Field Laboratory Evaluation of the GeneXpert Ebola Assay for Diagnosis of Ebola Virus Disease in Sierra Leone

LATE BREAKER ABSTRACTS

LB-1. Field Laboratory Evaluation of the GeneXpert Ebola Assay for Diagnosis of Ebola Virus Disease in Sierra Leone

Amanda Semper, DPhil[1]; M. Jana Broadhurst, MD, PhD[2]; Jade Richards, BTEC[3]; Geraldine M. Foster, PhD[3]; Andrew Simpson, FRCPath[3]; Elisabetta Groppelli, PhD[3]; Julie Johnson, PhD[3]; J. Dan Kelly, MD[4]; Tim Brooks, FRCPath, FRSPH[1,3]; Christopher H. Logue, PhD[5]; Ann Miller, PhD[2,6]; Megan Murray, MD, ScD[2,6]; Nira R. Pollock MD, PhD[2,7]; [1]Phe Microbiology Services, Rare and Imported Pathogens Laboratory, Porton Down, United Kingdom; [2]Partners In Health, Boston, Massachusetts; [3]Public Health England Laboratory, Port Loko, Sierra Leone; [4]Wellbody Alliance, Kono, Sierra Leone; [5]Public Health England, Porton Down, United Kingdom; [6]Harvard Medical School, Boston, Massachusetts; [7]Boston Children's Hospital, Boston, Massachusetts

Session: 210. Late Breaker Oral Abstract Session
Saturday, October 10, 2015: 10:30 AM

Background. Throughout the Ebola virus disease (EVD) epidemic in West Africa, field laboratory testing for EVD has relied on complex, multi-step RT-PCR assays; an accurate, sample-to-answer RT-PCR test would reduce time to results and potentially increase access to testing. We evaluated the performance of the Cepheid GeneXpert Ebola assay on clinical venipuncture whole blood (WB) and buccal swab (BS) specimens submitted to a field biocontainment laboratory in Sierra Leone for routine EVD testing by RT-PCR ("Trombley assay").

Methods. EDTA-WB (n = 218) and BS (n = 71) specimens were tested with Xpert (targets: GP and NP genes) and Trombley (target: NP gene) assays in parallel. All WB specimens were fresh; 84 of 218 were tested in duplicate on Xpert to compare WB sampling methods (pipette versus swab). Forty-three of 71 BS specimens had been previously frozen.

Results. Seven of 218 (3.2%) WB and 7 of 71 (9.9%) BS samples had invalid Xpert results and were excluded, leaving 211 WB and 64 BS samples with valid Trombley and Xpert results. For WB, 22 of 22 Trombley-positive samples were Xpert-positive [sensitivity 100% (95% CI 84.6–100)] and 181 of 189 Trombley-negative samples were Xpert-negative [specificity 95.8% (91.8–98.2)]. Seven of 8 Trombley-negative, Xpert-positive (Xpert Ct range 37.7–43.3) WB samples were confirmed to be follow-up submissions for previously Trombley-positive EVD patients, suggesting a revised Xpert specificity of 99.5% (97.1–100). For Xpert-positive WB (n = 22), Xpert NP Ct values were consistently lower than GP Ct values (mean difference 4.12, SD = 1.00); Trombley (NP) Ct values closely matched Xpert NP Ct values (mean difference 0.09, SD 1.56). Xpert results (pos/neg) for WB sampled by pipette versus swab were concordant for 78 of 79 (98.7%) WB samples, with comparable Ct values for positives. For BS, 20 of 20 Trombley-positive samples were Xpert-positive [sensitivity 100% (83.2–100)] and 44 of 44 Trombley-negative samples were Xpert-negative [specificity 100% (92.0–100)].

Conclusions. The Xpert Ebola test had excellent performance on WB and BS samples in a field laboratory setting as compared to an established RT-PCR benchmark. Future studies should evaluate feasibility and performance outside of a biocontainment laboratory setting to facilitate expanded access to testing.

Disclosures. **All authors:** No reported disclosures.

Open Forum Infectious Diseases 2015;2:67–70

DOI: 10.1093/ofid/ofv130.1