World Health Organization

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WHO Global Clinical Platform for Ebola virus disease
Data for public health response

Global Clinical Data Platform

EBOLA VIRUS DISEASE CASE REPORT FORM (CRF)

MODULE 3

INTRODUCTION

The CRF is designed to collect data obtained direct from patient examination and interview, and from review of hospital or clinical notes of people with probable or confirmed Ebola disease (caused by Zaire and Sudan species).

The CRF captures data from patients being managed as inpatients in Ebola Care Centres. 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 three modules:

Module 1:	To be completed on the first day of presentation or admission to the Ebola Care Centre (ECC).
Module 2:	Daily Form: To be completed on inpatient days (minimum every 3 days)
Module 3:	To be completed at last visit, either hospital discharge, transfer, last outpatient follow-up or death.

GENERAL GUIDANCE

Participant identification numbers consist of a site code and a participant number.

Please email the data management team at evd_clinicaldataplatform@who.int and they will provide instructions for data entry and will assign you a 5-digit site code at that time.

EVD case report form (CRF): module 3, 29 November 2022

WHO reference number: WHO/EVD/Clinical_CRF/Module_3/2022.1

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I. CASE IDENTIFICATION/DEMOGRAPHIC DETAILS

ECC number: [_____]	Site/facility name: [_____]

II. TREATMENT SUMMARY OVER ADMISSION

Type	
Investigational Interventions Did Patient receive any investigational interventions? ☐ Yes ☐ No ☐ Unknown Indicate protocol: [_____] Which treatments are available at the facility at this time (even if not given to the patient) Remdesivir: ☐ Available ☐ Not available mAB 1: ☐ Available ☐ Not available if available, name:_____ mAB 2: ☐ Available ☐ Not available if available, name:_____ Steroids: ☐ Available ☐ Not available	☐ Administered under standard of care ☐ Administered under MEURI or EAP ☐ Administered under randomized clinical trial ☐ Other protocol Indicate all therapies that were administrative. Specify dose, route and duration, and indicate if any adverse events were noted ☐ **Remdesivir** Dose (mg): [__][__][__] Duration (total days): [__][__] Dose (mg): [__][__][__] Duration (total days): [__][__] Infusion reaction: ☐ Yes ☐ No Adverse event, specify: [_____] ☐ **MBP-134** *(Sudan ebolavirus)* Dose [__][__][__]mg or [__][__][__]ml (20mg/ml) Infusion reaction: ☐ Yes ☐ No Other adverse event, specify: [_____] ☐ **mAb-114** *(Zaire ebolavirus)* Dose [__][__][__]mg or [__][__][__]ml (ansuvimab 50mg/ml) Infusion reaction: ☐ Yes ☐ No Other adverse event, specify: [_____] ☐ **REGN-EB3** *(Zaire ebolavirus)* Dose [__][__][__]mg or [__][__][__]ml (atoltivimab16.67mg/maftivimab 16.67mg /odesivimab 16.67mg /ml) Infusion reaction: ☐ Yes ☐ No Other adverse event, specify: [_____] ☐ **Steroids** Dose: [_____] Route: ☐ oral ☐ IV Duration (total days): [__][__] Dose: [_____] Route: ☐ oral ☐ IV Duration (total days): [__][__] Adverse event, specify: [_____] ☐ **Other** specify [_____] Dose: [_____] Route: [_____] Duration (total days): [__][__] Dose: [_____] Route: [_____] Duration (total days): [__][__] Dose: [_____] Route: [_____] Duration (total days): [__][__] Adverse event, specify: [_____]

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Over the course of admission, did the patient receive any of the following?

Antibiotic: ☐ Yes ☐ No ☐ Unknown
If yes, specify all that apply:
☐ Penicillin/ampicillin/amoxycillin
☐ Ceftriaxone/ cefalexin/ other *cephalosporin*
☐ Erythromycin/ azithromycin/ other *macrolide*
☐ Ciprofloxacin / *other quinolone*
☐ Cotrimoxazole / *other sulphonamide*
☐ Doxycycline / *other tetracycline*
☐ Meropenem / *other carbapenem*
Antimalarial: ☐ Yes ☐ No ☐ Unknown

Enteral feeding:
☐ Yes, total duration (days) [__][__]
☐ No

Blood products
Blood transfusion ☐ Yes ☐ No ☐ Unknown
If yes, specify how many units [__][__]
Fresh frozen plasma ☐ Yes ☐ No ☐ Unknown
If yes, total volume of FFP (mL): [__][__][__][__]
Platelets ☐ Yes ☐ No ☐ Unknown
If yes, total units of platelets: [__][__]

IV fluid therapy ☐ Yes ☐ No ☐ Unknown
Total fluid [_____] L

Access type
☐ Peripheral IV ☐ Intra-osseous ☐ CVC

Vasopressors
Epinephrine: ☐ Yes ☐ No ☐ Unknown
If yes, total duration (days): [__][__]
Norepinephrine: ☐ Yes ☐ No ☐ Unknown
If yes, total duration (days): [__][__]
Dopamine: ☐ Yes ☐ No ☐ Unknown
If yes, total duration (days): [__][__]

Oxygen therapy: ☐ none given
☐ nasal cannula ☐ face mask without reservoir ☐ face mask with reservoir bag
☐ high flow nasal oxygen (HFNO). For HFNO specify total duration (days) [__][__]
If any of the above oxygen devices, give maximum rate used (L/min): [__][__]
Other respiratory support: ☐ non-invasive ventilation (CPAP/BiPAP), specify total duration (days) [__][__]

Renal replacement therapy (eg dialysis) ☐ Yes ☐ No ☐ Unknown
if yes, total duration (days) [__][__]

Invasive mechanical ventilation ☐ Yes ☐ No ☐ Unknown
if yes, total duration (days) [__][__]

End of life care ☐ Yes ☐ No ☐ Unknown

III. PREGNANCY AND NEONATAL OUTCOMES – *must complete at discharge for ALL pregnant patients*

Delivery:
Outcome of delivery: ☐ Live birth ☐ Miscarriage (< 22 weeks' gestation) ☐ Stillbirth (> 22 weeks' gestation/> 500 g WHO definition)
☐ Did not deliver (discharged with intact pregnancy)
In case of birth: Number of neonates: ☐ One ☐ Two ☐ More than two
Mode of delivery: ☐ Vaginal birth ☐ Vacuum ☐ Caesarean section
If caesarean section, specify indication [_____]

Neonatal information	Neonate 1	Neonate 2
Weight:	[__][__] . [__] kg	[__][__] . [__] kg
Apgar:	_____1 min _____5 min_____10 min	_____1 min _____5 min_____10 min
NICU admission:	☐ Yes, on which day after birth [__][__] ☐ No	☐ Yes, on which day after birth [__][__] ☐ No
Infant feeding:	☐ Breastmilk ☐ Expressed breast milk ☐ Breast milk substitute ☐ Mixed feeding	☐ Breastmilk ☐ Expressed breast milk ☐ Breast milk substitute ☐ Mixed feeding
Neonatal death:	☐ Yes, on which day after birth [__][__] ☐ No	☐ Yes, on which day after birth [__][__] ☐ No
Neonatal discharge Status and date:	☐ Discharge ☐ Referral ☐ Death Date of discharge/referral/death (dd/mm/yy): [__][__]/[__][__]/ 20[__][__]	☐ Discharge ☐ Referral ☐ Death Date of discharge/referral/ death (dd/mm/yy): [__][__]/[__][__]/ 20[__][__]

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Specific Maternity Ebola Diagnostic Tests				
EBOV PCR Done in:				
Amniotic fluid	☐ Yes, date: [__][__]/[__][__]/ 20[__][__]	CT Value [__][__]	☐ No	☐ Not Done
Neonate- blood	☐ Yes, date: [__][__]/[__][__]/ 20[__][__]	CT Value [__][__]	☐ No	☐ Not Done
Breastmilk	☐ Yes, date: [__][__]/[__][__]/ 20[__][__]	CT Value [__][__]	☐ No	☐ Not Done

IV . DISCHARGE DETAILS

Date of Discharge/transfer from health facility/death (dd/mm/yyyy): [__][__]/[__][__]/ 20[__][__] Discharge Time [__][__] : [__][__]

Final Diagnosis:

☐ Zaire Ebola virus disease
☐ Sudan Ebola virus disease
☐ other Ebola species disease (specify): [_____]
☐ Not a case (specify other diagnosis): [_____]

Outcome at discharge

☐ Full recovery withOUT sequelae at time of discharge
☐ Full recovery WITH sequelae
If yes, specify: ☐ hearing loss
☐ ocular complications
☐ extreme fatigue
☐ arthralgia
☐ neurologic complications, specify: [_____]
☐ other, specify: [_____]
☐ Dead, if yes, specify date of death: [__][__]/[__][__]/ 20[__][__]
☐ Referred to another facility. If yes, which facility: [_____]
☐ Left against medical advice

Survivor care:

Survivor counselling provided ☐ Yes ☐ No ☐ Unknown
Discharge kit provided ☐ Yes ☐ No ☐ Unknown
Enrolled in survivor program ☐ Yes ☐ No ☐ Unknown If yes, follow-up visit date: [__][__]/[__][__]/ 20[__][__]

If intact pregnancy, secure delivery plan (specify): [_____]

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