

US-WHO INTERNATIONAL CLINICAL NETWORK EBOLA VIRUS DISEASE CLINICAL DATA

Public reporting burden of this collection of information is estimated to average 45 minutes per response, including reviewing existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information, sending it to the collection sponsor, and a person is not required to respond to a collection of information unless it displays a valid collection number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Washington Headquarters Office, Paperwork Project Director, Paperwork Reduction Project (0920-XXXX), U.S. Department of Health and Human Services, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-XXXX)

The data collection instrument collect data from 12 different domains:

- Demographics and Background
- First Signs and Symptoms
- Signs and symptoms at first admission (generally within 7 days of onset)
- Signs and symptoms at second admission (generally within 7 days of onset)
- Clinical findings during hospitalization
- Interventions employed during hospitalization
- Treatments employed
- Investigational Therapeutics given
- Admission laboratory values (from final admission)
- Laboratory testing during hospitalization
- Virology and Immunology laboratory results
- Outcomes

Detailed demographic and clinical information is vital to gaining insights about the disease. In order to protect patient privacy, please deliver the completed form to the CD using your unique SFTP address and password. Only your center and the CD

COLLECTION TOOL

Form Approved
OMB No. 0920-XXXX
Exp. Date XX/XX/20XX

er response, including the time for reviewing instructions, searching
ing the collection of information. An agency may not conduct or
ys a currently valid OMB control number. Send comments regarding
ns for reducing this burden to CDC/ATSDR Information Collection
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ains including:

(in Africa)
ally following medical evacuation)

n)

out your center's experience caring for Ebola patients.
e CDC via the secure encrypted file transfer protocol (FTP)
IC will be able to view and download your forms.

Demographics and Background

Patient number (Facility name and number, for example, Emory 1, Emory 2, etc...)	Clinical location (Country of final care)	Clinical location (City in Europe or US of final care)	Patient AGE in YEARS	GENDER Male/Female
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Chronic co-morbidities (None, or provide list of all co-morbidities)	Country where EBOV infection was confirmed (RT-PCR+ for EBOV)	Country where EBOV exposure/infection occurred	Date of symptom onset	Time (days) from illness onset to diagnosis of EBOV infection by RT-PCR	Time (days) from illness onset to FIRST hospital admission	Time (days) from illness onset to FINAL hospital admission
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Medically- evacuated from West Africa (YES/NO)	For Medically evacuated patients, time (days) from illness onset to admission at receiving hospital outside of West Africa	If Medevac, by whom? (Phoenix Air, Medic Air)	Imported EVD case (not medically evacuated) (YES/NO)?	Locally- acquired (secondary nosocomial transmission in Europe or US) (YES/NO?)	Occupation (physician, nurse, laboratorian, pharmacist, other healthcare professional, other (specify))	Worked in Ebola treatment unit (YES/NO)?
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Worked in Healthcare facility (but not an Ebola treatment unit) (YES/NO)?	Location of FIRST hospital admission (Country 1st Hospital)?	Location of FINAL hospital admission (Country FINAL Hospital)?
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**Signs and symptoms PRIOR TO
ADMISSION**

Patient number	Feverishness (temperature not measured (YES/NO)?	Fever (measured elevated temperature) (YES/NO)?	How measured? (axillary, oral, rectal)	Headache (YES/NO)?	Weakness (YES/NO)?	Fatigue (YES/NO)?
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Lethargy (YES/NO)?	Muscle aches (YES/NO)?	Decreased appetite (YES/NO)?	Nausea (YES/NO)?	Vomiting (YES/NO)?	Diarrhea (YES/NO)?	Abdominal pain (YES/NO)?	Sore throat (YES/NO)?
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Nasal congestion (YES/NO)?	Rhinorrhea (YES/NO)?	Cough (YES/NO)?	Joint aches (YES/NO)?	Any treatments given PRIOR TO HOSPITALIZATION? (YES/ NO)	Antimalarials (please list)	Antibiotics (please list)
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Signs and symptoms present on day of Admission to Initial Hospital

Patient number	<u>Date of admission to initial hospital</u>	Feverishness (temperature not measured (YES/NO)?	Fever (measured elevated temperature) (YES/NO)?	Admission temperature (Celsius)	Temperature measured by: temporal, ocular, oral, rectal, axillary?
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Gastrointestinal tract

Joint aches (YES/NO)?	Conjunctival injection (YES/NO)?	Hiccups (YES/NO)?	Decreased appetite (YES/NO)?	Nausea (YES/NO)?	Vomiting (YES/NO)?	Diarrhea (YES/NO)?	Abdominal pain (YES/NO)?
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Respiratory tract

Sore throat (YES/NO)?	Pharyngitis (YS/NO)?	Glossitis (tongue inflammati on) (YES/NO)?	Nasal congestion (YES/NO)?	Rhinorrhea (YES/NO)?	Cough (YES/NO)?	Hemoptysis (YES/NO)?	Shortness of breath (YES/NO)?
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Neurological

Difficulty breathing (YES/NO)?	Tachypnea (YES/NO)?	Oxygen saturation (pulse oximetry on room air) (%)	Altered Mental Status or Confusion (YES/NO)?	Agitation (YES/NO)?	Unresponsive, coma (YES/NO)?	Epistaxis - bleeding from nose (YES/NO)?	Bleeding from gingiva, or inside mouth (YES/NO)?
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Hemorrhagic manifestations

Mental Health

Petechiae anywhere (YES/NO)?	Hematemes is (YES/NO)?	Melena (YES/NO)?	Hematoche zia - frank blood in stool (YES/NO)?	Bloody diarrhea (YES/NO)?	Oozing from IV catheter site (YES/NO)?	Anxiety (YES/NO)?	Depression (YES/NO)?
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Signs and symptoms present on day of Admission to FINAL Hospital

Patient number	<u>Date of admission to final hospital</u>	Feverishness (temperature not measured (YES/NO)?	Fever (measured elevated temperature) (YES/NO)?	Admission temperature (Celsius)	Temperature measured by: temporal, ocular, oral, rectal, axillary?
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Gastrointestinal tract

Joint aches (YES/NO)?	Conjunctival injection (YES/NO)?	Hiccups (YES/NO)?	Decreased appetite (YES/NO)?	Nausea (YES/NO)?	Vomiting (YES/NO)?	Diarrhea (YES/NO)?	Abdominal pain (YES/NO)?
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Respiratory tract

Sore throat (YES/NO)?	Pharyngitis (YS/NO)?	Glossitis (tongue inflammati on) (YES/NO)?	Nasal congestion (YES/NO)?	Rhinorrhea (YES/NO)?	Cough (YES/NO)?	Hemoptysis (YES/NO)?	Shortness of breath (YES/NO)?
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Neurological

Difficulty breathing (YES/NO)?	Tachypnea (YES/NO)?	Oxygen saturation (pulse oximetry on room air) (%)	Altered Mental Status or Confusion (YES/NO)?	Agitation (YES/NO)?	Unresponsive, coma (YES/NO)?	Epistaxis - bleeding from nose (YES/NO)?	Bleeding from gingiva, or inside mouth (YES/NO)?
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Hemorrhagic manifestations

Mental Health

Petechiae anywhere (YES/NO)?	Hematemes is (YES/NO)?	Melena (YES/NO)?	Hematoche zia - frank blood in stool (YES/NO)?	Bloody diarrhea (YES/NO)?	Oozing from IV catheter site (YES/NO)?	Anxiety (YES/NO)?	Depression (YES/NO)?
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Patient number	Number of days of fever (Temp >38C)?	Number of days of diarrhea?	Maximum number of stools/day	Maximum diarrhea volume/24 hours (in mls)	Number of days of vomiting?
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al Findings During Hospitalization in Europe or US

Bleeding or oozing at IV catheter sites (YES/NO)?	Oliguria (YES/NO) (<500 ml urine/day)?	Anuria (YES/NO) (<100 ml urine/day)?	Hypoxia (YES/NO)? (if YES, list lowest pulse oximetry on room air)?	Hypoxemia (YES/NO)? (If YES, list PaO2)	Pulmonary edema (by CXR)? (YES/NO)?
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Pulmonary edema (by ultrasound)? (YES/NO)?

Pneumonia (by CXR)? (YES/NO)

Bilateral pneumonia (YES/NO)?

Pulmonary edema by ultrasound (YES/NO)?
Unilateral pneumonia (YES/NO)?

Respiratory failure (YES/NO)?

Date/ day of illness when this was diagnosed?	Hypoxemic respiratory failure (YES/NO)?	Hypercarbic respiratory failure (YES/NO)?	Acute Respiratory Distress Syndrome (ARDS) (YES/NO)?	ECG PaO ₂ /FIO ₂ changes (lowest) (YES/NO)?	If yes, what?
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Arrythmia (YES/NO)?	If arrhythmia, what rhythm?	Date/ day of illness when this was documented diagnosed? ileus (YES/NO)?	Suspected or Date/ day of documented illness when colon this was obstruction diagnosed? (YES/NO)?	Suspected or documented intestinal paresis (YES/NO)?
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Abdominal distension (YES/NO)?	Bacteremia (positive blood culture) (YES/NO)?	Gram positive bacteremia (YES/NO)?	Gram negative bacteremia (YES/NO)?	Specific bacteria identified - list name	Date/ day of illness when this was first Sepsis isolated? (YES/NO)?
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	Systemic Inflammatory Response	Peripheral edema	Delirium	Encephalopathy	Seizure
Septic Shock (YES/NO)?	Syndrome (YES/NO)?	(YES/NO)?	(YES/NO)?	(YES/NO)?	(YES/NO)?

Encephalitis
(YES/NO)?
[how
diagnosed?]

Coma
(YES/NO)?

Other infections
diagnosed
(malaria, typhoid,
etc)? (Y/N)

What other
infections? (please
list)

Interventions during

Patient number	Peripheral intravenous line (not PICC) (YES/NO)?	Peripherally inserted central catheter (PICC line) (YES/NO)?	Central venous catheter placement (YES/NO)?	Dialysis catheter insertion (YES/NO)?
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Hospitalization in Europe or the US

Intravenous fluids	Normal saline (YES/NO)?	Maximum NS volume /24 hours	Lactated Ringers (YES/NO)?	Maximum LR Supplemental volume /24 oxygen per nasal hours canula (YES/NO)?
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Supplemental oxygen per face mask (YES/NO)?

External audio auscultation (YES/NO)?

Non-invasive ventilation (YES/NO)?

Number of days of **Invasive** mechanical Non-invasive ventilation (YES/NO)?

Number of days
of invasive Continuous renal
mechanical replacement therapy
ventilation (CVVHD) (YES/NO)?

Number of days Vasopressor or
Inotrope use
of CRRT (YES/NO)?

Number of days of
vasopressor or
inotrope use

Rectal tube placed
(YES/NO)?

Foley tube
placed
(YES/NO)?

Resuscitation for
cardiac arrest
(YES/NO)?

If YES, chest
compressions
(YES/NO)?

If YES,
epinephrine
given (YES/NO)?

If YES, atropine
given (YES/NO)?

If YES,
bicarbonate
given
(YES/NO)?

If YES,
transcutaneous
pacing given
(YES/NO)?

Treatments given during Hospitalization

Patient number	Anti-emetics (YES/NO)?	If YES, list anti-emetic 1	If YES, list anti-emetic 2 (YES/NO)?	Loperamide	Anticonvulsants (YES/NO)?
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If YES, list anticonvulsants (ES/NO)?	Anxiolytics	If YES, list anxiolytics	Whole blood transfusion	Fresh frozen plasma	Platelet transfusion	IVIG
(ES/NO)?			(YES/NO)?	(YES/NO)?	(YES/NO)?	(YES/NO)?



Antibiotics (YES/NO)?	If YES, please list all antibiotics given	Antifungal (YES/NO)?	If yes, please list all (other than antifungals for Ebola) given	Antivirals (YES/NO)?	If yes, please list all antivirals	Anti- malarials given	(YES/NO)?
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If YES, list anti-malarial 1	If YES, list Corticosteroids anti-malarial 2 (YES/NO)?	Hydrocortisone (YES/NO)?	Methylprednisolone (YES/NO)?	Dexamethasone (Y/N)	Sedation (YES/NO)?
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If YES, List sedative 1	If YES, List Analgesia sedative 2 (YES/NO)?	Aspirin (YES/NO)?	Acetaminop hen Paracetomo (YES/NO)?	I (YES/NO)?	Ibuprofen (YES/NO)?
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Other NSAID (YES/NO)?	Narcotics (YES/NO)?	Paralytics (YES/NO)?	If YES, list paralytic 1	If YES, list paralytic 2	Albumin (YES/NO)?	Potassium (YES/NO)?
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If YES, was
intravenous
potassium
given
(YES/NO)?

If YES, was
oral
potassium
given
(YES/NO)?

Calcium
(YES/NO)?

Magnesium
(Yes/ No)?

Investigational therapies for EBOV infection

ZMAPP

Patient number	ZMapp (YES/NO)?	If YES, intravenous dosing given (e.g. 50mg/kg)?	If YES, total number of doses given?	If YES, dosing frequency?	If YES, started on what illness day?
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ZMAB

If YES, any <i>suspected</i> <i>adverse</i> <i>reaction</i> (YES/NO)?	If adverse reaction, list ZMab all (YES/NO)?	If YES, intravenous dosing given (e.g. 50mg/kg)?	If YES, total number of doses given?	If YES, dosing frequency?	If YES, started on what illness day?
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TKM-Ebola

If YES, any <i>suspected</i> <i>adverse</i> <i>reaction</i> (YES/NO)?	If adverse reaction, list TKM-Ebola all (YES/NO)?	If YES, intravenous dosing given (0.3mg/kg)?	If YES, total number of doses given?	If YES, dosing frequency?	If YES, started on what illness day?
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Favipiravir (T-705)

If YES, any suspected adverse reaction (YES/NO)?	If adverse Favipiravir reaction, list (T-705) all (YES/NO)?	If YES, oral loading dose given?	If YES, oral maintenanc e dose given?	If YES, total number of doses given?	If YES, dosing frequency?
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Brincidofovi

If YES, started on what illness day?	If YES, any <i>suspected</i> <i>adverse</i> <i>reaction</i> (YES/NO)?	If adverse Brincidofovi reaction, list <i>r</i> (CMX-001) all (YES/NO)?	If YES, oral loading dose given?	If YES, oral maintenanc e dose given?	If YES, total number of doses given?
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r (CMX-001)

If YES, dosing frequency?	If YES, started on what illness day?	If YES, any <i>suspected</i> <i>adverse</i> <i>reaction</i> (YES/NO)?	If adverse reaction, list Amiodarone all (YES/NO)?	If YES, oral dosing given?	If YES, total number of doses given?
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Amiodarone

If YES, dosing frequency?	If YES, started on what illness day?	If YES, any <i>suspected</i> <i>adverse</i> <i>reaction</i> (YES/NO)?	If adverse reaction, list FX06 all (YES/NO)?	If YES, intravenous dosing given)?	If YES, total number of doses given?
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FX06

Convalesce

If YES, dosing frequency?	If YES, started on what illness day?	If YES, any <i>suspected</i> <i>adverse</i> <i>reaction</i> (YES/NO)?	If adverse reaction, list Convalescent all plasma (YES/NO)?	If YES, volume of plasma given (ml or cc)	If YES, total number of transfusions given?
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nt plasma

	If suspected reaction, was it TRALI (transfusion associated acute lung injury) (YES/NO)?	If suspected reaction, was it TACO (transfusion associated circulatory overload) (YES/NO)?	Other investigational therapeutic (YES/NO)?	If YES, Please list other therapeutic
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Laboratory testing results on at Ad

Patient number	<i>Point of care laboratory testing used</i> (YES/NO)?	If YES, iSTAT used (YES/NO)?	If YES, PICCOLO used (YES/NO)?	If YES, specify other test Sodium device (mEq/liter)
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mission at Final Hospital

Potassium (mEq/liter)	Chloride (mEq/liter)	Bicarbonate (mEq/liter)	Creatinine [mg/dL (US); umol/liter (Europe)]	BUN [mg/dL (US); mmol/liter (Europe)]	Glucose [mg/dL (US); mmol/L (Europe)] off IV glucose	Calcium (mmol/L)
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**Ionized
Calcium**

[mg/dL
(US);
mmol/L
(Europe)]

Magnesium

(mEq/L)

AST (U/L)

ALT (U/L)

CK (U/L)

Lactate

[mg/dL (US);
mmol/L
(Europe)]

Total bilirubin

[mg/dL (US);
mmol/L
(Europe)]

Albumin
(g/dL)

WBC (x 10 ⁹ /L)	Absolute lymphocyte count (x 10 ⁹ /L)	Abosoulte neutrophil count (x 10 ⁹ /L)	Platelets (x 10 ⁹ /L)	HgB (g/dL)	Hct (%)	Prothrobin time (seconds)
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**Partial
thromboplastin
time (seconds) INR**

**D-dimer
(ng/ml)**

Laboratory testing results anytime during Final Hospitalizatio

	Sodium	Potassium	Chloride	Bicarbonate	Creatinine	BUN
Patient number	lowest value (mEq/liter)	lowest (mEq/liter)	lowest (mEq/liter)	lowest (mEq/liter)	highest [mg/dL (US); umol/liter (Europe)]	highest [mg/dL (US); mmol/liter (Europe)]

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Glucose lowest [mg/dL (US); mmol/L (Europe)] off IV glucose	Glucose highest [mg/dL (US); mmol/L (Europe)] off IV glucose	Calcium lowest (mmol/L)	Ionized Calcium lowest [mg/dL (US); mmol/L (Europe)]	Magnesium lowest (mEq/L)	AST highest (U/L)	Illness day (not hospital day) of peak AST associated with <i>Ebola virus disease</i> (not drug reaction)
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	Illness day (not hospital day) of peak ALT associated with Ebola virus disease (not drug reaction) (U/L)	CK highest (U/L)	Lactate highest [mg/dL (US); mmol/L (Europe)]	Total bilirubin highest [mg/dL (US); mmol/L (Europe)]	Albumin lowest (g/dL)	WBC lowest (x 10 ⁹ /L)
ALT (U/L)						

Illness day (not hospital WBC day) of <i>highest</i> (x lowest WBC 10 ⁹ /L)	Illness day (not Absolute hospital lymphocyte day) of count <i>highest lowest</i> (x WBC 10 ⁹ /L)	Abosoulte neutrophil count <i>lowest</i> (x 10 ⁹ /L)	Platelets <i>lowest</i> (x 10 ⁹ /L)	HgB <i>lowest</i> (g/dL)
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Hct lowest (%)	Prothrombin time highest (seconds)	Partial thromboplastin time highest (seconds)	INR highest	D-dimer highest (ng/ml)
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Virology and Immunology Testing Results During Entire Clinical Course until de

testing on

patient number	Name of RT-PCR assay?	Where was RT-PCR assay performed (e.g. CDC, Ministry of Health laboratory, etc.)?	Initial Ct value in blood	Illness day of initial Ct result in blood (viral blood copies/ml)	First available EBOV RNA level in blood	Illness day of first available EBOV RNA level in blood
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ath or at discharge

blood

Lowest Ct value	Highest blood EBOV RNA level <i>Illness day of lowest Ct value in (viral blood copies/ml)</i>	Illness day of highest blood EBOV RNA level <i>Illness day of highest blood EBOV RNA level</i>	Illness day for 1st negative RT-PCR result in blood <i>Illness day for 1st negative RT-PCR result in blood</i>	Illness day for 2nd consecutive negative RT-PCR result in blood <i>Illness day for 2nd consecutive negative RT-PCR result in blood</i>	Initial Ct value in urine
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URINE

First available <i>Illness day</i> of initial Ct level in urine (viral copies/ml)	<i>Illness day of first available</i> EBOV RNA Was saliva level in tested urine (YES/NO)?	If YES, was saliva positive for EBOV by RT-PCR (YES/NO)?	If positive, when did saliva 1st become tested negative? (YES/NO)?
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OTHER CLINICAL SPE

If YES, was
sweat
positive for
EBOV by RT-
PCR
(YES/NO)?

If positive,
when did
swaet 1st Was **stool**
become tested
negative? (YES/NO)?

If YES, was
stool
positive for
EBOV by RT-
PCR
(YES/NO)?

If positive,
when did
stool 1st Was a **rectal**
become **swab** tested
negative? (YES/NO)?

If YES, was a
rectal swab
positive for
EBOV by RT-
PCR
(YES/NO)?

CIMENS

If positive, when did rectal swab 1st become negative? (YES/NO)?	Was a skin swab tested PCR	If YES, was a skin swab positive for EBOV by RT- PCR (YES/NO)?	For female patients, when did was a skin swab 1st become negative? (YES/NO)?	was a vaginal swab positive for EBOV by RT- PCR (YES/NO)?	If positive, when did vaginal swab 1st become negative?
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	Serology
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For male patients, was a semen specimen collected in the hospital (YES/NO)?	If YES, was a semen specimen positive for EBOV by RT-PCR (YES/NO)?	If positive, when did semen 1st become negative? Was EBOV (or how serological long testing documented positive) (YES/NO)?	If YES, <i>first illness day</i> that EBOV IgM titer was detected?	If YES, <i>first illness day</i> that EBOV IgG titer was detected?
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Outcomes

Patient number	Alive at 14 days after illness onset (YES/NO)?	Alive at 28 days after illness onset (YES/NO)?	Died (YES/NO)?	For fatal cases, <i>time (days)</i> <i>from illness</i> <i>onset to death</i>
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For survivors	
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Duration of Final Hospital Admission to documented clearance of EBOV viremia (total number of days in Final Hospital to 2nd consecutive negative RT-PCR result in blood)

Duration of days Final Hospital Admission (total number of in Final Hospital to discharge or death)

Required supplemental oxygen at discharge (YES/NO)?

Required diaylsis at discharge (YES/NO)?

Clearance of EBOV viremia by one negative RT-PCR result in blood (YES/NO)?

<u>Discharge criteria used</u>	<u>Condition at</u>
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Clearance of
EBOV viremia
by two
consecutive
negative RT-
PCR results in
blood
(YES/NO)?

EBOV RNA not
detected by RT-
PCR in blood and
urine (YES/NO)?

EBOV RNA not
detected by RT-
PCR in any
clinical
specimens
(YES/NO)?

Weakness
(YES/NO)?

Weight loss
(YES/NO)?

Anemia
(YES/NO)?

Discharge

Disposition

Fatigue (YES/NO)?	Any lab abnormalities (YES/NO)?	If YES, what labs remained abnormal?	Home (YES/NO)?	Rehabilitatio n center (YES/NO)?
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