Ethics, regulatory and pharmacovigilance

PO - (8381) - REGULATING CLINICAL TRIAL DURING AN EBOLA EMERGENCY; THE LIBERIAN EXPERIENCE

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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 limited resource environment especially during an ebola outbreak or Health Emergency is challenging. Until the devastating Ebola Virus Disease (EVD) outbreak in 2014, the Liberia Medicines and Health Products Regulatory Authority (LMHRA) had absolutely no capacity for effective clinical trial regulations. This paper describes the main challenges encountered by LMHRA in regulating clinical trials in Liberia during the largest ebola outbreak that affected West Africa in 2014 and 2015.

Methods: By carefully documenting activities during the ebola 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 resource, the lack of expertise in clinical trial, inaccurate and insufficient information about the functions of the LMHRA, poor coordination among key stakeholders, and the lack of a well-developed regulatory framework, gave rise to challenges that adversely influenced the LMHRA clinical trial oversight performance during the Ebola outbreak.

Conclusions: While it is true that several challenges have to be addressed when regulating a clinical trial in a limited resource environment during any disease outbreak or international medical emergency but building local expertise in clinical trials through mentorship and training cannot be over emphasized. By taking advantage of grants from developmental partners, National Medicines Regulatory Authorities in resource-limited environment can develop capacity for clinical research.