

Global Clinical Data Platform CHOLERA 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 suspected, probable or confirmed cholera.

The CRF captures data from patients being managed as inpatients in cholera treatment centre (CTC), cholera treatment unit (CTU) or dedicated inpatient ward. Data may be collected prospectively or retrospectively. The data collection period is defined as the period from hospital admission, or first visit, to discharge from care, transfer or death.

This CRF has three modules:

Module 1: To be completed on the first day of presentation or admission to the CTC,

CTU or ward.

Module 2: Daily form: to be completed daily on inpatient days.

Module 3: To be completed at hospital discharge, transfer or death.

GENERAL GUIDANCE

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

Please e-mail the data management team at <u>globalclinicaldataplatform@who.int</u> and they will provide instructions for data entry and will assign you a 5-digit site code at that time.



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I. CASE IDENTIFICATION/DEMOGRAPHIC DETAILS

ID number: [Site/facility name: []
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II. TREATMENT SUMMARY OVER ADMISSION

II. TREATMENT SUMMART OVER ADMISSION						
Over the course of admission, did the patient receive any of the following?						
Antibiotic: ☐ Yes ☐ No ☐ Unknown	Enteral feeding:	Intravenous fluids:				
If yes, specify all that apply:	☐ Yes, total duration (days) [][]	☐ Yes ☐ No ☐ Unknown				
☐ Penicillin/ampicillin/amoxycillin	□ No □ Unknown	Total intravenous fluids given over				
☐ Ceftriaxone/cefalexin/other cephalosporin	Electrolyte replacement:	admission				
☐ Erythromycin/azithromycin/other <i>macrolide</i>	Potassium (K+) ☐ Yes ☐ No ☐ Unknown	[_][_] . [_] L				
☐ Ciprofloxacin/other quinolone	50% Glucose ☐ Yes ☐ No ☐ Unknown					
☐ Cotrimoxazole/other sulfonamide	Zinc (Zn++) ☐ Yes ☐ No ☐ Unknown	Access type (check all that apply)				
☐ Doxycycline/other tetracycline		☐ Peripheral IV ☐ Intra-osseous ☐ CVC				
☐ Meropenem/other carbapenem	*If patient on F75/F100/RUTF then no zinc Oral rehydration solution:	4				
	Yes □ No □ Unknown	Vasopressors (epinephrine,				
	Treatment of fluid overload:	norepinephrine or dopamine):				
	Furosemide ☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown				
	Taresening E 100 Ellio E cimilettii	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): [][]						
End of life care ☐ Yes ☐No ☐ Unkno	wn					

III. CHOLERA TESTING

Cholera stool specimen collection done?		
☐ Yes ☐ No ☐ Unknown		
Tests ordered on admission:	Collection date: (dd/mm/yyyy)	
Cholera RDT: ☐ Yes ☐ No ☐ Unknown	[][] /[][] / 20 [][]	☐ Positive ☐ Negative ☐ Indeterminate
☐ Crystal VC ☐ Other: []		
Rectal Swab: ☐ Yes ☐ No ☐ Unknown	[_][_] /[_][_] / 20 [_][_]	☐ Positive ☐ Negative ☐ Indeterminate
If yes, specify: []		
Cholera stool O1 / O139 culture	[_][_] /[_][_] / 20 [_][_]	Stool culture
(admission): ☐ Yes ☐ No ☐ Unknown		☐ Positive ☐ Negative ☐ Indeterminate
If yes, specify: []		If positive, <i>V. cholerae</i> strain []
Pregnancy test	[][] /[][] / 20 [][]	☐ Positive ☐ Negative
☐ Yes ☐ No ☐ Unknown		
If yes, specify: ☐ Urine ☐ Serum		
COVID-19	[_][_] /[_][_] / 20 [_][_]	□ RDT □ PCR
☐ Yes ☐ No ☐ Unknown		☐ Positive ☐ Negative ☐ Indeterminate



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IV. LABORATORY TEST RESULTS

Please enter the most abnormal test result during admission for each below.

Test	Collection date (dd/mm/yyyy)	Result	Normal range		
Haemoglobin (Hb)	[_][_] /[_][_] / 20 [_][_]	[][] . [] g/dL	11.0–13.5		
Haematocrit	[_][_] /[_][_] / 20 [_][_]	[_][_].[_] %	36–50		
Platelets	[_][_] /[_][_] / 20 [_][_]	[][][] x10 ⁹ /L	150–400		
Sodium	[_][_] /[_][_] / 20 [_][_]	[][] . [] mmol/L	135–145		
Potassium (K+)	[_][_] /[_][_] / 20 [_][_]	[][] . [] mmol/L	3.5–5.0		
Urea	[_][_] /[_][_] / 20 [_][_]	[][] . [] mmol/L OR [][] [][] mg/dL	1.2–3.0		
		[][] mg/dL OR	0.74–1.35		
Creatinine	[_][_] /[_][_] / 20 [_][_]	[][][] µmol/L	65–120		
Chloride	[_][_] /[_][_] / 20 [_][_]	[][] . [] mmol/L	95–105		
Bicarbonate (HCO ₃)	[_][_] /[_][_] / 20 [_][_]	[][] . [] mmol/L	2–29		
Lactate	[_][_] /[_][_] / 20 [_][_]	[][] . [] mmol/L	< 2.0		
Magnesium	[_][_] /[_][_] / 20 [_][_]	[][] . [] mmol/L	1.5–2.0		
/. PREGNANCY AND NEONATAL OUTCOMES – must complete at discharge for ALL pregnant patients					
Is the patient pregnant (or experienced pregnancy during admission)? ☐ Yes☐ No☐ Unknown Foetal Movements felt by mother?					

Foetal Movements fel	- own					
Foetal heartbeat hear ☐ Yes ☐ Reduced ☐	d? I No □Not Examined □ Unknown					
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 []						
F						
Neonatal information	Neonate 1	Neonate 2				
Weight:	[][] . [] kg	[_][_] . [_] kg				
Apgar:	1 min5 min10 min	1 min5 min10 min				
NICU admission:	☐ Yes, on which day after birth [][]	☐ Yes, on which day after birth [][]				
	□No	□ No				
Infant feeding:	☐ Breastmilk☐ Expressed breast milk	☐ Breastmilk☐ Expressed breast milk				
	☐ Breast milk substitute☐ Mixed feeding	☐ Breast milk substitute☐ Mixed feeding				
Neonatal death:	☐ Yes, on which day after birth [][]	☐ Yes, on which day after birth [][]				
	□No	□ No				
Neonatal discharge	☐ Discharge	□ Discharge				
Status and date:	□ Referral	□ Referral				
	□ Death	□ Death				
	Date of discharge/referral/death	Date of discharge/referral/ death				
	(dd/mm/yy): [][]/[]/ 20[][]	(dd/mm/yy): [][]/[]/ 20[][]				



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VI. DISCHARGE DETAILS

Date of discharge/transfer/death (dd/mm/yyyy): [][]/[]/ 20[][] Discharge time [][] : [][]
Final diagnosis:	
☐ Confirmed cholera	
☐ Probable cholera	
☐ Suspected cholera	
☐ Not a case (specify other diagnosis): [
Outcome at discharge:	
☐ Full recovery withOUT sequelae at time of discharge	
☐ Full recovery WITH sequelae	
If yes, specify:	
☐ Malaise	
☐ Other, specify: []
☐ Dead, if yes, specify date of death: [_][_]/[_][_]/ 20[_][_]	•
☐ Referred to another facility. If yes, which facility: [1
☐ Left against medical advice	
Post discharge care:	
Discharge kit provided (oral rehydration solution, soap, hygiene kit)	☐ Yes ☐ No ☐ Unknown