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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

Williams B, Howell J, Doyle J, Latham N, Draper B,
Layton C, Bramwell F, Membrey D, Mcpherson M, Roney J, Thompson A, Hellard ME

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Disclosures

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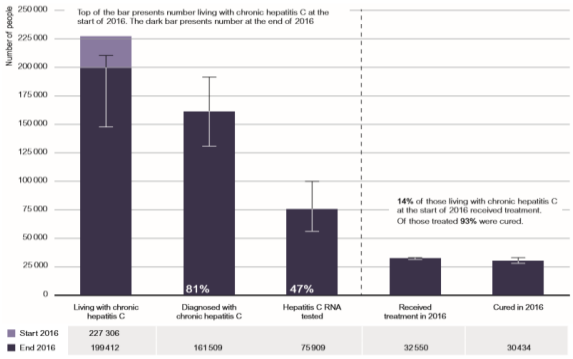
Australia has high rates of diagnosis

- 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.



Annual Surveillance Report, Kirby Institute (2017)

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%

Khuroo et al. 2015, McHugh et al. 2017, Grebely at al. 2017, Llibre et al. (2017)

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

Training



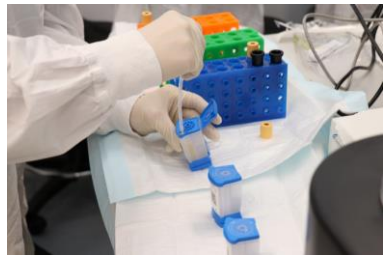



Photo credit: A. Morgan, Burnet.

Implementation

Photo credit: A. Morgan, Burnet.

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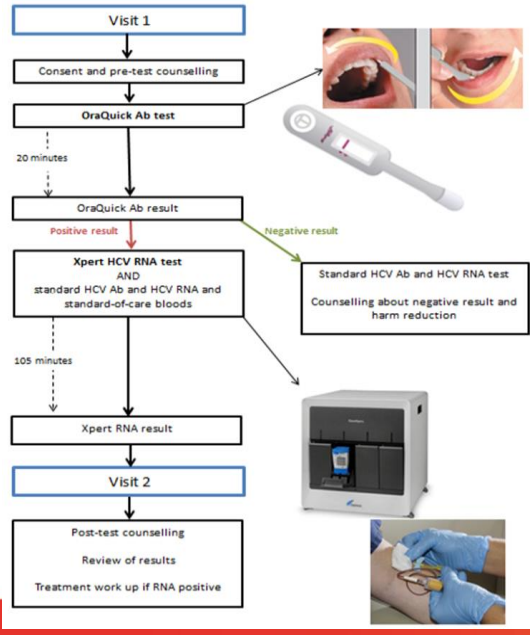
Rapid-EC Protocol



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Participant Characteristics – n=174

- **Demographics**

41 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

Participant Characteristics – n=174

- **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

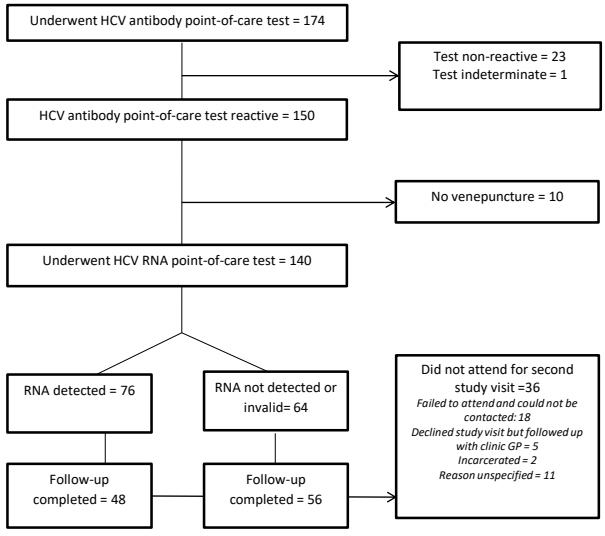
- **Previous hepatitis C treatment**

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



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

- **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

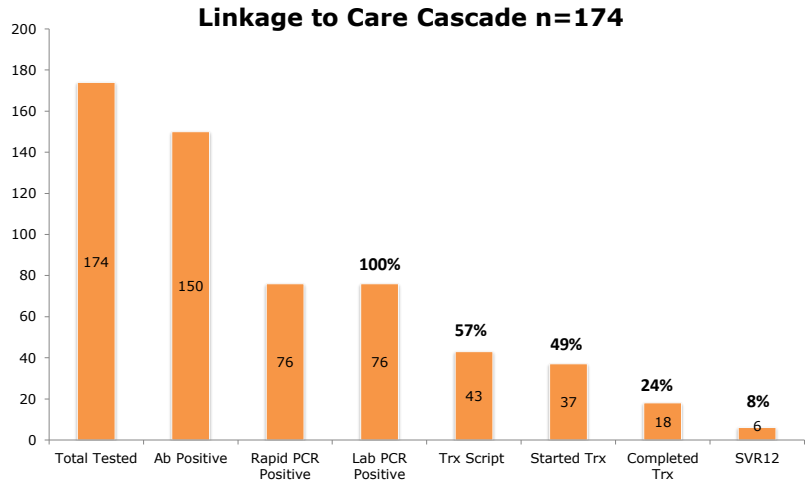
- A total of 174 participants completed POC testing for HCV antibodies
- 150 (86%) had a reactive result and of these
- 140 (93%) underwent a POC HCV RNA test
- 76 (54%) had detectable RNA
- Test Performance:
  - 2 Indeterminate
  - 1 false negative Xpert
  - 2 false positive Xpert

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)

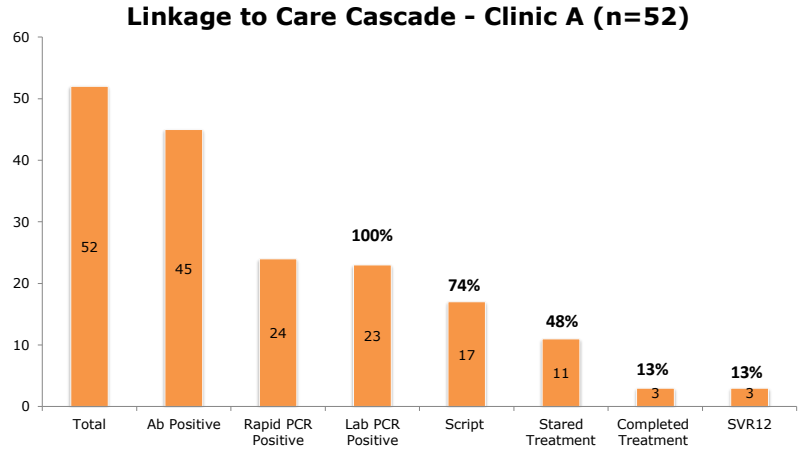
Linkage to Care

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



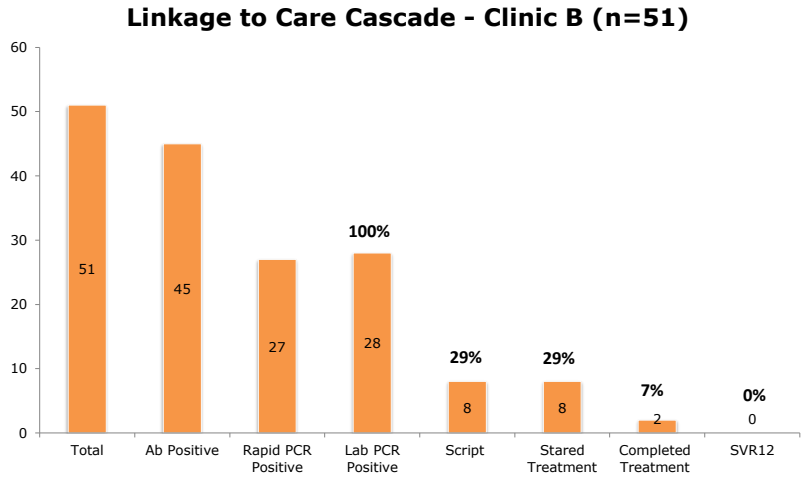
Linkage to Care by Clinic

- At 6 months follow up 17/23 were provided with a script - 74% treatment uptake



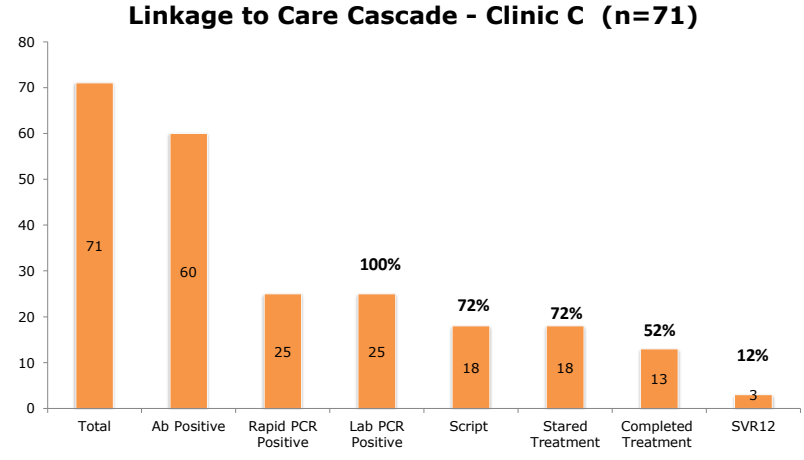
Linkage to Care by Clinic

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



Linkage to Care by Clinic

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



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

Acknowledgements

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