Straight To The Point – Lessons From The Rapid-EC Study: A Point-Of-Care Hepatitis C Testing Pilot In Needle And Syringe Programs Targeted To People Who Inject Drugs In Australia

Dr. Alisa Pedrana, PhD
Burnet Institute, Melbourne Australia


Disclosures

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Australia has high rates of diagnosis

- Australia has high rates of antibody diagnosis (81%) among key populations, in 2016, of which ~47% of those had a hepatitis C RNA test to confirm HCV current infection
- Point-of-care-tests (POCTs) may help to overcome barriers preventing people who inject drugs (PWID) accessing testing and progressing to hepatitis C treatment.

Point of Care Diagnostics for HCV

- **HCV Antibody**
  - At least 30 products
  - Testing on saliva, finger-stick blood, serum, plasma or whole blood
  - Accuracy varies
    - OraQuick - 95-99% sensitivity, 99% specificity

- **HCV RNA**
  - Xpert HCV viral load (WHO pre-qualification)
  - Plasma or serum, finger-stick being validated
  - 105 minutes to result (finger-stick 60 minutes)
    - Serum: 95.8% agreement with Abbot RealTime
    - Sensitivity: serum – 100%, finger-stick – 95.5%
    - Specificity: serum – 99.1%, finger-stick – 98.1%
  - Genedrive HCV ID Kit (CE Marking)
    - Requires plasma sample and 90 minutes to result
    - Sensitivity 98.6%, Specificity 100%


A Role for Point-of-Care testing?

- Possible benefits of POC tests for HCV:
  - Facilitating testing uptake
    - Can be conducted by non-clinical staff
    - Opportunistic testing in outreach settings
    - Avoid venepuncture for as long as possible
  - Preventing loss to follow-up
    - Same day diagnosis
    - Fewer visits to treatment
  - Allow for testing when lab facilities are not accessible

Rapid-EC Pilot Study – 2017

- **AIM:** To explore the feasibility of providing rapid HCV point-of-care testing at needle and syringe exchange programs (NSPs) co-located in 3 community health clinics in Melbourne.

- **METHOD:**
  - NSP site staff (NSP worker, community health worker or nurse) trained to offer rapid testing for HCV
  - OraQuick HCV Ab mouth swab test
  - Xpert HCV viral load
  - Alongside standard-of-care bloods
  - Offered same-day results on site, via phone/SMS, or upon return visit
  - Follow up review for pre-treatment assessment and link to GP for treatment
  - Demographic, behavioural and acceptability surveys & interviews
  - $30 reimbursement for study participation

- **RECRUITMENT PERIOD:**
  - June to November 2017
**Rapid-EC Sites and Outcomes**

**3 large community health clinics in metro Melbourne**
- Co-located NSP services
- On-site specialist drug and alcohol services
- General practitioners able to prescribe DAA
- Multidisciplinary team of staff, including nurses, community health workers, NSP staff and GPs familiar with the clinic structure and client base

**Outcomes of interest**
- Acceptability and uptake of rapid HCV POC testing, and linkage to care
- Feasibility of integrating rapid HCV POC testing into primary care setting
- Assess ability of healthcare & non-healthcare staff to deliver rapid HCV POC
- Real-world example of POC integration into HCV models of care

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**Training**

![Training images](Photo credit: A. Morgan, Burnet.)
Implementation

Photo credit: A. Morgan, Burnet.

Rapid-EC Protocol

Visit 1
- Consent and pre-test counselling
- OraQuick Ab test (20 minutes)
- OraQuick Ab results
  - Positive result
  - Xpert HCV RNA test and standard HCV Ab and HCV RNA and standard-of-care bloods (120 minutes)
    - Xpert RNA result
- Negative result
  - Standard HCV Ab and HCV RNA test
  - Counselling about negative result and harm reduction

Visit 2
- Post-test counselling
- Review of results
- Treatment work up if RNA positive
Participant Characteristics – n=174

- **Demographics**
  - Median Age, IQR 35 – 48
  - 69% Male
  - 19% Aboriginal and/or Torres Strait Islander
  - 74% Previous incarceration

- **Education**
  - 29% completed primary school education or less
  - 50% completed secondary school

- **Housing**
  - 19% Living with family/friends or boarding/guesthouse
  - 32% Unstable accommodation, homeless or other unspecified

- **Drug Use**
  - 94% Injecting drug use last 6 months
  - 47% Currently on OST
  - 47% Receptive sharing of any equipment in last 6 months

- **97% reported a previous hepatitis C Test**
  - 28% Tested with past 12 months
  - 42% Tested > 12 months
  - 30% last test unknown

- **Last hepatitis C test result**
  - 3% Ab negative
  - 31% Ab positive & PCR negative
  - 44% PCR positive
  - 22% Don’t know / can’t recall

- **Previous hepatitis C treatment**
  - 22% previously treated for HCV

- **Knowledge of DAA treatment**
  - 95% correctly reported that new hepatitis C treatment was available to everybody, including people who currently inject
  - 90% incorrectly reported that Hepatitis C treatment is only available through hospitals
**Participant Flow & Testing outcomes**

Underwent HCV antibody point-of-care test = 174

- Test non-reactive = 23
- Test indeterminate = 1

HCV antibody point-of-care test reactive = 150

- No venepuncture = 10

Follow-up completed = 48

- 150/174 (86%) OraQuick reactive
- 7 False negative OraQuick tests

Underwent HCV RNA point-of-care test = 140

- RNA detected = 76
- RNA not detected or invalid = 64

Follow-up completed = 56

- 76/140 (54%) Xpert positive
- 2 Indeterminates – insufficient sample
- 1 false negative Xpert
- 2 false positive Xpert
- 1 likely contaminated due to HCW accidently mixing samples

**Outcomes**

**Acceptability**
- A total of 174 participants completed POC testing for HCV antibodies
- 150 (86%) had a reactive result and of these
- 140 (93%) underwent a POC HCV RNA test
- 76 (54%) had detectable RNA
- Test Performance:
  - 2 Indeterminate
  - 1 false negative Xpert
  - 2 false positive Xpert

**Feasibility**
- 7/140 (5%) participants waited on-site to receive their POC RNA result
- 85 (61%) opted for a phone call/text message.
- 104/140 (74%) attended the follow up visit 2 within a median of 11 days (IQR 7-20 days)
**Linkage to Care**

- At 6 months follow up 43/76 were provided with a script - 57% treatment uptake

**Linkage to Care Cascade n=174**

**Linkage to Care by Clinic**

- At 6 months follow up 17/23 were provided with a script - 74% treatment uptake
Linkage to Care by Clinic

- At 6 months follow up 8/28 were provided with a script - 29% treatment uptake

**Linkage to Care Cascade - Clinic B (n=51)**

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<th>Ab Positive</th>
<th>Rapid PCR Positive</th>
<th>Lab PCR Positive</th>
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Linkage to Care by Clinic

- At 6 months follow up 8/28 were provided with a script - 72% treatment uptake

**Linkage to Care Cascade - Clinic C (n=71)**

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<td><strong>Clinic C</strong></td>
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Qualitative Interviews with Clients

- 19 semi-structured interviews with participants who had undergone all tests
- Major themes:
  - Acceptability of NSP location and staff
  - Rapid result and avoiding venepuncture not always client’s primary concern
  - Current RNA tests aren’t rapid enough for many people

Qualitative findings – NSP involvement

“The thing is I come here anyway unlike the doctors. I don’t need to specifically have come here to get tested. [It’s] heaps more convenient that I was offered that at a place that I come to frequently.”

“the way they talk to you. They have a really good understanding of what it’s like to have hep C and they don’t judge us because we’re users... That goes a really long way...because when you go to get test ...to see if you have hepatitis C or other things, it’s already a bit degrading ‘cause it makes you feel a little bit unhealthier than the rest of society. These people don’t make you feel that way.”
Qualitative findings – downsides of rapid tests

“I’d rather just do the blood work [from a vein]. Cause I’m not just worried about hep C. I’m worried about the whole lot. So I’d rather do the blood ’cause then I’ll know I haven’t got hep C, hep B and HIV.”

"Get it from a vein, so it can be as accurate as possible.”

Qualitative results – value of rapidity

“Two hours is too long...I’m not going to wait two hours for a test when they can just ring me.”

“If it took 12 months to find out [the result] you’d be freaking out, but a couple of weeks it doesn’t bother me cause I know there’s going to be a plan at the end of it...”
Limitations of the Study

• Possibly a highly engaged sample and only those willing to have venepuncture

• Acceptability & feasibility study only, unable to evaluate impact

• Follow up attendance likely underestimated

Conclusions

• Conducting point-of-care testing in NSPs is highly feasible and acceptable to PWID

• Non-healthcare staff can be trained to deliver rapid POC tests

• Currently available POC RNA tests are too slow to provide a reliable same-day diagnosis

• Point-of-care testing helped link PWID into the hepatitis C care cascade – with 56% treatment uptake at 6 months

• Promising results – but clearly a need for further evaluation to assess impact on testing and treatment uptake among larger sample
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