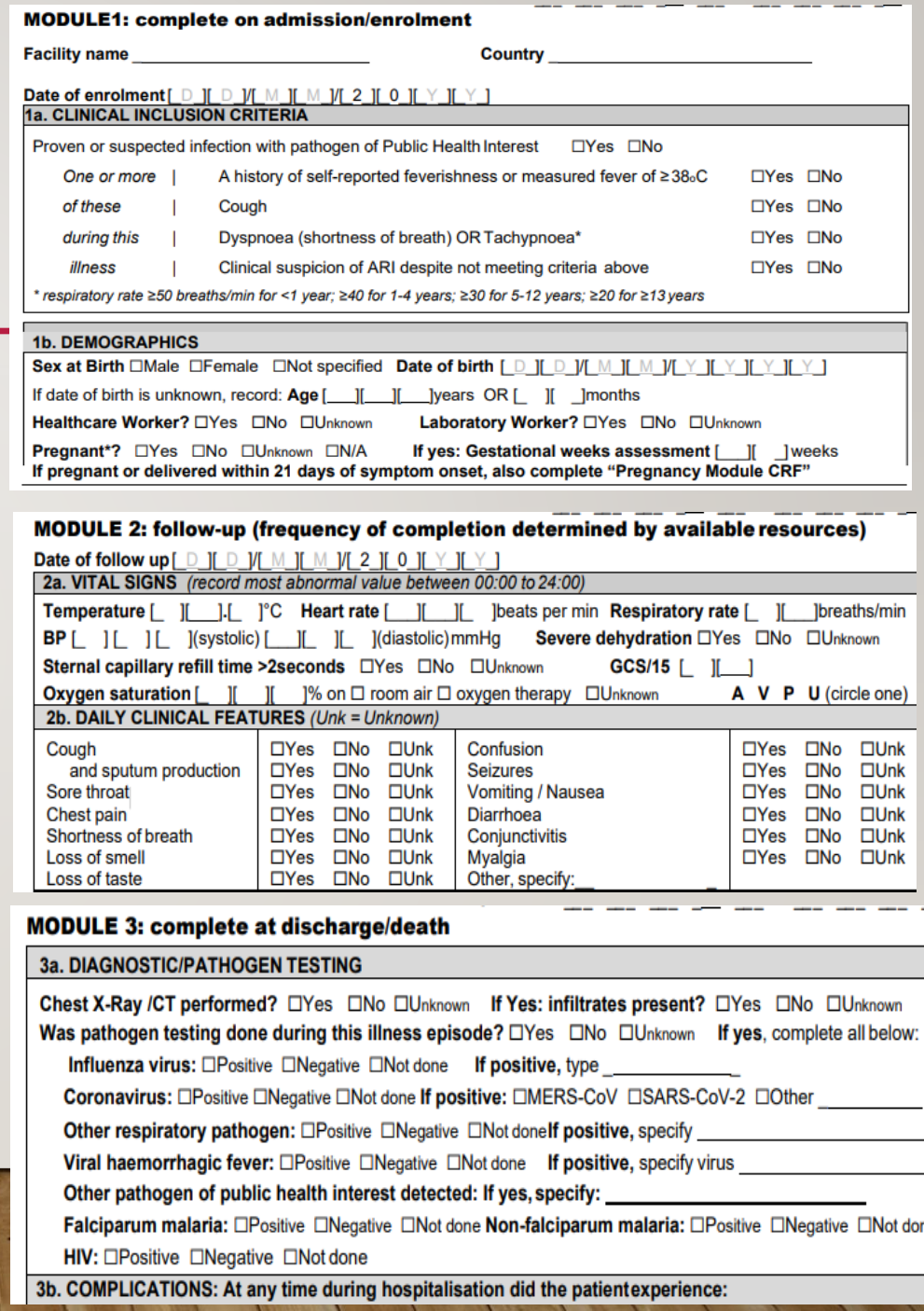
Information Package

- Information sheet
- Term of Use
- Instructions to complete CRF
- Instructions to upload clinical data to the Global Clinical Platform

Links to detailed information and instructions

CRF DESIGN AND STRUCTURE
consists of 3 modules

- Module 1 to be completed on the first day of admission to the health centre
- Module 2 to be completed on first day of admission to ICU or high dependency unit. Should also be completed daily for as many days as resources allow.
- Module 3 to be completed at discharge or death



MODULE1: complete on admission/enrolment

Facility name _____ Country _____

Date of enrolment [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

1a. CLINICAL INCLUSION CRITERIA

Proven or suspected infection with pathogen of Public Health Interest ☐Yes ☐No

One or more	A history of self-reported feverishness or measured fever of ≥ 38₀C	☐Yes	☐No
of these	Cough	☐Yes	☐No
during this	Dyspnoea (shortness of breath) OR Tachypnoea*	☐Yes	☐No
illness	Clinical suspicion of ARI despite not meeting criteria above	☐Yes	☐No

** respiratory rate ≥50 breaths/min for <1 year; ≥40 for 1-4 years; ≥30 for 5-12 years; ≥20 for ≥13 years*

1b. DEMOGRAPHICS

Sex at Birth ☐Male ☐Female ☐Not specified **Date of birth** [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

If date of birth is unknown, record: **Age** [___][___][___]years OR [_][_]months

Healthcare Worker? ☐Yes ☐No ☐Unknown **Laboratory Worker?** ☐Yes ☐No ☐Unknown

Pregnant*? ☐Yes ☐No ☐Unknown ☐N/A **If yes: Gestational weeks assessment** [___][_]weeks

If pregnant or delivered within 21 days of symptom onset, also complete "Pregnancy Module CRF"

MODULE 2: follow-up (frequency of completion determined by available resources)

Date of follow up [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

2a. VITAL SIGNS *(record most abnormal value between 00:00 to 24:00)*

Temperature [_][___].[_]°C **Heart rate** [___][___][_]beats per min **Respiratory rate** [_][___]breaths/min

BP [_][_][_](systolic) [___][_][_](diastolic) mmHg **Severe dehydration** ☐Yes ☐No ☐Unknown

Sternal capillary refill time >2seconds ☐Yes ☐No ☐Unknown **GCS/15** [_][___]

Oxygen saturation [_][_][_]% on ☐ room air ☐ oxygen therapy ☐Unknown **A V P U** (circle one)

2b. DAILY CLINICAL FEATURES *(Unk = Unknown)*

Cough	☐Yes	☐No	☐Unk	Confusion	☐Yes	☐No	☐Unk
and sputum production	☐Yes	☐No	☐Unk	Seizures	☐Yes	☐No	☐Unk
Sore throat	☐Yes	☐No	☐Unk	Vomiting / Nausea	☐Yes	☐No	☐Unk
Chest pain	☐Yes	☐No	☐Unk	Diarrhoea	☐Yes	☐No	☐Unk
Shortness of breath	☐Yes	☐No	☐Unk	Conjunctivitis	☐Yes	☐No	☐Unk
Loss of smell	☐Yes	☐No	☐Unk	Myalgia	☐Yes	☐No	☐Unk
Loss of taste	☐Yes	☐No	☐Unk	Other, specify: _____			

MODULE 3: complete at discharge/death

3a. DIAGNOSTIC/PATHOGEN TESTING

Chest X-Ray /CT performed? ☐Yes ☐No ☐Unknown **If Yes: infiltrates present?** ☐Yes ☐No ☐Unknown

Was pathogen testing done during this illness episode? ☐Yes ☐No ☐Unknown **If yes**, complete all below:

Influenza virus: ☐Positive ☐Negative ☐Not done **If positive,** type _____

Coronavirus: ☐Positive ☐Negative ☐Not done **If positive:** ☐MERS-CoV ☐SARS-CoV-2 ☐Other _____

Other respiratory pathogen: ☐Positive ☐Negative ☐Not done **If positive,** specify _____

Viral haemorrhagic fever: ☐Positive ☐Negative ☐Not done **If positive,** specify virus _____

Other pathogen of public health interest detected: If yes, specify: _____

Falciparum malaria: ☐Positive ☐Negative ☐Not done **Non-falciparum malaria:** ☐Positive ☐Negative ☐Not done

HIV: ☐Positive ☐Negative ☐Not done

3b. COMPLICATIONS: At any time during hospitalisation did the patient experience:

SCOPE - STANDARDIZATION OF COVID IN PREGNANCY

Undertake standardized data collection and documentation of clinical outcome of pregnant women and newborns

Standardize treatment protocol for COVID-19 infection in pregnancy across participating hospitals

- This INDIA initiative will enrol all pregnant and post-partum women with lab confirmed COVID-19 to any of the 4 WHO CCs and 17 tertiary care 'satellite centres' (total 21)
- Detailed information will be gathered for COVID Positive pregnant women and their newborns using the WHO Case-Report Forms
- Additionally, clinical information will be recorded for pregnant women & newborns who are clinical suspects (in ratio of at least 2 for every COVID+ve pregnant woman)
- Duration– 2nd April to 31st September 2020 (with possibility of further extension)

SCOPE - STANDARDIZATION OF COVID IN PREGNANCY

- To document transmission of infection , laboratory specimens to be collected for all prospectively recruited antenatal women :
  - Maternal nasopharyngeal swab: RT-PCR
  - Neonatal nasopharyngeal swab RT-PCR
  - Histopathology of placenta
  - Amniotic fluid RT-PCR
  - Breast Milk RT PCR

  Additionally, if possible
  - Cord Blood RT-PCR
  - Cord Blood IgM

- Follow up for 6 weeks after delivery for clinical recovery of mother and well-being of the baby and if possible a single neonatal brain imaging for any evidence of hypoxic injury or clinical follow up for neurodevelopmental outcome

AIM

India Pediatric Covid Case Registry aims to describe the clinical presentation, management and outcomes associated with COVID-19 infection and disease amongst pediatric age group in India.

OBJECTIVES

- To undertake standardized data collection and documentation of clinical course and outcome in children admitted with COVID 19 disease
- To standardize treatment protocol of COVID-19 disease in children across the Registry Centres (reporting hospitals)
- To provide descriptive analysis on clinical presentation, management, and outcomes associated with COVID-19 among pediatric patients across India

ELIGIBILITY

- Children aged 0-18 years with positive COVID-19 diagnostic test (e.g., RT-PCR and/or serology) admitted to participating hospitals from March to December 2020 are eligible for the registry. The data of children who are already diagnosed and treated are also included.
- Study Period: August 2020 to March 2021

SCOPE AND DURATION

Standardized case report forms (adapted from WHO CRF) will be filled for all children with laboratory-confirmed COVID-19, admitted to the hospital with between March and December 2020.

Data will be collected **retrospectively** if obtained after the admission date.

Retrospective Data from hospital case records March-August 2020

Prospective Data using WHO forms for August- December 2020/March 2021

DATAFLOW

Registry centres will abstract data from information that was originally collected for the diagnosis and management; will include patient's medical records (such as case sheet & investigation reports)

De-identified demographic, clinical and outcome data will be entered into standardised formats , online & offline, as feasible for individual units

'Limited access' to study data ; will be restricted to designated/ authorised members only

Aggregated anonymised data shall be made available

IMPLEMENTATION PLAN

- 25 Centres will be identified through voluntary participation; designated nodal person (Coordinators) at each centre
- Ability to share data: Ethical clearance /approval from local authorities , as applicable
- Orient Coordinators and staff on data collection using standardized case report formats and online applications for data entry
- Orientation on standard case management protocols
- Quality assurance of data submitted by participating Centers by designated team
- Reminders/feedback/ & troubleshoot provided by designated team on weekly and need basis.
- Periodic updates shared by the Taskforce with the participating centres

VALUE ADD

1

Bring data from both public & private hospitals; expand scope for representation of smaller hospitals & private setups

2

Standardize care of patients with COVID 19 disease in participating Centres

3

Enable apex institutions & professional associations to provide timely, frequent and India specific guidance

4

Serve other predetermined scientific, clinical, & policy purposes in India