EVALUATION OF THE XPERT® HCV FINGERSTICK VIRAL LOAD POINT-OF-CARE-ASSAY

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Background:
Point-of-care hepatitis C virus (HCV) RNA testing is advantageous over antibody testing (which only indicates previous exposure), enabling diagnosis of active infection in a single visit. The aim of this study was to evaluate the performance of the Xpert® HCV Viral Load Fingerstick assay (Xpert HCV VL FS) from samples collected by finger-stick capillary whole-blood and the Xpert® HCV Viral Load Assay from plasma samples collected by venepuncture.

Methods:
Plasma and finger-stick capillary whole-blood samples were collected from participants in an observational cohort enrolled at four sites in Australia (three drug treatment clinics and one homelessness service). This study evaluated the sensitivity and specificity of the Xpert® HCV VL FS assay for HCV RNA detection (finger-stick) and the Xpert® HCV Viral Load Assay (plasma) compared with the Abbott RealTime HCV Viral Load assay by venepuncture (reference standard).

Results:
Of 223 participants enrolled, 181 had HCV RNA testing results for the three assays tested. Participants receiving HCV therapy were excluded from analyses (n=16). HCV RNA was detected in 36% ([95% CI 29-44], 60 of 165). Sensitivity of the Xpert® HCV Viral Load Assay for HCV RNA quantification in plasma collected by venepuncture was 100.0% (95% CI 93.9–100.0) and specificity was 100.0% (95% CI 96.5–100.0). Sensitivity of the Xpert® HCV VL FS assay for HCV RNA quantification in samples collected by finger-stick was 100.0% (95% CI 93.9–100.0) and specificity was 100.0% (95% CI 96.5–100.0).

Conclusion:
The Xpert® HCV VL FS test can accurately detect active infection from a finger-stick sample in one hour allowing single-visit HCV diagnosis, representing an advance over current diagnostic algorithms which involve sequential antibody and RNA testing. This advance offers an opportunity to move towards a single-visit HCV diagnosis.

Disclosure of Interest Statement:
The Xpert Finger-stick HCV VL FS cartridge was developed by Cepheid in collaboration with Foundation for Innovative New Diagnostics. The sponsors had no role in the analysis and interpretation of the study results. The views expressed in this publication do not necessarily represent the position of the Australian Government.

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