Feasibility and outcomes of a hepatitis C screening programme in community pharmacies

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ABSTRACT

AIMS: To ascertain the feasibility and outcomes of point-of-care testing for hepatitis C virus (HCV) antibodies in people with risk factors screened in community pharmacies.

METHODS: Ten pharmacies in the Waitematā District Health Board piloted point-of-care antibody HCV screening with consenting participants. Individuals with a positive HCV antibody result had a confirmatory HCV RNA test performed at a local laboratory, with pharmacist follow-up to discuss the result. RNA positive individuals were referred to their general practitioner for further follow-up including antiviral therapy. Number of tests, number of positives and number treated were collected. Pharmacists completed a survey about their experiences.

RESULTS: Of 192 participants, seven (3.6%) had positive tests on screening, four of whom had a positive RNA assay and received HCV medication, and one of whom had a positive RNA assay but has not yet received treatment. Two had negative RNA results. Pharmacist feedback was very positive with most wishing to continue the point-of-care testing service. Most wanted to be able to treat HCV in order to improve linkage to care.

CONCLUSIONS: Pharmacy point-of-care testing with immediate results and pharmacist follow-up of positive results can aid diagnosis of HCV in at-risk populations and help treatment uptake.

Almost 40,000 adult New Zealanders (prevalence 0.8%) have chronic hepatitis C virus (HCV) infection with an additional 1,000 new infections per annum. An estimated 20,000 remain undiagnosed, and many who have been diagnosed have been lost to follow-up and not treated.1,2 The Ministry of Health reports that “untreated, up to 20–25% will develop cirrhosis. Without successful treatment, 2–5% of those with cirrhosis will progress to life-threatening liver cancer or liver failure every year”.1 With the ageing cohort effect of those infected in the 1970s and 1980s, HCV has become the leading indication of liver transplantation in New Zealand.2,3 Earlier diagnosis and treatment will prevent the morbidity, mortality and costs associated with these complications.4 Therefore there is a goal to eliminate HCV infection in New Zealand.5

In New Zealand, glecaprevir-pibrentasvir for 8 or 12 weeks is funded for all patients with compensated HCV6 and is associated with a 98% cure rate.7

Most New Zealanders with chronic hepatitis C were infected through injecting drug use.3 People who inject drugs (PWID) may be unaware of the risk of HCV exposure.8,9 Others do not seek testing or treatment because of the real and perceived stigma associated with injecting drugs.9–11 Some health providers might not think to test for HCV in PWID or may be unaware of the previous drug injecting history.9 Screening rates among key risk populations in New Zealand are low.5 To increase treatment uptake, the rate of diagnosis and linkage to care needs to be increased through greater community awareness and targeted testing.3
Community pharmacies provide an ideal situation to educate the public of risk factors for HCV infection. This is facilitated by provision of a private room for discussion. Some pharmacies also offer needle exchange, opioid substitution treatment (OST) dispensing, and/or are open for extended hours, increasing opportunities for testing PWID or previous PWID populations.

HCV testing in community pharmacies has been piloted successfully in the UK and US, mostly screening needle exchange or OST clients.

Point of care (POC) rapid diagnostic screening tests provide rapid results for HCV antibodies on either a finger prick blood sample or buccal swab. A positive antibody result indicates previous exposure, with a second blood test for HCV RNA or HCV antigen needed to confirm active HCV infection.

Therefore, this project aimed to answer the following question: what are the feasibility and outcomes of rapid diagnostic point-of-care (POC) testing for HCV in people with risk factors screened in a range of New Zealand community pharmacies, with initial follow-up of positive antibody results by the pharmacist?

The specific objectives were to determine:

- How many POC tests are undertaken per pharmacy?
- What are the risk factors for HCV exposure in those who are tested?
- What proportion of tests result in positive POC screening results?
- What proportions of positive POC results are associated with active chronic HCV infection, and how many start treatment, are cured and are lost to follow-up?
- What were the experiences, perspectives and recommendations of participating pharmacists?

Methods

The trial was registered in the Australian New Zealand Clinical Trials Registry (ACTRN12618000657224p). The Central Health and Disability Ethics Committee approved the study (18/CEN/61/AM04).
The inclusion criteria were: New Zealand residents aged 16 years and over who self-identified that they had one or more risk factors: tattoo or body piercing using unsterile equipment, blood transfusion before 1992, injecting drugs, ever lived or had medical treatment in a high-risk country, incarceration, born to a mother with HCV or aged 35–69 years. The last risk factor was based on population prevalence in New Zealand and included to destigmatise the testing by removing the need to disclose life-style factors. Exclusion criteria were: people who did not provide informed consent, people under 16 years of age, and people who were not New Zealand residents (but proof of residency was not required). Pharmacists were requested to ask potential participants if they had a previous positive HCV test, and if they revealed they had a previous positive test, to advise that the POC test would still show a positive. However, an undisclosed previous positive test was not an exclusion criterium.

Initial promotion was limited to a small printed sign on the counter about HCV testing and risk factors and butterfly lapel pins. Following lower than expected uptake, new promotional material from March 2019 included colourful counter-display material, leaflets regarding the HCV test and risk factors, posters for the pharmacy and Facebook posts boosted to 40–65-year-olds. People could request the test after seeing promotional material or discussion with a pharmacy staff member. The pharmacist was not to ask which risk factor/s applied.

Following informed consent, the participant's name, date of birth, national health index number (a unique number for New Zealanders), contact details and general practitioner (GP) details were collected. Participants self-completed a questionnaire that was sealed and given to the pharmacist (unseen by the pharmacist). The questionnaire collected demographics, risk factors for HCV, previous HCV testing and reasons why testing was not conducted before, questions that were based on investigator suggestions. A finger prick collect was taken and the test conducted. After five minutes the test was recorded as positive or negative with the participant immediately informed verbally of their result. Participants with a positive screening test were given a laboratory test form for confirmatory HCV RNA testing, full blood count, liver function tests and renal function with the results going to the pharmacy and the participant's GP (if the participant agreed). Those with a positive result were referred to their GP with a letter sent directly to the GP or provided to the participant. Non-completion of the lab test within four weeks stimulated telephone follow-up by the pharmacist to encourage completion.

Pharmacies were paid $25 for each test. Participants received no payment.

Laboratory test and treatment information were accessed by a researcher for all participants with a positive screening test.

At the end of the study, each pharmacy was emailed a link to an online questionnaire with 40 questions for completion by pharmacists involved in the study. These questions were based on the previous experience of the authors, comments from pharmacists during the research, and research elsewhere investigating pharmacist prescribing of HCV treatments.21

Data were entered into an excel spreadsheet for analysis. Analysis involved simple descriptors and chi square test using Fisher Exact Test.

Results

A total of 192 participants were screened with 5–42 tests per pharmacy, and on average 1.5 participants screened per month per pharmacy.

Participants screened for HCV were 62% female, with an average age of 51.6 years (range 16–85 years, Figure 1). People could identify with multiple ethnicities, and while most reported NZ European or other European ethnicities (74%), Māori (15%), Pasifika (7%), Indian (4%); Chinese (3%), and other ethnicities (10%) were also reported.

Participants’ reported risk factors for HCV exposure are provided in Table 1. Participants could identify with multiple risk factors and 10% reported previous testing. Reasons for not being tested before included thinking they were not at risk (63%); not knowing about HCV (31%), and not knowing it could be treated (16%).
Test uptake varied over time, with greater uptake when pharmacies started testing, with new promotional material distributed, and in the final month of the study.

Seven people received positive screening test results (3.6%), coming from four pharmacies, all of which had conducted at least 19 tests. Three pharmacies with two positives each provided needle exchange and OST and promoted the service well with two using promotional material on an in-store television screen for some of the time. A mall pharmacy with neither needle exchange nor OST services found a single positive. One pharmacy with a very proactive pharmacist in a suburban area known to have higher rates of HCV conducted 27 tests, all of which were negative. The pharmacists’ survey revealed that people who tested positive were not well known to the pharmacist, and some had never been seen before.

The participants who received a positive result from their screening were aged 23–65 years old (average 49.7 years; five were aged 48–65 years). Four were male and three were female. Five reported NZ European ethnicity and two reported Māori and NZ European ethnicity. Six had a GP. These participants reported 1–4 risk factors each and were more likely than those testing negative to report injected drug use, tattooing or piercing with unsterile equipment or prior incarceration (Table 1).

All seven participants with positive screenings had further blood tests for RNA, with five positive RNA and two negative RNA results (Figure 2). Of the five with positive RNA results, three participants were new diagnoses with no laboratory evidence of previous testing. The other two with positive RNA results had laboratory evidence showing a previous positive RNA result with previous loss to follow-up following failure to attend a scheduled appointment.

Four of the five participants with a positive RNA test received HCV treatment. None have had post-treatment blood tests for sustained virologic response yet. The remaining HCV RNA positive participant was a 23-year-old male who had been found RNA positive and lost to follow-up approximately two years before being screened in the pharmacy. He took 12 months and much encouragement from the pharmacist to have his RNA blood test but had not started treatment as at May 2020. Both participants who received negative RNA results were previously known to be negative RNA.

Pharmacist feedback

Fifteen pharmacists responded to the survey (52% response from 29 pharmacists who conducted tests), with at least one response from each pharmacy. They reported 1–35 years’ experience in pharmacy (average 11.6 years), and eight were male. Eight were European, four Korean, and three were other ethnicities, and they had personally conducted an estimated 2–23 tests (average 9.5 tests).

Eleven pharmacists (73%) wanted to continue offering funded HCV screenings; four pharmacy employees answered that...
it was not their decision, and no pharmacist answered in the negative. Fourteen respondents (93%) rated the likelihood of recommending it to other pharmacists 7 out of 10 or higher, because of potential health gains for patients, professional satisfaction, patient convenience and the opportunity to address low awareness or build relationships.

Most pharmacists estimated testing and discussion took 15 or 20 minutes (range 5–20 minutes). Pharmacists who conducted six or more tests reported most tests arose from staff recommendation while those who conducted few tests reported participants mostly requested testing, and one reported their clients were low risk for HCV. Pharmacists estimated that 0–40% (average 13%) of their mentions of the test resulted in a test being taken.

Getting people to do the test (eight respondents), and/or insufficient time for the patient (two respondents) or pharmacist (four respondents, including paperwork concerns) were common challenges. Several respondents reported some people appeared reluctant to be tested, including some who the pharmacist considered likely to be at high risk, and people unwilling to participate in a study. One pharmacist worried about offending people when raising the test. Pharmacists used explanations (eg, about the condition, current treatment options and/or confidentiality) and information sheets, developed specific questions for approaching people, or built rapport to overcome challenges.

Five pharmacists experienced a positive screening result, all in people unknown to the pharmacist or occasional users of the pharmacy. The pharmacists felt capable of managing the positive result. Three pharmacists reported multiple follow-ups with a participant with a positive result to get the RNA blood test and treatment.

“So satisfied our pharmacy was able to start one of our positive participants on Maviret. I have followed him up and he is doing well [and] was thankful… our [other] positive participant, we tried constantly to get him to get his [laboratory RNA test]… We still keep in contact…”

Two-thirds of responding pharmacists supported pharmacist-prescribing of HCV treatment, to aid access and increase treatment uptake. Two pharmacists disagreed and four others did not know, being uncomfortable about treating a serious illness or considering co-morbidities, or considering the GP more appropriate.

Pharmacists appreciated the promotional material provided, particularly posters, counter cards and leaflets. Two pharmacists used in-store TV screens with slide images promoting the service, and another created a window display to raise awareness.

Table 1: Risk factors in those testing negative and those testing positive on the initial screening.

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Negatives (n=185)</th>
<th>Positives (n=7)</th>
<th>Fisher Exact Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever received a tattoo or body piercing using unsterile equipment</td>
<td>54 (29%)</td>
<td>6 (86%)</td>
<td>0.0041; p&lt;0.01</td>
</tr>
<tr>
<td>Ever injected drugs</td>
<td>9 (5%)</td>
<td>4 (57%)</td>
<td>0.0004; p&lt;0.01</td>
</tr>
<tr>
<td>Had a blood transfusion before 1992</td>
<td>18 (10%)</td>
<td>2 (29%)</td>
<td>0.1575; n.s.</td>
</tr>
<tr>
<td>Ever lived or received medical treatment in a high-risk country</td>
<td>31 (17%)</td>
<td>1 (14%)</td>
<td>1.0; n.s.</td>
</tr>
<tr>
<td>Ever been in prison</td>
<td>7 (4%)</td>
<td>4 (57%)</td>
<td>0.0002; p&lt;0.01</td>
</tr>
<tr>
<td>Been born to a mother living with hepatitis C</td>
<td>4 (2%)</td>
<td>1 (14%)</td>
<td>0.1711; n.s.</td>
</tr>
<tr>
<td>Been born between 1949 and 1983</td>
<td>114 (62%)</td>
<td>5 (71%)</td>
<td>0.7109; n.s.</td>
</tr>
</tbody>
</table>
Figure 2: Outcomes for participants with positive screening results.

10 pharmacies participated (7 for 15 months, 3 for 8 months)

192 people consented and screened

Seven positive on screening (3.6%)
185 negative on screening (96.3%)

Seven had RNA blood tests conducted (3.6%)
185 had no further testing (96.3%)

Positive
5 had positive RNA blood tests (2.6% of all participants)

Negative
2 had negative RNA blood tests

Treated
4 received HCV treatment (2.1% of all participants)

Untreated
1 untreated as at May 2020

1 received second negative RNA to confirm status
1 Fibroscanned for fatty liver

None received post-treatment tests to ascertain treatment response
Discussion

HCV testing uptake in this current study (1.5 tests per pharmacy per month) was similar to reported rates in two previous community pharmacy pilots, eg, 0.4 and 1.7 tests per pharmacy per month. Higher testing uptake (2.4–4.6 tests per pharmacy per month) has been reported where pharmacies targeted needle exchange and/or OST users, paid participants incentives and/or had little time commitment for the pharmacists. In this current study, the wider range of pharmacies, and testing anyone who thought they had a risk factor, potentially lowered the positive rate, but probably increased awareness and uptake for people with previous injected drug use or other risk factors (eg, blood transfusion). Although most individuals testing positive had a GP, they still chose to have the free test in the pharmacy, and three of the four people treated were new diagnoses. This suggests the importance of raising awareness through different routes.

In the current study, most people testing positive were unknown to the pharmacist, suggesting most were not OST or needle exchange users at that pharmacy. Pharmacists were asked to check if they had had a previous positive test and if so not to test again. Many people who are OST or needle exchange users may already know they are positive for HCV and therefore might have been dissuaded from testing. However, this study suggests that pharmacy can help re-engage individuals lost to follow-up. Most people with chronic HCV infection are no longer accessing needle exchange or OST, (Gane E, personal communication 2020) and therefore testing needs to be wider than these populations.

A US study which tested people with at least one HCV risk factor using a phlebotomist in pharmacies with results later provided by telephone had an 8% positive screening rate, but high loss to follow-up. The current study had little attrition, with all participants with a positive POC HCV antibody result receiving follow-up HCV RNA testing and four of the five who were HCV RNA positive treated by a GP. While discussing the study and conducting the testing, pharmacists could build rapport and raise awareness of the importance of diagnosis and treatment, and new improved treatment, which likely helped, and pharmacists reported multiple follow-ups.

Most pharmacists participating in the survey were positive about allowing pharmacists to prescribe antiviral treatment. Scottish research has found pharmacist prescribing of HCV treatment increased test uptake and approximately doubled the numbers treated when using pharmacist screening and prescribing versus pharmacist screening and a conventional nurse-led pathway. Others recommend aiding and simplifying access to diagnosis and/or treatment for HCV to eliminate the disease, and prevent complications and health system costs. We recommend using the pharmacist as part of the healthcare team, and other pharmacy staff, to raise awareness about chronic hepatitis C and the availability of safe and effective treatment. In 10 pharmacies over 7–15 months, only four people with HCV received treatment from this initiative, but some of these people may not have otherwise received treatment. The training was only provided to pharmacists and intern pharmacists, and widening this to other staff might increase frequency of mentions and tests. More people are likely to be identified and treated (as in Scotland) if pharmacists could also prescribe HCV treatment. In future, pharmacists, who have been suitably trained, should be permitted to prescribe glecaprevir and pibrentasvir, thereby further simplifying HCV management and increasing access to care and curative treatment. Other sites could be usefully investigated for screenings, eg, emergency departments of hospitals, accident and emergency private providers, or community laboratories. In 2015, the New Zealand Government signed the WHO declaration to eliminate hepatitis C by 2030. Unfortunately, the recently updated Markov model has suggested that New Zealand will not reach that target until 2038, despite the availability of fully funded, safe and effective therapy. This delay is due to the low rate of testing and linkage to care. Wider access to testing and treatment in the community will be essential if New Zealand is to achieve the WHO elimination targets.
Strengths and weaknesses

Study strengths included the variety of pharmacy characteristics, involvement of every pharmacy invited and follow-up of patients to ascertain the proportion treated.

Using metropolitan Auckland pharmacies might not reflect rates in other New Zealand regions. There is no knowledge of how many people noticed the HCV screening information in the pharmacy and pharmacists did not record the number of people approached so an accurate response rate was unavailable.

The study relied on self-reporting of risk factors, and some may have been under-reported. We also did not ask if they were currently injecting drugs or taking OST, however none of those who tested positive were well-known to the pharmacist, suggesting they were not receiving OST from that pharmacy. No participants treated for HCV had a follow-up HCV RNA test to ascertain sustained viral response as expected within recommended GP care, possibly because their GP was unaware of the need for this test, or the participant felt so well they believed themselves cleared. We could not measure if raising awareness through the pharmacy increased uptake of testing through doctors. Consumer feedback was not collected.

Only 15 pharmacists responded to the survey, a low response rate, partly because some pharmacists had left the participating pharmacy. Non-responders may have had different views from respondents. However, all pharmacies invited participated and screened patients, and all pharmacies had at least one pharmacist positive about HCV screening, supporting the feasibility of the screening.

The ethnicity of people tested included an over-sampling of Māori and European and under-sampling of Asian compared to the Waitematā DHB population.

Conclusion

Despite aiming to eliminate HCV by 2030, New Zealand is unlikely to meet this target until 2038, despite the fully funded availability of effective therapy. Therefore, initiatives which provide wider access to testing in the community should be a priority in this country’s first National Hepatitis C Action Plan. The success of the recent NHS Scotland community pharmacy HCV programme and the results from this pilot study in a single district health board would support a larger study of pharmacy point-of-care HCV antibody testing in New Zealand to determine whether community pharmacies could become a key part of our national HCV elimination strategy.
Compromising interests:
NG is a member of the Board of the Pharmaceutical Society of New Zealand, and has received funding from Green Cross Health, the Pharmaceutical Society and the Pharmacy Guild of New Zealand. She has no other relevant interests to report. JP reports honorariums from pharmaceutical companies for speaking on HCV, and has no other relevant interests to report. EG reports being Chair of the Ministry of Health Hepatitis C Implementation Committee, and Chair of the Northern Regional DHB Alliance Hepatitis C Steering Group.

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