# Viral hepatitis testing and treatment in community pharmacies: a systematic review and meta-analysis

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## Summary

**Background** The World Health Organization seeks to eliminate viral hepatitis as a public health threat by 2030. This review and meta-analysis aims to evaluate the effectiveness of programs for hepatitis B and C testing and treatment in community pharmacies.

**Methods** Medline, Embase, Cochrane CENTRAL, and Global Health were searched from database inception until 12 November 2023. Comparative and single arm intervention studies were eligible for inclusion if they assessed delivery of any of the following interventions for hepatitis B or C in pharmacies: (1) pre-testing risk assessment, (2) testing, (3) pre-treatment assessment or (4) treatment. Primary outcomes were proportions testing positive and reaching each stage in the cascade. Random effects meta-analysis was used to estimate pooled proportions stratified by recruitment strategy and setting where possible; other results were synthesised narratively. This study was pre-registered (PROSPERO: CRD42022324218).

**Findings** Twenty-seven studies (4 comparative, 23 single arm) were included, of which 26 reported hepatitis C outcomes and four reported hepatitis B outcomes. History of injecting drug use was the most identified risk factor from pre-testing risk assessments. The pooled proportion hepatitis C antibody positive from of 19 studies testing 5096 participants was 16.6% (95% CI 11.0%–23.0%; heterogeneity $I^2$ = 96.6%). The pooled proportion antibody positive was significantly higher when testing targeted people with specified risk factors (32.5%, 95% CI 24.8%–40.6%; heterogeneity $I^2$ = 82.4%) compared with non-targeted or other recruitment methods 4.0% (95% CI 2.1%–6.5%; heterogeneity $I^2$ = 83.5%). Meta-analysis of 14 studies with 813 participants eligible for pre-treatment assessment showed pooled attendance rates were significantly higher in pharmacies (92.7%, 95% CI 79.1%–99.9%; heterogeneity $I^2$ = 72.4%) compared with referral to non-pharmacy settings (53.5%, 95% CI 36.5%–70.1%; heterogeneity $I^2$ = 92.3%). The pooled proportion initiating treatment was 85.6% (95% CI 74.8%–94.3%; heterogeneity $I^2$ = 75.1%). This did not differ significantly between pharmacy and non-pharmacy settings.

**Interpretation** These findings add pharmacies to the growing evidence supporting community-based testing and treatment for hepatitis C. Few comparative studies and high degrees of statistical heterogeneity were important limitations. Hepatitis B care in pharmacies presents an opportunity for future research.

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**Keywords:** Hepatitis B; Hepatitis C; Community pharmacy; Testing; Treatment

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## Research in context

### Evidence before this study

There is emerging evidence supporting decentralisation of hepatitis B and C care away from specialists in tertiary centres to non-specialists in community-based services, such as primary care services, harm reduction and drug addiction centres, and needle and syringe programs. Pharmacies present another potential community-based service to access testing and treatment for hepatitis B and C for people underserved by existing models. Point-of-care testing and dried blood spot testing for have been effectively used in non-pharmacy community settings and could be employed in pharmacies to simplify testing and facilitate linkage to treatments. MEDLINE, Embase, Cochrane CENTRAL and Global Health we searched for all dates up to 12 November 2023 without language restrictions using the terms related to hepatitis B, hepatitis C, pharmacists, and pharmacies. Studies were included if they examined pre-testing assessment for hepatitis B and/or C risk factors, testing, attendance at pre-treatment initially testing positive and/or treatment. Both single and double arm studies were included. Twenty one studies were identified through electronic databases and six through other sources.

### Added value of this study

To the authors' knowledge, this is the first systematic review to comprehensively examine the effectiveness of community pharmacy-based programs delivering elements of the cascade of care for either hepatitis B or C. This review demonstrates community pharmacy-based testing programs for hepatitis C have great potential to complement existing services and increase case detection. Beyond testing, provision of the entire cascade of care within the pharmacy setting improves retention in care.

### Implications of all the available evidence

The findings from this review add to the growing body of evidence supporting task shifting of hepatitis C testing and treatment away from tertiary centres to community services, including pharmacies. Resourcing pharmacies to provide testing and treatment could aid in achieving the World Health Organization hepatitis C elimination goals.

## Introduction

Hepatitis B and hepatitis C infection are substantial global health threats.[1] The World Health Organization (WHO) estimated 296 million and 58 million people worldwide were living with chronic hepatitis B and C infection respectively in 2019, with approximately 1.5 million new infections for each hepatitis B and C, and approximately 820,000 and 290,000 deaths from hepatitis B and C related causes respectively, with most of these due to chronic liver disease and liver cancer.[1]

In 2016, WHO called for global elimination of viral hepatitis as a public health threat by 2030.[2] Strategies were outlined to achieve goals of 90% reduction in new infections, a 65% reduction in deaths, and treatment of 80% of chronic infections. Over the 2016–2021 period, global response to hepatitis B and C virus gained some momentum, but access to testing and treatment remained well below needs, and mortality was increasing.[1] In 2019, only 30.4 million (10.2%) and 15.3 million (26.2%) of people with chronic hepatitis B and C infection respectively were estimated to be aware of their status.[1] This highlights the need for novel strategies and an expanded hepatitis health workforce to meet the needs of people underserved by existing models of care.

Community pharmacies, henceforth referred to as pharmacies, have potential to enhance service provision for some people at risk of hepatitis B or C. In many countries pharmacies have become key sites for the implementation of preventative health programs, for example through needle and syringe provision[3] and immunisation services.[4] Pharmacies could also be an alternative access point for people who, in other healthcare settings, face barriers to care such as geographic accessibility, stigma, and cost.[5,6] The strong relationship many pharmacists have with the individuals and communities they serve, alongside their highly accessible setting, could be harnessed to engage more people in care.[7]

Point-of-care and dried blood spot (DBS) testing technologies for hepatitis B and C present opportunities to simplify testing processes, increase case detection, and facilitate linkage to treatment in community settings, particularly low resource settings.[8,9] Hepatitis B and C point-of-care testing programs have already shown meaningful public health benefit across various community settings including community outreach,[10–13] harm reduction and addiction centres,[14–16] and health-facility settings.[17–19] Pharmacies present another potential community setting to employ point-of-care testing programs and establish pathways to treatment with local prescribers or in pharmacies themselves.

To the authors' knowledge, no systemic review exists specifically examining pharmacies as a setting for viral hepatitis care provision. This systematic review and meta-analysis aims to evaluate the effectiveness of programs for hepatitis B and C testing and treatment in pharmacies in terms of case detection and progress through the care cascade.

## Methods

### Search strategy and selection criteria

This systematic review was undertaken and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[20] The methods of analysis and defined inclusion criteria were specified in the unamended study protocol, which was registered with and available through the International Prospective Register of Systematic Reviews (PROSPERO; CRD42022324218).

Studies were eligible for inclusion if they examined delivery of any of the following components in the cascade of care for hepatitis B and/or C in the pharmacy setting as an intervention: (1) pre-testing assessment for hepatitis B and/or C risk factors, (2) testing, (3) pre-treatment assessment after initially testing positive, and/or (4) treatment. To be eligible studies had to report data on primary outcomes of interest for this review, being the number and proportion of positive cases detected and the number and proportion reaching each stage of the care cascade. Both single arm studies reporting progress through the care cascade beginning in pharmacies without a comparator setting and studies comparing progress through the care cascade in pharmacies with non-pharmacy settings after referral from the pharmacy were eligible for inclusion. Reviews, news articles and editorials were not eligible.

Four electronic databases (MEDLINE, Embase, Cochrane CENTRAL and Global Health) were searched for all dates up to 12 November 2023 without year or language restrictions. The search strategy used terms relating to hepatitis B, hepatitis C, pharmacies, and pharmacists. The full search strategies are outlined in the Appendix. One reviewer additionally searched the abstract booklets from the following international conferences from 2017 to 2022: European Association for the Study of the Liver, American Association for the Study of the Liver, The Asian Pacific Association for the Study of the Liver, The International Network on Health and Hepatitis in Substance Users, and the International Viral Hepatitis Elimination Meeting. One reviewer also performed backward citation tracking by hand searching the reference lists of included studies and forward citation tracking using the "Cited by" function in google scholar to identify any further studies for inclusion.

Results from the electronic database search were uploaded into Covidence (Veritas Health Innovation Ltd., Melbourne, AU) which was used to electronically identify and exclude duplicate records as well as to manage the study selection process. Two reviewers (MJH and EB) independently screened articles, first by title and abstract, then by full-text, to determine eligibility for final inclusion. Disagreements were resolved by discussion with a third reviewer (JSD). If multiple publications reported results from the same study and time period (i.e. did not contribute unique data for any outcomes) only the publication with the most comprehensive and complete data was included in the review. While reviews, news articles and editorials were not eligible for final inclusion, the full-text of these publication types were reviewed if relating to the topic to identify relevant references. Throughout the study selection and subsequent data analysis steps of this systematic review, if further information relating to a study was required, the first or last author was contacted by email on two occasions at least two weeks apart. If the query related to eligibility criteria and there was no response after two attempts, the study was excluded.

### Data analysis

Data were extracted by one reviewer and checked by another (MJH and EB). Discrepancies in data extraction were resolved through discussion with a third reviewer (JSD). Where available, data were extracted on study characteristics including: study dates and locations; number of participating pharmacies; participant eligibility criteria; study design; and recruitment strategy. Regarding recruitment strategy studies were categorised as those that recruited by targeting on people with a specified risk-factor (e.g. people on opioid agonist treatment (OAT)), those that only used other methods, including performing risk assessments for hepatitis B or hepatitis C risk factors or through self-referral for testing regardless of risk status, and those that used a combination of targeting and other methods.

Primary outcomes which were extracted included (1) the number of individuals with pre-testing assessment for hepatitis B or C risk factors and the most common risk factor identified, (2) the number of participants tested and the number with a positive antibody, RNA or antigen result (3) the number of individuals attending pre-treatment assessment after initially testing positive, and (4) the number commencing treatment, completing treating, having a test for sustained virologic response (SVR) for hepatitis C and achieving SVR. In addition to absolute numbers at each cascade stage, for comparative studies effect estimates such odds ratios comparing pharmacies with non-pharmacy settings were also extracted. Pre-treatment assessment was defined within individual studies and included activities such as confirmatory RNA tests and cirrhosis assessments. Study arms were also categorised by setting for pre-treatment assessment and treatment, being either at the pharmacy, external to the pharmacy (non-pharmacy), or a combination of pharmacy and non-pharmacy settings. SVR for hepatitis C was defined as a negative hepatitis C RNA test at least 12 weeks after completion of treatment.

We calculated proportions testing positive, attending pre-treatment assessment, and initiating treatment based on the numbers eligible at each stage, as defined within each study, as the denominator. For hepatitis C treatment, the proportions completing treatment, having an SVR test and achieving SVR were calculated with

the number initiating treatment as the common denominator. Random effects meta-analysis was used to calculate pooled proportions from both comparative and single arms studies by treating each arm in the comparative studies as a single arm study. Proportions were pooled in forest plots both in total and disaggregated by subgroups including the recruitment strategy and setting of care. Statistical heterogeneity among studies was assessed by calculating an $I^2$, with >50% considered as a high level of statistical heterogeneity.[21] To explore sources of heterogeneity we conducted a meta-regression on potentially important covariates that were sufficiently reported in included studies. The remaining results were synthetised narratively. Analyses were performed using STATA (Version 17.0 for Windows; StataCorp, College Station, Texas).

Secondary outcomes of interest were the cost-effectiveness of interventions, for which the incremental cost-effectiveness ratio (ICER) was extracted, and program evaluations, for which the results of surveys and qualitative interviews with pharmacists and study participants were extracted.

Risk of bias of was assessed using the relevant Joanna Briggs Institute critical appraisal tools for randomised controlled trials,[22] quasi-experimental studies[22] and case series.[23] Assessments were completed independently by two reviewers (MJH and EB), with discrepancies resolved by discussion with the third reviewer (JSD).

### Ethics approval and consent to participate

Not applicable.


### Role of the funding source

There was no specific funding for this project, however, MJH and EB's positions are supported by the Specialist Training Program funding initiative of the Australian Government Department of Health, which had no role in the design or conduct of this study.


## Results

The search yielded 3827 records from electronic databases and 11 from other sources. After removal of 958 duplicates, 2869 records were screened at the titles and abstracts stage and 159 full-text records were assessed for eligibility. Twenty-two studies met eligibility criteria, but were not included due to overlapping data with other studies with most comprehensive and complete data sets. These, together with studies excluded due to insufficient information to determine eligibility and those for which the full text was not found are listed in the Appendix. In total 27 studies were included, with 21 identified through the electronic database search and six through other sources. Twenty-three studies contributed to meta-analyses (Fig. 1). Of the included studies, there were 16 peer reviewed journal articles, 8 conference abstracts, and three reports. Four of the included studies were comparative studies and the remainder were single arm intervention studies. The studies were spread across 11 countries and included between one and 61 pharmacies. Twenty-six studies reported hepatitis C outcomes, four reported hepatitis B outcomes, 12 reported outcomes relating to program evaluation and three reported outcomes from cost-effectiveness analyses (Table 1).

### Hepatitis C

Of the 26 included studies reporting hepatitis C outcomes, two studies did not contribute new hepatitis C data due to overlap with other studies, but were still included in the review as they contributed results relating to hepatitis B[29] and cost-effectiveness.[42] The designs of the remaining 24 studies are summarised in Table 2 and the results for the primary outcomes of (1) pre-testing risk assessment, (2) testing, (3) attendance at pre-treatment assessment and/or (4) treatment are summarised in Table 3.

#### *Pre-testing risk assessment*

Eight studies recruited participants by only targeting people with a specific risk-factor, six studies recruited by other methods such as assessing for any hepatitis C risk factor and/or self-referral regardless of risk factors, eight studies used a combination of targeting and other methods, and the remaining two studies did not clearly report recruitment methods (Table 2). In the 15 studies performing pre-testing risk assessments, the most common risk factors identified were injecting drug use (IDU) (n = 6), birth cohort (n = 3), tattoos (n = 1), both birth cohort and tattoos (n = 1), OAT (n = 1), and same sex intercourse (n = 1). The remaining two studies did not report risk assessment outcomes (Table 3).

#### *Testing*

Studies used rapid antibody tests (RATs) (n = 11), DBS tests (n = 8), point-of-care RNA testing (n = 3), and in-house capillary blood spot testing (n = 1). One study did not report the test used (Table 2).

In total 6025 participants received an initial test in pharmacies across the 24 studies, with the number tested ranging from 17 to 1296 per study (Table 3). Two studies assessed testing uptake at pharmacies compared with other settings among people on OAT.[24,25] One found participants had higher odds of testing (OR 16.95, 95% CI 7.07–40.64, $p < 0.001$), when tested in the pharmacy by an in-reach nurse compared with being counselled by the pharmacist then referred to standard care outside the pharmacy.[24] The other found a higher odds of DBS testing (OR 2.25, 95% CI 1.48–3.41, $p < 0.001$) in pharmacies compared with other settings.[25] In the other two comparative studies, all participants were tested at the pharmacy.[26,27] In the intervention arms, positive cases were followed up and treated within

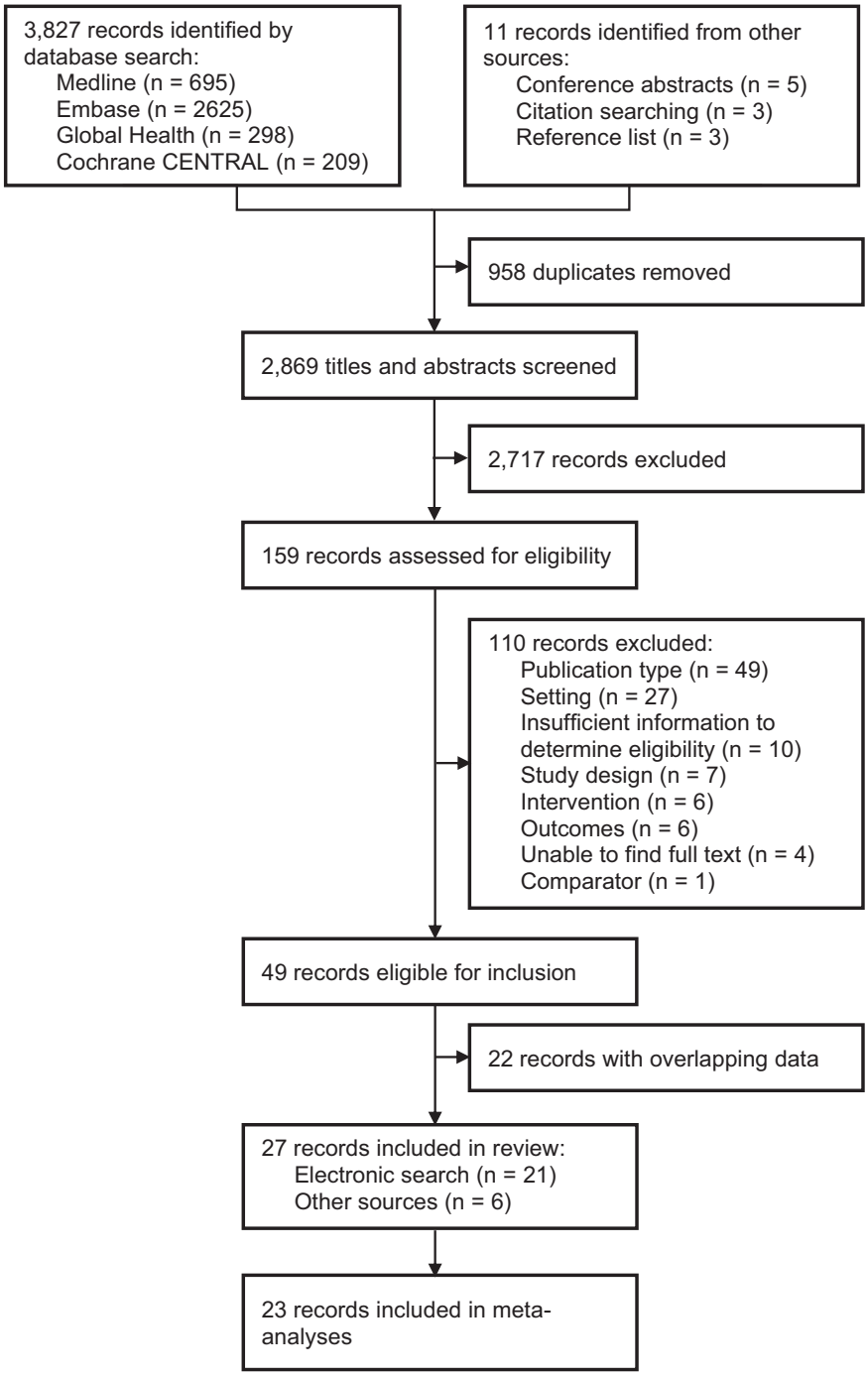


***Fig. 1:*** **Schematic diagram of search results and selection process.**

the pharmacy, while in the control arms positive cases were referred out to standard care. Testing uptake was higher in the intervention arm in both studies. Among the single arm intervention studies, pharmacists or pharmacy staff conducted testing within the pharmacy in all studies, with the exception of two: one with testing conducted by in-reach nurses; the other by in-reach phlebotomists (Table 2). Test uptake was 11.2%,[43] 33.3%[47] and 57.1%[50] in the three single arm studies with available data.

| Author | Year | Publication type | Countries | Study period | Number of participating pharmacies | Primary outcomes reported | | Secondary outcomes reported | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Hepatitis C | Hepatitis B | Program evaluation | Cost effectiveness |
| **Comparative studies** | | | | | | | | | |
| Byrne[24] | 2022 | Journal | Scotland, Wales, Australia | 2019–2021 | Intervention: 20<br>Control: 20 | Yes | No | No | No |
| Radley[25] | 2017a | Journal | Scotland | 2014 | Intervention: 6<br>Control: 30 | Yes | No[c] | Yes | No |
| Radley[26] | 2017b | Journal | Scotland | 2015–2016 | Intervention: 4<br>Control: 4 | Yes | No[c] | Yes | Yes[b] |
| Radley[27] | 2020 | Journal | Scotland | 2016–2018 | Intervention: 28<br>Control: 27 | Yes | No[c] | No | No |
| **Single arm studies** | | | | | | | | | |
| Boothman[28] | 2019 | Conference | England | 2018–NR | 5 | Yes | No | No | No |
| Buchanan[29] | 2016 | Journal | England | 2014–2015 | 22 | Yes[b] | Yes | No | No |
| Buchanan[30] | 2020 | Journal | England | 2014–2016 | 20 | Yes | No | No | Yes |
| Dong[31] | 2017 | Journal | USA | 2016 | 1 | Yes | No[c] | Yes | No |
| Figueira[32] | 2022 | Journal | Portugal | 2018–2019 | 21 | Yes | Yes | Yes | No |
| Fong[33] | 2019 | Conference | Canada | 2018 | 5 | Yes | No | No | No |
| Fuchs[34] | 2020 | Conference | Canada | 2019 | 1 | Yes | No | No | No |
| Gauld[35] | 2020 | Journal | New Zealand | 2018–2019 | 10 | Yes | No | Yes | No |
| Ghazzawi[36] | 2023 | Journal | Sierra-Leone | 2019–2022 | 1 | No | Yes | No | No |
| Hepatitis C Trust[37] | 2010 | Report | England | 2010 | 19 | Yes | Yes | Yes | No |
| Januszka[38] | 2023 | Journal | USA | 2020–2022 | 3 | Yes | No | No | No |
| Kherghehpoush[39] | 2023 | Journal | USA | 2020–2021 | 1 | Yes | No | No | No |
| Klepser[40] | 2022 | Journal | USA | 2015–2018 | 61 | Yes | No | No | No |
| Kugelmas[41] | 2017 | Journal | USA | 2017 | 45 | Yes | No | No | No |
| Manca[42] | 2020 | Journal | Scotland | 2015–2017 | 33 | Yes[b] | No | Yes | Yes |
| Palmer[43] | 2020 | Conference | Wales | NR | 16 | Yes | No | Yes | No |
| Remy[44] | 2021 | Conference[a] | France | 2019–2021 | 29 | Yes | No | Yes | No |
| Rogers[45] | 2020 | Conference | England | NR | 6 | Yes | No | No | No |
| Selfridge[46] | 2022 | Conference[a] | Canada | 2020–2022 | 4 | Yes | No | Yes | No |
| Stämpfli[47] | 2022 | Journal | Switzerland | 2021 | 25 | Yes | No | Yes | No |
| Stephen[48] | 2019 | Conference | Scotland | NR | 1 | Yes | No | No | No |
| Verma[49] | 2018 | Report | England | 2017–2018 | 6 | Yes | No | Yes | No |
| Verma[50] | 2019 | Report | England | 2018–2019 | 6 | Yes | No | Yes | No |

[a]Additional data provided by author from unpublished manuscript. [b]Study included in review, but relevant data not extracted due to being superseded by other included studies. [c]Testing for hepatitis B conducted, but outcomes were not reported, NR = not reported.

*Table 1:* **Characteristics of included studies and outcomes assessed.**

Among the 19 studies with antibody results, the proportion positive ranged from 0.0% to 53.4% (Table 3). In these 19 studies, 5096 participants were tested for hepatitis C antibodies and contributed 21 antibody positive proportions to the meta-analysis. The pooled proportion antibody positive was 16.6% (95% CI 11.0%–23.0%). Statistical heterogeneity across studies was high ($I^2$ = 96.6%) (Fig. 2). In the meta-regression for the proportion antibody positive, statistically significant sources of heterogeneity were study recruitment strategy, region, and most common risk factor (Appendix, Table S1). Subgroup meta-analysis by recruitment strategy showed the proportion antibody positive to be: 32.5% (95% CI 24.8%–40.6%) for studies using targeted recruitment only of people with a specified risk factor; 17.2% (95% CI 8.2%–28.5%) for studies targeting a specified risk factor and using other recruitment methods; and 4.0% (95% CI 2.1%–6.5%) when identifying people at-risk through other methods alone (Fig. 2). Subgroup meta-analysis by region (Appendix, Figure S2) and most common risk factor (Appendix, Figure S3) are presented in the appendix. Among the 15 studies with RNA results, the proportion positive ranged from 2.6% to 37.5% (Table 3). Meta-analysis of proportions testing hepatitis C RNA positive was not performed due to methodological heterogeneity between studies, with some studies testing for RNA at the initial test and others at the pre-treatment assessment.

| | Targeted Groups | Pre-test risk assessment performed | Test | Initial testing | Pre-treatment assessment | Treatment |
|---|---|---|---|---|---|---|
| **Comparative studies** | | | | | | |
| Byrne[24] | | | | | | |
| Intervention | OAT | No | Genedrive RNA | By in-reach nurse in CP | By in-reach nurse in CP | By in-reach nurse (UK), and remote physician (Aus) |
| Comparator | | | | By community out-reach clinics (UK) or GP (Aus) | By community out-reach clinics (UK) or GP (Aus) | By community out-reach clinics (UK) or GP (Aus) |
| Radley 2017a[25] | | | | | | |
| Intervention | OAT | No | DBS | By pharmacist in CP | NA | NA |
| Comparator | | | | Standard care by other providers | | |
| Radley 2017b[26] | | | | | | |
| Intervention | OAT | No | DBS | By pharmacist in CP | By pharmacist in CP (via local pathology service) | By pharmacist in CP |
| Comparator | | | | | By specialist hepatitis team at treatment centre | Specialist hepatitis team at treatment centre |
| Radley 2020[27] | | | | | | |
| Intervention | OAT | No | DBS | By pharmacist in CP | By pharmacist in CP | By pharmacist in CP |
| Comparator | | | | | By specialist hepatitis team at treatment centre | By Specialist hepatitis team at treatment centre |
| **Single arm studies** | | | | | | |
| Boothman[28] | OAT,NSP | Yes | CBT | By pharmacy staff in CP | By hospital outreach team at CP or local clinic | By hospital outreach team at CP or local clinic |
| Buchanan[30] | OAT,NSP | Yes | DBS | By pharmacist in CP | By specialist hepatitis team at local hospital | By specialist hepatitis team at local hospital |
| Dong[31] | NA | Yes | OraQuick RAT | By pharmacist in CP | NA | NA |
| Figueira[32] | NA | Yes | RAT | By pharmacist in CP | NA | NA |
| Fong[33] | Birth Cohort | Yes | OraQuick RAT | By pharmacist in CP | By GP at local practice | NA |
| Fuchs[34] | OAT | Yes | NR | By in-reach nurse and pharmacist in CP | By in-reach nurse and remote physician at CP | By in-reach nurse and remote physician at CP |
| Gauld[35] | NA | Yes | SD Bioline RAT | By pharmacist in CP | By pharmacist in CP (via local pathology service) | By GP at local practice |
| Hepatitis C Trust[37] | OAT,NSP | Yes | DBS | By pharmacist in CP | NA | NA |
| Januszka[38] | NA | Yes | OraQuick RAT | By pharmacy students and technicians in CP | Clinic external to pharmacy with client linkage support | Clinic external to pharmacy |
| Kherghehpoush[39] | Homeless | Yes | OraQuick RAT | By pharmacist in CP | Low barrier health care clinics | NA |
| Klepser[40] | Birth Cohort | Yes | OraQuick RAT | By pharmacist in CP | NA | NA |
| Kugelmas[41] | NA | Yes | OraQuick RAT | By in-reach phlebotomist in CP | Unclear setting, follow up supported by remote HCV management specialist | NA |
| Palmer[43] | OAT, NSP | No | DBS | By pharmacy staff in CP | NA | NA |
| Remy[44] | NA | Yes | DBS | By pharmacist in CP | Either at CP by mobile hepatitis team or at hospital | Either at pharmacy or at hospital by mobile hepatitis team |
| Rogers[45] | NR | NR | GeneXpert RNA | By pharmacist in CP | Clinic external to CP | Clinic external to pharmacy |
| Selfridge[46] | OAT | Yes | OraQuick RAT | By pharmacist in CP | Phlebotomist or clinic external to CP supported by study nurse | Clinic external to CP supported by study nurse |
| Stämpfli[47] | NA | Yes | OraQuick RAT | By pharmacist in CP | NA | NA |
| Stephen[48] | OAT | No | DBS | By pharmacist in CP | By hepatology nurse specialist at CP | By hepatology nurse specialist at unclear location |
| Verma 2018[49] | NSP | No | OraQuick RAT | By pharmacist in CP | Service external to CP with optional peer-worker support | Service external to CP with optional peer-worker support |
| Verma 2019[50] | NSP | No | GeneXpert RNA | By pharmacist in CP | Service external to CP with optional peer-worker support | Service external to CP with optional peer-worker support |

DBS, Dried Blood Spot; CBT, capillary blood test; CP, community pharmacy; HCV, hepatitis C; GP, General Practitioner; NR, not reported; RAT, rapid antibody test; OAT, Opioid Agonist Treatment (representing people accessing this service at the pharmacy); NSP, Needle Syringe Program (representing people accessing this service at the pharmacy); NA, Not applicable; NR, Not reported.

***Table 2:*** **Design characteristics of included studies examining components of the hepatitis C cascade of care.**

| | Most common risk factor from pre-test assessment | Initial testing n (%) | Antibody positive n (%) | RNA positive n (%) | Pre-treatment assessment n (%) | Initiating treatment n (%) | Completing treatment n (%) | SVR test n (%) | SVR n (%) | Treatment period complete |
|---|---|---|---|---|---|---|---|---|---|---|
| **Comparative studies** | | | | | | | | | | |
| Byrne[24] | | | | | | | | | | |
| Intervention | NA | 144 | NA | 23 (16.0) | 23 (100.0) | 22 (100.0) | 19 (86.4) | 18 (81.2) | 18 (81.2) | Yes |
| Comparator | | 17 | NA | 6 (35.3) | 5 (83.3) | 5 (100.0) | 4 (80.0) | 2 (40.0) | 2 (40.0) | |
| Radley 2017a[25] | | | | | | | | | | |
| Intervention | NA | 43 | 13 (30.2) | NA | NA | NA | NA | NA | NA | NA |
| Comparator | | 75 | NR | | | | | | | |
| Radley 2017b[26] | | | | | | | | | | |
| Intervention | NA | 94 | 30 (31.9) | 10 (10.6) | 20 (76.9)[a] | 3 (100.0) | 3 (100.0) | 3 (100.0) | 3 (100.0) | Yes |
| Comparator | | 58 | 17 (29.3) | 2[b] (3.4) | 6 (40.0) | 1 (100.0) | 1 (100.0) | 1 (100.0) | 1 (100.0) | |
| Radley 2020[27] | | | | | | | | | | |
| Intervention | NA | 245 | 77 (31.4) | 27 (11.0) | 176 (80.3) | 112 (66.7) | 108 (96.4) | 102 (91.1) | 98 (87.5) | Yes |
| Comparator | | 145 | 31 (21.4) | 23 (15.9) | 137 (64.2) | 61 (72.3) | 58 (95.1) | 46 (75.4) | 43 (70.5) | |
| **Single arm studies** | | | | | | | | | | |
| Boothman[28] | IDU | 32 | 9 (28.1) | 7 (21.8) | 5 (71.4) | 5 (100.0) | 5 (100.0) | 2 (40.0) | 2 (40.0) | No |
| Buchanan[30] | IDU | 186 | NR | 13 (7.0) | 12 (92.3) | 6 (50.0) | 6 (100.0) | 6 (100.0) | 6 (100.0) | Yes |
| Dong[31] | Birth cohort | 83 | 1 (1.2) | NA | NA | NA | NA | NA | NA | NA |
| Figueira[32] | SSI | 126 | 0 (0.0) | NA | NA | NA | NA | NA | NA | NA |
| Fong[33] | Birth cohort | 135 | 2 (1.5) | NA | NR | NA | NA | NA | NA | NA |
| Fuchs[34] | OAT | 128 | NA | 42 (32.8) | NR | 23 (Unclear) | 4 (17.4) | NR | NR | No |
| Gauld[35] | Birth cohort | 192 | 7 (3.6) | 5[b] (2.6) | 7 (100.0) | 4 (80.0) | Unclear | 0 | NA | No |
| Hepatitis C Trust[37] | IDU | 234 | 35 (15.0) | 14 (6.0) | NA | NA | NA | NA | NA | NA |
| Januszka[38] | Birth cohort and tattoo | 236 | 11 (4.7) | | 4 (33.3) | NA | NA | NA | NA | NA |
| Kherghehpoush[39] | IDU | 50 | 22 (44.0) | NA | Unclear | NA | NA | NA | NA | NA |
| Klepser[40] | NR | 867 | 181 (29.9) | NA | NA | NA | NA | NA | NA | NA |
| Kugelmas[41] | Tattoo | 1296 | 103 (7.9) | NA | 29 (31.9) | NA | NA | NA | NA | NA |
| Palmer[43] | NA | 56 | 16 (28.6) | 4 (7.1) | NA | NA | NA | NA | NA | NA |
| Remy[44] | NR | 656 | 45 (6.9) | 13 (2.0) | 13 (100.0) | 13 (100.0) | 13 (100.0) | NR | NR | Yes |
| Rogers[45] | NA | 203 | NA | 30 (14.8) | 20 (66.7) | 12 (66.7) | 12 (100.0) | NR | NR | No |
| Selfridge[46] | IDU | 200 | 64 (32.0) | 26[b] (13.0) | 55 (85.9) | 25 (96.2) | NR | NR | 19 (76.0)[c] | No |
| Stämpfli[47] | IDU | 145 | 8 (5.5) | NA | NA | NA | NA | NA | NA | NA |
| Stephen[48] | NA | 25 | 5 (20.0) | 5 (20.0) | 5 (100.0) | 5 (100.0) | 3 (60.0) | 3 (0.6) | 3 (0.6)[c] | No |
| Verma 2018[49] | NA | 178 | 95 (53.4) | 18[b] (10.1) | 23 (27.0) | 16 (88.9) | 1 (6.3) | 1 (6.3) | 1 (6.3) | No |
| Verma 2019[50] | NA | 176 | NA | 66 (37.5) | 21 (35.0) | 18 (85.7) | 14 (11.8) | Unclear | 4 (22.2) | No |

[a]Requested by pharmacist but collected by external phlembotomist. [b]RNA testing occurred at the follow up appointment, not at the initial testing, and is therefore dependent on the follow up rate. [c]Definition of SVR not reported IDU, injecting drug use; OAT, Opioid Agonist Therapy; SSI, same-sex intercourse.

*Table 3:* **Results of included studies examining components of the hepatitis C cascade of care.**

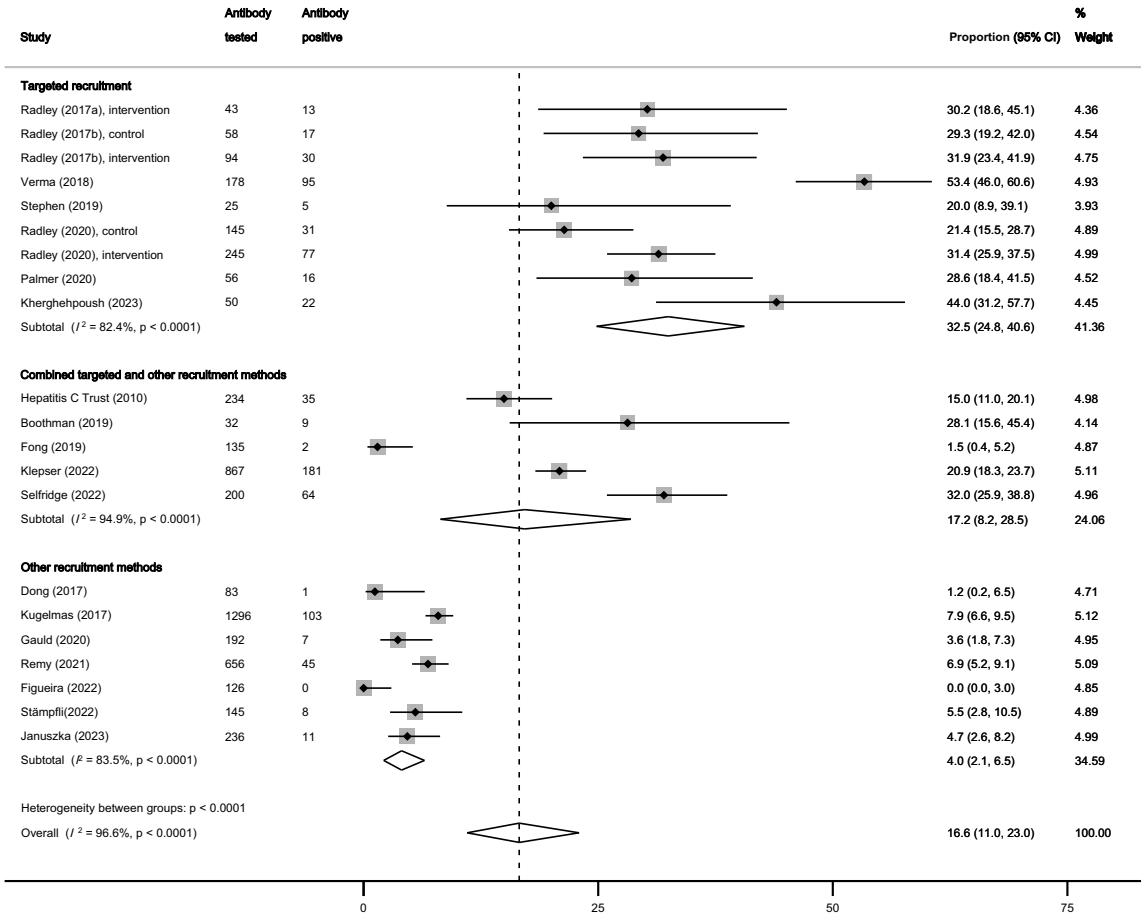


***Fig. 2:*** **Meta-analysis of proportion of participants antibody positive stratified by study recruitment strategy**.

*Pre-treatment assessment attendance*

In the three comparative studies examining attendance at pre-treatment assessment after initially testing positive, attendance in the pharmacy setting was compared with attendance at non-pharmacy settings (Table 2). In all three studies attendance rates were higher in the pharmacy setting (Table 3). In the 14 single-arm studies examining pre-treatment assessment attendance, assessment settings were non-pharmacies (n = 8), pharmacies (n = 3), and combination of pharmacies and non-pharmacies (n = 2). One study did not report the pre-treatment assessment setting. Three studies reported using workers to support participants to navigate the follow-up process (Table 2). Eleven of the single arm studies reported attendance data with attendance proportions ranging from 27.0% to 100.0% (Table 3).

Fourteen studies contributed 17 attendance proportions to the meta-analysis from 813 participants eligible for pre-treatment assessment. The pooled proportion attending was 71.6% (95% CI 57.0%–84.4%). Statistical heterogeneity across studies was high ($I^2$ = 93.2%) (Fig. 3). In the meta-regression of the proportion attending pre-treatment assessment, setting of care was a statistically significant source of heterogeneity (Appendix, Table S1). Subgroup meta-analysis by pre-treatment assessment setting showed the attendance proportions to be: 92.7% (95% CI 79.1%–99.9%) for pharmacies and 53.5% (95% CI 36.5%–70.1%) for non-pharmacies. Proportions for the combined pharmacy and non-pharmacy group were not pooled as there were only two studies in this group (Fig. 3).

*Treatment*

Three comparative studies examined treatment in the pharmacy compared with non-pharmacy settings (Table 2). Of these, two studies reported the pharmacy had higher of odds of treatment initiation [(OR 1.89, 95% CI 1.28–2.79, p = 0.0015)[27] and (OR 4.29, 95% CI 1.43–12.92, p = 0.010)[24]] and SVR [(OR 2.38, 95% CI 1.56–3.63, p < 0.0001)[27] and (OR 8.64, 95% CI 1.82–40.91, p = 0.007)[24]]. The other comparative study

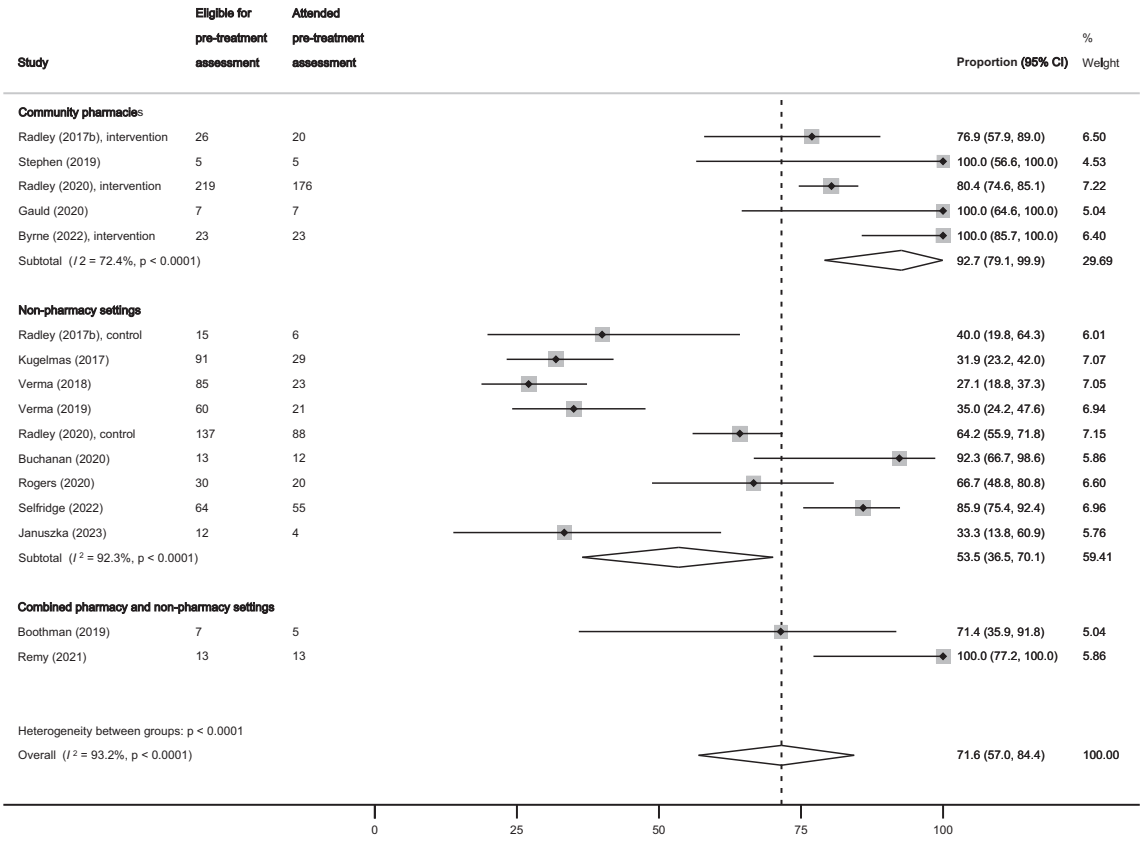


***Fig. 3:*** **Meta-analysis of proportions attending pre-treatment assessment with stratification by setting.**

reported three participants treated through the pharmacy pathway and one through the non-pharmacy pathway but did not report comparative statistics.[26] Of the 10 single arm intervention studies examining treatment outcomes, treatment settings were non-pharmacy settings (n = 6) and pharmacies (n = 2) (Table 2). In the single arm studies with clear data, treatment initiation rates ranged from 50.0% to 100.0%. Completion and SVR rates ranged from 6.3% to 100.0%, though only 2 of the studies had sufficiently long study period for completion of treatment by all participants (Table 3). Twelve studies contributed 15 proportions to the meta-analysis from 324 participants eligible for treatment. The pooled portion initiating treatment was 85.6% (95% CI 74.8%–94.3%). Statistical heterogeneity across studies was high ($I^2$ = 75.1%) (Appendix, Figures S3 and S4). In the meta-regression of the proportion initiating treatment, setting of care was not a statistically significant source of heterogeneity, however year of publication was significant (Appendix, Table S1). Meta-analysis of proportions initiating treatment by setting (Appendix, Figure S3) and year of publication (Appendix, Figure S4) are presented in the appendix. Meta-analysis of proportions completing treatment for hepatitis C, having an SVR test, and achieving SVR were not performed as few studies examined the entire treatment period and the numbers treated were low.

## Hepatitis B

Four studies reported relevant hepatitis B outcomes.[29,32,36,37] In a study from England, 88 people attending pharmacies for OAT or Needle Syringe Program (NSP) services or by self-referral with risk factors were tested with DBS tests.[29] Of these, one (1.1%) participant tested positive for hepatitis B surface antigen and subsequently had spontaneous clearance. In another other study from England 234 people with specified hepatitis B and/or C risk factors were tested with DBS tests. Four (1.7%) were hepatitis B surface antigen positive.[37] In a study from Portugal, 60 people were tested for hepatitis B with no positive test results.[32] In a study from Sierra Leone, 920 people were tested, of which 161 (17.5%) were positive for hepatitis B surface antigen.[36] The authors of the three comparative studies using DBS testing were contacted for further information and advised only one positive hepatitis B case was detected from the total 660 tests conducted.[25–27]

### Secondary outcomes

Program evaluation and cost-effectiveness outcomes are summarised in the Appendix.

### Risk of bias assessment

Results of risk of bias assessments are summarised in the appendix (Appendix, Table S2).

## Discussion

Pharmacies are an important and acceptable setting for hepatitis C testing. The high pooled proportion antibody positive of 17.4%, and proportions RNA positive ranging from 2.0% to 37.5% are similar to those seen in studies of other community settings with high-risk populations, including addiction treatment centres,[51] supervised drug consumption services,[52] NSPs,[51,53] and community correctional services.[54] Recruiting participants for testing by only targeting people with a specified risk factor, such as people on OAT or people accessing NSP services, produced an even higher pooled proportion antibody positive (32.5%). However, less targeted testing of people with any risk factor for hepatitis C or people self-referring for testing regardless of risk factors still produced a pooled antibody positive proportion of 3.9%, which is much higher than the estimated global hepatitis C prevalence of 0.7%[55] and may miss fewer cases. Higher testing uptake in pharmacies compared with other settings and the program evaluation data support pharmacies as an acceptable setting for testing, particularly when there is an established relationship between the pharmacists and the client and space for confidential counselling and testing. Access to hepatitis C testing in pharmacies therefore presents an important option for clients and has great potential to complement existing services and increase hepatitis C case detection.

Pharmacies can also play an important role in delivering the entire cascade of care from testing through to treatment. Offering clients the entire care cascade in pharmacies increased testing uptake compared with offering testing alone. Moreover, attendance rates at pre-treatment assessment were much higher in the meta-analysis when this occurred in the pharmacy compared with referral out to non-pharmacy settings (92.7% vs 57.6%). Treatment initiation rates in the meta-analysis were similar across settings. This likely because the referral, which introduces the potential for loss to follow up, with the exception of one study, occurred prior to the pre-treatment assessment step after testing positive. Research assessing fully decentralised hepatitis C testing and treatment models entirely within community harm reduction and addiction treatment centres has similarly found higher of follow-up compared with referral out to standard care at hospitals.[16,19] Taken together, this demonstrates, whenever possible, pharmacy-based hepatitis C programs providing all steps in the care cascade from testing to treatment within the same service have the greatest potential benefit in terms of progress through the care cascade.

The findings from this review add to the growing body of evidence supporting task shifting of hepatitis C testing and treatment away from specialists to non-specialists and decentralising care to community settings and primary care.[19,56] Through provision of hepatitis C testing and treatment, pharmacies and pharmacists could aid in achieving the WHO hepatitis C elimination goals. To maximise this opportunity, the design of pharmacy-based programs should consider other potential facilitators of success identified in the included program evaluations, such as developing leadership and enthusiasm among pharmacy staff, sharing the workload among pharmacy staff or with in-reach workers, educating pharmacists on how to identify people at risk of hepatitis C and on how to approach clients for testing in a sensitive manner. Programs need to be appropriately funded. Pharmacists musts be remuneration to ensure financial sustainability of programs. Removing financial access barriers for clients such as through provision of incentives and no cost testing and other services will help to facilitate program success.[57] Cost-effectiveness as a potential barrier to program success warrants consideration, given the widely differing results from the included analyses, and the finding of pharmacy-based hepatitis C care being less cost-effective than NSPs and addiction treatment centres. Integrating pharmacies with NSP, addiction treatment services, mental health services and primary care either within or external to the pharmacy could improve cost-effectiveness, while improving the holistic nature of the care provided, and may increase treatment uptake, adherence and cure.[19,57,58]

There was sparce literature on hepatitis B. Available studies from high-income were mostly designed to detect hepatitis C, with many targeting high risk populations for hepatitis C such as those on OAT and accessing NSP services. This likely contributed to the low yield for hepatitis B. Conversely, the study from Sierra Leone, where hepatitis B is endemic, had a high proportion positive among those tested. Pharmacy-based testing for hepatitis B in endemic countries has potential but requires further research. In high-income countries, community-based programs targeting migrants from high prevalence countries for hepatitis B testing and linkage to care have shown promise.[59,60] Pharmacies therefore present another potential community setting for such programs in high-income countries, though this has not been specifically researched.

Two systematic reviews have examined some elements of the hepatitis C cascade of care in pharmacies, with each finding only two primary literature sources.[56,61] To the authors' knowledge this is the first systematic review to comprehensively examine the effectiveness of community pharmacy-based programs in delivering elements of the care cascade for either

hepatitis B or C. The recency of the publications included (only one study before 2016) and inclusion of several conference abstracts highlight the novelty and rapid changing nature of this research field. Included studies were spread geographically across 11 different countries, though there was only one country from a low-income country, limiting generalisability of results.

This review was limited by the quality of included studies, with only four comparative studies identified in the literature. Regarding risk of bias, in the comparative studies, recruitment of participants was not concealed, though participants were selected from similar cohorts with a defined risk factor. Blinding of participants and researchers was not possible in the study designs. Referral pathways may have differentially impacted follow-up data collection in the control and intervention arms, thereby introducing measurement bias. However, these studies were strengthened by randomisation of pharmacies and their intention to treat analyses. Many of the single arm studies did not clearly report inclusion criteria. Reporting of clinical information of participants and demographic information of participating sites was overall poor. However, these studies did use standardised and validated measures for detecting hepatitis C and mostly reported outcomes clearly.

There was high statistical heterogeneity between the studies. The meta-regression identified some statistically significant sources of heterogeneity, however inconsistent reporting between studies limited the number of potentially important covariates that could be assessed. Diversity in the single arm study designs did allow for subgroup comparisons in the meta-analyses by recruitment strategy and setting of care, which improved heterogeneity within the subgroups. The heterogeneity is likely driven by multiple factors which could not be completely accounted for statistically in the meta-regression, including methodological heterogeneity in study designs, demographic diversity in populations and pharmacies studied and differences in pharmacy services provided.

In summary, pharmacies and pharmacists are well-positioned to contribute to the global hepatitis C elimination effort. Pharmacies are an acceptable setting for testing, with high test uptake and can be high yield for case detection with both targeted testing to people with a specified risk factor, or less targeted testing strategies. Providing the entire care cascade from testing through to treatment, whenever possible, within the pharmacy setting will improve progress through the cascade by increasing test uptake and minimising loss to follow-up. There are several important facilitators of program success including having an established relationship between the pharmacists and the client, having space for confidential counselling and testing, and sharing workload among pharmacy staff or with in-reach workers. Further research is needed into the role of pharmacies for hepatitis B testing and treatment, hepatitis C treatment and the cost-effectiveness of pharmacy-based hepatitis C care.

#### Contributors

MJH, JFD, AR, SN, CB, MEH, and JSD conceived and designed this study. MJH and EB searched literature bases and extracted data from eligible studies. MJH, EB, and MT performed the statistical data analysis. MJH, EB, and JSD accessed and verified all the data included in this study. MJH, EB, and JSD wrote the original draft of the manuscript. MJH, EB, MT, JFD, AR, SN, CB, JR, PH, MEH and JSD contributed to the interpretation of data and writing of the manuscript. MJH, EB, and JSD contributed to project administration. MEH and JSD helped acquire funding from the Australian Government for MJH and EB's positions at their institute. JSD supervised the study. All authors reviewed and approved the final version before submission. All authors had access to all data used in this study, approved the final version of the manuscript, and accepted the responsibility for the decision to submit the manuscript for publication.

#### Data sharing statement

The all data are presented in the manuscript and appendix. Further data that supports the findings of this study are available from the corresponding authors upon reasonable request.

#### Declaration of interests

MJH and EB's institute received funding for their positions through Specialist Training Program funding initiative of the Australian Government Department of Health, which had no role in the design or conduct of this study.

MT declared receipt of investigator-initiated research grants, speakers' honoraria, and consultancy fees from Gilead Sciences, unrelated to the submitted work.

JFD's institute has received grant funding from Gilead Sciences and JFD declared receipt of honoraria from Gilead Sciences, all unrelated to the submitted work.

AR's institute has received research grants from Camurus, MSD, and Gilead Sciences, unrelated to the submitted work.

SN declared receipt of untied research funding from Seqirus to study prescription opioid poisonings and was a named investigator (no funds received) on an implementation trial of buprenorphine depot funded by Indivior, both unrelated to the submitted work.

CJB declared receipt of honoraria from the International Network on Health and Hepatitis in Substance Users (INHSU); bursary support in the form of payment and waiving of fees from the European Association for the Study of the Liver (EASL); and grant fees from the Scottish Society of Physicians, all unrelated to the submitted work.

JR declared receipt of honoraria from Gilead Sciences and Abbvie and support from Abbvie for conference attendance, unrelated to the submitted work.

PH's institutes received grant funding from the Australian Government Department of Health, the National Health and Medical Research Council and the Australian Research Council, unrelated to the submitted work.

MEH and JSD's institute receives funding from Gilead Sciences and Abbvie for investigator-initiated research, unrelated to the submitted work.

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#### Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2024.102489.

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