Sub-clinical infection, household transmission and long-term sequelae among Ebola Virus Disease survivors, their households and neighbours in Sierra Leone

Study protocol

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Summary

The present study proposal by Save the Children and the London School of Hygiene and Tropical Medicine intends to investigate two areas where major questions remain concerning Ebola Virus Disease, namely:

1. The burden of short and longer term psychosocial disability, as well as wider household impacts, attributable to Ebola Virus Disease in survivors and their families;;
2. The extent to which asymptomatic infections among people never presenting as a case may explain observed transmission dynamics and disease patterns; while fragmentary evidence suggests the occurrence of such infections, more accurate quantification of their extent, and of how intra-household transmission actually takes place, would greatly improve efforts to model the evolution of the current and future epidemics, and inform critical decisions on the relative importance of isolation, behaviour change, vaccination and other public health measures.

We propose to shed light on the above questions by systematically investigating a cohort of some 165 patients discharged between November 2014 and March 2015 from Kerrytown Ebola Treatment Centre, their household members, and neighbourhood controls, through laboratory testing for Ebola-specific antibodies, in-depth investigation of likely intra-household transmission events; qualitative exploration of household and individual-level socio-economic and livelihoods effects.

Field work is proposed to take place between May and October 2015.

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1 Introduction

This research study will address two key questions in Ebola Virus Disease (Ebola): the prevalence of and risk factors for long-term psychosocial sequelae; and the prevalence and implications of asymptomatic or subclinical infections. It will be conducted as a collaboration between the London School of Hygiene and Tropical Medicine (LSHTM) and Save the Children. Save the Children has operated an Ebola Treatment Centre (ETC) at Kerrytown, Sierra Leone, on behalf of the Ministry of Health and Sanitation, as a result of which a cohort of approximately 165 Ebola survivors, nearly all from the Western Area of Sierra Leone, have been discharged.

Very little is known about the long-term sequelae of Ebola virus disease from a clinical or psychosocial viewpoint. Despite reports of a "post-Ebola syndrome", including vision problems, actual data are scarce.[1-5] Published studies have been based on small numbers and short time-frames, and reports of persistent health problems have been imprecise or anecdotal, and have lacked comparison groups (see review in Appendix 1). Although some survivors' clinics have been set up, it is important to include active follow-up at home, to ensure representativeness.

The possibility of asymptomatic and subclinical infection has been suspected since the first outbreaks,[6,7] but the extent and therefore the implications for infection spread have only been studied in a few settings and the results are not easy to interpret. In areas endemic for Ebola or other filoviruses, positive serology may reflect background zoonotic transmission rather than asymptomatic infections from person-person transmission.[8-14] Improved knowledge of who gets infected would improve understanding of infection spread and patterns of disease. To what extent has herd immunity contributed to control? Have asymptomatic individuals in households of Ebola cases avoided exposure, or avoided getting ill despite infection? Does the relatively low incidence rate of Ebola in children and young adults simply result from low exposure, or is there a higher proportion of asymptomatic infection in this group? Does intensity of exposure correlate not just with risk of infection but with risk of disease given infection, and with disease severity?

The 2013-2015 epidemic of Ebola gives an unprecedented opportunity to address all these questions. There are large numbers of survivors who can be followed-up, and background filovirus infection is unlikely. (It is possible that Ebola has been present in Sierra Leone previously,[15] but given the absence of previous recognised outbreaks it is unlikely to be widespread.) By measuring Ebola antibody levels in survivors, their household contacts, and neighbourhood controls, together with detailed questioning on exposures, we can assess the extent of asymptomatic infection. Follow-up will initially be conducted within one year of the survivor's disease.. The results of the immunological study should greatly improve understanding of transmission and hence estimates and predictions of disease spread.

2 Aims and objectives

The aims of this study are as follows:

1. To assess the prevalence of and risk factors for short and longer term psychosocial sequelae attributable to Ebola Virus Disease;
2. To improve understanding of the spread and consequences of Ebola infection by assessing the prevalence of and risk factors for asymptomatic infection, including the intensity of exposure in Ebola-affected households.

Specific objectives include:

1. To measure Ebola antibodies in survivors, their household members and neighbourhood controls
2. In survivors and their households:
   2.1. Establish likely sources of transmission and intensity of contact (including of deceased members) to correlate with outcomes
   2.2. Identify factors associated with outcomes of Ebola, including socio-demographic and clinical factors from the acute disease episode, and intensity of exposure
   2.3. Identify common social strategies employed by survivors to adapt to Ebola and its sequelae

3 Methods

3.1 Recruitment

The study will take place in Sierra Leone where there is the largest number of confirmed cases. The initial study will focus on the ~165 survivors from the Save the Children Ebola Treatment Centre (ETC) in Kerry Town. The study may be extended in future to other cohorts of survivors in the Western Area, subject to amendment of the present study proposal.

Survivors and their household members (all ages, defined as people living together within the same residential structure and sharing meals) will be recruited, together with neighbourhood controls to assess background Ebola antibody positivity. Neighbourhood controls will be selected from an area that has been relatively spared by the Ebola outbreak, excluding individuals with any known exposure. The survivors are already well known to the study field staff, so initial contact for this study will be made by phone. For the neighbourhood controls, intensive community sensitisation will take place in the small area selected for the study. Written informed consent for the study will be sought from all adult participants and from adult guardians of child participants.

3.2 Data collection

Data collection will involve survivors, all household members of survivors, and controls. They will be seen at home initially, or at a local community centre/clinic.

The data collection will consist of:

Survivor household interview to establish levels of exposure: In each survivor household interviews will be conducted to try to reconstruct the course of the outbreak in the household including sources of infection and degrees of exposure to sick individuals of each household member (including any deceased members). These interviews will be semi-structured, with probing questions.

Antibody tests.

Self-administered oral fluid samples will be requested for antibody testing using IgG capture ELISA from survivors, all household members of survivors and from the neighbourhood controls. These new tests, developed by Richard Tedder of Public Health England, are currently being validated in Freetown. There are no existing commercial, fully-validated tests for Ebola antibodies. Unpublished on Richard Tedder's test to date show positive results on 2/2 Ebola survivors in the UK, and negative results on all of ~100 individuals in the UK and ~45 individuals from the Gambia with no known exposure to Ebola. There is a very high degree of correlation of antibody concentration (measured as optical density) between the plasma and oral fluid in survivors in the ongoing validation tests. The tests will be conducted in Sierra Leone.

Qualitative study of impact

For a sub-sample, qualitative assessments will aim to understand the long-term impact of Ebola on survivors. We will conduct an ethnographic study incorporating in-depth interviews with 30-50 Ebola survivors, and their caregivers, as well as providers and other individuals involved in survivor care networks. We will include males and females, and a range of impairments. In order to assess the long-term and evolving social impacts of post-Ebola disability, research will cover explanatory models of Ebola and post-Ebola symptoms (and how these models reinforce wider social/political narratives about Ebola), effects of Ebola and long-term sequelae on social relationships (including marriage potential) and livelihoods, the emergence of Ebola survivor communities, and processes of re-integration of Ebola survivors with and without long-term sequelae. Survivors will be interviewed on several occasions over six months, providing data at different time points, and an opportunity to build rapport facilitating a more open exchange. Interviews will be semi-structured and be complemented by focus group discussions with survivors and care givers as well as unstructured observations of survivor care networks.

3.3 Sample size

The frequency of asymptomatic infection in household contacts of Ebola cases is unknown. Previous studies have been conducted in areas where Ebola outbreaks have occurred previously: background filovirus infections may be more common and the specificity of the tests is uncertain.

Of the 165 survivors, 4 are known to have died, some may not be living with anyone who was in the household at the time they had Ebola, and some will not be from and/or currently living in Western Area. We estimate that there will be at least 100 households in Western Area containing survivors and other household members who were there at the time of the illness so who were potentially exposed. Given the large household sizes, there should be at least 500 such members. We would also recruit about 100 controls. This would give us about 80% power to detect differences at a 5% level of significance between controls and household contact if the prevalence of antibodies to Ebola was (for example) 0% vs 6%, or 1% vs 8%, or 2% vs 10%.

3.4 Analysis

Analyses will:

- Describe the prevalence of Ebola-specific antibodies (suggesting asymptomatic infection) in household contacts and community controls
- Describe antibody levels among survivors as a function of time since infection.
- Describe the history of disease and exposure in the survivor households to estimate level of exposure of those who got Ebola Viral Disease, those with evidence of asymptomatic infection and those with no evidence of infection.
- Assess risks of infection and disease in relation to degree of exposure, age, sex.
- Describe the spectrum of psychosocial outcomes among survivors, and their families, including stigma, integration and coping strategies

3.5 Dissemination of results

The results of the study will be disseminated through reports, academic papers, and presentations. We will ensure that negative results are also reported. All publications will be open-access. We will also share the results directly with the government of Sierra Leone and other organizations working on Ebola.

4 Human subjects' protection

4.1 Consent and risk to participants

The study protocol will be submitted for review to the appropriate ethics review board in Sierra Leone and at the London School of Hygiene & Tropical Medicine.

There will be minimal risk to the participants, namely from experiencing duress during the I interview. Through training the study staff, using staff who already have built a rapport with the survivors, letting survivors tell their own story, and with proper supervision, this risk will be minimized. Each team will include at least one field worker with training in psychosocial support.

By working closely with groups already providing support to survivors we aim to minimise any risk of stigma attached to the visits. There is a possibility that the attention received by survivor households and the chosen controls will attract jealousy. We will attempt to minimise this by explaining the purpose of the study, and the procedure used to select controls, and by not providing payments to participants. Because we are taking up people's time we will provide refreshments during the interview, and give each household a hygiene kit.

We will recruit children into the cohort study, though only after completing the informed consent process with the child's guardian. For older children we will also ask for the child's assent to participate in accordance with Sierra Leonean age cut-offs for child participation in research. Some female participants may be pregnant. These women remain eligible; they will be directed to locally available facilities for their ante- and post-natal care (including the MSF-Spain facility in Freetown for survivors).

Participants will be informed that their participation is voluntary and that they are free to discontinue their participation at any time, or to participate in the interview but not give saliva samples. Participation in the study will not affect the participant's ability to receive medical care. Because it may take several months for the antibody tests to be ready, and because the results have no direct benefit to the individuals involved, the results will not be available to the participants. We will ask the participants if they are willing to be re-contacted by the study team in the future.

4.2 Data handling

We recognize that maintaining participant confidentiality is not only an essential part of such research, but is of particular concern here due to the high levels of stigma that have been associated with Ebola. Staff will receive training on ensuring patient confidentiality, and all data collected on study participants will be secured (locked if paper or password-protected/encrypted if electronic). An anonymised version of the raw database(s), stripped of identifying information like name, address, etc. will be created, and only the anonymised one will be shared with researchers on this project. For participants from small areas, only aggregate location information will be retained in this database, such as district. Only select members of the data team will have access to the raw data including the personal identifiers, for the purpose of entering the information into an electronic database, checking for errors, and producing the anonymised version. Access to the anonymised dataset will still be restricted to individuals who are actively involved in the study. The electronic database will be password protected on a secure server owned by Save the Children with a copy at the London School of Hygiene & Tropical Medicine.

4.3 Storage of patient samples

We will store residual oral fluid for possible later testing, for example if more accurate tests become available. We will ask permission from the Sierra Leone ethics committee for any further tests. Participants will be given the option of choosing not to have samples stored.

5 Study team

5.1 Save the Children

Sembia Johnson, Community Health Manager, Save the Children Kerry Town

Francesco Checchi, Senior Humanitarian Health Lead, Save the Children and Honorary Senior Lecturer, LSHTM

5.2 London School of Hygiene and Tropical Medicine

Judith Glynn, Professor of Infectious Disease Epidemiology (lead)

Hilary Bower, Epidemiologist, formerly medical coordinator, MSF

Shefali Oza, Epidemiologist, research and health information adviser for Kerry Town ETC

Jennifer Palmer, Anthropologist, Research Fellow in Humanitarian Crises

Sujit Rathod, Research Fellow in Epidemiology

5.3 Collaborators

Foday Sahr, 34 Military, Freetown, Sierra Leone

Janet Scott, Clinical Lecturer, University of Liverpool

Calum Semple, Clinical Senior Lecturer, University of Liverpool

Richard Tedder, Public Health England

Michaela Hubmann, Anthropologist, Edinburgh University

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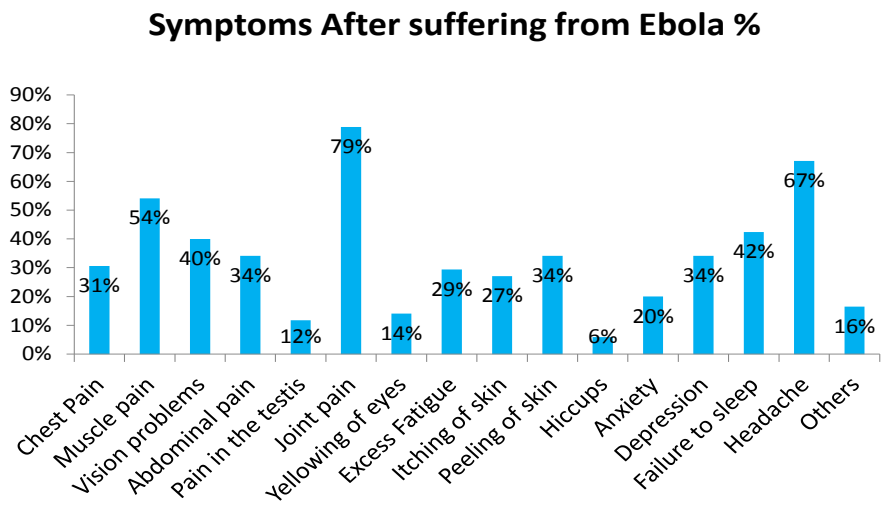
7 Appendices

7.1 Appendix 1: Previous research on physical and mental sequelae

We searched PubMed for reports on Ebola and "survivors" or "sequelae", and read descriptions of previous outbreaks that characterised clinical symptoms in case there were descriptions of longer term outcomes. We also searched Google for Ebola and survivors or post-ebola syndrome.

Reference	Year of outbreak	Outbreak	Strain	Sample size	Maximum follow-up	Findings
WHO 1977[17]	1976	Yambuku, Zaire (DRC)	Zaire	?	? 2 months	"In at least two survivors psychotic behaviour was observed up to two months after recovery from the disease. They both showed character changes with confusion, anxiety, restlessness and aggressive behaviour."
WHO 1978[18]	1976	Sudan	Sudan	?	? 2 months	"Many complained of pain and weakness for 6-8 weeks after discharge" "Sometimes ... bizarre behaviour continued for several weeks after recovery"
Bwaka[1]	1995	Kikwit, DRC	Zaire	19	2 weeks – 2 months	"Most of them presented with a number of late complications" Arthralgia 7, Ocular disease 3 , Suppurative parotitis 1, unilateral orchitis 1, hearing loss or tinnitus 2, suspected pericarditis 1.
Rowe[4]	1995	Kikwit, DRC	Zaire	29	Within 6 months	Seen several times. Results reported by number of interviews, not per person: Arthralgia(48%), Myalgia (24%), abdominal pain (12%) extreme fatigue (8%), anorexia (7%) – all more than in household contacts Fever, headache, diarrhoea, dysphagia, hiccups, haemorrhage no more frequent in survivors than in contacts. "Physical examination of involved joints did not reveal redness, swelling, or reduced range of motion or passive movement" Audiometry: 11/28 some defecit (control data not given)
Rowe[4]	1995	Kikwit, DRC	Zaire	20	21 months	General health worse than before outbreak (70%) vs 18% contacts Ability to work worse (70%) vs 7% contacts Myalgia at least once/week (excluding those with myalgias before outbreak): 9/19 survivors vs 1/27 contacts Myalgia major health problem (excluding those with myalgias before outbreak): 5/19 survivors vs 0/27 contacts Arthralgia at least once/week (excluding those with arthralgias before outbreak): 8/13 survivors vs 1/26 contacts Arthralgia major health problem (excluding those with arthralgias before outbreak): 9/14 survivors vs 0/26 contacts Audiometry: 7/8 some defecit but only 4 self-reported hearing loss. Control data not given but not significantly different after adjusting for age and sex
Kibadi[2]	1995	Kikwit, DRC	Zaire	20	3 months	3/20 uveitis (same patients as in Bwaka paper) + 1 extra non-cohort survivor. Uveitis diagnosed 7-12 weeks after onset of Ebola. Responded to topical atropine and steroids.
De Roo[19]	1995	Kikwit, DRC	Zaire	34	< 2 months	12 felt rejected by society; 11 saw the disease as divine punishment; 9 reported no psychological

						consequences (except grief for bereavements); "all felt their experience strengthened their belief in God"
Okware[20]	2000/1	Gulu, Uganda	Sudan	257?	?	"Convalescence among survivors was slow and took several weeks. It was associated with several residual problems such as weight loss, dehydration, difficulty in hearing, mental disturbances and general weakness."
Wendo[5]	2000/1	Gulu, Uganda	Sudan	257	12 months	News report only. No proper numbers, no comparison group. 60 of 257 patients still attended follow-up clinic. "complications include abdominal pains, loss of vision, loss of hearing, impotence, bleeding, psychological problems, and general weakness" " Most of the survivors have become poorer because they can no longer work as much as before they became ill. Some are unable to perform simple exercises such as riding a bicycle"
Ocowun	2000/1	Gulu, Uganda	Sudan	?	7 years	Anecdotal news report of survivors with symptoms http://www.newvision.co.ug/D/9/183/602136 "Many are still suffering from headaches, general body pains, general weakness, poor vision and reduced sexual abilities". No comparison group
Lee-Kwan[3]	2014	Sierra Leone	Zaire	~100	?< 2 months	Assessment of survivor needs done in October 2014: 10 focus groups (87 people), 12 in-depth interviews, and six direct observation field notes were reviewed and coded to identify emerging themes "most common symptoms reported were blurred or partial loss of vision, dizziness, headache, sleeplessness, and myalgia" "Survivors also raised concerns regarding psychosocial issues (e.g., stigma and shame that prevents reintegration into their community, as well as survivor guilt) and financial burden" "Many reported being shunned by the community"
Arwady[21]	2014	Liberia	Zaire	22	< 3 months	Follow-up of intensive reintegration programme. "No major reintegration problems have occurred to date" "All who were employed have returned to work, all orphans continue to live with their designated guardians" "There have been no housing issues, attacks on survivors, or other episodes of community unrest."
WHO	2014	Kenema, Sierra Leone	Zaire	85	? < 3 months	WHO news item: http://www.who.int/tdr/news/2014/ebola-survival-return/en/ "WHO is supporting the establishment of a dedicated Ebola Survivors Clinic. All Ebola survivors in the Kenema District were invited to Kenema Government Hospital for interviews with healthcare workers." "Many of the survivors are discharged with the so-called Post-Ebola Syndrome" WHO news item http://www.who.int/features/2014/post-ebola-syndrome/en/ We are seeing a lot of people with vision problems," says Dr Margaret Nanyonga, psychosocial support officer for the World Health Organization in Kenema. "Some complain of clouded vision, but for others the visual loss is progressive. I have seen 2 people who are now blind." From Andy Ramsay and Maggie Nanyonga: interviews with 85 survivors:

						 Others include: palpitations(7), Mental confusion(2), Erectile dysfunction(1), Deafness(1), Amenorrhea(1), Neurological(1), Deafness(1), Numbness(1), Amenorrhoe(1) Also considerable stigma. Symptoms were reported within 3 months of Ebola. Symptoms have improved over time, with treatment.
MSF Switzerland	2015	Freetown, Sierra Leone	Zaire	72	?<2 months	[personal communication] 27 referred to eye clinic. Of 21 seen: 7 uveitis, 2 iritis, 3 allergy, 3 cataract, 3 no abnormality found, 3 corneal abrasions In another series 88/156 referred to eye clinic: 40/55 seen so far had uveitis.

7.2 Appendix 2: Information sheet and consent form (to be translated)

Sub-clinical infection and long-term sequelae among Ebola Virus Disease survivors, their households and neighbours in Sierra Leone

PARTICIPANT INFORMATION SHEET

My name is XX and am I working with Save the Children in Kerry Town. We are carrying out a study to understand how Ebola was transmitted in this community, and how survivors and their families have been affected by it.

You/your child(ren) are being invited to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve. I will read information to you about this study. Please ask me if there is anything that is not clear or if you would like more information.

WHAT ARE WE TRYING TO LEARN WITH THIS RESEARCH STUDY?

Many of the people who survived Ebola have continued to have symptoms and other problems. We would like to understand what problems Ebola survivors and their families are experiencing so we know how best to help them.

Also, although Ebola Virus Disease can be very severe, some people may get only very mild or no symptoms. How often this occurs is not known, but is very important for understanding how the disease spreads and therefore how to control it. By testing small samples of saliva we can see if infections are occurring without symptoms. We hope that the findings from this study will help improve our understanding of Ebola transmission.

WHY ARE WE ASKING YOU TO PARTICIPATE?

[*for survivors*] We are asking everyone who was treated at the Kerry Town ETC to take part in the study.

Or

[*for household members]* We are asking everyone who is a household member of an Ebola survivor from the Kerry Town ETC to take part in the study.

Or

[*for neighbourhood controls*] We are asking you/your child because we want to look at a group of people who did not have Ebola to compare with Ebola survivors. We chose all the houses in this neighbourhood because it is an area which has had relatively little Ebola.

WHAT HAPPENS IF I DON'T WANT TO PARTICIPATE IN THE STUDY?

You are free to refuse to participate in this study, or to withdraw your participation at any time. Refusal to participate or withdrawal will not affect you/your child in any way.

WHAT WILL MY PARTICIPATION IN THIS STUDY INVOLVE?

for survivors and household members]

If you choose to participate in this study, we will ask you for up to about two hours of your time. We will also ask you if you are happy for us to see you again for more in depth questions about how Ebola has affected you and your household.

[If you choose to participate in this study, we will ask about who lives in this household and you/your child will be asked a few questions. Then we will ask you about what happened in the household when Ebola came, and about contact with anyone with Ebola.

We will also help you/your child to take a sample of saliva for testing for antibodies to Ebola.

All of the samples will be analysed in Sierra Leone. It may take some time to get the results and we will not be able to make them available to you.

Or

[*for community controls*] If you choose to participate in this study, you/your child will be asked to complete a short questionnaire. We will also ask about contact with anyone with Ebola.

We will then help you/your child to take a sample of saliva for testing for antibodies to Ebola.

All of the samples will be analysed in Sierra Leone. It may take some time to get the results and we will not be able to make them available to you.

[for survivors only]

We would also like permission to access your/your child's medical records from when you/your child had Ebola and from the survivor's clinic so that we can see how the antibodies we measure are related to the illness.

IF I/MY CHILD AM FOUND TO HAVE ANTIBODIES TO EBOLA WHAT DOES IT MEAN?

If your sample is positive, it is possible that you have had an Ebola infection but it may be a false positive result (the tests are not 100% accurate). It does not mean that you have Ebola virus disease. It does not mean that you are infectious. Importantly, a positive test does not mean that you are immune (protected) – you may still be able to get Ebola, so there is no benefit in knowing the result..

WHAT HAPPENS TO THE BLOOD AND SALIVA SAMPLES?

We would like to store your/your child's saliva samples for possible later testing, for example if more accurate tests become available. You can choose if you want us not to store your samples, and you can also tell us at any time in the future to have your stored samples destroyed. If we want to do further tests on the stored samples we will ask for permission first, from the Sierra Leone ethics committee.

ARE THERE ANY RISKS INVOLVED WITH PARTICIPATING IN THIS STUDY?

There are no direct risks from participating. Some of the questions we will be asking may remind you of very painful events, such as when you were sick or when you lost family members. If these questions are too difficult for you to answer, you are free to stop the interview at any time or leave the study completely.

ARE THERE ANY BENEFITS INVOLVED WITH PARTICIPATING IN THIS STUDY?

The team will be able to provide psychosocial counselling if required

WILL I BE ALLOWED TO WITHDRAW FROM THE STUDY IF I CHANGE MY MIND?

Taking part in this study is voluntary. Should you wish to withdraw from the study at any point or not to answer any of the questions you are free to do so. You can also choose to answer the questions but not to give a saliva sample. It will not affect you in any way.

WHO WILL SEE THE INFORMATION THAT IS COLLECTED?

Personal identifiers will be removed from the questionnaire before analysis, and all data will be stored in a way that only authorised people can access it. Your personal information will not be revealed in any published information.

WHO TO CONTACT IF YOU WANT MORE INFORMATION, OR IF YOU HAVE A PROBLEM?

If you want more information before deciding to take part, or have questions at any time, please contact Ms Sembia Johnson, Save the Children, tel. 078375722, email sembia.johnson@savethechildren.org. If you have any further concerns, you can also contact the Sierra Leone Ethics and Scientific Review Committee, PCMH, Forah Bay Road, Freetown, who know of this study.

CONSENT FORM

I understand that if I agree to participate in this study, the following will happen:

- I will indicate my agreement at the end of this form
- I will be asked questions about my/my child's background and health, and exposure to Ebola
- *[survivors only]* I understand that the research team will access the medical records from when I/my child had Ebola and from the survivor's clinic
- I/ my child will be asked to provide a saliva sample that will be tested for antibodies to Ebola
- I understand that I can refuse to participate in the study or in parts of the study without giving any reason
- I understand that I/my child can take part in the study but choose not to have my/my child's saliva samples stored
- I will not receive any payment for my/my child's participation in this study

Confirmation

- I confirm that I have understood the information for this study. I have had all my questions answered to my satisfaction, and I voluntarily agree to participate/for my child to participate in this study.
- I understand that the lead researcher or any researcher as part of this study, will not identify me/my child by name in any manner, and in any reports using information obtained from this interview, and that my/my child's confidentiality as a participant in this study will remain secure
- I understand that I can leave the study at any time
- I give permission for my/my child's saliva to be collected: YES NO (circle one)
- I give permission for my saliva to be stored for further tests: YES NO (circle one)
- [*Survivors only*] I give permission for researchers to contact me again for more in depth questions: YES NO (circle one)

Print name: _____

Child's name (if on behalf of child): _____

Signature or thumb print: _____

Date _____

Signature of child for assent (age 12+): _____

Name of person taking consent: _____

Signature of person taking consent: _____ Date _____