Evaluation of Simplified HCV Diagnostics in HIV/HCV Co-infected Patients in Myanmar

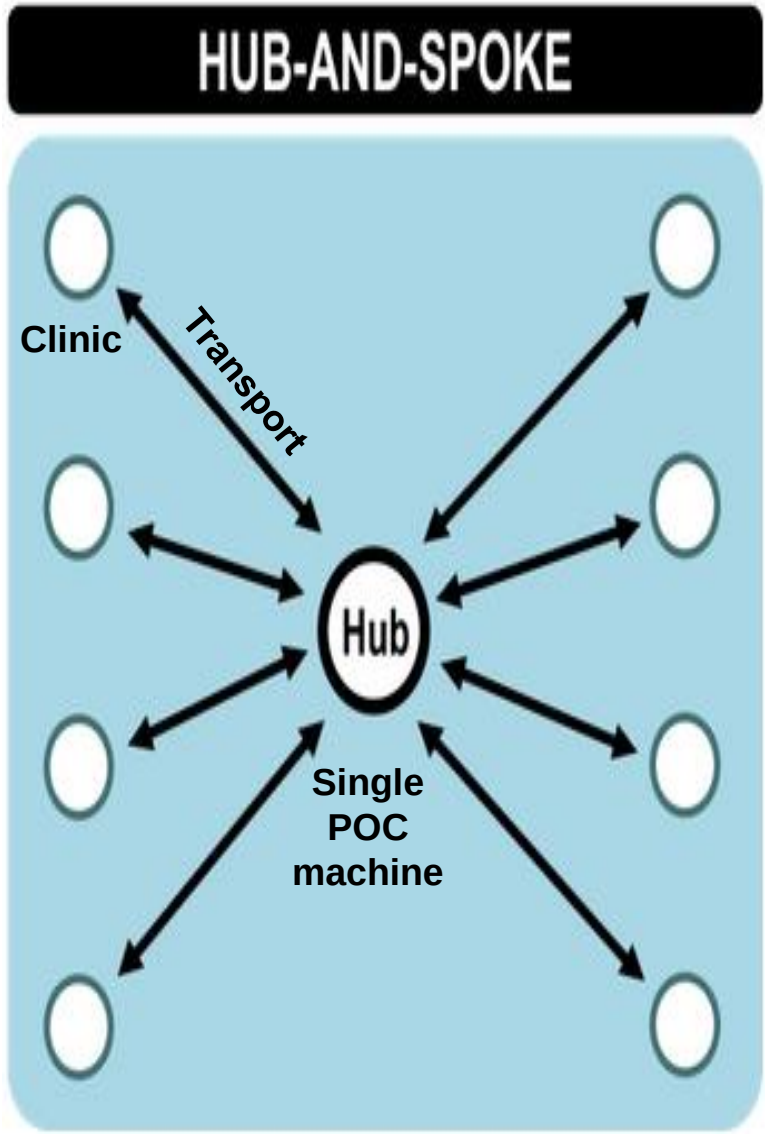
Phyo Pyae Nyein and Shane Tillakeratne
Sabai Phyu
Myint Myint Yee
Mya Mya Lwin
Kyaw Linn Htike
May Thu Aung
Jason Grebely
Tanya Applegate
Josh Hanson
Prof. Gail Matthews and Dr. Kyaw Swar Lin

Conflicts of interest

- G.M. reports grants from Gilead Sciences and grants from AbbVie. J.G. reports grants from Merck, grants from Cepheid, during the conduct of the study; grants and personal fees from AbbVie, grants and personal fees from Gilead Sciences, grants and personal fees from Merck, grants and personal fees from Cepheid, grants from Hologic, and grants from Indivior, outside the submitted work. All others declare no potential competing interests.

HCV testing and treatment in Myanmar

- Need for HCV treatment scale-up in Myanmar
- Cost of diagnostics and DAA therapy are barriers
- Onsite - Point of Care (POC) molecular testing may not be viable in resource-limited settings
- Decentralisation of current HCV testing and treatment algorithms required – a Hub-and-Spoke testing model may be more successful



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Study Design

- 22nd January 2019 to 3rd February 2020
- Screened HIV-1/HCV antibody-positive participants in Yangon, Myanmar
- Two HCV RNA testing samples at screening and 12 weeks post-treatment (SVR12) visits:
  - 100 µl Finger stick capillary whole blood sample transported in Microvette®
    Tested on **Xpert HCV VL Fingerstick Assay**

  - Local standard of care: 6mL HCV RNA plasma derived from whole-blood via venepuncture
    Tested on **Xpert HCV Viral Load assay** on the GeneXpert
- If HCV RNA detected (>10 IU/mL) at screening by standard of care : DAA therapy initiation
- Primary endpoint: SVR12 by intention-to-treat (ITT)
- Sensitivity and specificity of **Xpert HCV VL Fingerstick Assay** vs local gold standard, using a hub-and-spoke testing model

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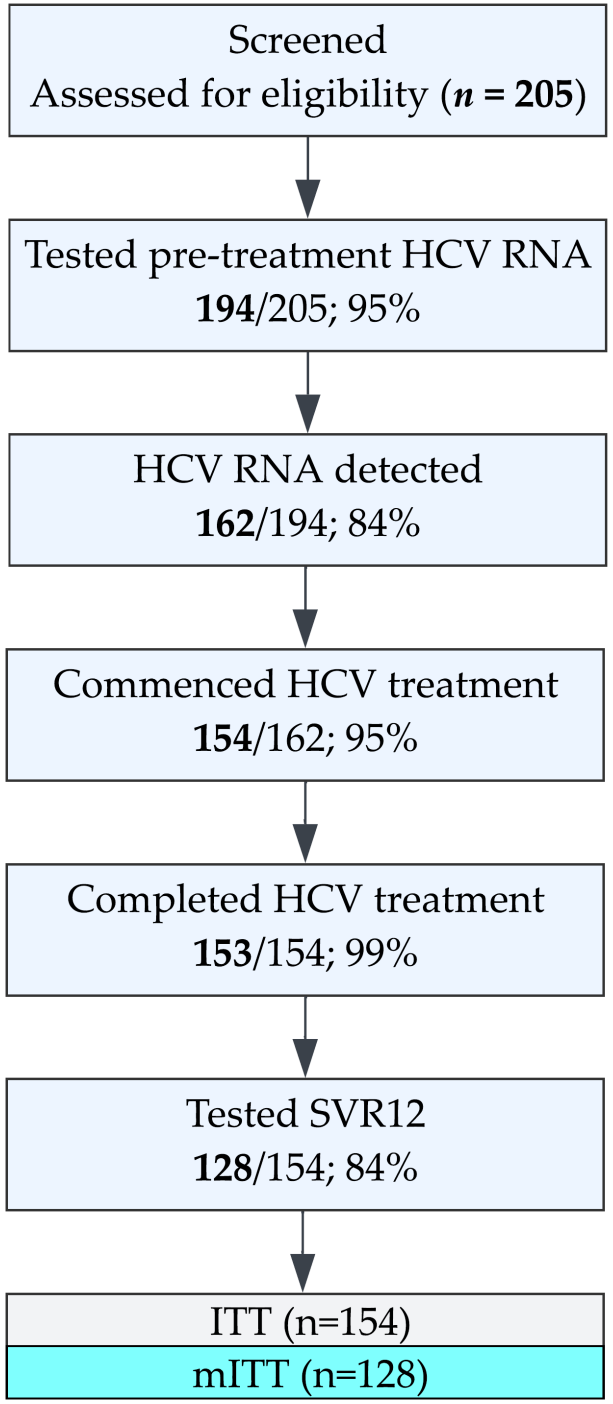
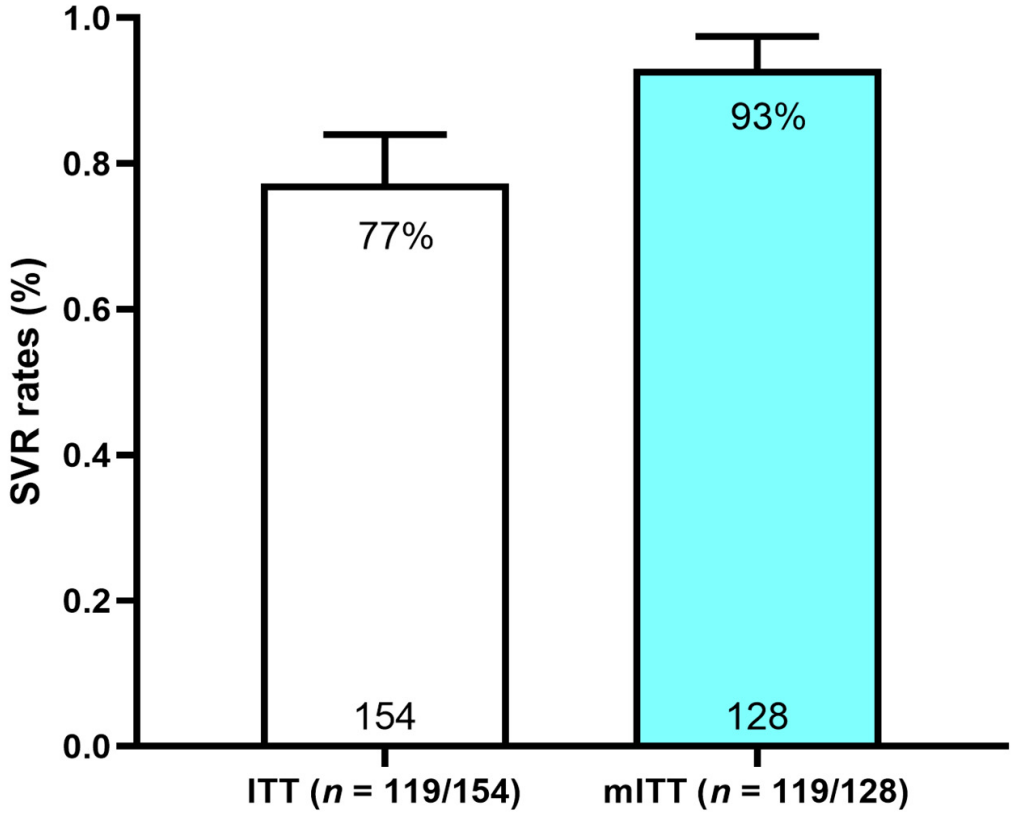
Results





SVR by standard of care *n* = 119

Virological failure *n* = 9

Intention-to-treat (ITT): received atleast ≥1 dose of drug

Modified intention-to-treat (mITT): patients with available SVR12 HCV RNA results

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Xpert HCV VL Fingerstick Assay vs. Standard of care

- 299 paired samples (from both assays) with valid test results
- Sensitivity: 99.4% (95% CI 96.7–100.0)
- Specificity: 99.2% (95% CI 95.9–99.9)
- Positivity predictive value (PPV) 99.3% (95.8% – 99.9%)
- Negative predictive value (NPV) 99.2% (95.0% – 99.8%)

	Quantifiable	Unquantifiable	Total
Xpert HCV VL Fingerstick Assay (Finger-stick capillary whole blood)			
Detected	163	1	163
Undetected	1	134	136
Total	164	135	299

- Analysis was also performed as first-pass (without retesting of samples)

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Conclusion

- Excellent SVR rates among those who returned for post-treatment HCV RNA testing
- High sensitivity and specificity of the Xpert HCV VL Fingerstick Assay for HCV RNA detection by fingerstick capillary whole-blood
- Feasibility and promise of the hub-and-spoke model in a resource-limited setting

Thank you