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"We are the heroes because we are ready to die for this country": Participants' decision-making and grounded ethics in an Ebola vaccine clinical trial

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ABSTRACT

The 2014–2016 Ebola epidemic presented a challenging setting in which to carry out clinical trials. This paper reports findings from social science research carried out in Kambia, Northern Sierra Leone during first year of an Ebola vaccine trial (August 2015–July 2016). The social science team collected data through ethnographic observation, 42 in depth interviews; 4 life narratives; 200 exit interviews; 31 key informant interviews; and 8 focus group discussions with trial participants and community members not enrolled in the trial. Whilst research often focuses on why people refuse vaccination, we instead explore participant motivations for volunteering for the study, in spite of prevailing anxieties, rumours and mistrust during and after the Ebola outbreak. In so doing the paper contributes to on-going debates about research ethics and community engagement in resource poor contexts, offering reflections from an emergency and post-epidemic setting. We analyse participants' perceptions of the risks and benefits of participations, highlighting the importance of a contextual approach. We focus on four types of motivation: altruism; curiosity and hope; health-seeking; and notions of exchange, and argue for the role of social science in developing grounded research ethics and community engagement strategies that can take into account context and local realities.

1. Introduction

The 2014–2016 Ebola epidemic in Guinea, Liberia and Sierra Leone was the largest in history, with over 14000 cases and approximately 4000 deaths in Sierra Leone alone (Centers for Disease Control and Prevention (CDC), 2016). At the time of the outbreak, there was no licensed vaccine or treatment available for Ebola, leading to the rapid establishment of clinical trials of experimental products. The time pressure under which researchers had to work was complicated further by limited research experience in the affected countries, and a protracted history of structural violence having eroded trust in both national and international organisations across the region (Wilkinson and Leach, 2015).

As the disease spread, reports were rife of community resistance to medical intervention, mistrust of healthcare facilities, and stigmatisation of health workers and survivors (Chandler et al., 2015; Fairhead et al., 2006). Rumours spread about the potential origins of the disease, including political conspiracies and international blood-stealing cartels (Bolten and Shepler, 2017; ICG, 2015; Leach, 2015). In a time of uncertainty, the establishment of clinical trials for experimental treatments and vaccines raised significant challenges for researchers and community engagement teams.

In this paper, we report findings from anthropological research carried out during an Ebola vaccine trial, EBOVAC-Salone, based in Kambia, Sierra Leone. This trial, funded by the Innovative Medicines Initiative, is evaluating the safety and immunogenicity of the Ad26.ZEBOV/MVA-BN-Filo prime-boost Ebola vaccine regimen in an affected population. Enrolment of healthy adults into a small, open-label initial stage of the study took place in October 2015. In March 2016, enrolment began into a randomised, controlled study stage, which first recruited adults before recruiting adolescents and lastly children aged 1 year and older. The discussion in this paper is based on

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research carried out in Kambia between August 2015, as the trial was being set up and as the epidemic was on-going but reaching its final stage, and July 2016, as the second stage of the trial had begun for adult participants and four months after the last official declaration of the end of the epidemic. Through ethnographic methods, interviews and life narratives, we explored the subjective experiences of participants in the early stages of this trial. We asked why, in an environment of fear, rumours and mistrust, Kambians volunteered to take part in the trial. The aim of this paper, therefore, is to analyse participant motivations for volunteering for an Ebola vaccine study, and to consider the implications of such motivations for clinical research ethics and community engagement in trials in low-resource settings.

Although research on motivations for healthy participants to volunteer in clinical trials has been limited, particularly in developing countries (Stunkel and Grady, 2011), there is a growing body of work on community engagement and research ethics in resource poor settings (Leach et al., 1999; Molyneux and Bull, 2013; Molyneux and Geissler, 2008). This literature has pointed to the complexity of context-specific social and economic factors that shape the experience of participants in clinical research and therefore the practical implications for seeking consent against this backdrop. In particular, a number of studies have pointed to the "subjective experiences of social and economic constraints on voluntariness" and the ways in which "inequalities and social power permeate all community engagement and consent activities" (Molyneux and Bull, 2013, p. 5; 10). There is also some evidence around decision-making in clinical research, including for example a number of studies that show the importance of access to healthcare in mothers' decisions to enrol their children in clinical studies in countries with limited service availability (Mtunthama et al., 2008; Nabulsi et al., 2011). We hope to contribute to this burgeoning literature by offering reflections from the context of an epidemic and emergency outbreak response.

Decision-making lies at the foundations of research ethics and how we think about informed consent. The essence of research ethics standards since their inception has been the notion that people should "not only decide freely whether to participate in clinical research, but decide with an understanding of the relevant facts" (Flory et al., 2008, p. 645). On-going debates in bioethics also address the basis of decision-making in terms of the implications of the potential "misconceptions" or "misestimations" of clinical study participants (Horng and Grady, 2010; Kimmelman, 2007). Similarly, strong disagreements about whether participation in medical research ought to be remunerated or even considered as a form of labour—most starkly represented in the title of Dickert and Grady's (1999) provocative paper, *What's the Price of a Research Subject?*— reflect a preoccupation with the ethical implications of the motivations for taking part in clinical studies. These questions underpin the broader concern with how we define the social value of research and how this can be determined empirically (Rid and Shah, 2017).

Existing literature on immunisation programmes and risk communication also offers a useful framework for thinking through motivations. This body of work has focused in particular on the determinants of "vaccine hesitancy" along three domains: confidence (trust in the product and the provider), complacency (perception of need for the vaccine) and convenience (access) (Larson, 2013). Recent attempts to measure hesitancy to take vaccines across contexts have shown that confidence is the primary factor (Larson et al., 2015). In particular, intentions to take vaccines, especially newly introduced ones, have been found to correlate with trust in the broader healthcare system (Larson et al., 2015; Marlow et al., 2007; Ozawa and Stack, 2013). An emphasis on confidence in the context of vaccination campaigns highlights the need to engage with the concept of risk.

Over the years, scholars have increasingly asked for risk communication to take into account the social construction of risk (Larson et al., 2012; Slovic, 1994; Hobson-West, 2003; Abraham, 2009; Beck, 1992). This means firstly considering how different systems of knowledge, and varying levels of trust in the sources of information provided, influence individual assessments (Hobson-West, 2003). In addition, it entails an appreciation of how risk is publicly perceived. Slovic (1994), for example points to a crucial mismatch between expert assessments of risk (measured for example by expected fatalities) and public perceptions of "riskiness" which rely on a much richer combination of assessments, including familiarity with the type of accident, the threat posed to future generations and so on. A train wreck that could kill hundreds of people may be perceived as less of a risk than terrorist attacks with far fewer victims. Similarly, Beck (1992) suggested that perceptions of how risk is distributed across society matters for how messaging around risk is received. These insights show that social, cultural and political dimensions of risk perception must be central to how we understand public attitudes to health interventions.

When transposed to the context of clinical studies during a complex emergency such as that produced by the Ebola epidemic in West Africa, these issues take on particular salience and raise questions for the ethics of medical research during outbreaks. Understanding why participants in the EBOVAC-Salone trial decided to put themselves forward to take an experimental vaccine during a time of uncertainty, despite significant ambivalence towards external intervention, and in a region with limited experience of medical research, thus presents an opportunity to revisit these questions in an empirically grounded manner. In so doing we build on existing literature on research ethics in resource poor settings to consider how experiences with an unprecedented emergency in West Africa can contribute to growing calls for ethical approaches that can take social, political and economic contexts seriously.

Whilst it may seem obvious why people would opt to take part in a study of a vaccine to protect from Ebola in the immediate aftermath of a deadly epidemic, we show that in fact the value of research and vaccination in a context of high levels of mistrust was socially contested. Indeed, as we have previously shown (Enria et al., 2016), the value of qualitative research alongside a clinical trial can help show how contextual factors shape perceptions of and attitudes towards biomedical interventions, including perceptions of risk that may be counter to those of clinical risk assessments. Taking subjective assessments seriously then, not only helps us understand possible tensions between clinical and social ethics but also to see what determines participation in a vaccine trial where vaccine hesitancy is prevalent. Our aim is not to assess the quality of informed consent on the EBOVAC-Salone trial on its own terms. Instead, we hope to show how, by taking into account individual participants' reflections on their motivations for joining a clinical trial in a post-epidemic setting, we can contribute to the development of a "grounded ethics" framework cognizant of local realities, and to suggest what the implications might be for community engagement for clinical research in developing countries.

Our approach stems from the anthropology of medical research, which explores social critiques and understanding of "postcolonial techno-science" (Fairhead et al., 2006). Through the lens of social narratives about science, anthropologists of clinical trials have shown the different "cultural worlds and material concerns" of researchers and communities hosting research (Fairhead et al., 2006). Applying this lens to the Ebola crisis and its aftermath, we show how EBOVAC-Salone participants' articulations of their motivations to join the trial were framed around socially shared and collectively negotiated meanings that were often external to the clinic.

After a methodological discussion, we explore the significance of rumours and mistrust in Kambia during and after the Ebola epidemic. This contextualizes participants' decision-making and lays the foundations for an analysis of how their perceptions of risk were shaped by history and social engagements with the epidemic. We then outline the four main motivations reported by vaccine trial participants: altruism; curiosity and hope; health seeking; and exchange. The paper concludes with reflections on how examining participants' decision making presents opportunities and challenges for research ethics grounded in