EVALUATION OF HCV RNA TESTING FROM FINGER-STICK CAPILLARY DRIED BLOOD SPOT AND VENEPUNTURE-COLLECTED SAMPLES: A COHORT STUDY

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Background: Simplified HCV diagnostic strategies to increase testing and linkage to care are needed. Novel collection methods such as finger-stick capillary dried blood spots (DBS) have advantages over standard phlebotomy, especially among people who inject drugs where venous access may be a barrier to testing. The aim of this study was to evaluate the diagnostic performance of the Hologic Aptima HCV Quant assay for the detection and quantification of HCV RNA with finger-stick capillary DBS and venepuncture samples.

Methods: Plasma and finger-stick capillary DBS samples were collected from participants in an observational cohort enrolled at six sites in Australia (four drug treatment clinics, one homelessness service and one needle and syringe programme). We compared the sensitivity, specificity, bias and agreement of the Aptima HCV assay for HCV RNA detection by finger-stick capillary DBS with venepuncture (gold standard). Retesting was performed on samples that had undetectable HCV RNA in plasma and detectable/unquantifiable HCV RNA (<10 IU/mL) in DBS.

Results: Of 175 participants enrolled in December 2016, 164 participants (11 participants on DAA therapy were excluded) had paired viral load results. HCV RNA was detected in 45 (27%) of 164 participants based on the Aptima assay in plasma. Among 38 people with undetectable HCV RNA in plasma and detectable/unquantifiable HCV RNA (<10 IU/mL) in DBS, 32 samples were available for re-testing (all HCV undetectable). Sensitivity for HCV RNA detection in DBS was 95.6% (95% CI 84.9-99.5%) and specificity was 94.1% (95% CI 88.3-97.6%). Sensitivity for HCV RNA quantification in DBS (≥10 IU/mL in plasma) was 100% (95% CI 91.8% to 100%) and specificity was 100% (95% CI 97% to 100%). Finally, a small bias of 0.37 Log_{10} in plasma over DBS (95% CI 0.78-1.55) was observed with good agreement (R^2=0.96).

Conclusion: The Aptima HCV Quant assay can detect active infection from DBS with acceptable diagnostic performance and is clinically comparable to plasma. Repeat testing of HCV RNA detectable/unquantifiable samples suggest that a quantifiable result is a more reliable indicator for active infection.

Disclosure of Interest Statement:
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