TRAINING MANUAL ON COMMUNITY ENGAGEMENT METHODS FOR CLINICAL TRIALS

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SUMMARY

Amidst the dynamic changes taking place in the field of research and response to outbreaks there are gaps in our understanding of community engagement within outbreak efforts, and specifically within biomedical research responding to outbreaks. Community engagement and patient and public involvement (PPI) are now recognized as essential in the design, implementation, and dissemination of clinical trials. This is crucial not only for upholding research ethics but also for enhancing the quality, relevance, and uptake of research outcomes. However there is limited evidence on the mechanisms through which community engagement is expected to work, and the outcomes it is expected to generate. The work of social science and community engagement within the PREVAC Ebola vaccine trial have provided us with unique learnings on approaches that can be mobilized to involve communities in the search for a vaccine against Ebola and other diseases.

The PREVAC-UP Ebola vaccine trial conducted in Sierra Leone, Liberia, Mali and Guinea included a large community engagement programme informed iteratively by the work of a social science team since 2015. In 2022 we held regular meetings, and undertook document reviews, between the social science and community engagement teams in Guinea and Sierra Leone sites in order to develop a training manual that included i. a realist informed Theory of Change (ToC) for the community engagement in each site ii. collated training materials. These were initially developed separately, based on longstanding work in each site, and then integrated in order to describe commonalities.

The Theory of Change helped us illustrate how the PREVAC-UP community engagement intervention was organised and expected to work including it's relationship with social science research. We identified four critical elements: i. identifying powerful (and marginalised) actors for collaboration and establishing community champions ii. social science and community engagement feedback loops iii. dialogue around trial protocols iv. bringing the team and intervention close to people. Our Theory of Change links the local and programmatic contexts to the postulated mechanisms of change including: addressing concerns in a post-outbreak setting, adopting behaviours if they are promoted by trusted

leaders and peers, feedback opportunities/dialogue and demonstrating reciprocity, and de-medicalising the relationship with trial participants. These mechanisms of change operated in a post-outbreak context of distrust to influence expected outcomes of the intervention: recruiting community members to take the vaccine, retention of participants in the trial, some adaptation of trial processes to local contexts and feedback, ethical research conduct and participatory conduct of clinical research processes.

This manual provides guidance on how to implement community engagement activities within a vaccine trial and outbreak research including how these activities work, for whom and under what circumstances. This can equip future trialists with community engagement approaches as well as help shed light on the different context in which these approaches may be effective.

BACKGROUND

The needs of research participants

Community engagement and patient and public involvement (PPI) in the design, conduct and dissemination of clinical trials is now understood as essential. Both in terms of research ethics *and* positive impact on quality, uptake, and relevance of research. The later can contribute to an outbreak response, with recent evidence also revealing improved enrolment of trial participants (Boivin et al., 2018; Crocker et al., 2018). There are specific challenges of conducting clinical trials during an outbreak including those related to trial design, community engagement during an outbreak, the regulatory environment around such trials and operational constraints (Mooney et al., 2018). Given these challenges there is a risk that the concerns and realities of potential trial participants and communities are neglected, rather than placed at the centre of such research.

Since the COVID-19 pandemic, and the 2013-2016 Ebola outbreak in West Africa, there has been a shift in global norms and practices around the role of social science and community involvement in outbreak response and research. The absence of respectful engagement with communities during the West African Ebola outbreak has been extensively critiqued. Numerous ethical and other questions were also raised by the pressing need to roll out experimental products during the recent outbreaks (Ebola in West Africa, COVID-19 globally) in the absence of approved treatments and vaccines.

In the aftermath of the outbreak consensus developed that community needs and perspectives must be central to future response and research efforts and that local realities demand a different though complementary set of research skills than the biomedical tools traditionally harnessed for outbreak response. Governance modalities of health crises had previously reduced populations to the simple category of beneficiaries of intervention, however multiple and complex forms of citizen engagement have been observed in the various countries where the Ebola response has been deployed. This meant that social scientists were given a ‘place at the table’ and since this period there has been an unprecedented demand for social science contributions to Ebola preparedness, response and recovery including research (Graham et al., 2018; Moon et al., 2015). Greater integration of community engagement across outbreak response efforts including clinical trials has been reflected by WHO architecture such as the 2016 GPP-EP guidelines (WHO, 2016). These outline the foundational principles underpinning partnerships among trial stakeholders in situations of crisis: respect, fairness,

integrity, transparency, accountability, and autonomy (Hankins, 2016). 'Risk communication and community engagement' has also been established as an outbreak response pillar.

The social history of Ebola and community engagement

The PREVAC trial was developed in response to the 2013-2016 Ebola epidemic in West Africa, forming part of ongoing efforts to combat the largest Ebola outbreak to date. This epidemic generated widespread rumours and controversial narratives about its origins and prompted community reactions often perceived as resistance to public health interventions led by the State and its partners. These have even taken violent forms, the most obvious of which has been observed in Wome, a village in Guinea Forestière where eight members of a social mobilization team were murdered. The lessons learned from this experience, which were also leveraged for the implementation of PREVAC, highlight that community reactions, often labelled as reluctance, can instead be understood as resistance to epidemic management methods perceived as poorly adapted to the context. This stance also critiques the governance approach, with populations expressing a desire to move beyond being passive beneficiaries of interventions, seeking instead to play an active role in public action processes.

Collaboration between social science and community engagement: experience from past clinical trials

There is a growing body of experience from clinical and vaccine trials that show how social science can inform community engagement and PPI efforts, as well as other broader aspects of clinical trials conducted during outbreaks and crises. Work during recent Ebola outbreaks has provided understanding of how interdisciplinary community liaison and social science teams can work within a clinical trial. This research has highlighted the importance of using social science to inform trial set up, procedures and ethics, support community engagement to track and address rumours and concerns around the trial, and to engage with motivations for participating in a trial for an experimental product (Dada et al., 2019; Enria et al., 2016; Mooney et al., 2018). These reflections highlight the importance of understanding rumours through a contextual lens (for example as commentary on broader social and political dynamics), and identifying community dynamics, rather than treating them as homogenous. They can also help with recognising who has authority and influence in different communities, and can help to identify pathways for meaningful community engagement. For example, trust has been built in communities around trials when local leaders are engaged, involved in communicating the purpose of research, and when they decide to take part in trials themselves (Dada et al., 2019). Above all, engagement needs to be understood as an iterative exercise; publics are not static and are often brought together through the very process of research. It is critical to attend to the ways in which practices of inclusion and exclusion can be played out and amplified through the research process (Montgomery and Pool, 2017).

Gaps in methodological and implementation evidence

There is a growing body of experience from clinical and vaccine trials on how social science can inform community engagement and PPI efforts, as well as other broader aspects of clinical trials conducted during outbreaks and crises. However, despite the rapid evolution in the field of research and response to outbreaks there remains very little consensus on the goals of community engagement within outbreak efforts, and specifically the goals of these efforts within biomedical research. These goals are often seen as inherent, or necessary for ethical research, however community engagement can also have an instrumental purpose. Overall, there is limited evidence on community engagement activities, the mechanisms through which they are expected to work, and the outcomes they are expected to generate.

The PREVAC community engagement and social science intervention

PREVAC is a multi-site safety and immunogenicity study of three Ebola vaccine strategies taking place in Sierra Leone, Liberia, Mali and Guinea. PREVAC is a continuation of the response to the Ebola outbreak which between December 2013 and June 2016 was responsible for over 11,000 deaths in West Africa, particularly in Guinea, Sierra Leone and Liberia. The PREVAC initiative responds to the shortcomings of the available Ebola control devices and technologies.

PREVAC is built on the principle of partnership at several scales: between research institutions, pharmaceutical companies, national health authorities but also communities (the focus of this manual). During the same time period was a related vaccine trial, EBOVAC, in which similar community engagement and social science activities were implemented.
Developing and conducting a clinical trial in a post-epidemic context marked by socio-political tensions and a general crisis of confidence has raised many questions on the ways in which communities can be involved in the response to public health interventions. Conducting community engagement and social science in this context has provided us with unique learnings on the added value of community engagement to involve communities in the search for a vaccine against Ebola virus disease. Governance modalities of health crises had previously reduced populations to the simple category of beneficiaries of intervention, however multiple and complex forms of citizen engagement have been observed in the countries affected by the 2014-2016 Ebola outbreak.
The extensive community engagement work carried out alongside the PREVAC trial in each site has been used to improve trial participant recruitment, lost to follow up, retention, as well as link to the social science work to understand acceptability, uptake and social impact of the trial.
Social science has conducted long term in situ ethnography and interviews with trial participants and community members to understand participant experiences of the vaccine trials, vaccine deployment and the long-term impact of the Ebola epidemic.

Outcomes of PREVAC community engagement and social science intervention

Although this manual does not aim to illustrate causality between the community engagement methods and certain outcomes, many of the original (instrumental) goals of the community engagement intervention such as recruiting participants to take the vaccine, and retaining them in the trial have been achieved. Other (more inherent) goals are typically not measured. Between March 2017 and October 2018, a total of 2330 adult and minor participants over 1 year old in Guinea out of the 4789 participants included in the 4 countries. The trial had high retention rates with more than 96% of participants still retained after 12 months of follow-up, about 93% at 24 months, and 91% at 36 months and 88% at 48 months of follow-up.

COMMUNITY ENGAGEMENT METHODS USED IN PREVAC-UP

The process of developing our Theory of Change

In order to share lessons learnt from community engagement activities we wanted to document our methodological approaches to community engagement. Given there are a number of training

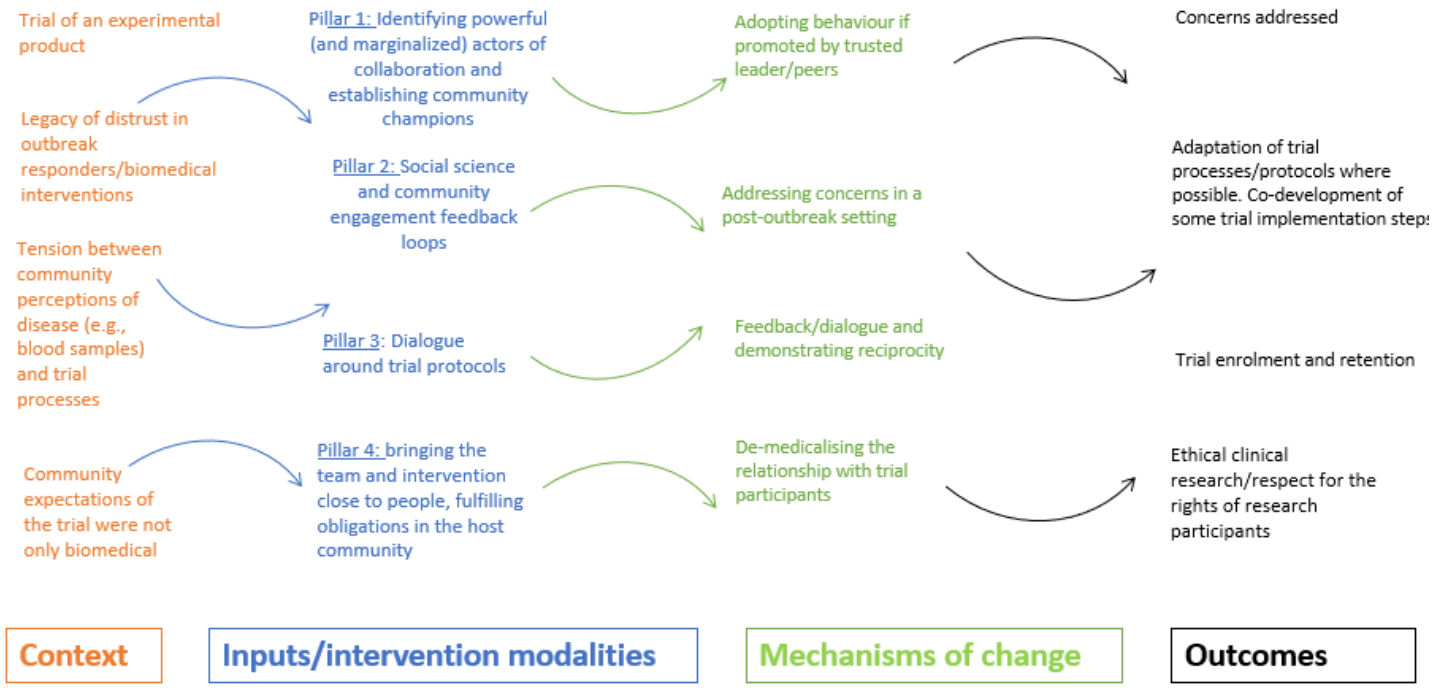
guidebooks on this topic (SMOUT et al., 2018) we proposed to focus specifically on the methodological aspects of PREVAC-UP community engagement. We developed a realist informed Theory of Change (Pawson and Tilley, 1997) which explains how our community engagement and social science methods worked, why they worked, in what circumstances and for whom. The goal was to tease out the methods and make explicit the mechanism and context through which these methods brought about change (i.e. uptake of the vaccine and incorporation of community perspectives by the trial) in each country.

In order to develop our theory of change we undertook the following activities:

- Regular meetings between African and European partners
- Document review of available program records

We drew upon and adapted the framework by Funnell, S. and Rogers, P. (2011). We outlined the ***context*** in which the community engagement activities took place, the four main pillars to the community engagement ***intervention***, the ***mechanisms*** through which these brought about change and the expected ***outcomes*** according to the teams. These are outlined below in figure 1.

Figure 1: *Realist informed theory of change for the community engagement and social science intervention within PREVAC-UP vaccine trial*



The following section details the four pillars of the community engagement intervention (outlined in blue in Figure 1).

Pillar 1: Mapping powerful (and marginalised) actors for collaboration and establishing community 'champions'

In both trial sites and in interconnected neighbourhoods/villages, local 'champions' (religious, customary, political leaders, etc.) were recruited for communication, social mobilization and

community engagement activities. Obtaining moral support from 'champions' allowed the follow-up of events (rumours, incidents, etc.) and their management, they were also given relevant information to answer people's questions about the study.

Across sites social science methods were used to identify trusted opinion leaders and 'champions': individuals who influenced opinion, gate-kept traditions and local knowledge, and influenced community actions. Once identified the community engagement team worked with trusted opinion leaders and traditional authorities to build confidence in the trial, vaccine and also fed back on the trial processes based on community perspectives.

Pillar 2: Social science and community engagement feedback loops: identifying and addressing concerns

The role of social science to support community engagement in outbreak responses and research is increasingly well understood. In our trial sites, a social science team acted as investigators for the effects of trials on individual lives, listening to individuals, community concerns and expectations about the study, through ethnographic and other qualitative methods. Teams deployed these methods to produce more contextualised recommendations for community engagement and the clinical teams to be able to tailor their operations in locally relevant ways (see figure 1).

In a context of mistrust and crisis these social science teams have been able to provide feedback to community liaison teams, for example, to directly address rumours that the experimental vaccine was infecting participants with Ebola. Similarly, prevalent fears around trial procedures such as blood taking, which have been identified in other kinds of clinical research for Ebola, were identified and formed the basis of community-led engagement strategies. The social science research also indicated a range of motivating factors behind participation in the early stages of the trial, including the notion of 'sacrifice' or duty as a citizen, and hope or belief in the power of the vaccine to prevent Ebola (e.g. Enria et al., 2016; Tengbeh et al., 2018). These insights can not only inform more nuanced messaging but can also enable clinicians to think about the framing of discussions around informed consent and to ensure that trial procedures are well understood.

Pillar 3: Dialogue around trial protocols: participant and community feedback on trial decisions

Community information sessions (often using a participatory format) focused on protocol elements such as the vaccines used in the vaccine study, vaccine strategies used, the principle of randomization, inclusion and exclusion criteria as well as the question of management and the different benefits related to participation in the vaccine study are shared with the communities.

The experience of mobilizing traditional forms of communication in the fight against the Ebola epidemic led to investing social communication as a tool for social promotion of the PREVAC trial. If traditional communication implies a verticality of the relationships between the transmitters and recipients of the information and with a unidirectional character, social communication is rather based on a bidirectional character with a horizontal form between the different categories in interaction.

Pillar 4: Bringing the team and intervention close to people: de-medicalising the relationship with trial participants, fulfilling obligations in the host community and choosing legitimate interlocuters

As part of the anthropological research for the preparation of the implementation of the vaccine study, the communities expressed expectations of the promoters, expectations that were not specifically biomedical. Therefore, the community engagement approach also involved some form of reciprocity in interactions between vaccine study sponsors and communities residing in the

intervention areas. Indeed, the experience of Ebola management has highlighted criticism around the attitudes and behaviors of health workers and actors involved in response activities and their effect on community responses to the system. Faced with this situation, it was important to recognize that the acceptability of the vaccine was not only related to its intrinsic qualities, it also depended on the bearers of the vaccine. Reducing the relationship between the technical device of the trial and the communities to a simple relationship between technicians and participants who volunteer for vaccine experimentation is a counterproductive form of achieving community engagement.

It was therefore important to de-medicalise these relationships through different processes. The first was the community based support, the second was to participate in the social life of participants (contribute to social events such as baptisms, weddings, funerals, etc.) and the third was embeddedness of staff. A major activity for the community engagement staff during trial implementation was the follow up of trial participants in their homes and communities towards their retention in the trial and the monitoring of adverse events. This often went beyond follow up for biomedical purposes and included staff participating in the social life of the community in order to demonstrate reciprocity and fulfil obligations in the host community given that acceptance of the vaccine also depended on acceptance of the trial team themselves.

Using both our social science and community engagement experience in the sites the following are recommendations for trials, especially in the context of outbreaks:

■Formative research - an initial phase of stakeholder outreach and engagement is needed to identify key stakeholders, understand accepted channels of communication, local power dynamics and how decisions are made in communities.

■Stakeholder engagement plans - a phase of discussions with the key stakeholders identified in the formative research should take place in order to discuss trial design (and where appropriate seek feedback), implementation planning, and setting out a place for community engagement activities that will vary across contexts and relevant communities of prospective participants. These discussions may need to occur at different levels (regional, national, local).

■Protocol development - deliberative engagement with communities should feed into protocol development and clinical trial design during epidemics. Methods are emerging for this work (for example those being developed under the AViD study and the ALERRT consortium) and these could be rapidly adapted for different contexts.

■Informed consent process - community groups and key stakeholders should be consulted to test informed consent language; to ensure that informed consent forms are translated into relevant languages; where necessary (e.g. low literacy contexts) to consider alternative approaches, including video and audio.

■Standard of prevention and care - frameworks and guidelines of prevention and care should be developed with reference to a particular context and the constraints faced in that setting (e.g. of providing care during a pandemic). The standard of prevention and care for trials continues to evolve and communities are encouraged to define what is a locally relevant standard of care. A consensus should be reached by stakeholders on the standard of prevention and care to be provided.

■Payments – considerations should be taken about the recruitment of staff that might fuel local tensions in contexts of high poverty. Similarly, considerations about reimbursements should take into account local economies. Community dialogue is important to address these tensions

■Follow up and exit - considerations must be made with regard to the length of time for follow up and exit. There is a requirement to create reciprocal relationships with trial participants during and after trials have been conducted.

■Trial closure, results dissemination and access to trial products - trials should develop open access resources following the closure of a trial to disseminate results. Considerations should be made for clear and accessible communication following the publication of results, and trialists' expectations should be managed through continued communication during each phase of the study.

COMMUNITY ENGAGEMENT TRAINING MATERIALS

The following section outlines examples of community engagement training materials and tools used by PREVAC-UP teams that can be adapted for the scaling up of community engagement activities in future clinical trials. These training materials were used according to the methods described above and are intended to be adapted to a specific trial and context.

1. Community Engagement Principles/Values and Meanings

Principles & OED Definition(s)	Stanford Encyclopaedia of Philosophy	What does this mean for CE in and for research and response in epidemics?
Trust *Noun* Firm belief in the reliability, truth, or ability of someone or something. Acceptance of the truth of a statement without evidence or investigation. A person or duty for which one has responsibility. *Verb* Believe in the reliability, truth, or ability of. Allow someone to have, use, or look after (someone or something of importance or value) with confidence. Commit someone or something to the safekeeping of. Have faith or confidence. Place reliance on (luck, fate, or chance)	Trust is an attitude that we have towards people whom we hope will be trustworthy, where trustworthiness is a property, not an attitude. For trust to be warranted (i.e. plausible) in a relationship, the parties to that relationship must have attitudes toward one another that permit trust.	Trust is contingent on how communities and research/response feel toward each other based on the properties of each other's' behaviours, which are the basis on which they make judgements about each other. That means **communities must be 'convinced' of the trustworthiness of response/research through actions that demonstrate trustworthiness**, not messages that request it without delivering on the behaviours on which trusting attitudes can be built.
	Trusting requires that we can, 1) be vulnerable to others (vulnerable to betrayal in particular); 2) think well of others, at least in certain domains; and 3) be optimistic that they are, or at least will be, competent in certain respects. Each of these conditions for trust is relatively uncontroversial. There is a further condition which is controversial, however: that the trustor is optimistic that the trustee will have a certain kind of motive for acting. Controversy surrounds this last criterion, because it is unclear what, if any, sort of motive we expect from people we trust.	Communities coping with emergencies (epidemics or others) are likely to be more vulnerable than they might otherwise be, so the *choice to be vulnerable* to research/response is perhaps curtailed in such circumstances, though we ought not assume desperation and zero agency as people do not cease to be agents when they are vulnerable. Thinking well of the response/research, having optimism that it is competent and well-motivated (the second, third and controversial fourth criterion) are all relevant in the application to research in emergencies. **These all must be (a) real/in existence and (b) demonstrable to communities. CE and communications cannot achieve (b) without (a)**. This also partly explains why the messenger matters as much or more than the message, a theme that seems to be part of many recent guidelines on RCCE. Trust in promises/contracts like statehood and citizenship or action plans for epidemics manage uncertainty and fear of the unknown, which are parts of chaotic human life all the time but exacerbated in epidemics. CE becomes a forum for negotiating and mutually validating the obligations research, response and communities have to manage the elevated levels of chaos.
	While, paradigmatically, trust is a relation that holds between two individuals, forces larger than those individuals inevitably shape their trust in one another. Social or political climate contributes to how trustworthy people tend to be and therefore to whether trust is justified… societies that are oppressive make it irrational in general for the people who are oppressed to trust those who oppress them (Baier 1986, 259; Potter 2002, 24). "Social trust," as some call it, is low in these circumstances (Govier 1997, Welch 2013).	The **properties of behaviour** taken up in attitudes of trust or distrust among communities toward response/research (and in the opposite direction) are **not isolated to the response itself**. Frustration in the DRC with the mass of attention on Ebola with a relative lack of interest on war, sexual violence, hunger, maternal health, and any non-Ebola disease undermines the development of trusting attitudes because the response is **situated in a grossly unjust global distribution of resources and balance of power**—of which eastern Congo is arguably the greatest failure. The moral calculus by people from Eastern Congo that determines whether trusting attitudes emerge rightly accounts for this context. What trust is cultivated in the actions of ignoring an ongoing crisis for decades only to respond overwhelmingly to one affecting relatively few people compared to other illnesses?

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	The basic argument for the need to trust what others say is that no one person has the time, intellect, and experience necessary to learn, independently, facts about the world that many of us do know. Examples include the scientific fact that the earth is round, the moral fact that the oppression of people from social groups different from our own can be severe (Jones 1999), and the mundane fact that we were born on such-in-such a day (Webb 1993, 261).	The demands on our attention are too great for every person to know how to design and deliver response/research in emergencies. We must rely on the experiences and knowledge of others to succeed in **cooperative endeavours**, which **requires that we trust their knowledge, capacity and abilities** (and motivations). This is true for communities who need the guidance of the response/research spheres to make decisions, and of response/research who need the guidance of communities to apply knowledge through cooperative acts of translation—the interactive two-way dialogue of CE. The pathway by which knowledge is collectively validated in many communities likely differs from that of the scientific method (most social learning methods are not the scientific method), but this can be reconciled in deliberation if scientific knowledge can humble itself as *a* way of knowing instead of *the* way of knowing. Members of communities ravaged by diseases are inherently capable of empathizing with the scope of the challenge facing research and response teams. In the context of COVID-19, misinformation easily fills gaps in understandings where some do not have the resources or background knowledge to validate new information. Changing evidence, especially early in an epidemic, can undermine trust in institutions that will need to lead the response. (CDC and COVID-19)
	People lose the ability to trust often as a result of trauma (Herman 1991). The trauma caused by physical violence, for example, can profoundly reduce one's sense that the world is a safe place, with caring people in it. The question, "How can trust be restored once it has been lost?" is relevant to people who lose trust not in everyone or everything, but rather in particular people or particular institutions. For example, in some parts of the world people tend to trust the medical profession much less than they did in the past (O'Neill 2002; Pellegrino 1991b). How could their trust in this profession be restored? Although often destroying trust is quick and dirty, creating trust is slow and painful (Uslaner 1999; Baier 1986). The reasons have to do with what kind of mental attitude trust is. It is not the sort of attitude that we can simply will ourselves to have, although we can cultivate it.	That **trust cannot be willed but can be cultivated** is instructive. The metaphor of anthropologists as firefighters in emergencies points to the mistake of response/research making efforts to cultivate trustworthiness only after it has been broken—which is likely to be 'painful and slow' and this is damaging in the context of time-sensitive emergencies. Insensitivity to the trauma of emergencies (and the additional work it requires in terms of cultivating trust) on the part of researchers/responders ought not be characterized as a problem that the community brings to burden research/response but a feature of reality that the response either attempts to engage and address or tries to ignore to its own risk. It ought not be mischaracterized as an unfair burden imposed by communities. The extent to which segments of the response/research are viewed as monolithic complicates whether some institutions within the response are trusted and others not. Likewise, the extent to which communities are viewed as monolithic by the response/research complicates whether different 'communities' are being engaged in trust-building processes. A context of broken trust in a conflict zone is particularly relevant here too. Political interests in undermining science may also disrupt discourse that would otherwise reveal which institutions are trustworthy and working to the community/public benefit.
	In general, cultivating trust is only morally wise if trusting would be wise in the circumstances, which in turn would depend on whether factors are present that roughly indicate that trust would be justified. Is, for example, the social or political climate of one's society conducive to one trusting well?	Whether the conditions are present that indicate trust would be justifiable looks beyond the role of community engagement to the whole research/response presence and action. **If community engagement is, as I understand it, a mechanism partly for cultivating trust (among other purposes and meanings), it cannot do so if the research/response is characterized by actions that are not trustworthy**. In the same way that a sales pitch for product that does not work is bound to fail, CE for a response/research that is not responsive to community needs, or, worse, is overtly disruptive and antagonistic, is bound to fail to cultivate trust because the actions on which trust might be based will not be able to sustain any promises (contracts) to the community about the future actions of the response/research.
Transparency *Noun*	Characteristic of governments, companies, organisations and individuals of being open in the clear disclosure of information, rules,	Actively practicing transparency is **essential to cultivating trust** and demonstrating respect. If trust is an attitude based on perceived properties of behaviour, then the **behaviour of response/research must be articulated (and verifiable) to the communities** who need to understand the facts on which

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The condition of being transparent **Transparent** *Adjective* Easy to perceive or detect. Having thoughts or feelings that are easily perceived; open. (of an organization or its activities) open to public scrutiny.	plans, processes and actions. [SEP has no entry on transparency, so this understanding is borrowed from Transparency International's Anti-Corruption Glossary, a good working understanding of how transparency is understood in practice by a leading organization promoting good practice around it.]	to base their attitudes. Lack of transparency on the part of the response/research denies the opportunity for members of communities to make judgements that constitute trusting attitudes. Lack of transparency in the form of rendering incomplete or false explanations of response activities risks such information gaps (lacunas to the epistemologists) being filled by rumours or misinformation that might serve the purpose of filling a gap in understanding and undermine response/research efforts at the same time. Rumours are predictable products of such lacunas, left by insufficient work in dialogue, not unreasonable inventions of community members. Lastly, lack of transparency also disrespects the capacities of community members (supposed beneficiaries) to make judgements about the response work.
	As a principle, public officials, civil servants, the managers and directors of companies and organisations, and board trustees have a duty to act visibly, predictably and understandably to promote participation and accountability and allow third parties to easily perceive what actions are being performed.	The question of ***who* practices transparency** matters in emergencies with multiple organizations and agencies operating with different levels of hierarchy in established and emerging systems. Despite the diversity of actors, central planning and command structures usually emerge, and commitments to transparency at that level must be realized. Although transparency *has value*, it is *a practice* that requires management structures and institutional coordination to be done well. A complex response has many opportunities to be unclear, and to create lacunas, so the practice of engagement toward rendering the efforts transparent must be active, both deep and wide, and sustained.
Empathy *Noun* The ability to understand and share the feelings of another.	The purpose of this entry is to clarify the empathy concept by surveying its history in various philosophical and psychological discussions and by indicating why empathy was and should be regarded to be of such central importance in understanding human agency in ordinary contexts, in the human sciences and for the constitution of ourselves as social and moral agents.	Empathy is a central feature of human life because of the condition of **human plurality**. English descriptions of empathy need the suffixes 'to' and 'with' because it is relational; its practice requires more than one of us. Epidemics as products of contagion across multiple humans are by definition things that happen to *us*—not to me or you. (Though, epidemics can happen to a *them*.) Understanding action by moral agents in an epidemic requires that we consider **our capacity to understand and interpret the feelings of another**, particularly in the context of the types of collective action (though not *uniform* action) required to respond to epidemics.
	The psychologist Edward Titchener (1867–1927) introduced the term "empathy" in 1909 into the English language as the translation of the German term "Einfühlung" (or "feeling into"). Lipps conceives of empathy as a psychological resonance phenomenon that is triggered in our perceptual encounter with external objects. More specifically, these resonance phenomena are triggering inner "processes" that give rise to experiences similar to ones that I have when I engage in various activities involving the movement of my body.	Empathy as a 'perceptual encounter with external objects' wherein what is encountered resonates with something existing shows how it is **hinged on plurality**: it requires a *self* and an *other*. There is an epistemic quality to the encounter, for we cannot find some psychological resonance with what we do not know exists. Community engagement and qualitative research should help us with the required learning of 'feeling into' something. It must reveal the things or experiences or events on which such resonance is based. We cannot empathize with what we cannot see or are unaware of. Public health responses and research in epidemics are often a collision of 'worlds' of people who do not understand each other well: researchers and researched. **Empathy as an ability or capacity is required in the methods of engagement of communities in epidemics** if the languages, subjectivities (ways of being), ways of treating one another and other features need to be reconciled in the collective planning and action-taking that emerges in research during epidemics. What opportunities besides CE do non-participants have to learn enough about trials and their scientists to be able to 'feel into'? If there is to be bidirectionality, there is learning to be done on the side of community members as well.

Principles & OED Definition(s)	Stanford Encyclopaedia of Philosophy	What does this mean for CE in and for research and response in epidemics?
	Hermeneutic thinkers insisted that the method used in understanding the significance of a text or a historical event has to be fundamentally distinguished from the method used in explaining an event within the context of the natural sciences… Understanding the meaning of a text, an action, or work of art requires us to relate it to the primary realm of significance; that is, our own mental life accessible through introspection… Even though Dilthey himself never used the empathy terminology, his position certainly facilitated thinking about understanding as a form of empathy. No wonder then, that at this time the concepts of empathy and understanding were used almost interchangeably in order to delineate a supposed methodological distinction between the natural and the human sciences… Notable exceptions in this respect are R.G. Collingwood and his followers, who suggested that reenacting another person's thoughts is necessary for understanding them as rational agents.	Where empirical inquiry seeks **variables** to *measure*, *predict* and *control*, hermeneutical inquiry seeks **meanings** to *understand*. Hermeneutical inquiry overlap with empathy in that it is a method for understanding the vessels in which we 'feel into.' It seeks undistorted understandings of meaning in languages of perspicuous contrast—that is, clarity and fidelity to those whose lives and experiences they describe. Re-descriptions and translations are hermeneutically insufficient tools for understanding because they distort meanings with which we then cannot empathise. **True understanding *is* interchangeable with empathy because understanding requires the intellectual and emotional investment of recreating the conditions of the 'primary realm of significance' in our own minds.** Community engagement, then, has a lofty assignment in giving us the space to achieve these understandings. It is why CE methods are dialogical and deliberative in nature when they have any chance of being meaningful at all—or successful in managing/checking the power and resource differentials between researchers and researched in **a process of deliberation, not an announcement of activities**. And these models of CE ask what change is attributable to that engagement because with true learning about an *other* comes the more radical requirement that we *change*. It is as Gadamer said: You understand differently if you understand at all. Empathy is **not just a willingness to listen or learn**, but a **commitment to rearranging one's cognitive framework for situating what is learned and acting on that change**.
	Philosophers, influenced by considerations of Heidegger and also the later Wittgenstein, have started to think of **individual agents as socially and culturally embedded creatures** and have started to conceive of **the mind of individual agents as being socially constituted**. Understanding other agents thus presupposes an understanding of the cultural context within which an agent functions. Moreover, in the interpretive situation of the human sciences, the cultural background of the interpreter and the person, who has to be interpreted, can be very different. In that case, I can not very easily put myself in the shoes of the other person and imitate his thoughts in my mind… Making sense of other minds has, therefore, to be seen as an activity that is a culturally mediated one.	Anthropology is a discipline that has p**ractical methods for seeing individuals as socially and culturally embedded creatures**. Its methods for acknowledging culture of interpreter and interpreted and forwarding of lenses for understanding 'data' lend it to supporting the cultural mediation of 'making sense of other minds' in CE in epidemics. However, **anthropologists are not the whole answer to transcending culturally mediated acts** of making sense of the minds of others. This is true for what they can provide for the biomedical response and epidemiologists on one hand, and for members of communities in North Kivu on the other hand. A set of practices that constitute an academic discipline are not the same as empathy—they do not close the space between us but give us the knowledge with which we can close the space. Only love can erase it; and in the public sphere and negotiations around the shape of a response, respect for each other's humanity must stand where we will never know each other well enough to love each other. Who are the best mediators and how do we put them in place to do the work in an outbreak? What are our roles as listeners if the mediation is always bound to be imperfect because it's a truly difficult task?
Recognition *Noun* Identification of someone or something or person from previous encounters or knowledge Acknowledgement of the existence, validity, or legality of something Appreciation or acclaim for an	Arguably, if you recognize another person with regard to a certain feature, as an autonomous agent, for example, you do not only admit that she has this feature but you embrace a positive attitude towards her for having this feature. Such recognition implies that you bear obligations to treat her in a certain way, that is, you recognize a specific normative status of the other person, e.g., as a free and equal person.	Histories of oppression in medical research have taught the lesson that individuals and communities will be recognized in their full humanity only for the duration of a clinical trial and in strictly defined ways. People who participated in trials of HIV and TB drugs lost access to experimental treatments once they proved effective and were marketable. Many died after making such a contribution to science. What recognition of their humanity was shown in those trials? This is not the colonial period, but the 1990s. Recent comments by French doctors about doing clinical trials of COVID-19 treatments in Africa showed no recognition of the 'specific normative status' of the African scientists already working on the continent—never mind an acceptance of the obligation to treat non-scientists 'a certain way' in line with their status as free, equal persons that comes with recognition. In a context where these racist colonial discourses still operate, demonstrations of recognition in CE must do more work to show that they take account of such histories and of present racist discourses that pervade in global health.

Principles & OED Definition(s)	Stanford Encyclopaedia of Philosophy	What does this mean for CE in and for research and response in epidemics?
achievement, service, or ability Formal acknowledgement by a country that another political entity fulfils the conditions of statehood and is eligible to be dealt with as a member of the international community	Most theories of recognition assume that in order to develop a practical identity, persons fundamentally depend on the feedback of other subjects (and of society as a whole). According to this view, those who fail to experience adequate recognition, i.e., those who are depicted by the surrounding others or the societal norms and values in a one-sided or negative way, will find it much harder to embrace themselves and their projects as valuable. Misrecognition thereby hinders or destroys persons' successful relationship to their selves. It has been poignantly described how the victims of racism and colonialism have suffered severe psychological harm by being demeaned as inferior humans (Fanon 1952). Thus, recognition constitutes a "vital human need" (Taylor 1992, 26).	Many communities are **recognized only in their relation to a disease**. In DRC during Ebola, Congolese people are either susceptible (potential patients who need to be educated and whose risky behaviour needs to be curtailed, perhaps coercively), infected and exhibiting symptoms of the disease (need to be isolated and tested, perhaps coercively, need to be isolated and treated with experimental drugs, perhaps coercively) or recovered (need to enrol in long-term studies and give blood, urine, stool and semen samples for years). The view of a person through a lens of what their relationship is to Ebola is incomplete, fails to recognize their 'specific normative status' as another person, and limits the moral imagination of how that person ought to be treated (with implications on agency if a response is coercive). It erases all of them that is not Ebola—which is a lot both biologically and in terms of their human experience. CE must move us beyond understanding communities as they fall into the categories of a SIR model, and provide for **how their contributions to research will be treated as a valued contribution and taken up *because* they are valuable**.
	Recognition theory is thought to be especially well-equipped to illuminate the psychological mechanisms of social and political resistance. As experiences of misrecognition violate the identity of subjects, the affected are supposed to be particularly motivated to resist, that is, to engage in a "struggle for recognition." … To frame these political movements in terms of recognition highlights the relational character of morality—and justice: Justice is not primarily concerned with how many goods a person should have but rather with what kind of standing vis-à-vis other persons she deserves (Young 1990).	The social and political **resistance of the response effort** (to critique of it) might be explained in part by the conviction that their nobility of aim confers sanction to act. (It does not.) The attitude of urgency and dominance of empirical discourses around vectors, incidence, prevalence, mortality, and control measures outweigh the values underpinning CE in their moral calculus. It is as if to say: "It is scientifically proven that it's more important that I do you this favour immediately than for you to understand who I am and why I am in your home coercing your behaviour." The social and political **resistance of communities** might be explained in part by the conviction that they are only recognized in relationship to the disease in question. The erasure of features that are not epidemiologically relevant violates their status as moral equals. The insult to the self, this withdrawal of a 'vital human need' to be recognized as an equal, needs repairing. Remuneration and payment for clinical visits, lunches and per diems can all be small gestures that are less about how many goods a person should have, but what kind of standing they have among their human peers. CE must be flexible enough to accept the 'struggles for recognition' without depoliticising or placating it. It should be a framework that yields to the liberation movement of communities fighting for full recognition of their equal moral value.
	Instead of being approached as adults, women and people of different colour, for instance, were, for the most part of history, treated like children. They were regarded as "second-class citizens" (Taylor 1992, 37) not capable of responsibly reproducing and shaping the social norms of their communities.	Vulnerable groups form particular communities, no matter their level of cohesion. Certain professions or chronic illnesses may mean that a group of people already historically marginalised are also more susceptible and suffer from a higher rate of infections. Migrants in the US with COVID-19 or Twa communities in DRC with Ebola are examples of such **groups whose shared experience of vulnerability maps onto their historical/existing marginalisation**. This poses dangers as their recognition is reduced to be even further from equal moral beings as they are marked by stigma and associated with an undesirable disease.
Respect *Noun* A feeling of deep admiration for someone or something elicited by their abilities,	**Respect is a responsive relation**, and ordinary discourse about respect identifies several key elements of the response, including attention, deference, judgment, acknowledgment, valuing, and behaviour… When we respect something, we heed its call, accord it its due, acknowledge its claim to our attention. Thus, **respect involves**	

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qualities, or achievements. The state of being admired or respected. Used to express the speaker's approval of someone or something. Due regard for the feelings, wishes, or rights of others. *Verb* Admire (someone or something) deeply, as a result of their abilities, qualities, or achievements. Have due regard for (someone's feelings, wishes, or rights) Avoid harming or interfering with. Agree to recognize and abide by (a legal requirement)	**deference**, in the most basic sense of yielding: self-absorption and egocentric concerns give way to consideration of the object, one's motives or feelings submit to the object's reality, one is disposed to act in obedience to the object's demands.	
	The moralized analogue of *respekt* involves regarding the object as making a rightful claim on our conduct, as deserving moral consideration in its own right, independently of considerations of personal well being *Obstacle respect*, in (b), is a matter of regarding the object as something that, if not taken proper account of in one's decisions about how to act, could prevent one from achieving one's ends. The objects of (c) *directive respect* are directives: things such as requests, rules, advice, laws, or rights claims that may be taken as guides to action. One respects a directive when one's behaviours intentionally comply with it. The objects of (d) *institutional respect* are social institutions or practices, the positions or roles defined within an institution or practice, and persons or things that occupy the positions or represent the institution. Institutional respect is shown by behaviour that conforms to rules that prescribe certain conduct as respectful. Recognition respect is the disposition to give appropriate weight or consideration in one's practical deliberations to some fact about the object and to regulate one's conduct by constraints derived from that fact.	We have **obstacle respect** for communities in epidemics where we need to have **directive respect** (or recognition respect). Sailors have obstacle respect for the sea and sports teams for their opponents because they want to act in accordance with the sea or the other team's demands on their behaviour if they want to achieve certain ends. Researchers want to avoid clinical trials being shut down for bad headlines, and public health responders want to avoid Ebola Treatment Centres being burned down. So we engage communities to placate and depoliticise the struggles for recognition beyond the disease profile. Recognition respect would require us to fully mobilise and act upon our recognition of community members as moral equals whose insights, ideas, frustrations, desires and demands impinge on the conduct of research and public health responses directly. An announcement in a community meeting that the clinical trial management has decided to change travel reimbursements without prior consultation is a practice that constitutes obstacle respect. The social liaisons are charged with achieving the end of keeping the trial running by carrying out this action to maintain participation without spending as much money on travel reimbursements. It does not constitute a practice of directive/recognition respect that takes seriously the equal moral standing of participants as contributors in decision-making about a process that involves their lives and families. Respect for communities in research and response in epidemics means the expressed interests of community members have a rightful claim on the conduct of research and response. These claims are to be taken as guides to action, which is why the feedback loop that community engagement programs maintain have to plug into senior management and there should be demonstrable change from engagement or a record of why no change was necessary from the perspective of community members. The community's institutional respect for a trial or response should never be imagined to outstrip the directive/recognition respect the trial or response ought to demonstrate for the community.
Deliberation *Noun* Long and careful consideration or discussion. Slow and careful movement or thought.	Benhabib*	
Legitimacy *Noun* Conformity to the law or to rules. (with reference to a child) the quality	According to Weber, that a political regime is legitimate means that its participants have certain beliefs or faith ("Legitimitätsglaube") in regard to it: "the basis of every system of authority, and correspondingly of every kind of willingness to obey, is a belief, a belief by virtue of which persons exercising authority are lent prestige" (Weber 1964: 382). As is well known, Weber	

Principles & OED Definition(s)	Stanford Encyclopaedia of Philosophy	What does this mean for CE in and for research and response in epidemics?
of being legitimate. Ability to be defended with logic or justification; validity. **Legitimate** *Adjective* Conforming to the law or to rules. (of a child) born of parents lawfully married to each other. (of a sovereign) having a title based on strict hereditary right. Able to be defended with logic or justification; valid. Constituting or relating to serious drama as distinct from musical comedy, revue, etc.	distinguishes among three main sources of legitimacy—understood as the acceptance both of authority and of the need to obey its commands. People may have faith in a particular political or social order because it has been there for a long time (tradition), because they have faith in the rulers (charisma), or because they trust its legality—specifically the rationality of the rule of law (Weber 1990 [1918]; 1964).	
	The legitimacy of democratic decisions, then, depends on both procedural values and on the substantive quality of the outcomes that these deliberative decision-making procedures generate. As Habermas puts it: "Deliberative politics acquires its legitimating force from the discursive structure of an opinion- and will-formation that can fulfil its socially integrative function only because citizens expect its results to have a reasonable *quality*" (Habermas 1996: 304; see also Benhabib 1994; Knight and Johnson 1994; Cohen 1997a,b; Bohman 1997). In his view, only deliberative democratic decision-making can produce a decision everyone has reasons to endorse.	
	According to Beetham, a "power relationship is not legitimate because people believe in its legitimacy, but because it can be *justified in terms of* their beliefs" (Beetham 1991: 11).	

2. TRAINING OF RELIGIOUS LEADERS (IMAMS) ON THE NEW SENSITIZATION MESSAGES

TRAINING GUIDE

[insert details relevant to the trial]

TRAINING OBJECTIVES:

- To communicate the success of the study so far to religious leaders
- To provide religious leaders (imams) messaging which can be used during their sermons
- To seek support and buy in from religious leaders

8:30 to 9:00 a.m.	**REGISTRATION**				
TIME	**TOPIC**	**METHOD**	**HOW**	**OUTCOME**	**MATERIAL**
9:00 – 9:15	**AGENDA SETTING:** • **PRAYERS** • **INTRODUCTIONS** • **WELCOME**	**Group and lecture**	Ask trainees to present somebody to lead the opening prayers. Facilitators introduce themselves followed by trainees. The lead facilitator gives the welcome address and brief statement on trial mandate.	Trainees are better prepared for the training	None
9:15 – 9:45	**TRAINING EXPECTATIONS, CONCERNS, OBJECTIVES AND GROUND RULES**	**Brainstorm**	Ask participants to give their expectations of the training. Exhaust the list. On another flip chart, ask them to give their concerns. Displayed objectives on a prepared flip chart. Link objectives to expectations and concerns. Discuss with group and clarify issues. Ask participants to set rules for the training.	The rationale of the training is understood by trainees	Flip chart, marker, note pad and pen
9:45 --- 9:55	**BREAK**				
9::55 – 10:35	**ABOUT TRIAL** **(Trial Experience sharing)**	**Group work**	Use masking tape to form a large circle (called Trial pool) on the centre of the training room. Ask participants to stand round the circle. Tell participants that the circle represents trial mandate and activities in Sierra Leone and [INSERT LOCATION] District in particular. Ask pts to		Masking tape, flip chart and marker

		Summary	explain in turns what their understanding is about the Trial. Their distance from the circle/pool indicates the extent of degree of their knowledge about the trial using three levels: 'very close' means they have adequate knowledge, 'far away' means they have little or no knowledge and 'in-between' means they have some knowledge. Then, ask the least knowledgeable ones to explain what they know about the Trial, seconded by those with some knowledge and lastly, those closer to the circle/pool. Identify and clarify myths, misconceptions, concerns and respond to questions. Summarize the questions below: **What is the trial?** • The study is helping us to learn about a new vaccine against Ebola • Several different vaccines are being tested in different studies around the world including [INSERT LOCATION] and [INSERT LOCATION] **Why are we developing a vaccine against Ebola?** • If we know that a vaccine can stop people from getting Ebola, we will have a new way to stop future outbreaks of the disease Who **is running the trial?** The study is being run by a team of doctors and scientists from: • Sierra Leone Ministry of Health and Sanitation • Sierra Leone College of Medicines and Allied Health Sciences (COMAHS) • London School of Hygiene and Tropical Medicine • Pharmaceutical Companies • And other organisations	Trainees' previous knowledge is discussed.	
10:35 --- 10:50			**What progress has the trial made so far?** **[insert relevant details]** **Refer to sensitization messaging pack for**		None

	PROGRESSS OF THE TRIAL AND TARGET PARTICIPANTS	**Lecture**	**children aged 4-11 cohort. (key points):** • About 450 adults have received the vaccine in [INSERT LOCATION] and [INSERT LOCATION] and over 2,000 in other studies around the world including S/Leone. • Almost 100 children aged 12-17 have also received the vaccine so far in [INSERT LOCATION] and [INSERT LOCATION] and over 100 in others in Guinea, Kenya and Burkina Faso • Nobody who received the vaccine reported any serious problems • The recruitment for adults and adolescents aged 12-17 is over • The next stage is 96nchildren aged 4-11 and 96 children aged 1-3 years old.	Trust and confidence is maintained	
10:50 --- 11:00	**BREAK**				
11:00 --- 11:20	**TESTING THE VACCINE ON CHILDREN AND SAFETY**	**Lecture**	**<u>Why do we need to test the vaccine on children?</u>** • To learn more how the vaccine works on children. • It is completely normal to test vaccines or medicines in different age groups because the body system of children can work in different ways to that of adults **<u>Is this new Ebola vaccine safe, does it protect from Ebola?</u>** • We do not yet know if this vaccine is completely safe, but the safety of volunteers in the study is Trial's top priority. • This is why this study is happening to know if the vaccine works • The vaccine cannot cause Ebola. There	The safety, side effects of and reason for testing the vaccine on children is understood	Messaging pack, flip chart and marker

			is no Ebola virus in the vaccine **<u>What are the possible side effects from getting the vaccine</u>** • They might be a sore arm, muscle or joint pain, feeling tired, headache, feeling sick, and fever. • If volunteer feel unwell after receiving the vaccine, they should call the telephone number on their emergency card they will be given. A study nurse or doctor will be available at any time of night and day to give volunteers' advice if they feel unwell.		
11:20 --- 11:40	**BENEFITS OF THE TRIAL**	**Testimony**	**Note: Many of the adult participants have made testimonies in several of our sensitization activities in [INSERT LOCATION] and [INSERT LOCATION].** Arrange for an adult participant who is willing to give testimony on his/her experience with the trial for few minutes. (He/she might come from the trainees as well). Summarize the session. **<u>What are the benefits to participants of volunteering to take part in the study?</u>** • Participants will have a health screening which will help them to know their health status • Participants will receive free medical care for any illness caused by the vaccine and in all emergencies, • As well as if participants have a minor or short-term illness such as Malaria or chest infection even if it is not related to the vaccine. • If this vaccine is effective then participants could already be protected from Ebola in the case of another outbreak of the disease	Trainees have realistic information about the benefits of the trial	Marker and flip chart

			Conclude that the benefits to [INSERT LOCATION] District include: • The Emergency room at the [INSERT LOCATION] Government Hospital • Employment, training and giving experience to local staff		
11:40 --- 12:00	**RANDOMIZATION**	**Demonstration**	**<u>Will everybody who volunteers for the study receives the same vaccine?</u>** • No. But in Stage 1 of the study everybody who volunteered received the Ebola vaccine. • In the next Stage 2 of the study, three(3) out of every four (4) people who volunteered will receive Ebola vaccine, and one (1) out of four (4) people will receive a different vaccine called meningitis vaccine • This is so because we can compare the Ebola vaccine against a different vaccine Use stones to demonstrate the theory of randomization. Please use the messaging pack to explain further. **<u>Can I chose which vaccine I receive?</u>** • No. volunteers cannot choose which vaccine they receive---either Ebola or the meningitis vaccine.	Trainees demonstrated the theory of randomization	Stones, messaging pack
12:00 --- 12:30	**LUNCH**				
12:30 --- 12:45	**TAKING PART IN THE TRIAL**	**Lecture**	**<u>How do you enrol children for the study</u>** • Parents and children can sign up by contacting any of the trial clinics in [INSERT LOCATION] or [INSERT LOCATION], or by giving their name and telephone number and house address at a public meeting or event.	Trainees have clear knowledge on how to enrol children in the trial	Messaging pack, marker and flip chart

			• The clinic team will then call them and invite them to attend the clinic to answer certain questions • All children will be enrolled in the study for 1 year • They will visit the clinic 9 times over the year • Children aged 1 year old will visit the clinic 10 times **Why is Trial asking participants to provide ID documents when they come for screening** • This is because the clinic needs to have a way of confirming the age of the child attending for screening: • The clinic will accept any of the following: passport, national I.D card, birth certificate, under-5 or vaccination card, and other forms of identification that clearly show the participants name and age (e.g. school report card). If no document is available you can still enrol. **What will happen to those who take part in this study** • Volunteers will first attend a screening visit where they will be asked some questions about their health • They will also have to give a small amount of blood to check that you are healthy • If everything goes well, the person is able to take part in the study • They will receive a vaccine on two of the visits (about 2 months apart) • On the other visits they will be checked to make sure they are well and had no problem • At each visit they will be asked to give a small blood sample to know how the vaccine is working		

12:45 --- 1:00	**MAKING DECISION TO TAKE PART IN THE TRIAL**	**Lecture and discussion**	**Refer to the sensitization messaging pack for children aged 4-11 cohort: (key points):** **Who makes the decision to take part in the study? The child or their parent?** • The parent or legal guardian will be asked to sign a form to say that they agree for their child to take part. • For children aged 7 or above, the agreement of both the parent and the child is needed • In younger children aged 1-6 above, the parent or legal guardian will decide on behalf of their child. • It should be the child's parent or legal guardian who comes to the clinic to consent for their child • If a guardian signs the consent form on behalf of the child's parent, it is that guardian who will be responsible for all aspects of the child's participation in the Trial. **Generate discussion: why in older children both the agreement of the parent and child is needed and not for younger children?** **<u>Do children get paid for taking part</u>** Ask one trainee who is literate in English to read and facilitator explains: (key points): • Trial is not paying anybody to take part in the study. • Everybody who decides to take part in the study does so because they want to, and not because they want money. • Trial will provide compensation for time and transport costs at [INSERT AMMOUNT] for scheduled visit,	Trainees know who has mandate to enrol a child into the study	Messaging pack, flip chart and marker

			and [INSERT AMMOUNT] for an unscheduled visit. • When a parent/legal guardian accompanies their child to the clinic, both the parent and child will receive this compensation. **Explain the concept of scheduled and unscheduled visits.**		
1:00 ---1:15	**BLOOD TAKING**	**Case study**	Ask trainees to explain why they think blood is usually taken from them when they feel unwell and visit hospitals for medication. Ask trainees to explain real life experience---either they or any of their family members was sick and was treated at a big hospital. Discuss also about blood donation and transfusion in big hospitals and the quantity taken. **<u>Why does the study team need to take blood</u>** • We need to take a small amount of blood from participants at each of their visits to the clinic ---9 times in total • At the first visit, Trial needs to do this to check that the person is healthy, which includes checking their liver and kidneys are working normally • On later visits we need to do this so we can check what effect the vaccine is having on the body • But the amount of blood taken will not cause harm to the child	Trainees have clear and correct information on why the study team need to take blood	Messaging pack, marker and flip chart, TUBES
1:15 ---1:30	**PREGNANCY, CONTRACEPTION, FERTILITY AND MENSTRUATION**	**Lecture and discussion**	**<u>Who are the people that are ineligible to take part in the study</u>** • Pregnant women/girls, lactating mothers and children aged below 1 year. **(Ask pts to explain why? Reinforce their explanation.**	Trainees have a discussion on ineligibility of some group of people in the trial	Messaging pack, flip chart and marker

			Do people aged under 18 have to use contraception in order to take part in the study? • If anybody aged under 18 and is not sexually active ,can take part in the study and they do not have to use contraception • Anybody who is sexually active and is not using contraception/family planning cannot take part in the study • This is because it is very important that nobody who has recently taken the vaccines becomes pregnant within three months after receiving the vaccine (why?) • If they are aged under 18 years (male or female), however if somebody is sexually and is already using contraception he or she may be allowed to take part in the study • If they are aged under 18 years, however if somebody is sexually active and is not using contraceptive, they will only be able to take part in the study if they agree to use contraception for the first 3 months of the study and agree for their parents to be told about them using contraception. **Is it fine for girls to take the vaccine while menstruating** • Yes. So long as they are following the rules about contraception.		
1:30 - --1:45	**EVALUATION**	**Group work (Human Thermometer tool)**	Draw three faces on a flip chart paper: happy, medium and sad. Ask each participant to tick against one face in relation to their level of understanding of the content of the training. Count the number of ticks against each face and discuss the outcome of the evaluation. If the happy	Participants evaluate their level of understanding of the content of the training and provide recommendations .	Flip chart and marker

			face scored less or recorded fewer ticks. Then ask participants what went wrong, and let them give recommendations for improvement next time. Thank them.		

THANK YOU!!!!

3. DRAMA SENSITIZATION MESSAGING FOR CHILDREN RECRUITMENT

What is the trial?

- The trial is helping us to learn about a new vaccine against Ebola.
- Several different vaccines are being tested in different studies around the world including [INSERT LOCATION] and [INSERT LOCATION]
- [insert trial specific details]

Why the trial is developing a vaccine against Ebola?

- Ebola is a deadly disease that can spread very fast and kill within the shortest possible time.
- In the main time, Ebola has no specific medicine or cure
- If we know that a vaccine can stop people from getting Ebola, we will have a new way to stop future outbreaks of the diseases

What progress has the trial made so far?

- [insert trial specific details]

Why do we need to test the vaccine on children?

- To help us learn more how the vaccines work on children, and whether it can protect from Ebola or not
- It is completely normal to test vaccine or medicine in different age groups

Is this new Ebola vaccine safe, does it protect from Ebola

- We do not yet know if this vaccine is completely safe, but the safety of volunteers in the trial is top priority.
- This is why this study is happening to know if the vaccine works
- The vaccine cannot cause Ebola. There is no Ebola virus in the vaccine

What are the possible side effects from getting the vaccine

They might be a sore arm, muscle or joint pain, feeling tired, headache, feeling sick, and fever.

If volunteer feel unwell after receiving the vaccine, they call the telephone number on their emergency card they will be given. A study nurse or doctor will be available at any time of night and day to give volunteers' advice if they feel unwell.

What are the benefits to participants of volunteering to take part in the study?

- Participants will have a health screening which will help them to know their health status
- Participants will receive free medical care for any illness caused by the vaccine and in all emergencies,
- As well as if participants have a minor or short-term illness such as Malaria or chest infection even if it is not related to the vaccine.
- If this vaccine is effective then participants could already be protected from Ebola in the case of another outbreak of the disease

How do you enrol children for the study?

- Parents and children can sign up by contacting any of the Trial clinics in [insert details] or by giving their name and telephone number and house address at a public meeting or event.
- The clinic team will then call them and invite them to attend the clinic to answer certain questions
- All children will be enrolled in the study for 1 year

- They will visit the clinic 9 times over the year
- Children aged 1 year old will visit the clinic 10 times

Why is the trial asking participants to provide ID documents when they come for screening?

- This is because the clinic needs to have a way of confirming the age of the child attending for screening:
- The clinic will accept any of the following: passport, national I.D card, birth certificate, under-5 or vaccination card, and other forms of identification that clearly show the participants name and age (e.g. school report card). If no document is available, you can also come as long as the parent is able to confirm the true age of the child.

What will happen to those who take part in this study?

- Volunteers will first attend a screening visit where they will be asked some questions about their health
- They will also have to give a small amount of blood to check that you are healthy
- If everything goes well, the person is able to take part in the study
- They will receive a vaccine on two of the visits (about 2 months apart)
- On the other visits they will be checked to make sure they are well and had no problem
- At each visit they will be asked to give a small blood sample to know how the vaccine is working

Who makes the decision to take part in the study? The child or their parent?

- The parent or legal guarding will be asked to sign a form to say that they agree for their child to take part.
- For children aged 7 or above, the agreement of both the parent and the child is needed
- In younger children aged 1-6 above, the parent or legal guardian will decide on behalf of their child.
- It should be the child's parent or legal guardian who comes to the clinic to consent for their child
- If a guardian signs the consent form on behalf of the child's parent, it is that guardian who will be responsible for all aspects of the child's participation in the Trial.

Remember: Parents of children aged 11 and below must give consent for their child to participate in the study and must attend every clinic visit with their child

Do children or their parents get paid for taking part in the trial?

- The trial is not paying anybody to take part in the study.
- Everybody who decides to take part in the study does so because they want to, and not because they want money.
- The trial will provide compensation for time and transport costs at [INSERT AMMOUNT] for scheduled visit, and [INSERT AMMOUNT] for an unscheduled visit.
- When a parent/legal guardian accompanies their child to the clinic, both the parent and child will receive this compensation.

Why does the study team need to take blood?

- We need to take a small amount of blood from participants at each of their visits to the clinic ---9 times in total
- At the first visit, the trial needs to do this to check that the person is healthy
- On later visits we need to do this so we can check what effect the vaccine is having on the body

Is the amount of blood taking from adults the same as from children?

- The amount of blood taken from children will be less than it was for adults
- And the amount of blood taken will not cause harm to the child

How is the vaccine administered? Is it an injection or oral?

- It is given through injections into the upper arm using a clean needle

Note:

- Hydara Comedy Players to develop drama script, present to Team for vetting, rehears and conduct pre-test
- According to the general plan, drama performances are slated to begin week starting 19th June. This means adequate time is being allotted for the processes of the drama.

4. KEY MESSAGES FOR SCHOOL ASSEMBLY TALK
(10 to 15 minutes duration)
[insert details relevant to the trial]

1. There is a vaccine trial taking place in [INSERT LOCATION] District to learn if new vaccines could prevent people against Ebola.

2. If the vaccine is proven to be effective, we will have a new way to stop future outbreaks of the disease.

3. The trial is being run by a team of doctors and scientists led by Sierra Leone's College of Medicine and Allied Health Sciences (COMAHS), Ministry of Health and Sanitation and other local and international partners

4. [insert relevant details] e.g. We will now start to give the vaccines to children in 3 groups (adolescents aged 12-17, children aged 4-11 and infants aged 1-3).

5. Participants will have a health screening when they join the study which will help them to understand their health status. Only healthy children will be allowed to take part in the study.

6. They will receive free medical care for any illnesses caused by the vaccine and in all emergencies, as well as if a participant has a minor or short-term illness even if it isn't caused by the vaccine.

7. We cannot yet know if this vaccine is completely safe, but the safety of volunteers in the study is the study team's top priority.

8. This Ebola vaccine is being studied in other countries

9. We do not yet know if this vaccine works – that is why this study is happening and people in the study must continue to wash their hands with soap and water or with chlorine.

10. This vaccine cannot cause Ebola. There is no Ebola virus in the vaccine.

11. There are common side-effects which might be a sore arm, muscle or joint pain, feeling tired, headache, feeling sick, and fever. A study nurse or doctor will be available at any time of night or day to give volunteers advice if they feel unwell.

12. Pregnant women/girls and lactating mothers are not able to take part in the study. This is because we do not yet know how the vaccine might affect the unborn child or the infant through breast milk.

13. Participants will first attend a screening visit to know their health status.

14. All children will be enrolled in the trial for 1 year, and will visit the clinic 9 times over the year. The only exception to this is children aged 1 year old who will visit the clinic 10 times.

15. Parents and their children can sign up by contacting the trial clinics, or by giving their name and telephone number at a public meeting or event.

16. Nobody has to take part in the study if they don't want to and volunteers can decide to stop being a part of this study at any time.

17. The agreement of both the parent and the child is needed. In younger children aged 1-6, the parent or legal guardian will decide on behalf of their child.

18. Nobody will be paid to take part in this study. We will only provide compensation for time and transport costs. When a parent accompanies their child to the clinic, both the parent and the child will receive this compensation.

19. The parent or legal guardian must attend the clinic for the screening visit in order to give their consent. Children aged 12-17 can attend all other visits alone, or they can choose to attend with a parent or guardian.

20. We need to take small amount of blood to check that the person is healthy. On later visits we need to do this so we can check what effect the vaccine is having on the body.

21. The amount of blood taken from children will be less than it was for adults. The exact amount of blood taken will depend on the child's age, but the amount of blood taken will not cause harm to the child.

22. Anybody who is sexually active and is not using contraception cannot take part in the study. This is because it is very important that nobody who has recently taken the vaccines becomes pregnant, because we do not have enough information about how the vaccines could affect the unborn child.

23. The study team cannot provide contraception for anybody – male or female – if they are aged under 18 years, however if somebody is sexually active and is already using contraception he or she may be allowed to take part in the study.

24. The last but not the least, girls can even take the vaccine while menstruating, so long as they are following the rules about contraception.

5. PRIMARY SCHOOL PEER EDUCATORS TRAINING

SENSITIZATION MESSAGING FOR CHILDREN RECRUITMENT

[insert details relevant to the trial]

Main Topic	Questions	Answers
1. ABOUT THE TRIAL	What is the meaning of [INSERT TRIAL]?	Ebola vaccine or Ebola Vaccine
	What is the work of [INSERT TRIAL]?	The trial is testing a new vaccine against Ebola to see if it can help stop Ebola
	How many people that have received the vaccine so far?	• [insert details] • e.g. more than 2000 people all around the world] • About 450 adults in [INSERT LOCATION] and [INSERT LOCATION] • About 100 children aged 12 to 17 years old in [INSERT LOCATION] and [INSERT LOCATION]
	Who are the next group of people to receive the vaccine?	[insert details] • e.g. 96 children aged 4 to 11 years old] • 96 children aged 1 to 3 years old
	Why is the trial is developing a vaccine against Ebola?	To stop Ebola from returning again or future outbreaks of the disease
	Why do we need to test the vaccine on children?	To help the trial learn more about how the vaccines work on children, and help us know if the vaccine can stop children from catching Ebola.
	Who is running the trial?	• College of Medicine and Allied Health Sciences (COMAHS), • Ministry of Health and Sanitation, Sierra Leone • other local and international organizations

2. BENEFITS OF THE TRIAL	What are the benefits to participants of volunteering for the trial	There is a: • Free medical check-up to know whether the participant is healthy • Free medical care for minor illness like malaria • Free medical care for any illness caused by the vaccine • free medical care during emergencies like accidents
	How will [INSERT LOCATION] benefit from the study	The benefits include: • an Emergency Room at the [INSERT LOCATION] Government Hospital • Employment and training facility to local staff
3. ABOUTS THE VACCINES	Is this new vaccine safe?	• We do not yet know if this vaccine is safe or works • This why this study is happening • But the safety of participants is the highest concern of the trial • And the vaccine cannot cause Ebola
	What are the possible side effects from getting the vaccine?	Any medicine of vaccine can cause side effects, and it is the same with the trial vaccines. These may be common side effects like: • Sore arm, muscle/joint pain • Felling tired • Headache • Feeling sick • Fever If you are feeling unwell you or your parent can call on the Emergency telephone line at any time of the day or night
	Will everybody who volunteers for the study receive the same vaccine?	[insert relevant details] • No. We need to compare the Ebola vaccine with a different vaccine to help us know if it works. • 3 out of 4 people who volunteer will receive the Ebola vaccine • 1 out of 4 people who volunteer will receive a different vaccine against meningitis • All participants will receive 2 vaccines at intervals • All children 1 year olds will receive 3 vaccines at intervals • Nobody can chose which marlate he/she receives

4. TAKING PART IN THE STUDY	Who can take part in the study?	[insert relevant details] • Healthy children aged between 1 to 11 years who live in [INSERT LOCATION] and [INSERT LOCATION] Those who cannot take part are: • Pregnant women • Lactating mothers • Children aged below 1 year
	How will you enroll into the study?	• Parents/legal guardian will give the names of their children during trial public activities • By visiting any trial clinic in [insert location]
	What Identification document parent should bring to help know real age of their children?	• Passport, national ID card, birth certificate, under-5 card, school report card etc • If none of the above is available, the doctor can also interview the parent of the child to know their age
	What will happen to those who take part?	• You will first attend a medical check-up where you and your parent will be asked some questions • You will give small amount of blood to check that you are healthy • If everything goes well, you are able to take part in the study and receive the vaccines
	For how long will children be part of the study?	[insert relevant details] • 1 year • You will have to visit the clinic 9 more times over the course of 1 year • Children aged 1 year old will visit the clinic 10 times
	Do people have to take part?	• Taking part in the study is purely voluntary. Nobody will force you • Likewise, volunteers can stop being a part at any time of the study
	Who makes the decision to part in the study?	• The parent or legal guardian should say they agree • For children aged 7 years and above old, both the parent and the child should say they agree • In younger children, aged 1 to 6 years old, the parent or legal guardian will decide on behalf of their child

	Do children or their parent get paid to take part in the trial?	• No • The trial will only provide compensation for time and transport • [INSERT AMMOUNT] for scheduled visit and [INSERT AMMOUNT] for unscheduled visit • The parent and child will receive this amount of money each if the parent accompany the child to the clinic • Children below 7 years old will receive [INSERT AMMOUNT] for scheduled visit and [INSERT AMMOUNT] for unscheduled visit
	Do parents need to accompany their children to every visit?	• Yes, parents must attend the clinic at every visit with their child if their child is aged under 12 years
	What happens if a child gets sick?	• The child or their parents should call the emergency telephone number any time of the day or night, including at weekends • The trial will provide medical care • Children can also take their routine vaccine
BLOOD TAKING	Why does the study team needs to take blood?	• To check that the person is healthy • To check how the vaccine is working on the body • The amount of blood taken will be less than it was for adults • The amount of blood taken will not cause harm to the child

5. Trial Drama: Adolescents

V1

ACT 1 SCENE 1

(Fatu was singing while walking to the stream to wash when Pa. Jakato came out of the bush to play a love trick on her, coming from behind her quietly and covering her eyes with his two hands.)

Fatu – Who is this please?

Pa. Jakato – *(he whispers in her left ear)* Guess.

Fatu –Oooooh my God! I am not good at guessing.

Pa. Jakato – *(in a whisper again)* Just try.

Fatu – *(she smiles)* okay…… Pa. Jakato. It's you.

Pa. Jakato – How do you know?

Fatu – From your voice.

Pa. Jakato – So you mean you can now tell my voice?

Fatu –Yes! Even in the midst of other voices I can tell your voice.

Pa. Jakato – *(laughing and hugging Fatu)* Fatu let me now join you so that we can go to the stream and wash together.

Fatu – It's fine, let's go. Let me don't forget, Pa. Jakato. The teachers of Abu's school called us as parents to a meeting - the Trial team want to tell us about wanting to test the Ebola vaccine on our children to know if the vaccine will also work in children.

Pa. Jakato – You know Fatu, you've taken this Ebola vaccine, is that not so? Just look at yourself, what have you benefited?

Fatu –I have benefited a lot.

Pa. Jakato – *(He laughs loudly)* Then what have you benefited which I know nothing about?

Fatu – Okay, you don't understand. Let me explain things to you.

Pa. Jakato – *(He smiles and shakes his head.)* I'm waiting my dear. Come on, tell me.

Fatu – To start with, I have benefited by knowing my health status. You've not been responsible for my health throughout this year because the Trial study have been taking care of my health…

Pa. Jakato – *(Angrily.)* Shut up! Now listen and listen well, I don't care about whatever they've done for you. My son's blood will not be drained to death and my son will not take that Ebola vaccine for any reason of yours. Do I make myself clear?

Fatu – *(Fearfully)* Yes Sir. *(They leave for the stream)*

ACT 1 SCENE 2

(Pa. Jakato and Fatu return home. They meet their son Abu, sitting alone on the veranda, placing the elbow of his right hand on his leg and supporting his head with the same hand by holding his cheek. From a distance Fatu sees her son and calls his name twice but Abu does not respond to his mother's call, it's only for the third time of calling his name that he hears her. Abu turns and sees his parents coming; he gets up, laughing, and runs to welcome them.)

Abu –Welcome Papa and Mama

Fatu – Abu, why were you sitting like an orphan? What is your problem? *(Abu does not say a word to his mother).*

Pa. Jakato – Why were you so sad my son?

Abu – *(He answered)* Papa, I am worried about you and Mama will allow me to take the Ebola vaccine.

Pa. Jakato – *(Angrily).* Do you think it's good to take that Ebola vaccine?

Abu – *(Sadly).* But Papa, Mama took the Ebola vaccine and nothing happened to her.

Pa. Jakato – *(Angrily).* I know that your mother has convinced you. But I don't want to hear anything about this Ebola vaccine in this compound, ever again. (He left angrily).

Fatu – Abu my son, your father does not want you to take this vaccine and we have no choice but listen to him.

Abu – *(Crying).* But Mama, why is Papa not allowing me to take this vaccine?

Fatu – My son, he has a lot of wrong feelings about the vaccine. I have tried talking to him but he cannot understand me.

Abu – But Mama…….

Fatu – *(She interrupts).* Listen Abu, whatever God has destined will surely come your way. Okay? *(Abu answers "Okay" and they go into the house).*

ACT 2 SCENE 1

(Abu comes out of the house and sits on a bench in the front of the house singing a song in a broken voice. Mr. Kamara passes by the house and stops in order to check that Abu is OK.)

Abu – *(In a broken voice he sings.)*

Udat go listen mi?

Udat go kam now to mi help?

Udat go listen mi?

Udat go kam now to mi help?

Udat go listen mi…… Udat go kam now to mi help?

Udat go listen mi?

Udat go kam now to mi help?

Udat go listen mi?

Udat go kam now to mi help?

Udat go listen mi…… Udat go kam now to mi help?

Mr. Kamara – *(He stands for a while listening and looking at Abu.)* Good afternoon young boy.

Abu – Good afternoon Sir.

Mr. Kamara – How are you?

Abu – I am not fine.

Mr. Kamara – I can tell from your voice. My name is Mr. Kamara, and you?

Abu – My name is Abu Turay.

Mr. Kamara – What is your problem Abu?

Abu – Mr. Kamara, my father does not want me to take the Ebola vaccine. Mama tried talking to him but he will not listen to her.

Mr. Kamara – But Abu, why do you want to take the vaccine?

Abu – I want to know my health status but I also want to contribute to the success of the vaccine and to help my community, my country and the world in finding a prevention for Ebola.

Mr. Kamara – *(When he heard the words of the small boy he wildly open his eyes in astonishment and said.)* That is good Abu; I will see what to do in relation to that. Okay? *(Abu answered by nodding his head*). Get inside - let me go and talk to the Chief and I will see you later. *(Abu goes inside with hope and Mr. Kamara goes to see the chief.)*

ACT 2 SCENE 2

(The Chief King Kobloo is sitting on his veranda talking to his children about the importance of education when Mr. Kamara enters and greets him.)

Mr. Kamara – Good afternoon to this house.

Chief King Kobloo – Good afternoon, how are you?

Children – *(Together)* Good afternoon Sir.

Mr. Kamara – Good afternoon my children, how are you doing?

Children – We are fine.

Mr. Kamara – That's good my children. *(The children enter the house, leaving their father and Mr. Kamara to talk.)* Chief I am fine, and you?

Chief King Kobloo – My brother, this hot burning sun is too much…

Mr. Kamara – Chief, the sun is hot everywhere in the country.

Chief King Kobloo – I thought you that are educated do not feel the rays of the sun.

Mr. Kamara – Chief, this is a national problem. *(Chief nods his head.)* Anyway, Chief, I am here from Trial.

Chief King Kobloo – You are welcome. And what is the purpose of your visit?

Mr. Kamara – Pa. I want to have a meeting with you and your community people. We came here the last time to tell you its importance while we were studying the vaccine in adults so I also want to come and explain to your people the reasons why we would also like to test this Ebola vaccine in children.

Chief King Kobloo – That's fine. When do you want to have the meeting with us?

Mr. Kamara – Chief, will tomorrow morning at 8am be fine for you?

Chief King Kobloo – It's okay, let me call on the town crier to inform the people.

Mr. Kamara – Thank you Chief.

Chief King Kobloo – You are welcome. *(They say goodbye to each other; Mr.Kamara leaves before the Chief enters his house).*

ACT 3 SCENE 1

(It is the following morning. The community people, including Mr. Kamara, are now gathered at the Chief's compound to hear more information about the Trial study.)

Chief King Kobloo – *(He stands up and clears his throat.)* Good Morning to you all. May God bless us all. *(Everybody answers AMEEN!)* Let us begin by asking for the presence of the Almighty God. So, let's stand and pray individually. *(After the prayers he asks them to sit down and thanks everybody for answering to his call. He then asks Mr. Kamara to give them the information which he has for them.)*

Mr. Kamara – Good morning Chief. Good morning my good people. I believe most of you have heard about Trial; we are testing a new Ebola vaccine in [INSERT LOCATION] 1, [INSERT LOCATION] 2 and [INSERT LOCATION] to see if this new vaccine will help prevent Ebola. We've studied this vaccine in nearly 450 adults in [INSERT LOCATION] and there have been no serious problems. However, if this

vaccine works it will not be allowed to be used in children unless we also study it in children so this is what the Trial study would like to now do.

Pa. Jakato -- Yes! I have a question to ask you? Look at my boy. *(He points at his son Abu Turay.)* He is 15 years old now. Would you allow him to participate without even asking me?

Mr. Kamara – Thanks for that question. Anybody who is below 18 years does not have the right to decide for him or herself alone because the laws of our country still see that person as a child. You will have to sign a form saying that you agree for Abu to be part of the study.

Fatu – Let me also ask this question. You know that I have taken the Ebola vaccine and nothing happened to me, but maybe we were old enough to take the vaccine and that was why it did not affect us. Our children are young, how will we know that it won't affect them? *(Everybody answers Yes! Yes! Yes! at random).*

Mr. Kamara – I know a lot of people will have this fear. Let us listen very well. We've tested this vaccine on adults with no major problem. The safety of children in the study is the trial team's top priority. They have lots of doctors and nurses working for them so any child will be looked after very well.

Fatu – Let me ask also. How about the blood that they are going to take, will it be the same amount as they were taking from us?

Chief King Kobloo – I was about to ask the same question. Pa. Kamara, are they going to take a lot of blood from the children like they were taking from the adults?

Mr. Kamara – Thanks Fatu and Chief for that question. No, it will not be the same amount of blood that was taken from the adults. The amount of blood will depend on the age of the child. The younger they are, the less blood they will give. Giving this amount of blood should not cause your child any problems, the amount is much less than the blood that you usually donate at the hospital. Your body makes new blood all the time, like if you cut yourself, your body will create more blood to replace the blood you've lost. We take this blood as it is the only way to know if the vaccine is working in the body.

Pa. Jakato – *(His son Abu stood up and raise his hand to talk but he shouted at him by saying.)* Sit down! Look at how small you are. How can you want to talk when elders are talking?

Chief King Kobloo – *(Becoming angry.)* Pa. Jakato, I do not expect that from you. You were there when we had the meeting about starting to allow our children to be involved in decision making. Let's also allow them to be asking questions - it will help in the development of the homes and our community. *(Pa. Jakato apologises to the chief.)* Abu my son, please ask your question.

Abu – How are we going to benefit if we take the vaccine?

Mr. Kamara – That is a nice question. You are a clever boy. Abu, if you join the study you will be able to check your health, if the vaccine works then you might be

protected from Ebola and you will have helped your community, country and the world to help find a prevention for Ebola.

Fatu – But I have a concern - do people whose age is under 18 years have to use contraception in order to join the study?

Mr. Kamara – It is very important that somebody who has recently taken the vaccine does not become pregnant. Therefore, anybody who is sexually active and is not using contraception cannot take part in the study. The study team cannot recommend contraception for any male or female if they are less than 18 years old without their parent's permission. However, if somebody is sexually active and is already taking contraception then they may be allowed to take part in the study if they are happy for their parents to know and if they are otherwise OK.

Pa. Jakato – Wait oh! Are you going pay the children for taking part in the study? And do we have to accompany our children at every visit to the clinic?

Mr. Kamara –The children are not going to be paid for taking part in the study - we are not forcing anybody; if anybody wishes to take part, let it be done voluntarily. You don't have to come with your child after the first visit is complete, but you can accompany your child if you wish – that is for you to decide as a parent.

Pa. Jakato – Fatu, let us register Abu so that he will benefit too. I wish I had another child. And please, I want to know - I did not take the vaccine when you were giving the vaccine to adults, can I take the vaccine now?

Mr. Kamara – No, I'm sorry Pa. Jakato but we are now finished with giving the vaccine to adults. This next stage is for people who are below 18 years only. *(Pa. Jakato shakes his head in disappointment because he had wanted to take the vaccine now, but it's too late for him.)*

Fatu – Abu come and give your name *(Abu laughs and thanks Mr. Kamara.)*

Chief King Kobloo – I will also register my children. *(Everybody in the community is happy and give their children's names to Mr Kamara. They thank the Chief and leave for their houses).*

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