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Abstract

Need for Local Laboratory Reference Values in Recruitment into Studies of Emerging Infectious Diseases: Insight from Participant Screening for an Ebola Vaccine Trial in a Rural African Setting †

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Abstract: Introduction: The EBOVAC-Salone trial of a candidate Ebola two-dose vaccine regimen (Ad.ZEBOV/MVA-BN-Filo) was conducted in a research-naïve setting in rural northern Sierra Leone, where no local laboratory reference values (LRV) had been established. In the first stage (n = 43) of the trial, laboratory screening was based on internationally-derived protocol LRV (PLRV). For postrecruitment participant care, LRV derived from a West African population (WALRV) were used. We assessed what difference using WALRV rather than PLRV for screening might have made to the eligibility of volunteers. METHODS: We reviewed the laboratory screening results of study volunteers. Red blood cells (RBC), white blood cells (WBC), platelets (PTT), haemoglobin, haematocrit, creatinine, and alanine (ALT) and aspartate (AST) transaminases were measured. Overall and for each parameter, we compared the actually eligible proportion of volunteers using PLRV with the potentially eligible proportion using WALRV. **Results**: Of 102 (82 males, 20 females) volunteers, overall 55 (53.9% males) met PLRV eligibility criteria for inclusion, compared with 91 (89.2% males) who were within WALRV normal limits ($p < 0.0001$). Thus, 36 volunteers who failed laboratory screening using PLRV (76.6% of screening failures) might have been eligible if WALRV had been applied. Parameters with significant effect were haemoglobin (33 ineligible by PLRV, vs. 2 ineligible by WALRV; $p < 0.0001$); RBC (27 vs. 1; $p < 0.0001$); and PTT (18 vs. 6; $p = 0.0093$). Levels of creatinine and ALT did not present any differences. **Discussion**: Use of WALRV in eligibility assessment would potentially have led to considerable differences in the baseline laboratory characteristics of enrolled volunteers. Clinical trials are increasingly common and crucial in emerging infectious disease research. Our findings underscore the importance of locally-derived

LRV in clinical trials in sub-Saharan Africa, to avoid excluding potentially eligible study volunteers, and to better support routine clinical care and safety assessments. Appropriately designed studies are needed in each region to establish local LRV.

Keywords: Sierra Leone; Ebola; laboratory; laboratory reference values; clinical trial; participant screening; Africa; Emerging infectious diseases