Report

Training meetings for Ethics Committees members in West Africa on Emerging and Re-emerging infectious diseases epidemics

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1.0 Context

The events following the recent Ebola outbreak in West Africa highlighted the limited competency of IRBs in West Africa to handle clinical trial protocols including protocols that had to do conducting research during an infectious disease emergency. Yet the management of the epidemic was associated with lots of ethical issues, which were not only related to the research design but also the implementation of the research. It is therefore imperative to build the capacity of ethics committee to thoroughly handle and or review research protocols irrespective of the challenges they face. Critically, it was important to learn how to recognise the potential challenges with research protocol review, learn how to address them and build competency to conduct credible research protocol reviews irrespective of the complexity of the research protocols. At the same time, there is a need to share experiences in the management of ethics issues during the Ebola outbreaks. Many members of ethics committees in West Africa have expressed the need to share their experiences during the Ebola outbreak.

In view of the identified needs, the West African Task Force for the Control of Emerging and Re-emerging Infectious diseases (WATER), led by Prof Souleymane Mboup initiated the process of bringing together members of ethics committees in the countries affected by the Ebola epidemic in West Africa to address some of these gaps. The meeting served as both a training and consultative meeting. The meeting was help in Dakar from the 25th to the 27th of September, 2017. It was sponsored by OSIWA and technical support was provided by the New HIV Vaccine and Microbicide Advocacy Society (NHVMAS).

There were 24 participants at the three days training and consultative meeting. These included representatives of ethics committees from seven countries of West Africa (Liberia, Senegal, Guinea, Mali, Ghana, Nigeria, Gambia). The training was led by two international experts Dr Morenike Folyan and Dr Oliver Ezechi; and managed by the Scientific Officer of WATER, Dr Elhadji Mbaye.

At the end of each day, participants filled an evaluation to provide feedback on the daily sessions and make suggestions on how to improve the training. Participants also filled an evaluation form for the program on day 3. Participants also share highlights of the days 1 and 2 first thing each day of the meeting.
2.0 Highlights of the training on Day 1

- Clinical trials should prioritize community engagement as part of the study procedure. Community engagement should be considered a process and not an event and evidence of pre-consultations with study participants’ communities looked for.

- Communities should be engaged from conceptualization of the research protocol through to research design and research result dissemination. IRB should review the community engagement process for all clinical trials.

- Civil society must be more involved in the IRB activities in West Africa

- IRBs are extremely important gatekeepers to ensure ethical conduct of research. They also become liable for ethically or unethically conducted research when they give ethics approval. This training highlighted this salient role and responsibility of the IRBs.

- The role of IRBs does not end at ethics protocol review and approval. It includes the monitoring of the implemented protocols to ensure research team adhere to protocols. IRBs should also monitor the impact of the research on the population.

- Capacity building for IRB members on how to conduct research monitoring is essential. Capacity building is also needed for IRB to acquire the skills to manage research protocols they approve throughout the duration of the research.

- The importance of reviewing the CVs of study investigators cannot be over-emphasized. Some principal investigators are simply too busy to adequately play their roles.

- Research is not an emergency. During infectious disease epidemics, the process can be fast-tracked but all due diligence for proper review of the protocol needs to be maintained. This is important as the study participants and the community are important and all efforts needs to be instituted to protect them – their protection is the priority of IRBs.

- The main priority of IRBs is to protect research participants.

- How to determine compensation for research participation remains unresolved? It is important that we identify some fundamental principles that will guide this decision making process taking into context the peculiarities of the sub-region.

3.0 Highlights of the training on Day 2

- The socio-cultural, political, economic and health contexts of West Africa are different from those of other regions. Also, most research conducted in the
region are donor funded. These issues have implications for ways research ethics principles are interpreted and applied in the region. There is the need to harmonize ethics committees’ practices in the region. The HIV epidemic was the impetus for improved ethical practices in research conducted in Eastern and Southern Africa. The Ebola epidemic is and should serve as the impetus for improved ethical practices in research conducted in West Africa.

- Samples and data was a critical challenge during the Ebola epidemic. It is still a big issue of concern. IRBs should resolve to push researchers to invest in countries in Africa to conduct sample and data analysis. Where the need to export samples and data arise, material transfer agreements need to be signed. Customs should also be enabled to monitor sample exports.

- The onus is on IRBs to conduct risk-benefit analysis prior to making the decision about protocol approval and compensation. IRB competency has to be groomed on risk-benefit analysis. The component risk-benefit analysis should consider third parties.

- Protocols reviewers also need to be socially and culturally sensitive to be able to conduct comprehensive protocol reviews.

- The level of care in-country can be improved through the conduct of research. Where there is a need to refer participants for care, an MOU needs to be drawn up with the reference hospital. The MOU should be submitted with the protocol.

- When multi-center studies are being conducted, this should not be a reason not to build country competency. Protocols should be always reviewed to improve local capacity and promote capacity transfer.

- Money is not coercive but can cause undue inducement. Efforts should be made to prevent undue inducement, coercion and exploitation through research.

- Consents should be required for use of stored samples. Blanket consenting raises concerns. Consent forms should include some details of the type of research being planned for future use of stored samples.

- The composition of IRBs is critical. Who makes this decision and how do we prevent political influence on the operations of ethics committees especially where there the research is of national interest?
4.0 Highlights of the meeting on Day 3:

- Protocols whose target populations are vulnerable require full committee review. IRBs must improve the definitions of vulnerable populations and adapt those definitions to country contexts. In the current context, EVD survivors can be classified as vulnerable in West Africa. Research should not increase the vulnerability of participants.

- Informed consent process should be improved in low literate settings. Researchers should be encouraged to develop tools to evaluate understanding during the informed consent process.

5.0 Visit to IRESSEF

After the meeting, participants visited IRESSEF. During that visit, a meeting was held with Prof Souleymane Mboup, lead of WATER about the outcomes and next steps. He congratulated the organizers of the meeting and encouraged participants to institutionalize the formed network and publish their shared experiences in order to give more visibility to WATER. Publications are concrete meeting outcomes.

6.0 Meeting Outcomes

- The evaluation indicated that participants acquired new skills and knowledge from attending the meeting. The networking with other members of IRBs from other countries was very useful as people learnt from discussions about events and operations of ethics committees in other countries.

- All participants are interested to share their experiences in a join publication

- Participants launched the Network for ethics committees operating in West Africa on the 27th of September, 2017. The Network shall serve as a platform for collaboration in the region.

7.0 Recommendations

- Participants must organize step down training in their countries in order to share their newly acquired technical skill with other IRB members. Report of the step down training should be shared with WATER

- WATER must continue to support this network and step down meetings for participants.

- WATER will continue to support the Network of Ethics Committees in West Africa as its technical partner.
8.0. Next steps

➢ This meeting of the Network for ethics committees operating in West Africa was the second of such. The first was organized by WAHO in March 2015. The leadership for the Network was nominated. She would work with identified team members to develop the TOR for operations. The TOR should be ready for dissemination by the 15th of October, 2017. Other officials shall self-elect and shall ensure the sustainability of the Network. Administrative support for the Network shall be provided by WATER. NHVMAS shall provide technical support for the Network.

**Persons responsible:** Ms Gloria Mason, Elhadji, Nicole, Morenike

➢ Training to be stepped down. WATER to support the step down meeting. Each country to send a one pager proposal for the step down training. Financial support can be disbursed to each country based on a proposed program of step down training. The step down could focus on a topic or two of importance that is of country relevance that emanated from the meeting.

**Person responsible:** Elhadji Mbaye

➢ Blogs to be written about the meeting and shared widely with our peers. This is to fast-track the dissemination of the meeting outcomes. The blog will acknowledge the collaboration of NHVMAS for this process.

**Person responsible:** Morenike Folayan

➢ There should be social media dissemination of the meeting and outcomes. Pictures taken at the meeting can be used for the dissemination. People should share pictures, reports and tweets from the meeting.

**Persons responsible:** All participants

➢ A communique should be developed. This should state clearly what the outcomes of the meeting were and what the Network requires of the international community, the regional leaders, country governments, and the IRB ethos for the region. The draft should be ready for circulation by 5th of October, 2017. Final draft should be ready by 8th October, 2017.

**Persons responsible:** Mrs Ishola, Gloria Mason, Dr Newton and Louis

➢ Manuscripts should be developed for possible publications namely (i) history, politics and social context of West Africa and its implications for applying ethics principles for research; (ii) Framework for determining compensation and its applications for research conducted in West Africa; (iii) Legal Authorised Representatives for children and adolescents: implication for ethical practice in West Africa; (iv) priority actions to be taken by ethics committees during review of protocols for conduct of research during emergencies; and (v) ethical research misconduct in West Africa during the Ebola crisis. Manuscripts to be developed over the next one year. The first manuscript should be ready by the end of November.
Persons responsible: Morenike Folayan, Elhadji, Oliver Ezechi

- WATER shall support the participation of some members of the Network to the 2017 Annual Bioethics Forum in Nigeria. A platform shall be created for them at the meeting to discuss about the Network. Meeting scheduled for the 14th and 15th of December, 2017.

Persons responsible: Elhadji and Gloria Mason