

## About this report

This report is adapted from reports prepared for study participants and other stakeholders, and distributed at stakeholder meetings held in the Winter and Spring of 2018, where they served as a point of departure for discussions.

Focused on the moral experiences of study participants, this report represents only one part of the broader study's findings.

For more information, please contact one of the authors or a member of the research team.

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## What is the purpose of this report?

In 2016, we launched the "Perceptions and moral experiences of research conducted during the West Africa Ebola outbreak" study (the "Perceptions" Study). This study seeks to better understand practical and ethical experiences of research conducted during this public health crisis. To this end, we conducted **108 individual** interviews in Guinea, Liberia and Sierra Leone with 3 categories of people: (1) participants in clinical trials and other studies conducted between 2014-6; (2) researchers, and; (3) key research decision-makers (e.g.: government representatives, scientific committee members; survivors' association representatives).

This report describes what we learnt from category (1), people who participated and sometimes refused participation in research during the Ebola epidemic, and answers the following questions:

- How did people who participated in research conducted during the crisis experience their participation?
- What can we learn from these experiences?

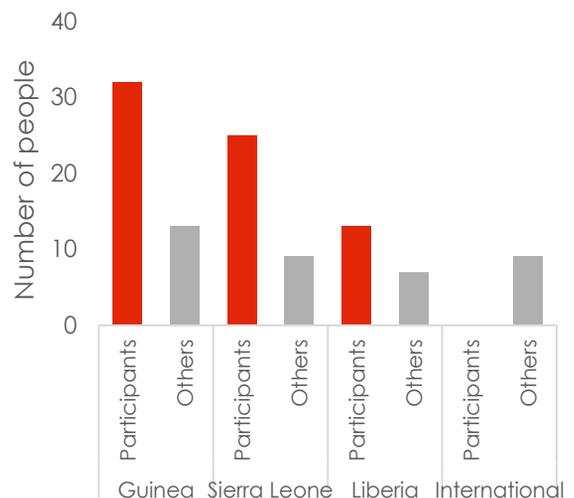
## Who did we consult?

Of the **108** people we interviewed, **70** had participated in clinical trials or other studies (the "participants").

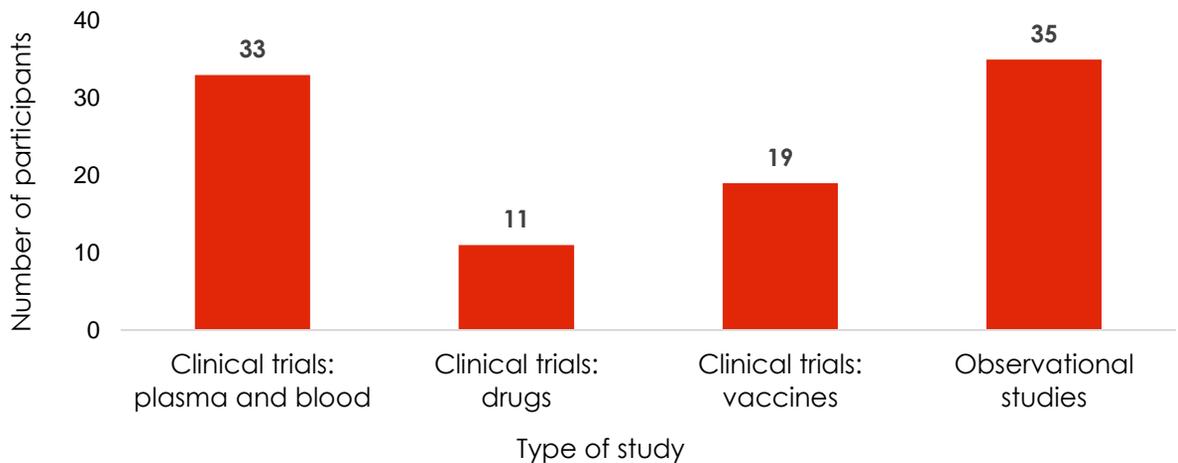
These 70 "participants" formed a very diverse group:

- 32 Guineans; 25 Sierra Leoneans; 13 Liberians
- Ages: 20 to 55 years old
- 32 (46%) women; 38 (54%) men
- 26 (37%) limited literacy
- 16 (26%) healthcare providers

### People interviewed for this project:



## Types of studies the 70 participants were involved in:



## How did people decide whether or not to participate in research?

Different people approached and lived the invitation to participate in research in different ways. Some participants describe having to make a decision about participating as an additional hardship in the midst of the already highly distressing Ebola crisis. In contrast, others understood the benefits of participation in such a way that they described feeling they did not really have a choice: participation represented their only change at survival.

We asked people to describe how they arrived at their decision about whether or not to participate in a study. Below, we present a summary of what they shared with us.

### Were people afraid of participating?

The participants described their worries about the studies for which their participation was solicited. The most commonly raised concerns were:

- Many people were afraid of the stigma they might face if members of their community learned that they had participated in a study,

or that they were Ebola survivors.

- Many people were afraid of the negative effects that experimental drugs or vaccines might have. Some worried that these treatments might kill them, or might cause sterility, blindness, or other health problems.
- Many people were concerned that research teams or staff at Ebola Treatment Centers (ETCs) could not be trusted.

### With whom did participants want to share their decision?

#### And were they free to do so?

Many people wanted to seek advice from loved ones before making their decision, or wanted to share their decision with loved ones. Some were unable to do so:

- Many people lost the loved ones with whom they would have wanted to talk about their decision to the ravages of the disease.

- Several participants found that the isolation measures imposed in the ETCs made it difficult for them to communicate with relatives. Some reported that healthcare providers or researchers discouraged them from contacting their loved ones.
- Some participants did not consult outside the ETC to keep their Ebola-positive status secret, fearing the stigma and discrimination they might face if their status became known to those around them.

Some people preferred to make their choice completely independently. Others entrusted the decision to spouses or family members. Many felt that the support and guidance they received from family was a source of strength and comfort. Many arrived at their own decision, but nonetheless felt that it was important to inform their loved ones of their choice, and to help them understand it.

## Who and what did participants consider when making their decision?

Participants were guided by a wide variety of motivations and concerns. They shared the following motivations with us.

Most commonly cited motivations:

### **Wanting to survive and regain health**

The vast majority of participants who joined studies hoped to gain access to interventions that would help them protect or restore their health.

### **Wanting to help others survive and regain health**

The vast majority of survivors who donated plasma wanted to save the lives of people affected by Ebola. Having

themselves suffered because of the disease, they felt a deep solidarity with people who were ill in the ETCs.

Additional motivations:

### **Wanting to find a cure or vaccine**

Some people who participated in studies wanted to help researchers evaluate the effectiveness of new treatments or vaccines, or better understand how the virus affects survivors' health.

### **Wanting to lead by example**

Some participants wanted to encourage relatives or friends to participate in a study (for instance, by getting vaccinated or by accepting a plasma transfusion). These people felt that by receiving a treatment and being unharmed, or getting better, they could convince others to do the same thing.

### **Trusting in God or destiny**

Some participants described putting themselves in God's hands. They had faith that it was their destiny to join a study, and that no matter what happened, God would be with them.

**It is clear that many participants were motivated by the desire to help others.**

Participants described the various individuals and groups whose interests they wanted to serve. These include:

- Their family members
- Members of their immediate community
- Other people suffering from Ebola and other Ebola survivors
- Their country and their fellow citizens
- Humanity in general

## How did people find and evaluate information about research studies?

We asked participants to tell us about the ways they obtained and evaluated the information they needed to make an informed decision. Here is a summary of what we learned:

### Not easy: contradictory information

Participants had to make sense of conflicting information from different sources. Upon being admitted into ETCs, people were often faced with two contradictory interpretations of the situation: one from members of their families or communities who said that the treatments given in the ETCs were dangerous; the other, from healthcare providers in the ETC, who said that the treatments they offered were the person's best hope for survival.

### Trust in certain groups

When trying to determine which sources were reliable, different participants put their trust in specific groups:

#### Healthcare providers and the health care system

Many people trusted healthcare providers. For these people, it was reasonable to believe what they were told by staff in ETCs or in survivor clinics.

In contrast, others were skeptical of healthcare providers and the healthcare system in general. These people doubted what they were told in the ETCs, and turned to other sources to evaluate the information that was given to them.

### Survivors' Associations

Survivors' associations played an important role in participant recruitment. Several participants told us that they decided to listen to what researchers had to say because these were working with the association or had successfully addressed the questions raised by association representatives. For some, only projects that were endorsed by the association were trustworthy.

Some participants were disappointed by survivors' association representatives who pushed them to participate in projects without giving them enough information to understand what was happening, and without following up. These incidents broke the trust they had placed in the associations.

### Personal and community ties

Some participants found it easier to trust people with whom they shared community or family connections. For example, one participant who was mistrustful of staff in the ETC recalls feeling reassured after a nurse came to tell him that she was from his family's village, and to encourage him to join a study.

### How else did participants determine what was true?

- Some participants turned to the media (internet, radio, television...) to seek additional information.

- When they did not know who to trust, many participants looked at what the recruiters were doing (e.g., had the recruiters themselves gotten the vaccine?).
- Many participants were interested in the experiences of people who had lived through the disease or had participated in studies. They wanted to observe what happened to others in order to better understand what might happen to them.

## A note on information shared by researchers

Several research teams organized information sessions where they presented visual and written materials, and helped participants understand the study before seeking their participation. Survivors/participants did not emphasize these information sessions as key in their decision-making.

## How did participants experience their participation in the research project?

We asked the participants to tell us about the experiences they had during their participation. What did they like? What did they find difficult or unpleasant? What did they think of the research practices they had witnessed?

Participants' experiences, and participants' feelings about these experiences, varied.

### What did the participants appreciate?

Participants liked several aspects of their interactions with research teams. The treatment and medical care to which their participation entitled them were particularly appreciated.

#### Free medical care

Several people appreciated the free medications and specialized care provided to them as participants.

#### Quality of care

Several participants emphasized the quality of care they received. Given the stigma and other challenges faced by survivors, some participants particularly appreciated the respect with which they were treated and the provision of psychosocial care.

#### Screening tests

Having access to tests screening for Ebola or other diseases, like HIV, made it possible for some participants to better protect their own health and the health of their loved ones.

#### Communication with the research team

Some participants appreciated the way the researchers communicated with them, and the time they took to fully explain their studies. Some participants felt reassured that researchers were upfront about potential risks and side effects, instead of focusing only on benefits.

## What did the participants find difficult, unpleasant, or unacceptable?

Participants experienced various kinds of difficulties.

### **Re-living painful memories**

Some participants found it difficult to participate in studies because doing so reminded them of painful or difficult experiences. For example, some survivors did not want to see any more blood or syringes. Others could not bear to hear about Ebola anymore.

### **Stigmatization**

Some participants faced stigma after members of their community learned that they had participated in studies. This problem affected vaccine trial participants, as well as Ebola survivors.

### **Lack of communication between research team and participants**

Some participants felt that they were not given the information they needed to make an informed decision. For example, some were not told about the side effects of the treatments they were going to receive. In the worst cases, participants did not understand the purpose of the research they were asked to participate in or the risks involved in participating.

### **Side effects**

Several participants suffered from side effects after receiving experimental interventions. Some participants lost trust in researchers after experiencing painful or unexpected effects that researchers had not

warned them of and were not willing to explain.

### **Painful or uncomfortable procedures**

To participate in certain research projects, participants sometimes had to undergo painful or uncomfortable procedures. For example, producing tears or giving blood.

### **Feeling at risk**

Some participants encountered situations that made them fear for their own or their loved ones' safety. These people were alarmed by the poor quality of the care provided by the research team, or by the state of the equipment being used.

### **Lack of confidentiality**

Several participants wanted their confidentiality to be maintained. A minority said that they refused to participate in studies because recruitment was done during meetings or in public places. Some also felt weary of the ways researchers followed up. For example, some participants worried about researcher home visits that could reveal their Ebola survivor or participant status to members of their community.

Some participants felt that their trust was betrayed by researchers because of what happened after their participation:

### **Lack of follow up**

Several people who received tests screening for diseases (like HIV or hepatitis) were never informed of their results. Similarly, some research teams did not hold restitution of findings sessions. As a result, some participants were never informed of the conclusions to which they contributed.

Because of this lack of follow-up, participants were often unable to get any answers to the questions that arose after their participation was over. Due to this, many people now live with uncertainty and fear about the long-term effects of the procedures they have undergone.

### **Compensation not delivered**

Some participants report not receiving the compensation or other benefits they were promised. Such situations appear to have arisen when organizations connecting participants to research teams failed to perform their obligations.

## **Were participants able to give informed consent?**

*Free and informed consent is a requirement in research ethics. Consent is free when participants are free to participate or to not participate in a study. Consent is informed when participants are told about and understand the risks, benefits, and procedures that come with participation.*

We wanted to understand if informed consent is possible under the difficult conditions presented by the Ebola outbreak.

To explore this question, we asked participants to tell us about how they were invited to participate in a study, and about the process through which they gave their consent.

### **Did the participants understand the nature of what was asked of them?**

*In order to give informed consent, participants must understand certain things about the study they are asked to join.*

The following things were not always clearly explained to potential participants:

#### **Freedom to refuse**

A person always has the right to refuse to

participate in a study. Some participants were explicitly told that they were free to refuse, others were not.

### **Distinction between research and health care**

Because recruitment was done by healthcare providers, in hospital settings (ETCs), some participants did not understand the distinction between the healthcare they were offered and the studies they were invited to join.

### **Uncertain efficacy of experimental treatments**

When the epidemic started, no one knew what drugs or vaccines would work. Researchers and health care providers who organized clinical trials hoped that the interventions they evaluated would be effective, but could not be sure that this would be the case.

Many people were told or thought that the drugs or plasma they were offered would heal them. Many others were told that the vaccines they were offered would protect them against Ebola – which was not known at the time. Some were even told that

vaccines would protect them against other diseases, such as malaria - which is not true.

However, some participants did receive accurate information, and were warned that the treatments they were offered might not work.

### **Potential risks**

Any medical procedure poses certain risks. Researchers did not always inform participants about potential risks and side effects. As a result, some participants felt surprised and alarmed by the side effects they experienced.

## **Other aspects that impacted informed consent**

### **Illness and stress**

*To give informed consent, a potential participant must be able to evaluate what is being asked of them. The disease and the stressful context of the epidemic made this difficult.*

In the ETCs, some people were too sick to understand what was going on around them, and were not in a position to make a decision. Some participants were unable to remember the explanations given to them in the ETC or the studies they had joined.

### **Recruitment by healthcare staff and survivors' associations**

*To be able to give free consent, participants must have the choice to participate or not. Saying no is sometimes difficult for participants who have a relationship with, or who are dependent on, the persons recruiting them.*

Ebola treatment center staff (medical or psychosocial) were responsible for explaining the studies to potential participants and for soliciting their participation. Survivors and people affected by Ebola knew these recruiters, and often felt grateful towards them for the care they had provided or were providing. Some patients and survivors felt obligated to follow recommendations made by the staff who were taking care of them, or who had taken care of them in the past.

Survivors' associations played a big role in recruitment. Sometimes these associations invited members of their community to meetings where research teams presented their projects. Sometimes survivors' association representatives directly solicited the participation of their members. Some participants told us that they felt obligated to participate because of their relationship with members of survivors associations who recruited them.

### **Limited choices**

*To give free consent, participants must have the choice to participate or not. During the epidemic, many people participated in studies in order to gain access to benefits that would otherwise have been inaccessible. For these people, there was no real choice because there were no alternatives.*

For patients or people at risk, the only way to access potentially effective treatments or vaccines was to participate in a study.

Some studies also offered medical benefits to their participants (access to care or testing). For many survivors, the only way to access this kind care was to participate in a study.

## A note on consent forms

*In European and North American countries, the norm is to use a consent forms to document a participant's voluntary decision to join a study. During the Ebola outbreak, the use of consent forms was not universal. In some cases, the forms were only signed after the fact.*

Participants seem to have appreciated consent forms when these documents were used. This allowed them to confirm their participation, and reassured them that it would be possible for them to contact the researchers, even if the majority did not ultimately go on to do so.

## Acknowledgements

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The **Humanitarian Health Ethics** (HHE) research group is a multidisciplinary team of researchers and practitioners collaborating together since 2009 with the aim of helping to clarify the ethical issues that are present in humanitarian healthcare practice. Our research benefits humanitarian and military healthcare practitioners, organizational policy makers, aid agencies and recipients of aid.

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