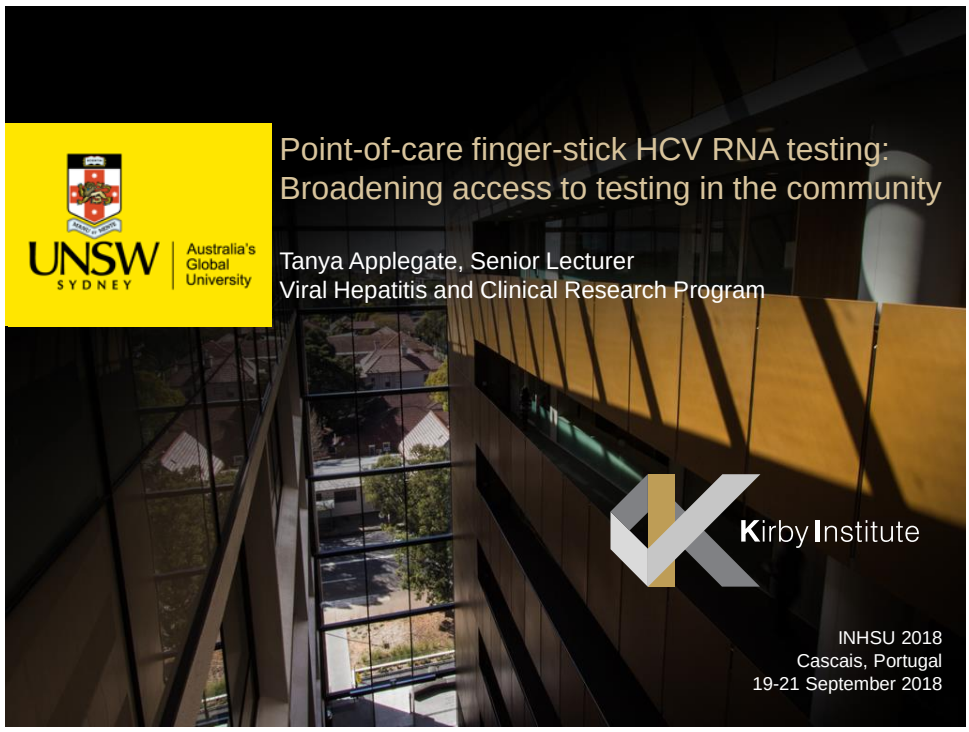


INHSU 2017

Disclosures

- Research and travel support from Abbott, Cepheid and Gilead

Today: Finger-stick HCV RNA testing…..

1. An opportunity to achieve “test and treat”
2. The evidence so far
3. Lessons learned
4. Integration ino screening strategies

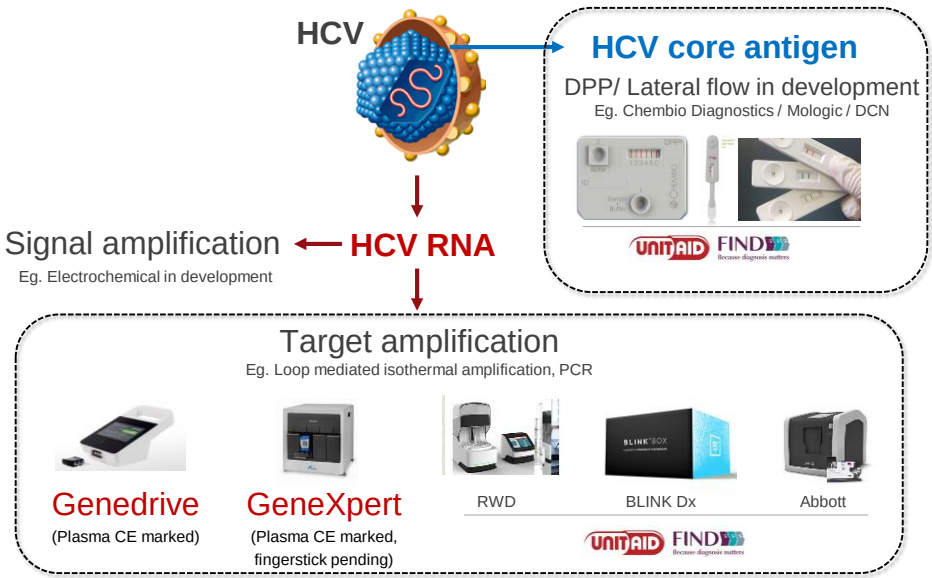
1. HCV finger-stick RNA testing – an opportunity

Immediate need for simple, affordable HCV testing

"The Holy Grail"

Applegate TL et al, *Infect Dis Clin N Am*, 2018, Grebely J et al, *Exp Rev Mol Diag* 2017

Point of care testing for active infection



GeneXpert® Diagnostic Systems

- Automated, self-contained, single use, random access
- Single platform for integration (HIV, HPV, TB)
- Minimal training, fast (~ 60-120min)
- Cost ~$15-17 (ex-works) per test in lower income countries
- > 17,000 instruments placed

HCV RNA - Xpert® HCV Viral Load assay (plasma)

- Easy-to-use point-of-care HCV RNA test

- Real-world performance for HCV RNA quantification very good
  - Xpert HCV Viral Load (plasma) – Sensitivity 99%, Sensitivity 96%[1]
  - Modified finger-stick assay (plasma cartridge) – Sensitivity 98%, Sensitivity 99%[2]

- WHO pre-qualified, CE - IVD marked (not yet available in Australia)

1. McHugh *J Clin Micro* 2017; 2. Grebely J, et al. *Lancet Gastro Hep* 2017

HCV RNA - Xpert® HCV Viral Load Fingerstick assay

- Developed in collaboration with FIND (*Foundation for New Innovative Diagnostics)*

Advantages

- Less invasive
- Easy collection
- No sample preparation
- Direct loading
- Minimal expertise
- Quick result

Awarded CE-IVD marking 19th Sep 2018

2. HCV finger-stick RNA testing – the evidence so far

LIVER LIFE

A liver health promotion intervention integrating point of care HCV RNA testing and non-invasive liver disease screening to enhance HCV assessment and treatment in drug and alcohol settings

Phase I - Development and testing of liver health messages

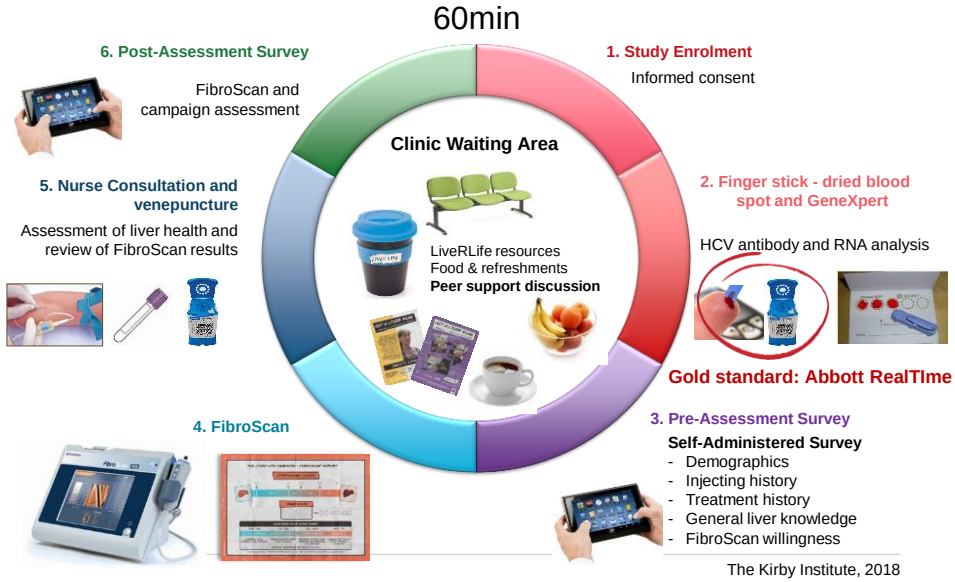
☑ PRINTED RESOURCES ☑ POSTER CAMPAIGN ☑ SHORT FILM ☑ FIBROSCAN REPORT ☑ STUDY WEBSITE

11

The Kirby Institute, 2018

LIVER LIFE

Phase II - campaign days (n > 1000)



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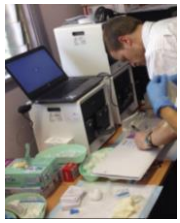
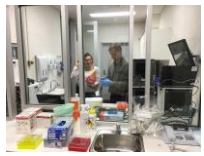
LIVER LIFE Phase II - campaign days (n > 1000)





The Kirby Institute, 2018

LIVER LIFE Sensitivity and specificity

n = 223 recruited, final study population n = 181 (on treatment excluded)

Ozanam Learning Centre | Rankin Court Darlinghurst | Adelaide Drug and Alcohol Health Service | Biala clinic

1x Homeless service

3x Opioid substitution treatment clinics

Results:

Xpert® HCV (≥10 IU/mL)	Abbott RealTime (≥12 IU/mL) Quantifiable	Unquantifiable	Total
Quantifiable	59	0	59
Unquantifiable	0	106	106
Total	59	106	165
Sensitivity	**100.0%** (95%CI, 92.4 – 100.0%)		
Specificity	**100.0%** (95%CI, 95.6 - 100.0%)		

Note: One sample not detected by Xpert® HCV VL FS assay while it was detected but below the limit of quantification (<12 IU/mL) by the Abbott RealTime assay.

Lamoury F et al, Journal of Infectious Disease, 2018

Multi-country finger-stick RNA assay evaluation

Preliminary data from sites	Abbott RealTime HCV VL N	Abbott RealTime HCV VL Sensitivity, % (95% CI)	Abbott RealTime HCV VL Specificity, % (95% CI)
Georgia (NCDC, HRS HEPA+)	287	95.8 (91.2-98.1)	100 (97.4-100)
Cameroon (CPC)	177	99.2 (95.6-99.9)	100 (93-100)
Greece (Hellenic Society for the Study and Control of AIDS)	148	96.3 (89.8-98.8)	100 (94.5-100)
Malaysia (Hospital Selayang)	78	100 (95.1-100)	100 (43.8-100)
US (Biocollections Ltd.)	193	100 (88.3-100)	100 (97.7-100)

Multi-country finger-stick RNA assay evaluation

Preliminary data from sites	ID %	Abbott RealTime HCV VL N	Abbott RealTime HCV VL Sensitivity, % (95% CI)	Abbott RealTime HCV VL Specificity, % (95% CI)	Xpert plasma HCV VL N	Xpert plasma HCV VL Sensitivity, % (95% CI)	Xpert plasma HCV VL Specificity, % (95% CI)
Georgia (NCDC, HRS HEPA+)	4.3	287	95.8 (91.2-98.1)	100 (97.4-100)	287	93.2 (87.9-96.3]	100 [97.3-100]
Cameroon (CPC)	8	177	99.2 (95.6-99.9)	100 (93-100)	182	99.2 (95.8-99.9]	100 [93-100]
Greece (Hellenic Society for the Study and Control of AIDS)	1.3	148	96.3 (89.8-98.8)	100 (94.5-100)	148	97.5 (91.4-99.3]	100 [94.6-100]
Malaysia (Hospital Selayang)	2.5	78	100 (95.1-100)	100 (43.8-100)	77	100 (95.1-100]	100 [43.8-100]
US (Biocollections Ltd.)	4.4	193	100 (88.3-100)	100 (97.7-100)	193	96.7 (83.3-99.4]	100 [97.7-100]
All	**4.5%**	**883**	**97.8** (96-98.8]	**100** [99.1-100]	**887**	**97** (95-98.2)	**100** (99.1-100)

ID = Rates of indeterminate results per site

Multi-country finger-stick RNA assay evaluation

Performance in HCV RISK group (one-step Dx)

Reference test	N	Sensitivity, % (95% CI)	Specificity, % (95% CI)
Abbott RealTime HCV VL	339	96.4 [87.9-99]	100 [98.7-100]
Xpert plasma HCV VL	339	88.5 [78.2-94.3]	100 [98.6-100]

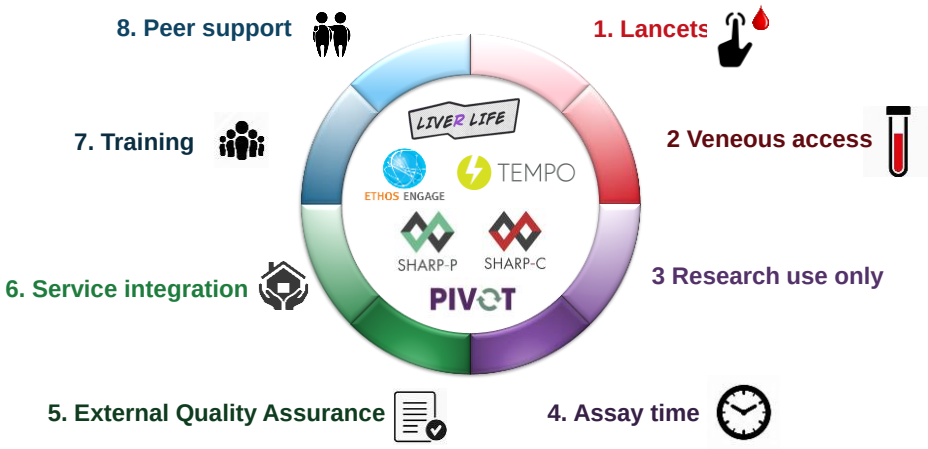
INHSU 2017

UNSW SYDNEY

Kirby Institute

3. HCV finger-stick RNA testing – lessons learned

LIVER LIFE The challenges and successes



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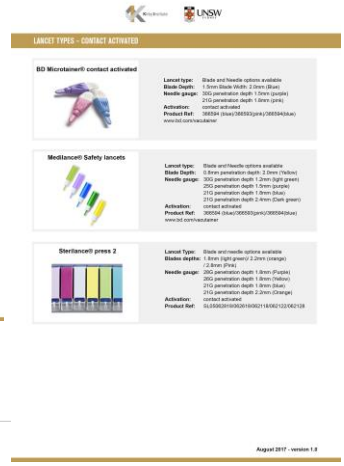
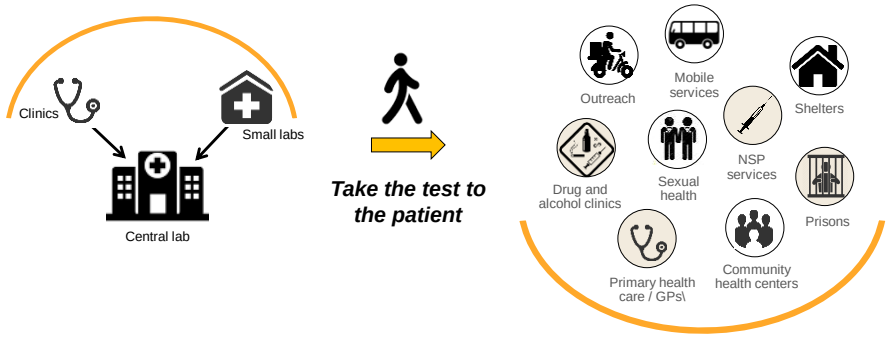
Training tools and videos

Example – Lancet guide



HCV finger-stick RNA testing – screening strategies

An “ecosystem” of diagnostic solutions



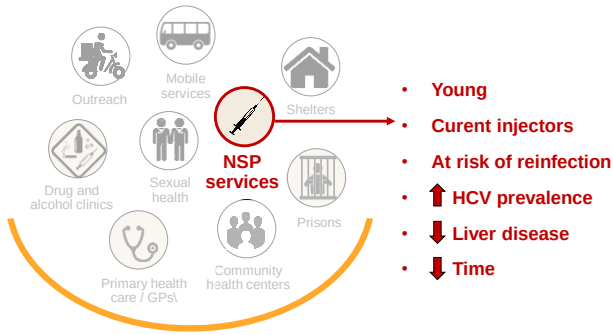
Centralised testing

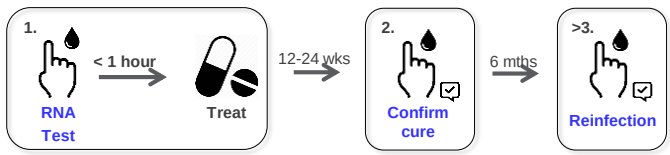
Decentralised services

Where might point of care HCV RNA testing work?

Adapted from Applegate TL et al, NA Clinics Infectious Disease, 2018

Each site is unique – e.g. needle and syringe services

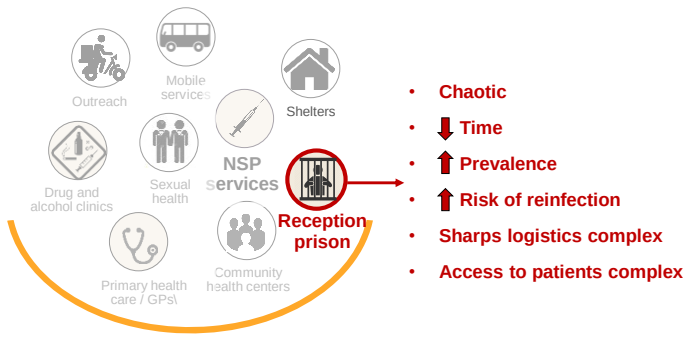




RNA HCV "test and treat" without liver staging

Adapted from Applegate TL et al, NA Clinics Infectious Disease, 2018

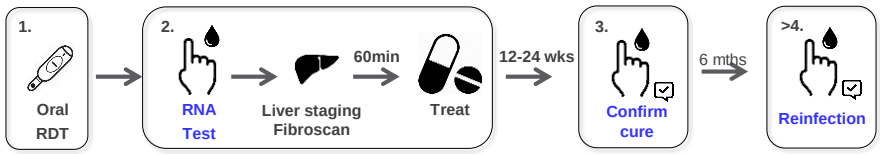
Each site is unique – e.g. reception prisons



Adapted from Applegate TL et al, NA Clinics Infectious Disease, 2018

Each site is unique – e.g. reception prisons

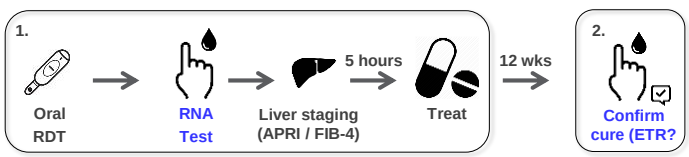
- Chaotic
- ⬇ Time
- ⬆ Prevalence
- ⬆ Risk of reinfection
- Sharps logistics complex
- Access to patients complex



Adapted from Applegate TL et al, NA Clinics Infectious Disease, 2018

Each site is unique – e.g. Community camps in LMIC

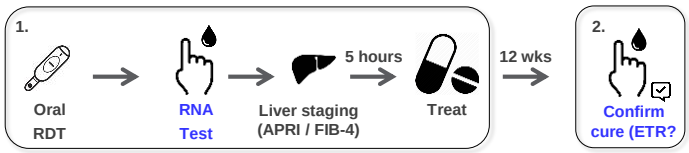
- ⬇ Cost of RDT is low ($1)
- ? Prevalence
- ⬆ Liver disease high
- ⬆ Time to wait



Adapted from Applegate TL et al, NA Clinics Infectious Disease, 2018

Each site is unique – e.g. Community camps in LMIC

- ↓ Cost of RDT is low ($1)
- ? Prevalence
- ↑ Liver disease high
- ↑ Time to wait



Adapted from Applegate TL et al, NA Clinics Infectious Disease, 2018

HCV finger-stick RNA testing – key messages

HCV finger-stick RNA point-of-care assay

1. Detects active infection with high performance in < 1 hour
2. One-step diagnostic solution allowing towards “test and treat”
3. Likely to enhance screening to scale up care in marginalised populations
4. Further research for real world implementation
5. Further reduction in cost and time is needed

Acknowledgments

Study participants

The Kirby Institute, UNSW
Gregory Dore
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Pip Marks
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Brendan Jacka
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NSW Users & AIDS Association
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Ozanam Learning Centre/Matthew Talbot
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Beth Catlett

AIVL
Jude Byrne

Hepatitis NSW
Paul Harvey

Abbott
Gavin Cloherty
Wade Foster
Andrew StJohn

Funding:

Research support:

Acknowledgments

- **Study participants**
- **Study sites**
  - Georgia, National Centre for Disease Control, Tbilisi (Maia Alkhazashvili), HRS Hepa plus (Manana Sologashvili)
  - Greece, Helenic Society for the Study of AIDS and Sexually Transmitted Diseases, Athens (Angelos Hatzakis)
  - Cameron, Centre Pasteur Cameroun, Yaoundé (Richard Njouom)
  - Malaysia, Hospital Selayang, Selangor (Tan Soek Siam)
  - US, Biocollections Ltd., Miami (Sixto Pacheco)
  - Denmark, Aarhus University Hospital, Blood Transfusion Centre, Aarhus (Christian Erikstrup)
- **FIND**
  - Elena Ivanova, Aurélien Mace, François Lamoury, Stefano Ongarello, Violet Chihota, Jennifer Kealy, Anna Mantsoki
- **Funders** (had no role in design, analysis and reporting)
  - Government of Netherlands
  - UNITAID
- **Disclosure**
  - This study was performed in collaboration with Cepheid. Cepheid donated Xpert cartridges to study sites for use during the clinical study and provided GX4 systems. Cepheid staff has supported training of study staff in Cameroon, Greece, Malaysia, US and Denmark on site monitoring visits to Greece, Denmark and Georgia sites. Cepheid has provided funding to the US site (Biocollections Ltd.).

Thank you.....