World Health Organization

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

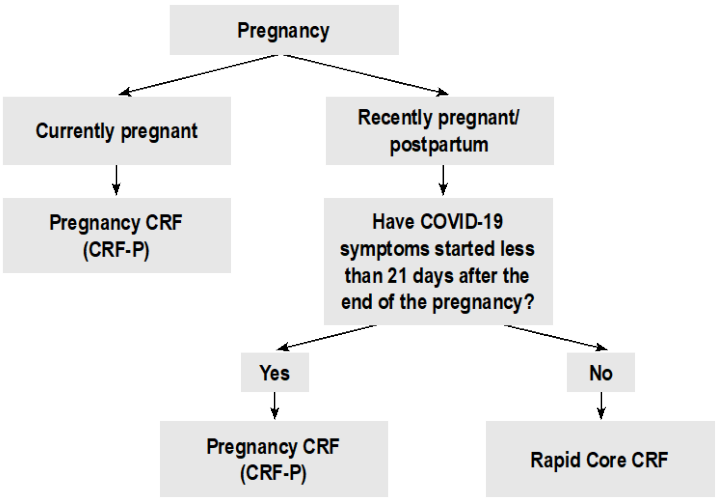
INTRODUCTION

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.

Complete at discharge/death

a. 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

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

Shock	☐Yes ☐No ☐Unknown	Bacteraemia	☐Yes ☐No ☐Unknown
Seizure	☐Yes ☐No ☐Unknown	Bleeding	☐Yes ☐No ☐Unknown
Meningitis/encephalitis	☐Yes ☐No ☐Unknown	Endocarditis	☐Yes ☐No ☐Unknown
Anaemia	☐Yes ☐No ☐Unknown	Myocarditis/pericarditis	☐Yes ☐No ☐Unknown
Cardiac arrhythmia	☐Yes ☐No ☐Unknown	Acute renal injury	☐Yes ☐No ☐Unknown
Cardiac arrest	☐Yes ☐No ☐Unknown	Pancreatitis	☐Yes ☐No ☐Unknown
Pneumonia	☐Yes ☐No ☐Unknown	Liver dysfunction	☐Yes ☐No ☐Unknown
Bronchiolitis	☐Yes ☐No ☐Unknown	Cardiomyopathy	☐Yes ☐No ☐Unknown
Stroke: ischaemic stroke	☐Yes ☐No ☐Unknown	Acute respiratory distress syndrome (ARDS)	☐Yes ☐No ☐Unknown
Stroke: intracerebral hemorrhage	☐Yes ☐No ☐Unknown		
Other	☐Yes ☐No ☐Unknown If Yes, specify:_____		

c. MEDICATION While hospitalized or at discharge, were any of the following administered:

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,** specify agent and maximum daily dose:_____

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

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

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

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

Non-steroidal anti-inflammatory (NSAID) ☐Yes ☐No ☐Unknown **If yes,** specify: _____

Systematic anticoagulation ☐Yes ☐No ☐Unknown

d. SUPPORTIVE CARE At ANY time during hospitalization, did the patient receive/undergo:

ICU or high dependency unit admission? ☐Yes ☐No ☐Unknown **If yes,** total duration: ____days

Date of ICU admission [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐ N/A

Date of ICU discharge [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐ In ICU at outcome ☐N/A

Oxygen therapy? ☐Yes ☐No ☐Unknown **If yes, complete all:** **Total duration**:_____days

O_2 flow: ☐ 1–5 L/min ☐ 6–10 L/min ☐ 11–15 L/min ☐ >15 L/min **Source of oxygen:** ☐Piped ☐Cylinder ☐Concentrator

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

Non-invasive ventilation? (e.g. BIPAP, CPAP) ☐Yes ☐No ☐Unknown **If yes,** total duration:_____days

Invasive ventilation (any)? ☐Yes ☐No ☐Unknown **If yes,** total duration:___ days

Extracorporeal (ECMO) support? ☐Yes ☐No ☐Unknown **If yes,** total duration:___ days

Prone position? ☐Yes ☐No ☐Unknown **If yes,** total duration:_____days

Inotropes/vasopressors? ☐Yes ☐No ☐Unknown **If yes,** total duration:_____days

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

e. OUTCOME

Outcome: ☐Discharged alive ☐Hospitalized ☐Transfer to other facility ☐Death ☐Palliative discharge ☐Unknown

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐Unknown

If discharged alive, ability to self-care at discharge versus before illness: ☐Same as before illness ☐Worse ☐Better ☐Unknown

Sections f–i (to be completed if delivery happened within 21 days of symptom onset)

f. DELIVERY, PREGNANCY AND MATERNAL OUTCOMES		
Delivery during admission	☐Yes ☐No	
Delivery date	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	
Mode of delivery	☐ Vaginal delivery ☐ Caesarean section	
Onset of labour	☐ Spontaneous ☐ Induced ☐ Cesarean section before labour ☐ Unknown	
Fetal presentation at delivery	☐ Cephalic ☐ Transverse ☐ Breech	
Amniotic fluid at delivery	☐ Clear ☐ Meconium stained ☐ Unknown	
Other maternal outcomes/pregnancy complications	Gestational diabetes	☐Yes ☐No ☐Unknown
	Gestational hypertension	☐Yes ☐No ☐Unknown
	Anaemia (Hb < 11 g/dL)	☐Yes ☐No ☐Unknown
	Hyperemesis	☐Yes ☐No ☐Unknown
	Intrauterine growth restriction	☐Yes ☐No ☐Unknown
	Placental previa/accreta/percreta	☐Yes ☐No ☐Unknown
	Bacterial infection prior to hospital visit	☐Yes ☐No ☐Unknown
	Pre-eclampsia/eclampsia	☐Yes ☐No ☐Unknown
	Placental abruption	☐Yes ☐No ☐Unknown
	Preterm contractions	☐Yes ☐No ☐Unknown
	Preterm labour	☐Yes ☐No ☐Unknown
	Preterm rupture of membranes	☐Yes ☐No ☐Unknown
	Early or midterm miscarriage	☐Yes ☐No ☐Unknown
	Haemorrhage	☐Yes ☐No ☐Unknown
	If haemorrhage, which type:	☐ Antepartum/intrapartum ☐ Postpartum haemorrhage ☐ Abortion-related
	Embolic disease	☐Yes ☐No ☐Unknown
	Anesthetic complication	☐Yes ☐No ☐Unknown

g. PREGNANCY STATUS AT DISCHARGE	
Pregnancy outcome	☐Undelivered ☐Spontaneous abortion ☐Induced abortion ☐Missed abortion ☐Macerated stillbirth ☐Fresh stillbirth ☐Livebirth ☐Post-abortion/postpartum on admission
Maternal death **If yes, what was the underlying cause of death?**	☐Yes ☐No ☐Abortive outcome ☐Hypertensive disorders in pregnancy, childbirth and the puerperium ☐Obstetric haemorrhage ☐Pregnancy-related infection ☐Other obstetric complication not included in above causes ☐Unanticipated complications of management (e.g. anaesthesia-related complications) ☐Indirect maternal death ☐Obstetric death of unspecified cause ☐Deaths from a coincidental cause (e.g. motor vehicle accident)

h. SAMPLE COLLECTION				
Any sampling conducted? If so, please describe the test and the results	☐Amniotic fluid	[_test description__]	[_date of collection__]	[_____result_____]
	☐Placenta	[_test description__]	[_date of collection__]	[_____result_____]
	☐Cord blood	[_test description__]	[_date of collection__]	[_____result_____]
	☐Vaginal swab	[_test description__]	[_date of collection__]	[_____result_____]
	☐Faeces/rectal swab	[_test description__]	[_date of collection__]	[_____result_____]
	☐Pregnancy tissue in the case of fetal demise/induced abortion	[_test description__]	[_date of collection__]	[_____result_____]
	☐Breastmilk	[_test description__]	[_date of collection__]	[_____result_____]

i. NEONATAL OUTCOMES	
Date of birth [DD/MM/YYYY] **Time of birth** [e.g. 14:21]	[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] [____:____]
Participant ID of the mother:	[___][___][___][___][___]-- [___][___][___][___] – [__Single digit Baby ID_]* *Complete one form per neonate
COVID-19 lab test of foetus or neonate	☐Performed ☐Not performed ☐Unknown If yes: [_sample collected__] [_test description__][_date of collection__] [_____result_____]
Apgar score at 5 minutes	Score: [___][___]
Gestational age	Weeks: [___][___] Days: [_____]
Birth weight	Grams: [___][___][___][___]
Respiratory distress syndrome	☐Yes ☐No ☐Unknown

Neonatal outcome	☐Discharged healthy ☐Discharged with complications/sequelae Details: [_____] ☐Clinical referral to specialist ward /other hospital Details: [_____] ☐Death Date of death: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_] ☐Unknown

If neonate died, primary cause of death	☐Preterm/low birth weight ☐Birth asphyxia ☐Infection ☐Birth trauma ☐Congenital/birth defects ☐Other ☐Unknown
Any congenital anomalies	☐Neural tube defects ☐Microcephaly ☐Congenital malformations of ear ☐Congenital heart defects ☐Orofacial clefts ☐Congenital malformations of digestive system ☐Congenital malformations of genital organs ☐Abdominal wall defects ☐Chromosomal abnormalities ☐Reduction defects of upper and lower limbs ☐Talipes equinovarus/clubfoot

This module contains section 3 (pages 9-13) from the full document "WHO Global COVID-19 Clinical Platform: Pregnancy Case Report Form"