4th HEPATITIS C TECHNICAL ADVISORY GROUP

TAG Meeting

EVALUATION OF THE DIAGNOSTIC PERFORMANCE OF THE XPERT® FINGERSTICK HCV VIRAL LOAD ASSAY

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Evaluation of the diagnostic performance of the Xpert® Fingerstick HCV Viral Load (VL) Assay

The Goal

- To evaluate the performance of the Xpert® Fingerstick HCV VL assay in the diagnosis of HCV in different populations and laboratory settings in high-income countries and LMICs using the Abbott RealTime HCV assay as a reference test

The Objectives of the HCV FS study

- Primary objective
  - To evaluate the sensitivity, specificity and quantitation of the Xpert® Fingerstick HCV VL assay for the detection of HCV in capillary and venous whole blood
- Secondary objective
  - To compare the sensitivity, specificity and quantitation of the Xpert® Fingerstick HCV VL assay in capillary and venous whole blood to that of CE IVD Xpert® HCV VL test in plasma.

Xpert Fingerstick HCV VL assay: workflow

Step 1

Collect blood using Minivette®

Step 2

Deposit sample

Step 3

Close Lid

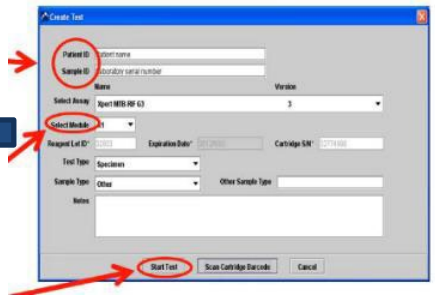
Step 4

Collect blood using Minivette®

Step 5

Collect blood using Minivette®

Step 6



Collect blood using Minivette®

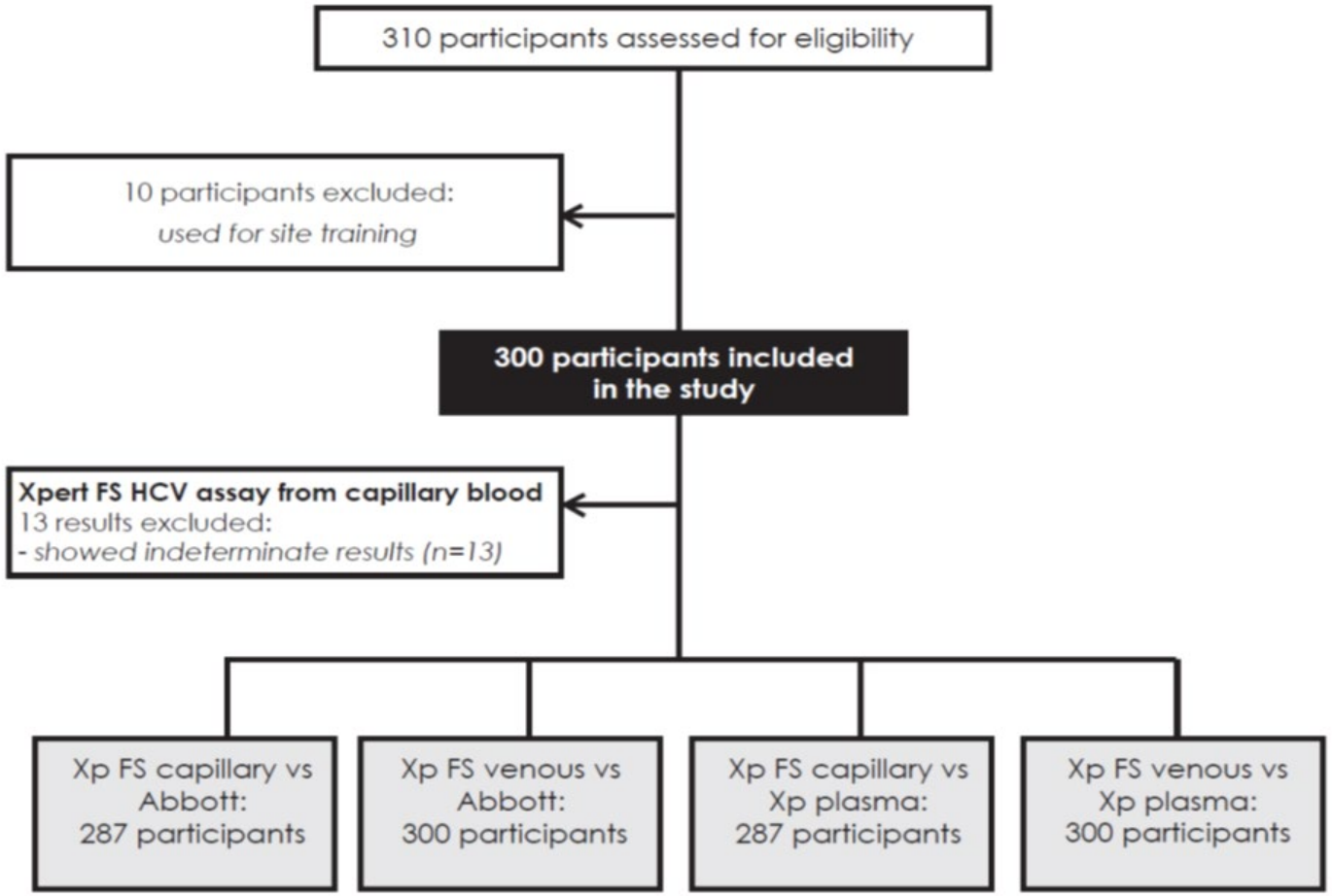
Step 7

Collect blood using Minivette®

Result: ≤ 60 min

Study enrolment overview

Between August 2017 and March 2018 we enrolled 310 participants at Harm Reduction site "Hepa plus"



Participant demographic description

# of participants	300
Age, years	44.8 (22-79)
Female sex, %	15% (46/300)
Other infections	
HIV infection	0.3% (1/300)
Currently on antiretroviral therapy	0% (0/300)
HBV infection	2% (7/300)
Population groups	
HCV seropositives	66% (199/300)
HCV risk	33% (100/300)
Known HCV infection	0.3% (1/300)
Risk factor exposure	
Exposure to unsafe medical procedures	37% (110/300)
Injection of non-prescription drugs	97% (292/300)
Positive HIV test result	0% (0/300)
Born to HCV-positive mother	0% (0/300)
Anti-HCV treatment within past 12 months	
IFN-only	1% (2/300)
IFN/DAA	14% (41/300)
DAA-only	0% (0/300)

Genotype distribution in HCV RNA positive participants

Genotype	%
GT1	42% (62/149)
GT2	4% (6/149)
GT3	30% (45/149)
GT4	0.7% (1/149)
GT5	0% (0/149)
GT6	0% (0/149)
Mixed	19% (28/149)
NA	5% (7/149)

Accuracy of the Xpert Fingerstick HCV assay for detection of hepatitis C infection

	Xpert Fingerstick HCV test vs Abbott RealTi*me* HCV test		Xpert Fingerstick HCV test vs CE-IVD Xpert® HCV Viral Load	
	Capillary blood	Venous blood	Capillary blood	Venous blood
Nr of participants	**287**	**300**	**287**	**300**
Sensitivity	**95.8% (137/143)**	**96% (143/149)**	**93.2% (137/147)**	**93.5% (143/153)**
Specificity	**100% (144/144)**	**100% (151/151)**	**100% (140/140)**	**100% (147/147)**
PPV	**100%**	**100%**	**100%**	**100%**
NPV	**96%**	**96.2%**	**93.3%**	**93.6%**
Accuracy	**97.9%**	**98%**	**96.5%**	**96.7%**

Rate of indeterminate results of Xpert® HCV VL FS assay

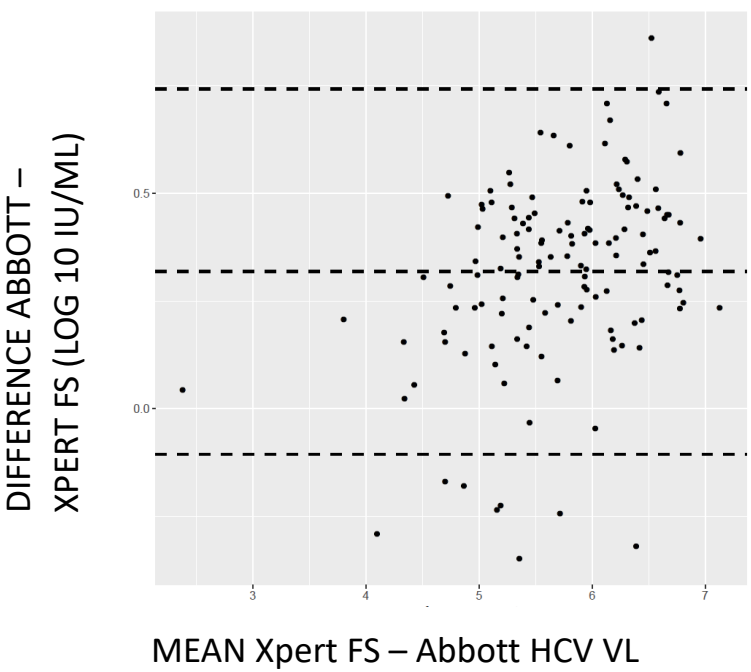
- **Out of 300 capillary blood samples tested by the Xpert® HCV VL FS assay, 13 (4.3%) gave indeterminate (no result, error or invalid) results**

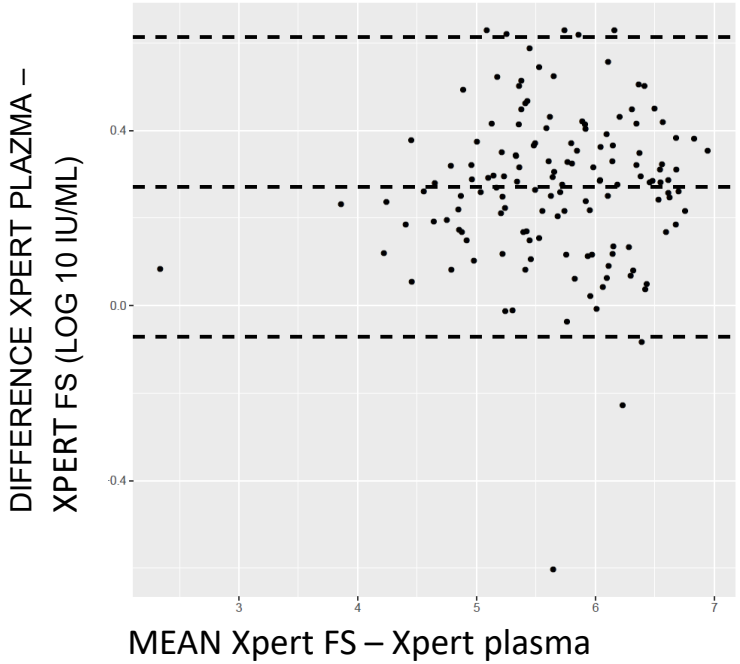
	Capillary blood	Venous blood
Number of tests performed	300	311
No Result	2 (0.7%)	2 (0.6%)
Error	8 (2.7%)	8 (2.6%)
Invalid	3 (1%)	1 (0.3%)
Total	13 (4.3%)	11 (3.5%)

Performance of Xpert FS HCV VL assay from capillary blood

Bland-Altman analysis

CI 95 %





CONCLUSION

- This study was conducted to evaluate the performance characteristics of the Xpert® HCV VL FS assay for detection and quantification of HCV RNA measured against two CE-marked assays widely used for HCV diagnosis and monitoring of treatment success.
- The new Xpert® HCV VL FS assay can be performed directly from a drop of capillary blood without any additional sample preparation step
- Results of the study show that while the Xpert® HCV VL FS assay is more easy to use and has a higher potential to be utilized in decentralized settings, its performance is comparable to that of currently used standard of care HCV viral load tests.
- Results obtained in Georgia demonstrated the 95.8% sensitivity and 100% specificity of the Xpert® HCV VL FS assay in capillary blood.

Acknowledgement

- **Study participants**
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