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An Unmet Need For Hepatitis C Testing At Needle And Syringe Services – Lessons Learned From The Rapid-EC Feasibility Study

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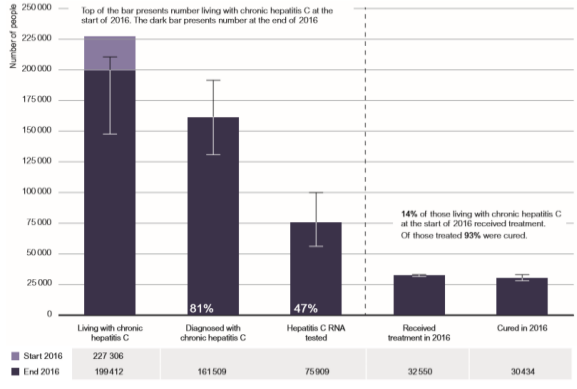
Australia has high rates of diagnosis

- 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)

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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 but best performing is OraQuick:
    Sensitivity: blood - 99.5%, oral fluid – 95.9%
    Specificity: blood – 99.8%. oral fluid - 99.4%
- **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% (92.0-100), finger-stick – 95.5% (84.5-99.4)
    - Specificity: serum - 99.1% (94.9-100), finger-stick – 98.1% (93.4-99.8)
  - Genedrive HCV ID Kit (CE Marking)
    - Requires plasma sample and 90 minutes to result
    - Sensitivity 98.6% (96.9-99.95), Specificity 100% (99.3-100)

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

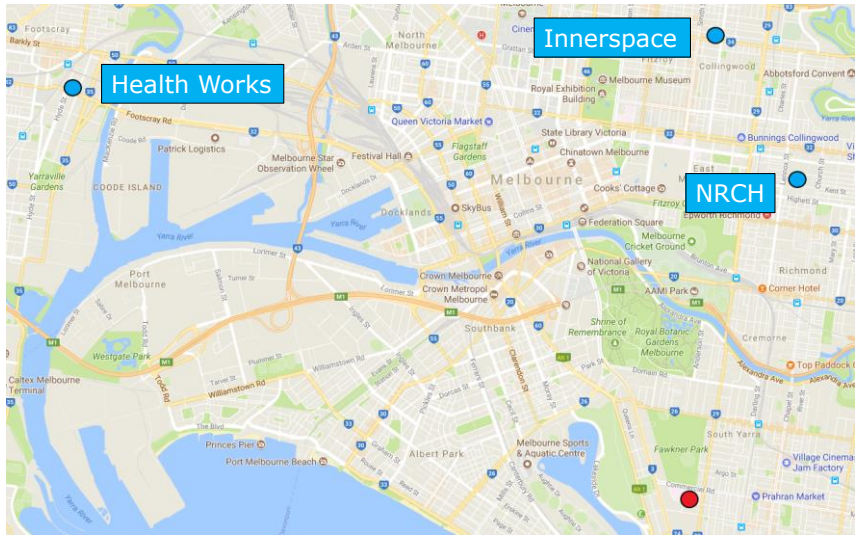
Rapid-EC Pilot Study – 2017

- **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.

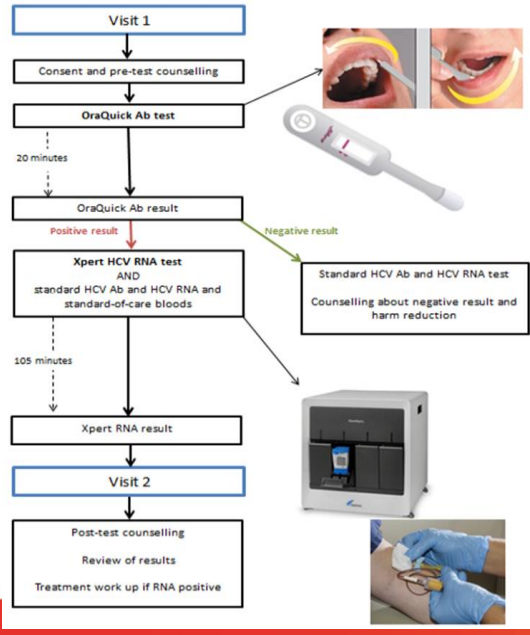
- **METHOD:**
  - NSP site staff (NSP worker, community health worker or nurse) offered rapid testing for HCV
  - OraQuick HCV Ab mouth swab test
  - Xpert HCV viral load
  - Alongside standard-of-care bloods
  - Offered same-day results on site, via phone/SMS, or upon return visit
  - Follow up review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

- **RECRUITMENT PERIOD:**
  - June to November 2017

Rapid-EC Sites



Rapid-EC Pilot Study



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Training

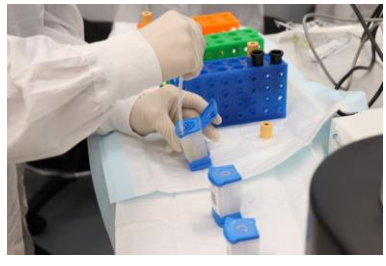

Photo credit: A. Morgan, Burnet.

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Implementation

Photo credit: A. Morgan, Burnet.

Participant Characteristics - Demographics

	Clinic 1 N = 52	Clinic 2 N = 72	Clinic 3 N = 51	Total N = 174
Variable	N (%)	N (%)	N (%)	N (%)
Age				
Median age (IQR)	44 (38 – 49)	44 (36 – 50)	37 (31 – 43)	41 (35 – 48)
Gender				
Male	37 (71)	53 (74)	28 (55)	118 (69)
Female	13 (26)	18 (25)	20 (40)	51 (30)
Education				
Further education	14 (27)	15 (21)	7 (14)	36 (21)
Secondary School education	34 (67)	42 (58)	10 (20)	86 (50)
Primary School education or less	3 (6)	15 (21)	33 (66)	51 (29)
Housing				
Owner occupier or renter	26 (51)	37 (51)	21 (42)	84 (49)
Living with family/friends or boarding/guesthouse	12 (24)	11 (15)	10 (20)	33 (19)
Unstable accommodation, homeless or other unspecified	13 (25)	24 (33)	19 (38)	56 (32)
Aboriginal and/or Torres Strait Islander				
Yes	10 (20)	8 (11)	15 (31)	33 (19)
Injecting drug use last 6 months				
Yes	42 (88)	63 (94)	49 (100)	154 (94)
Opioid Substitution Therapy				
Current OST	35 (69)	30 (42)	15 (30)	80 (47)
Previous OST	12 (24)	26 (37)	29 (58)	67 (39)
Never on OST	4 (8)	15 (21)	6 (12)	25 (15)
Previous incarceration				
Yes	36 (73)	55 (80)	34 (68)	125 (74)
Receptive sharing of any equipment in last 6 months				
Yes	24 (47)	33 (46)	25 (50)	82 (47)

Participant Characteristics – Hepatitis C history

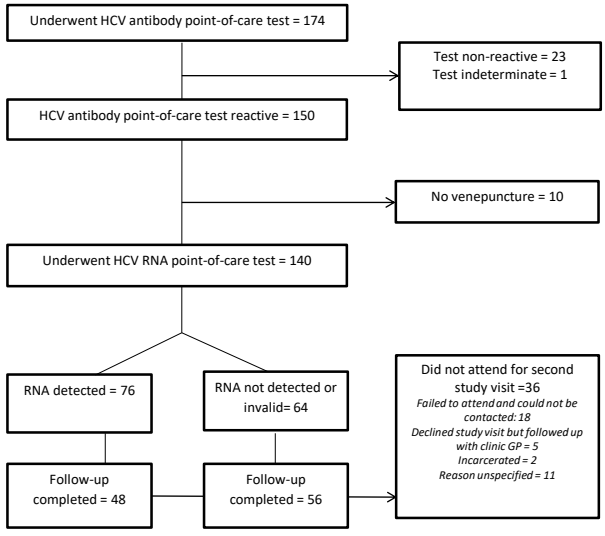
	Total Total N = 174
Previous hepatitis C test	%
Yes	167 (97)
Time since last hepatitis C test	
Last test date within 1 year	44 (28)
Last test date prior to 1 year or greater	67 (42)
Last test date entered as "unknown"	49 (30)
Last hepatitis C test result	
Ab negative	5 (3)
Ab positive and PCR negative	51 (31)
PCR positive	73 (44)
Don't know/Can't Recall	36 (22)
Previous hepatitis C treatment	
Yes	37 (22)
No	135 (78)

Hepatitis C Knowledge

Participants' hepatitis C knowledge	Total N = 174 N (%)
If you have a positive hepatitis C antibody test it means you have a current hepatitis C infection	108 (62)
New treatments for hepatitis C are available to everybody, including people who currently inject	166 (95)
New treatments for hepatitis C have around a 95% chance of curing hepatitis C	164 (94)
Hepatitis C treatment is only available through hospitals	161 (93)
If you get hepatitis C again after you've been treated, you can be treated again.	160 (92)

Participant Flow & Testing outcomes

Participants with Reactive OraQuick only



- **150/174 (86%) OraQuick reactive**
- **76/140 (54%) Xpert positive**

- 7 False negative OraQuick tests
- 1 false negative Xpert
- 2 false positive Xpert (1 likely contaminated)

Study Results

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
  - **To date 43/76 have initiated treatment (56% treatment uptake)**

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 within a median of 11 days (IQR 7-20 days)

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
- Feasibility study only, unable to evaluate impact
- Follow up attendance likely underestimated

Conclusions

- Conducting point-of-care testing in communities clinics with NSPs is feasible and acceptable.
- Currently available testing is too slow to provide a reliable same-day diagnosis.
- Point-of-care testing helped link PWID into the hepatitis C care cascade.
- Role for further evaluation to assess impact on testing and treatment uptake.

Acknowledgements

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