



WHO Global Clinical Platform
for Mpox
Data for public health response

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Global Clinical Data Platform

MONKEYPOX CASE REPORT FORM (CRF)

MODULE 5.2

INTRODUCTION

The CRF is designed to collect data obtained through examination, interview and review of hospital or clinic notes of patients with suspected, probable or confirmed monkeypox (mpox) infection. The CRF captures data from patients being managed in outpatient services or in community-based health services or during hospital admissions. Follow-up visits (Module 2) may be conducted in person or virtually as per local practice.

Data may be collected prospectively or retrospectively. The data collection period is defined as the period from hospital admission, or first clinic visit, to discharge from care, transfer, death or continued hospitalization without possibility of continued data collection.

This CRF has five modules:

- Module 1:** To be completed on the first day of presentation or admission to the health centre (baseline visit).
- Module 2:** To be completed on hospital days or follow-up visits (remote visits or visits to health centre) every 3–5 days and day 14.
- Module 3:** To be completed at the last visit, either hospital discharge, transfer, last outpatient follow-up or death.
- Module 4:** To be completed to record serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) for patients treated with tecovirimat under **WHO emergency use protocol for tecovirimat for monkeypox under MEURI framework**.
- Module 5.1:** To be completed if currently pregnant or recently pregnant ≤ 21 days.
- Module 5.2:** To be completed at end of pregnancy.

GENERAL GUIDANCE

Participant identification numbers consist of a site code and a participant number. You can register on the data management system by completing the [mpox registration form](#), and our data management team will contact you with instructions for data entry and will assign you a five-digit site code at that time. Please contact us at monkeypox_clinicaldataplatfrom@who.int for any further information.

MPX case report form (CRF): module 5.2, 27 March 2023

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MODULE 5.2. Pregnancy module

To be completed for women at the end of pregnancy, including abortion, miscarriage, stillbirth and delivery.

5h. DELIVERY, PREGNANCY AND MATERNAL CHARACTERISTICS (This form should be completed for pregnant patients with monkeypox irrespective of monkeypox recovery or discharge status to record delivery pregnancy, maternal and neonatal outcomes as applicable.)

Did this patient participate in the emergency use protocol for tecovirimat for monkeypox under MEURI framework?

Yes No Unknown

If yes, date of visit [_D_] [_D_] / [_M_] [_M_] / [_2_] [_0_] [_Y_] [_Y_]]

Delivery during course of monkeypox infection? Yes No

Delivery date [_D_] [_D_] / [_M_] [_M_] / [_2_] [_0_] [_Y_] [_Y_]]

Pregnancy outcome	<input type="checkbox"/> Spontaneous abortion ^a <input type="checkbox"/> Live birth <input type="checkbox"/> Induced abortion ^a <input type="checkbox"/> Missed abortion ^a <input type="checkbox"/> Macerated stillbirth ^a <input type="checkbox"/> Fresh stillbirth ^a <input type="checkbox"/> Post-abortion/postpartum on admission* ^a Date of pregnancy outcome [_D_] [_D_] / [_M_] [_M_] / [_2_] [_0_] [_Y_] [_Y_]]
Mode of delivery	<input type="checkbox"/> Vaginal delivery <input type="checkbox"/> Caesarean section
If C-section, indicate reason	<input type="checkbox"/> Prolonged labour <input type="checkbox"/> Abnormal positioning <input type="checkbox"/> Fetal distress <input type="checkbox"/> Birth defects <input type="checkbox"/> Repeat caesarean <input type="checkbox"/> Chronic health condition <input type="checkbox"/> Cord prolapse <input type="checkbox"/> Genital lesions <input type="checkbox"/> Cephalopelvic disproportion (CPD) <input type="checkbox"/> Unknown
Onset of labour	<input type="checkbox"/> Spontaneous <input type="checkbox"/> Caesarean section before labour <input type="checkbox"/> Induced <input type="checkbox"/> Unknown
Fetal presentation at delivery	<input type="checkbox"/> Cephalic <input type="checkbox"/> Transverse <input type="checkbox"/> Breech
Amniotic fluid at delivery	<input type="checkbox"/> Clear <input type="checkbox"/> Meconium stained <input type="checkbox"/> Unknown
Complications during the course of pregnancy	Gestational diabetes <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Gestational hypertension <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Anaemia (Hb < 11 g/dL) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Obstetric infections <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Intrauterine growth restriction <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Bleeding <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Pre-eclampsia <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Eclampsia <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Other (specify) _____
Acute or late-stage pregnancy complications	Placental previa/accreta/percreta <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Pre-eclampsia/eclampsia <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Placental abruption <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Preterm contractions <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Preterm labour <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Preterm rupture of membranes <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

	Puerperal septicaemia or severe infection <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown STI untreated (i.e. herpes, syphilis, chlamydia, gonorrhoea) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Haemorrhage <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If haemorrhage, which type: <input type="checkbox"/> Antepartum/intrapartum <input type="checkbox"/> Postpartum haemorrhage Abortion-related embolic disease <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Anaesthetic complication <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Maternal death In the event of maternal death and the patient is participating in WHO emergency use protocol for tecovirimat for monkeypox under MEURI framework please also complete Module 4.	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, what was the underlying cause of death? <input type="checkbox"/> Abortive outcome <input type="checkbox"/> Hypertensive disorders in pregnancy, childbirth and the puerperium <input type="checkbox"/> Obstetric haemorrhage <input type="checkbox"/> Pregnancy-related infection <input type="checkbox"/> Unanticipated complications of management (e.g. anaesthesia-related complications) <input type="checkbox"/> Indirect maternal death <input type="checkbox"/> Obstetric death of unspecified cause <input type="checkbox"/> Deaths from a coincidental cause (e.g. motor vehicle accident) <input type="checkbox"/> Other obstetric complication not included in above causes

5i. NEONATAL OUTCOMES (if applicable)	
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 _] <i>Please complete one form per neonate</i>
Monkeypox lab test of neonate	<input type="checkbox"/> Performed <input type="checkbox"/> Not performed <input type="checkbox"/> Unknown If yes [_ sample collected _] [_ test description _][_ date of collection _] [_ result _]
Apgar score at 5 minutes	Score [_][_]
Birth weight	Grams [_][_][_][_]
Respiratory distress syndrome	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Admission to NICU	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
Neonatal outcome	<input type="checkbox"/> Discharged healthy <input type="checkbox"/> Discharged with complications/sequelae Type of complication [_____] <input type="checkbox"/> Clinical referral to specialist ward /other hospital Type of specialty [_____] <input type="checkbox"/> Death Date of death [_ D _][_ D _][_ M _][_ M _][_ Y _][_ Y _] <input type="checkbox"/> Unknown

If neonate died, primary cause of death	<input type="checkbox"/> Preterm/low birth weight <input type="checkbox"/> Infection <input type="checkbox"/> Congenital/birth defects <input type="checkbox"/> Unknown	<input type="checkbox"/> Birth asphyxia <input type="checkbox"/> Birth trauma <input type="checkbox"/> Other, specify: _____
Any congenital anomalies	<input type="checkbox"/> Neural tube defects <input type="checkbox"/> Congenital malformations of ear <input type="checkbox"/> Congenital malformations of digestive system <input type="checkbox"/> Congenital malformations of genital organs <input type="checkbox"/> Chromosomal abnormalities <input type="checkbox"/> Reduction defects of upper and lower limbs	

5j. SAMPLE COLLECTION for monkeypox testing

Any sampling conducted? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, describe the test and the results	<input type="checkbox"/> Amniotic fluid	[_test description_] <input type="checkbox"/> PCR <input type="checkbox"/> Other, specify:	[_date of collection_] [_D_][_D_][_M_][_M_][_2_][_0_][_Y_][_Y_]	[_result_] <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Undetermined
	<input type="checkbox"/> Placenta	[_test description_] <input type="checkbox"/> PCR <input type="checkbox"/> Other [specify]	[_date of collection_] [_D_][_D_][_M_][_M_][_2_][_0_][_Y_][_Y_]	[_result_] <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Undetermined
	<input type="checkbox"/> Cord blood	[_test description_] <input type="checkbox"/> PCR <input type="checkbox"/> Other [specify]	[_date of collection_] [_D_][_D_][_M_][_M_][_2_][_0_][_Y_][_Y_]	[_result_] <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Undetermined
	<input type="checkbox"/> Vaginal swab	[_test description_] <input type="checkbox"/> PCR <input type="checkbox"/> Other [specify]	[_date of collection_] [_D_][_D_][_M_][_M_][_2_][_0_][_Y_][_Y_]	[_result_] <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Undetermined
	<input type="checkbox"/> Faeces/rectal swab	[_test description_] <input type="checkbox"/> PCR <input type="checkbox"/> Other [specify]	[_date of collection_] [_D_][_D_][_M_][_M_][_2_][_0_][_Y_][_Y_]	[_result_] <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Undetermined
	<input type="checkbox"/> Pregnancy tissue (in the case of fetal demise/induced abortion)	[_test description_] <input type="checkbox"/> PCR <input type="checkbox"/> Other [specify]	[_date of collection_] [_D_][_D_][_M_][_M_][_2_][_0_][_Y_][_Y_]	[_result_] <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Undetermined
	<input type="checkbox"/> Breastmilk	[_test description_] <input type="checkbox"/> PCR <input type="checkbox"/> Other [specify]	[_date of collection_] [_D_][_D_][_M_][_M_][_2_][_0_][_Y_][_Y_]	[_result_] <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Undetermined