

SEEING IS BELIEVING: TRIAL REGULATIONS VS. COMMUNITY ENGAGEMENT IN AN EBOLA VACCINE TRIAL

FACILITATOR'S NOTES

The story, set in the context of an Ebola outbreak, focuses on the difficulty of balancing internationally agreed protocols with demands in the field and the nature of social relationships between local staff and community members. Ethical guidelines can often feel detached from the realities of everyday interactions and can put staff working on clinical trials in difficult positions when the demands of the trial run counter to those of social relations on the ground. There are three key issues to be explored in this case study.

The first has to do with the fact that employees in an Ebola vaccine trial are not allowed to take the trial vaccine. The study coordinator calls this the 'conflict of interest rule.' The idea behind this is that employees may feel pressured to take the vaccine that their employer is trialing, and this would put in question the voluntary nature of their participation. In the context of an outbreak, this restriction for local staff inevitably raises concerns that do not arise when clinical trials are being done outside of epidemic settings. The case study thus requires the reader to think about how standardised ethical protocols may present different questions depending on the context in which they are taking place.

Secondly, the market trader's insistence that 'seeing is believing', brings up the issue of trust and social relations. The fact that two trial staff, John and Jane, are from the community where the trial is taking place and that, Hawa the market trader, is Jane's mother in law should lead us to reflect on the complexity of social relationships and the challenges faced by local staff when attempting to navigate the difficult terrains of community engagement in vaccine trials.

LEARNING OBJECTIVE

To explore the challenges of balancing the demands of internationally agreed protocols with demands in the field during an epidemic

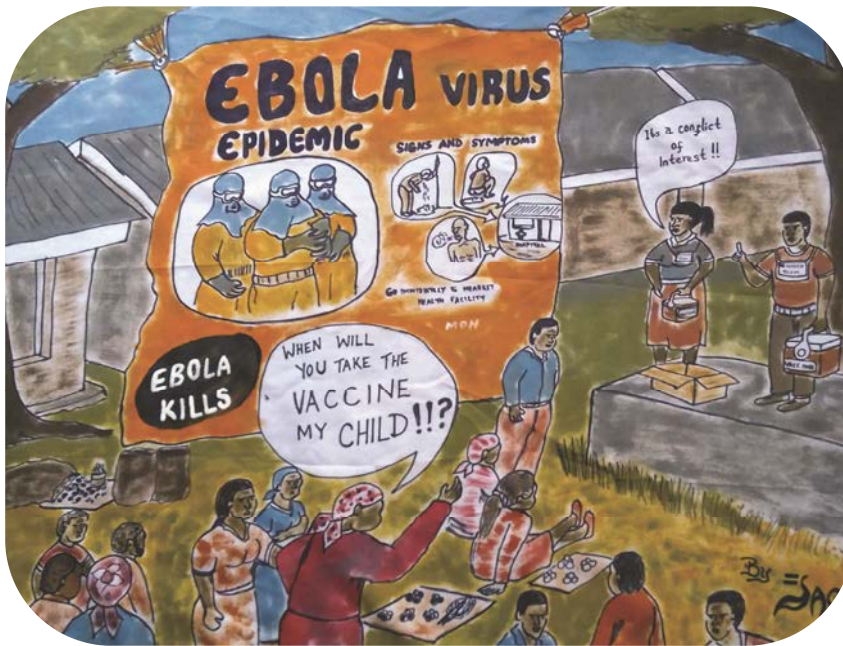
KEYWORDS

Rumour
Study rules
Recruitment
Community-based
fieldworkers
Community
engagement
Outbreak

Community members' concerns with the fact that local trial staff cannot take the vaccine should also prompt the reader to think through motives for participating in vaccine trials and the prominent role played by social relations and trust in community members employed by the study - especially under conditions of an outbreak or emergency.

Finally, the emergence of a rumour surrounding the potentially sinister motives of the vaccine trials depicts how anxieties surrounding vaccine trials - amplified by an epidemic – can be articulated through hearsay and how they can be understood as products of fears and mistrust. Furthermore, Jane's difficult personal experiences and her suggestion that perhaps she ought to lie about her ability to take the vaccine also suggest the very real worries that rumours create amongst trial staff both in terms of their potential impact on the running of the trial itself but also, and more importantly, in terms of the damage that they may cause to social relationships that will outlive the presence of the trial in the community.

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'WHEN WILL YOU TAKE THE VACCINE MY CHILD?!'

THE STORY

John and Jane are community liaison officers in an Ebola vaccine trial taking place in the middle of an Ebola epidemic. Because they are employed by the trial, John and Jane are told by their managers that they cannot receive the vaccine candidate, as it would constitute a conflict of interest¹. They are not entirely sure what this means. Despite their concerns about contracting the disease and their disappointment about not being able to receive the vaccine, John and Jane decide that they really want to be involved in the fight against the virus in their own community, and continue to work for the project.

As the trial gets underway, John and Jane are asked to organize community meetings to introduce the vaccine and to explain the modalities of the trial, including the fact that

participation is entirely voluntary. Their first meeting is with a group of market traders and is held in the hall of the town's market. After having given a short presentation about the trial, John and Jane open up the floor for questions. The first to ask a question is Hawa, the leader of the market traders – and Jane's mother in law. Hawa asks when the traders can expect to see Jane, John and all of their colleagues receiving the Ebola vaccine. "Seeing is believing", she adds, and says that once they have seen them take the vaccine publicly, people in the town will feel more confident in taking part in the trial. Jane and John look towards their supervisor, who nods to suggest they must tell the audience about the conflict of interest rule that prevents them from taking the vaccine. Once they have finished explaining, Hawa asks: "But you are our children, how do you expect us to take this if you won't?"

A few days after the meeting, rumours begin spreading that the trial vaccine is a slow poison, which will infect those who take it with Ebola to cause another epidemic in a few years' time. This, the rumour goes, is the reason why trial staff will not take the vaccine publicly. The study coordinator calls John and Jane to a meeting to discuss ways of addressing these concerns. At the meeting, Jane tells the coordinator about the market trader meeting, and that her mother in law has stopped talking to her and that people in her compound no longer trust her. She asks if they can tell the community that trial staff will in fact be allowed to take the vaccine in the near future.

QUESTIONS

1. What are the ethical issues at stake?
2. What do you think is the 'conflict of interest' alluded to that excludes staff from receiving the trial vaccine?
3. What do you think about the decision of excluding staff from the trial during an epidemic? Do you agree or disagree? Why?
4. Why do you think it was so important to Hawa that Jane and John take the vaccine in front of community members? Do you think it is fair of Hawa to expect Jane and John to take the vaccine?
5. How can we explain the rumours emerging in town after the meeting with the market traders?
6. What do you make of Jane's suggestion that she tells the community staff will take the vaccine later? Why do you think it is important to her that the community thinks she will be taking the vaccine at a later stage?
7. What are the possible responses the study coordinator could give to Jane's idea?

REFLECTIONS ON YOUR OWN EXPERIENCE

- 2 Have you experienced anything similar? How have you dealt with the possibility of losing community members' trust?
- 2 Can you think of any other examples where the trial's regulations come into conflict with local staff's commitments to their communities?
- 2 What are the key ethical differences between a trial under outbreak conditions and a routine trial on prevention or treatment of endemic disease?

ACTIVITY

Divide into groups of 4 and devise a community liaison strategy for countering rumours that the vaccine is slow poison and a communication strategy around why trial staff are not allowed to take the vaccine.

FURTHER READING

Marsh, V., Kamuya, D., Mlamba, A., Williams, S., Molyneux, S. (2010) Experiences with community engagement and informed consent in a genetic cohort study of severe childhood diseases in Kenya. *BMC Medical Ethics*, 11-13.

Global Campaign for Microbicides (2004) *Mobilization for Community Involvement in Microbicides Trials: A Report from a Dialogue in Southern Africa*. Washington DC, USA. Accessed 27th June 2016: <http://www.global-campaign.org/clientfiles/SA-community-involvement.pdf>

Larson, H., Cooper, L., Eskola, J., Katz, S., Ratzan, S. (2011) Addressing the Vaccine Confidence Gap. *The Lancet* 378:9790, 526–535.

Hantel, A., Olopade, CO. (2015) Drug and Vaccine Access in the Ebola Epidemic: Advising Caution in Compassionate Use. *Ann Intern Med* 162, 141-142.

ANTHROPOLOGY AND EBOLA WEB RESOURCES

The Ebola Response Anthropology Platform: <http://www.ebola-anthropology.net/> . Accessed 27th June 2016.

Series of anthropological blogs on Ebola: <http://somatosphere.net/series/ebola-fieldnotes> . Accessed 27th June 2016.

Anthropology and Ebola Communication page on the Ebola Communication Network website: <http://ebolacommunicationnetwork.org/anthropology-and-ebola-communication/> Accessed 27th June 2016.