Regulating Clinical Trials during an Ebola Emergency: The Liberian Experience

Abstract

**Background** Effective clinical trials oversight is a major function of a fully functional national medical products regulatory system. However, exercising clinical trial oversight in a resource-limited environment is challenging, in particular during an Ebola outbreak or health emergency. Until the devastating Ebola virus disease (EVD) outbreak in 2014, the Liberia Medicines and Health Products Regulatory Authority (LMHRA) had no capacity for effective clinical trial regulation. This presentation describes the main challenges encountered by LMHRA in regulating clinical trials in Liberia during the largest EVD outbreak that affected West Africa in 2014 and 2015.

**Methods** By carefully documenting activities during the EVD outbreak, interviewing key stakeholders, and discussions among the LMHRA clinical trial committee, key challenges observed during the outbreak were identified and documented.

**Results** Limited financial resources, lack of expertise in clinical trials, inaccurate and insufficient information about the functions of the LMHRA, poor coordination among key stakeholders, and the lack of a well-developed regulatory framework, adversely influenced the LMHRA clinical trial oversight performance during the EVD outbreak.

**Conclusion** It is true that several challenges need to be addressed when regulating a clinical trial in a limited-resource environment during any disease outbreak or international medical emergency. However, the importance of building local expertise in clinical trials through mentorship and training cannot be over-emphasised. By taking advantage of grants from developmental partners, national medicines regulatory authorities in resource-limited environments can develop capacity for clinical research oversight.