World Health Organization

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

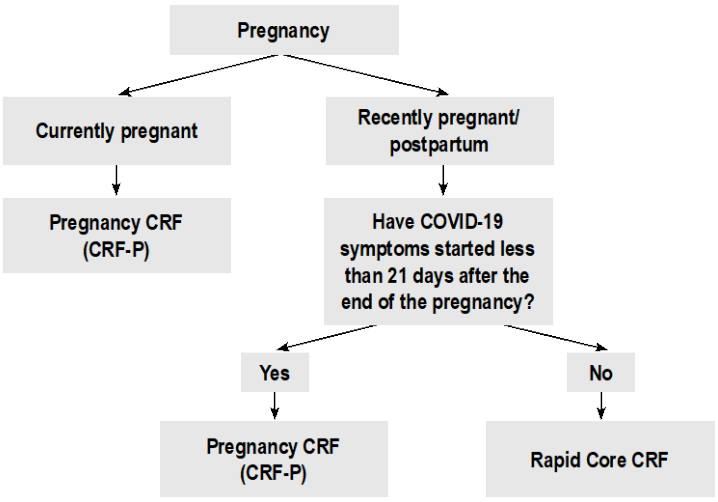
INTRODUCTION

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.

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Complete on hospital admission (within 24 hrs from hospital admission)

Facility name: _____ **Country:** _____

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

a. CLINICAL INCLUSION CRITERIA

One or more of these during this illness	A history of self-reported feverishness or measured fever of ≥38°C	☐Yes	☐No
	Cough	☐Yes	☐No
	Dyspnoea (shortness of breath) OR Tachypnoea*	☐Yes	☐No
	Clinical suspicion 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*

b. 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** OR [_][_] **days**

Health care worker? ☐Yes ☐No ☐Unknown **Laboratory worker?** ☐Yes ☐No ☐Unknown

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

If currently pregnant or recently pregnant (delivery within 21 days of symptom onset), complete all sections of this CRF

c. DATE OF ONSET AND ADMISSION VITAL SIGNS *(first available data at presentation/admission)*

Symptom onset (date of first/earliest symptom) [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Admission date at this facility [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

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

Respiratory rate [_][___]breaths/min

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

Sternal capillary refill time > 2 seconds ☐Yes ☐No ☐Unknown

Oxygen saturation: [__][ ][__]% on ☐Room air ☐Oxygen therapy ☐Unknown **A V P U** (circle one)

Glasgow Coma Score (GCS/15) [_][_] **Malnutrition** ☐Yes ☐No ☐Unknown

Mid-upper arm circumference [_][_][___]mm **Height:** [___] [___][___]cm **Weight**: [_][_][___]kg

d. CO-MORBIDITIES *(existing at admission) (Unk = Unknown)*

Chronic cardiac disease *(not hypertension)*	☐Yes	☐No	☐Unk	Diabetes	☐Yes	☐No	☐Unk
Hypertension	☐Yes	☐No	☐Unk	Current smoking	☐Yes	☐No	☐Unk
Chronic pulmonary disease	☐Yes	☐No	☐Unk	Tuberculosis (*active*)	☐Yes	☐No	☐Unk
Asthma	☐Yes	☐No	☐Unk	Tuberculosis (*previous*)	☐Yes	☐No	☐Unk
Chronic kidney disease	☐Yes	☐No	☐Unk	Asplenia	☐Yes	☐No	☐Unk
Chronic liver disease	☐Yes	☐No	☐Unk	Malignant neoplasm	☐Yes	☐No	☐Unk
Chronic neurological disorder	☐Yes	☐No	☐Unk	Other	☐Yes	☐No	☐Unk
				If yes, specify:			

HIV ☐Yes (on ART) ☐Yes (not on ART) ☐No ☐Unknown ART regimen_____

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e. PRE-ADMISSION AND CHRONIC MEDICATION Were any of the following taken within 14 days of admission:

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

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

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

Antiviral? ☐ Chloroquine/hydroxychloroquine ☐ Azithromycin ☐ Lopinavir/Ritonavir ☐ Other:_____

f. SIGNS AND SYMPTOMS Reported/assessed on the day of ADMISSION *(Unk = Unknown)*

History of fever	☐Yes	☐No ☐Unk	Lower chest indrawing	☐Yes	☐No ☐Unk
Cough	☐Yes	☐No ☐Unk	Headache	☐Yes	☐No ☐Unk
with sputum production	☐Yes	☐No ☐Unk	Altered consciousness/confusion	☐Yes	☐No ☐Unk
with haemoptysis	☐Yes	☐No ☐Unk	Seizures	☐Yes	☐No ☐Unk
Sore throat	☐Yes	☐No ☐Unk	Abdominal pain	☐Yes	☐No ☐Unk
Runny nose	☐Yes	☐No ☐Unk	Vomiting/nausea	☐Yes	☐No ☐Unk
Wheezing	☐Yes	☐No ☐Unk	Diarrhoea	☐Yes	☐No ☐Unk
Chest pain	☐Yes	☐No ☐Unk	Conjunctivitis	☐Yes	☐No ☐Unk
Muscle aches	☐Yes	☐No ☐Unk	Skin rash	☐Yes	☐No ☐Unk
Joint pain (arthralgia).	☐Yes	☐No ☐Unk	Skin ulcers	☐Yes	☐No ☐Unk
Fatigue/malaise	☐Yes	☐No ☐Unk	Lymphadenopathy	☐Yes	☐No ☐Unk
Loss of taste	☐Yes	☐No ☐Unk	Inability to walk	☐Yes	☐No ☐Unk
Loss of smell	☐Yes	☐No ☐Unk	Bleeding (haemorrage)	☐Yes	☐No ☐Unk
Shortness of breath	☐Yes	☐No ☐Unk	If bleeding, specify site(s):		
Stroke: ischaemic stroke	☐Yes	☐No ☐Unk			
Stroke: intracerebral haemorrhage	☐Yes	☐No ☐Unk			
Other	☐Yes	☐No ☐Unk			

If yes, specify: _____

g. MEDICATION On the day of admission, did the patient receive any of the following:

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 **If yes,** specify:_____

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

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h. SUPPORTIVE CARE On the day of admission, did the patient receive any of the following:

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

i. LABORATORY RESULTS ON ADMISSION *(*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		

j. PREGNANCY STATUS UPON ADMISSION

Pregnant not in labour	☐
Pregnant in labour	☐
Postpartum [days]*	☐ [days] Breastfeeding? ☐Yes ☐No
Post-abortion/miscarriage	☐
Number of foetuses	☐Singleton ☐Twin ☐Triplet ☐Other [number] ☐Unknown
Best estimate of gestational age in completed weeks	[_W_][_W_] weeks

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k. ABORTION OR MISCARRIAGE *(prior to admission)*	
Date of induced abortion or spontaneous abortion/miscarriage?	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Were symptoms of COVID-19 disease present at the time?	☐Yes ☐No ☐Unknown

l. OBSTETRIC HISTORY
Number of previous pregnancies beyond 22 weeks gestation [number]
Number of previous vaginal deliveries [number]
Number of previous cesarean deliveries [number]

m. Please tick any which apply to previous deliveries:	
Preterm birth (< 37 weeks' gestation)	☐Yes ☐No ☐Unknown
Congenital anomaly	☐Yes ☐No ☐Unknown
Stillborn	☐Yes ☐No ☐Unknown
Neonatal death (0–6 days)	☐Yes [day:] ☐No ☐Unknown
Weight < 2.5 kg	☐Yes ☐No ☐Unknown
Weight > 4.5 kg	☐Yes ☐No ☐Unknown

n. ALCOHOL, DRUGS – RISK FACTORS DURING THIS PREGNANCY	
Alcohol consumption	☐Yes ☐No ☐Unknown
Illicit/recreational drug use	☐Yes ☐No ☐Unknown

o. MEDICATIONS DURING THIS PREGNANCY *(Prior to onset of current illness episode)*	
Fever or pain treatment	**Acetaminophen/paracetamol** ☐Yes ☐No ☐Unknown
	NSAID/s ☐Yes ☐No ☐Unknown
	Other/s (specify): [ ]
Anticonvulsants	☐Yes ☐No ☐Unknown **If yes, specify generic name:** **[ ]**
Anti-nausea	☐Yes ☐No ☐Unknown **If yes, specify generic name:** **[ ]**
Prenatal vitamins and micronutrients	☐Yes ☐No ☐Unknown **If yes, specify generic name:** **[ ]**
Antivirals	☐Yes ☐No ☐Unknown **If yes, specify generic name:** **[ ]**
Antibiotics	☐Yes ☐No ☐Unknown **If yes, specify generic name:** **[ ]**

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p. ADMISSION SIGNS AND SYMPTOMS			
Vaginal watery discharge	☐Yes	☐No	☐Unknown
Vaginal bleeding	☐Yes	☐No	☐Unknown
Headaches	☐Yes	☐No	☐Unknown
Vision changes	☐Yes	☐No	☐Unknown
Right upper quadrant (abdominal) pain	☐Yes	☐No	☐Unknown
Decreased or no fetal movement	☐Yes	☐No	☐Unknown
Uterine contractions	☐Yes	☐No	☐Unknown

q. FETAL HEART RATE *(first available data at presentation/admission)*	
Fetal heart rate	**(FHR):** [_ _][_ _][_ _] beats/min

This module contains section 1 (pages 2-6) from the full document "WHO Global COVID-19 Clinical Platform: Pregnancy Case Report Form"