World Health Organization

Global COVID-19 Clinical Platform
WITH PREGNANCY MODULE – CRF-P

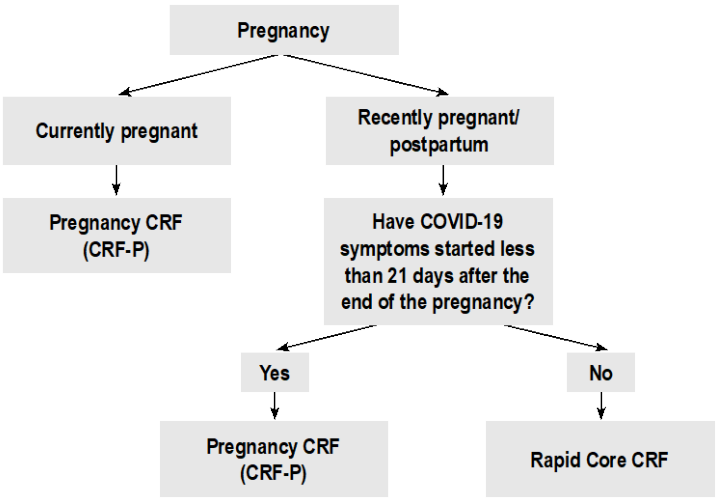
INTRODUCTION

In response to the COVID-19 pandemic, the World Health Organization (WHO) has launched a global COVID-19 anonymized clinical data platform (the "COVID-19 Data Platform") to enable State Parties to the International Health Regulations (IHR) (2005) to share with WHO anonymized clinical data related to patients with suspected or confirmed infections with SARS-CoV-2 (collectively "anonymized COVID-19 data"). The anonymized COVID-19 data received by WHO will remain the property of the contributing Entity and will be used by WHO for purposes of verification, assessment and assistance pursuant to the IHR (2005), including to inform the public health and clinical operation response in connection with the COVID-19 outbreak. To help achieve these objectives, WHO has established an independent Clinical Advisory Group to advise WHO on global reporting and analysis of the anonymized clinical COVID-19 data. State Parties and other entities are invited to contact WHO to obtain more information about how to contribute anonymized clinical COVID-19 data to the WHO Data Platform. To preserve the security and confidentiality of the anonymized COVID-19 data, State Parties and other entities are respectfully requested to take all necessary measures to protect their respective log-in credentials and passwords to the COVID-19 Data Platform.

The anonymized COVID-19 data will be stored in the WHO COVID-19 Data Platform, which is a secured, access-limited, password protected electronic platform. WHO will (i) protect the confidentiality and prevent the unauthorized disclosure of the anonymized COVID-19 data; (ii) implement and maintain appropriate technical and organizational security measures to protect the security of the anonymized COVID-19 data and the COVID-19 Data Platform. In accordance with Article 11(4) of the IHR (2005), WHO will not make the anonymized COVID-19 data generally available to other State Parties or entities until such time as any of the conditions set forth in paragraph 2 of Article 11 are first met, and following consultation with affected countries/entities. Pursuant to that same Article 11, WHO will not make the anonymized COVID-19 data available to the public, unless and until the anonymized COVID-19 data have already been made available to State Parties, and provided that other information about the COVID-19 epidemic has already become publicly available and there is a need for the dissemination of authoritative and independent information. To contribute data to the WHO COVID-19 Data Platform or to receive more information, please contact: COVID_ClinPlatform@who.int

DESIGN OF THIS PREGNANCY MODULE CASE REPORT FORM (CRF-P)

The CRF is designed to collect data obtained through examination, interview and review of hospital notes. Data may be collected retrospectively if the patient data are obtained after the admission date. The data collection period is defined as the period from hospital admission to discharge, transfer, death, or continued hospitalization without possibility of continued data collection. **This CRF-P should be completed for *pregnant women* or *recently pregnant women* who delivered within 21 days from onset of symptoms. If COVID symptoms started more than 21 days after the end of the pregnancy, please complete the Rapid Core CRF only.**



The Pregnancy CRF has 3 sections:

Module 1: to be completed on the first day of admission to the health centre.

Module 2: to be completed daily during hospital stay for as many days as resources allow. Continue to follow-up patients who transfer between wards.

Module 3: to be completed at discharge or death.

GENERAL GUIDANCE

Participant identification numbers consist of a site code and a participant number. Please contact us at **COVID_ClinPlatform@who.int**, and our data management team will provide you with instructions for data entry and will assign you a 5-digit site code at that time.

World Health Organization

PREGNANCY MODULE 2. Follow up (daily or as frequent as possible based on feasibility)

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 > 2 seconds ☐Yes ☐No ☐Unknown **A V P U** (circle one)

Oxygen saturation [_][ ][ ]% on ☐Room air ☐Oxygen therapy ☐Unknown **GCS/15** [_] [_]

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: _____		

2c. LABORATORY RESULTS *(*record units if different from those listed)*

Parameter	Value*	Units			Parameter	Value*	Units		
Haemoglobin		__ g/L	__ g/dL		**Creatinine**		__ mg/L	__ µmol/L	
WBC count		___ /mm^3	___ G/L (= x10^9/L)		**Sodium**		___ mEq/L = mmol/L		
Haematocrit		___ %			**Potassium**		___ mEq/L = mmol/L		
Platelets		___ /mm^3	___ G/L (= x10^9/L)		**Procalcitonin**		___ ng/mL	___ µg/L	
APTT/APTR		___ seconds			**CRP**		___ mg/L		
PT (seconds)		___ seconds			**LDH**		___ IU/L		
INR					**Creatine kinase**		___ IU/L	__ UKAT/L	
ALT/SGPT		___ IU/L			**Troponin**		___ ng/mL	__ µg/L	
AST/SGOT		___ IU/L			**ESR**		__ mm/hour		
Total bilirubin		___ mg/L	__ µmol/L		**D-dimer**		___ ng/mL	___ µg/L	
Urea (BUN)		___ g/L	___ mg/dL	___ mmol/L	**Ferritin**		___ ng/mL	___ µg/L	
Lactate		___ mg/dL	___ mmol/L		**IL-6**		___ pg/mL		

World Health Organization

2d. MEDICATION At any time during this 24-hour hospital day, did the patient receive:

Oral/orogastric fluids? ☐Yes ☐No ☐Unknown **Intravenous fluids?** ☐Yes ☐No ☐Unknown

Antiviral? ☐Yes ☐No ☐Unknown **If yes:** ☐Ribavirin ☐Lopinavir/Ritonavir ☐Neuraminidase inhibitor ☐Interferon alpha ☐Interferon beta ☐Other, specify: _____

Corticosteroid? ☐Yes ☐No ☐Unknown **If yes,** route: ☐Oral ☐Intravenous ☐Inhaled

If yes, please provide agent and maximum daily dose: _____

Antibiotic? ☐Yes ☐No ☐Unknown **Antifungal agent?** ☐Yes ☐No ☐Unknown

Antimalarial agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Experimental agent? ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Non-steroidal anti-inflammatory (NSAID) ☐Yes ☐No ☐Unknown

Angiotensin converting enzyme inhibitors (ACE inhibitors) ☐Yes ☐No ☐Unknown

Angiotensin II receptor blockers (ARBs) ☐Yes ☐No ☐Unknown

Systemic anticoagulation ☐Yes ☐No ☐Unknown

2e. SUPPORTIVE CARE At any time during this 24-hour hospital day, did the patient receive:

ICU or high dependency unit admission? ☐Yes ☐No ☐Unknown

Date of ICU/HDU admission [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Unknown

ICU/HDU discharge date [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Not discharged yet ☐Unknown

Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes,** complete all below:

O_2 flow: ☐ 1–5 L/min ☐ 6–10 L/min ☐ 11–15 L/min ☐ > 15 L/min ☐Unknown

Source of oxygen: ☐Piped ☐Cylinder ☐Concentrator ☐Unknown

Interface: ☐Nasal prongs ☐HF nasal cannula ☐Mask ☐Mask with reservoir ☐CPAP/NIV mask ☐Unknown

Non-invasive ventilation? (e.g. BIPAP, CPAP) ☐Yes ☐No ☐Unknown

Invasive ventilation (any)? ☐Yes ☐No ☐Unknown **If yes, what were the following values closest to 08:00:** PEEP (cm H_2O) _____; FiO_2 (%) _____; Plateau pressure (cm H_2O) _____; $PaCO_2$ _____; PaO_2_____

Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown

Prone position? ☐Yes ☐No ☐Unknown

Inotropes/vasopressors? ☐Yes ☐No ☐Unknown

Renal replacement therapy (RRT) or dialysis? ☐Yes ☐No ☐Unknown

2f. FETAL HEART RATE	
Fetal heart rate (record most abnormal value between 00:00 to 24:00)	**(FHR):** [_ _][_ _][_ _] beats/min

2g. TREATMENT DURING HOSPITALIZATION At ANY time during hospitalization, did the patient receive/undergo:	
Tocolysis	☐Yes ☐No ☐Unknown
Induction of labour	☐Yes ☐No ☐Unknown
Blood transfusion	☐Yes ☐No ☐Unknown

This module contains section 2 (pages 7-8) from the full document "WHO Global COVID-19 Clinical Platform: Pregnancy Case Report Form"