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Title: Ethics of conducting research during disease outbreaks – perceptions and recommendations from policy makers in Nigeria.

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Background

In the aftermath of the Ebola virus disease outbreaks, a number of manuscripts, abstracts and reports from consultations were published discussing ethical issues when conducting research in such situations. WHO also published a guidance document to support community engagement practices, a more overarching a guidance on how to best conduct ethical research in outbreak situations; with an article reporting the experiences of WHO in the review of studies during the Ebola epidemic in West Africa. There is however, little account of the perceptions, experiences and considerations from policy makers and RECs in the Ebola affected countries on their roles, capacities and other issues related to ethical conduct of research during disease outbreaks.

Methods

We conducted focus group discussions with policy makers involved in disease outbreak response in Nigeria. We documented their perceptions, experiences and recommendations on current institutional capacities, needs and the ethics review system to facilitate the conduct of research during disease outbreaks in Nigeria. A professional transcriber transcribed responses manually. The transcripts were grouped according to predetermined themes and analyzed as such by one investigator. The grouping and analyses were validated by a second investigator. Other investigators reviewed and approved the final analyses.

Results

Six FGDs with policy makers from National Primary Health Care Development Agency, Nigeria Center for Disease Control and Prevention, Nigeria Field Epidemiology and Laboratory Training Program were conducted.

Ethics review capacity and process - Policy makers felt that although there was a good system for ethics review in Nigeria, “*a fast track review*” system was necessary – “*to prevent excess mortality and morbidity*”. Where clinical trials are considered, the importance of taking “into consideration the perceptive[tion] of the people *including rumors, and other*” things that will militate against the investigation “*being proposed*” was emphasized, using a sort of “*baseline assessment of the community*”. However, the need to further build capacity of the ethics review committees and ensure they have needed resources including access to experts were recommended.

Systems and resources to conduct research during outbreak situations - Having in place, a framework for ethical conduct of research during disease outbreaks was recommended; arguing that, “it is unethical to lose the opportunity of *doing research during* outbreaks. Institutions like the NCDC and the National Health Research Ethics Committee (NHREC) can help facilitate advance preparation for ethics review committees, as well as mobilization of human resources,

policy makers, development of communication, and narratives that can quickly tell people about the risks and opportunities and the benefits of research during outbreaks.

There was a general perception of availability of competent professionals to serve as principal investigators or co-principal investigators (in international collaborative research situations). However, there is still a need for capacity strengthening of local researchers as a significant proportion have had limited experience due to limited research funding and opportunities. Policy makers considered the work of the NFELTP in producing a crop of experts in field epidemiology and its collaboration with the NCDC in the 2014 ebola outbreak response as a model for sustainability in promoting and conducting research during disease outbreak situations.

Importance of conducting research during disease outbreak - Policy makers opined that “research in outbreak situations is important”, because among other things... “beyond describing the magnitude of the outbreak” policy makers “are also interested in knowing the risk factors of the outbreak and what caused the outbreak”. In public health, emergencies, you cannot successfully stop an outbreak without evidence, researches.

The types of research studies needed however should be “determined by the situation”. *For diseases with known* “vaccines or established therapeutic regimen (like Meningitis) the priority will not be to test a new drug or a new vaccine. Rather studies to know the risk factors, why is it happening now, why is it happening in this place, why are more people dying, why is the morbidity rate higher than usual...are what would be priority”. “But if we had an outbreak on something like Ebola or some other disease or an emerging disease that doesn’t have established regimen and we have some candidate *drugs/vaccine*, clinical trials may be necessary.”

To ensure that research is integrated into outbreak responses and does not interrupt the response in the process, policy makers recommended the inclusion of “a research pillar as part of the incidence command system or an emergency operation center”.

Conclusion: Policy makers involved with disease outbreak response are supportive of research during such situations. They recommend specific guidance for fast track review, strengthen of RECs and the inclusion of research as a key pillar in the outbreak response command system as key strategies to promote ethical conduct of research during disease outbreak situations.