Research Protocol - Inpatient signs and symptoms and factors associated with death in children aged 5 years and younger admitted to two Ebola management centres in Sierra Leone, 2014: a retrospective cohort study

Inpatient signs and symptoms and factors associated with death among children aged ≤5 years admitted to two Ebola Management Centres in Sierra Leone, 2014: a retrospective cohort study

1 Context

The first case of Ebola virus disease in Sierra Leone was reported in May 2014 in the rural district of Kailahun. Médecins Sans Frontières (MSF) opened the first Ebola Management Centre (EMC) in Sierra Leone in Kailahun in June 2014 and in September 2014 opened a second in Bo, the second largest city in Sierra Leone. The case fatality in the West Africa epidemic has been highest in young children. However, data on children are scarce and clinical data across all ages in this epidemic have been limited to symptoms reported on arrival at treatment facilities rather than observed during admission.

2 Study objectives

2.1 Principal objective

We aim to describe the signs and symptoms of children aged ≤5 years confirmed with Ebola, on arrival to the EMC and during their admission.

2.2 Specific objectives

1. To describe the source case for children
2. To describe the viral load at presentation
3. To document the intervals between symptom onset and presentation for those who die and those who survive
4. To describe early symptoms of Ebola virus disease
5. To assess the association between risk factors and death

3 Methods

3.1 Study population

All children ≤5 years admitted to the Kailahun and Bo EMCs between June and December 2014 with confirmed Ebola virus disease.

3.2 Data sources

All patients with basic demographics are documented on line lists, facilitating identification of the study population.

A case investigation form is completed for each patient and includes demographic characteristics, exposure history, date of symptom onset, and past and present symptoms.

EVD is confirmed with quantitative reverse transcription polymerase chain reaction and results are given as cycle thresholds, a measure inversely related to viral load.

During admission a standardised chart is used to record specific symptoms and signs and axillary temperature.

In summary, data is available from line lists, case investigation forms and patient charts that include: daily symptom checklists, observations, and additional clinical notes.

3.3 Data analysis

Data will be entered into excel worksheets and primary sources will be reviewed to ensure accuracy and completeness.

Data cleaning and analysis will be done with Stata 11.2 (StataCorp Ltd).

We will describe epidemiological, demographic, and clinical characteristics on arrival and during admission and the viral load and assess the association between risk factors and death.

Chi-squared tests will be used to assess associations between demographic characteristics, laboratory results, occurrence of symptoms, and the probability of death while admitted to an EMC.

Variables of interest are age, sex, EMC site, duration of illness, delay to admission to EMC from symptom onset, viral load of first positive test and symptoms during admission.

To capture early symptoms (and limit recall bias) we will describe symptoms in a subgroup of children admitted within 3 days of symptom onset.

4 Benefits

There are no published articles describing clinical features in young children with Ebola during their inpatient stay. This analysis will document all young children managed by MSF in 2014 with Ebola in Sierra Leone. It should encourage clinicians and researchers to collect and analyse age-specific data and will support the formulation of next questions for the management and prognosis for children with Ebola. There will be no benefit for the individuals whose data has been used but has the potential to support future communities affected by Ebola.

No risks are identified from this work.

5 Ethical considerations

This protocol meets the MSF Ethical Review Board (ERB) exemption requirements as it pertained to retrospective routinely collected anonymous medical data. The Medical Director of OCA provided consent for the conducting of this analysis.

6 Dissemination and implementation of research findings

6.1 Responsibility

- Medical Coordinator, OCA Sierra Leone
- Manson Unit - OCA Ebola Team

6.2 Dissemination

Manuscript(s) will be submitted to a peer reviewed journal and communication strategies will be utilized to promote dissemination.

Results will be shared within MSF and with stakeholders in Sierra Leone and West Africa.

6.3 Implementation

Results should trigger better age stratified data collection and child centered interventions.