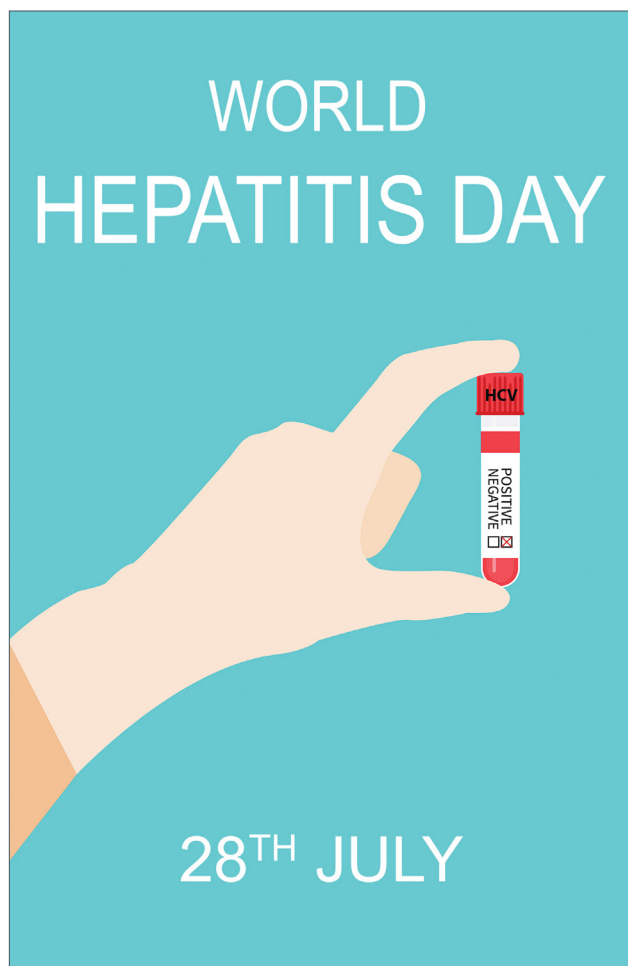


CCDR

CANADA COMMUNICABLE DISEASE REPORT

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CCDR

CANADA COMMUNICABLE DISEASE REPORT

The *Canada Communicable Disease Report* (CCDR) is a bilingual, peer-reviewed, open-access, online scientific journal published by the Public Health Agency of Canada (PHAC). It provides timely, authoritative and practical information on infectious diseases to clinicians, public health professionals, and policy-makers to inform policy, program development and practice.

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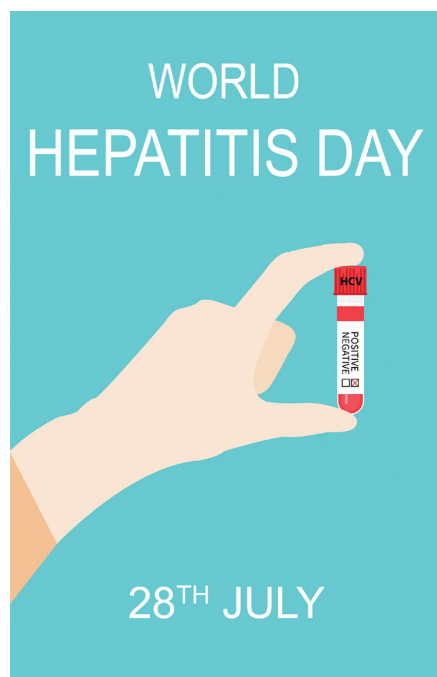
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Impact of availability of direct-acting antivirals for hepatitis C on Canadian hospitalization rates, 2012–2016

D Schanzer^{1*}, L Pogany¹, J Aho¹, K Tomas¹, M Gale-Rowe¹, JC Kwong^{2,3,4,5}, NZ Janjua^{6,7}, J Feld^{8,9}

Abstract

Backgrounds: Hospitalizations associated with hepatitis C virus (HCV) infection and liver disease increased on average by 6.0% per year from 2004 to 2010 in Canada and were projected (in 2010) to increase by another 4% by 2016. The first generation of direct-acting antivirals (DAAs) became available in 2012. In 2014, a second generation of effective and well-tolerated DAA therapy was authorized in Canada. The impact of DAA therapy on the HCV-associated disease burden in Canada has not been documented.

Objectives: To assess the potential impact of DAA therapy on the disease burden by a) comparing the actual hospitalization rates associated with HCV infection and liver disease following the introduction of DAAs in Canada with the 2010 baseline projection and b) documenting the associated uptake of anti-HCV therapy.

Methods: The hospital records of inpatients diagnosed with chronic HCV and chronic liver disease were extracted from the Canadian Discharge Abstract Database (DAD) by fiscal year for 2004–2016. We compared the actual number of hospitalizations to the baseline projection by year and for selected 5-year birth cohorts (1925–1989). The monthly number of new prescriptions for anti-HCV regimens was extracted from the IQVIA CDH CompuScript database (formerly IMS Health), aggregated to annual levels by age group and compared with hospitalization trends.

Results: Compared to the baseline projection, there was a slight reduction in hospitalizations in 2014/15 and 2015/16. This slight reduction was followed by a more significant decline in 2016/17 (32% below expected; 95% confidence interval [CI]: 27%–37%). The largest declines were observed for patients born before 1960 (age 55 or older) at 40% below expected in 2016/17. The number of new anti-HCV prescriptions increased from 5,484 in fiscal year 2012/13 to a peak of 17,775 in 2015/2016. The number of new prescriptions corresponds to approximately 1.3 and five times the number of hospitalizations in 2012/13 and 2015/16, respectively.

Conclusions: In Canada there has been a modest decrease in HCV and liver-related hospitalizations following a significant increase in uptake of second-generation DAAs in 2015. However, the burden is still high. Linked health administrative databases created to monitor the disease burden in the new treatment era should provide additional insight with the linkage of treatment history and disease stage to individual outcomes.

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Keywords: hepatitis C, disease burden, trends, hospitalization, monitoring the impact of DAA treatment

Introduction

Hepatitis has been identified as an international public health issue for years (1). Over 15 years ago, Canada identified chronic hepatitis C virus (HCV) as a major contributor to the growing burden of cirrhosis, hepatocellular carcinoma (HCC) and liver transplantations (2,3). In Ontario, HCV was identified as the infectious disease accountable for the largest disease burden

in terms of health adjusted life years (4). A Canadian modelling study estimated that the prevalence of viremic hepatitis C cases peaked between 2003 and 2013; it also predicted the prevalence of advanced liver disease would increase until 2030 as the infected population ages (5). Another Canadian study, based on hospitalization data, established that a large part of this growing

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burden was driven by the “baby boomer” cohort. The study found that the number of hospitalizations for HCV-associated chronic liver disease (CLD) increased 6.0% per year from 2004 to 2010 (6). As of 2010, hospitalizations were highest for those born between 1950 and 1959, and were projected to increase to 1.5 times the 2010 levels as this cohort approaches age 70 in 2025–2035 (6).

In 2012, the first generation of direct-acting antivirals (DAAs) was introduced in Canada. These agents achieved high rates of sustained virologic response and offered hope of reversing the trends in the prevalence of advanced liver disease. However tolerability was an issue and uptake remained relatively limited.

In 2014, a second generation of highly effective DAAs became available. These new regimens provided cure rates of >95% against all main genotypes with a short course of well-tolerated therapy (8–24 weeks). Second generation DAAs are now being considered a major medical breakthrough that have revolutionized the treatment of HCV infection, thus enabling much greater treatment uptake and the prospect of a major reduction in HCV-related morbidity and mortality (7).

Based largely on the improvement in treatment for HCV, the World Health Organization (WHO) called for the elimination of viral hepatitis as a public health threat (7). The WHO has set targets aiming to reduce mortality by 65% by 2030, compared to 2015 levels, and recommends ongoing monitoring so countries can assess whether they are on track to meet these ambitious goals (7).

It will be a number of years before mortality data are available. Monitoring trends in hospitalization rates is a viable alternative and offers several advantages over mortality data. Hospitalization data are more timely than mortality data. The number of deaths coded to HCV as the underlying cause of death in the mortality database (8) is considered an underestimate. In addition, mortality data has limited statistical power due to the smaller number of deaths that will delay the detection of any changes in the trend.

However, in order to use hospital data it must be taken into account that the population-level reductions in disease burden associated with the new treatments may not be large enough in the short term to offset the anticipated increase in hospitalizations (6). This arises from three considerations linked to the nature of how this disease progresses. First, the short term reduction in the risk of hospitalization is expected to be limited primarily to the treatment of patients with compensated cirrhosis who are at risk of progressing to decompensated cirrhosis. Second, treating patients who do not currently have advanced liver disease will prevent progression to cirrhosis in the long term. Third, patients with advanced liver disease, and particularly those with decompensated cirrhosis and/or HCC, may not improve much after achieving sustained virologic response, potentially leading to limited or no change in hospitalization rates (9,10).

In Canada, the study by Schanzer et al. in 2014, established a baseline projection of HCV and CLD hospitalizations based on trends prior to the introduction of DAAs (6). This study found that the increasing risk of hospitalization within each 5-year birth cohort was primarily a function of age, and that stratification by

5-year birth cohort was required to control for the differences in exposure to HCV.

The objective of the current study was to use previously calculated projections as a baseline scenario corresponding to the hypothetical situation of “no change in treatment,” and then to compare this baseline projection with the actual number of hospitalizations associated with HCV and CLD, and to document the uptake of antiviral therapy at a population level.

Methods

Data sources

Hospital discharge records for patients admitted to an acute care hospital with a diagnostic code of chronic HCV (ICD-10 code B18.2) and CLD (K70–K77, R18) including HCC (C22) in any of the diagnostic fields were extracted from the Canadian Institute of Health Information (CIHI) patient-specific Discharge Abstract Database (DAD) (11) for the period spanning April 2004 to March 2017. Fields related to age, date of discharge, inpatient deaths and HCC were retained. As the province of Quebec does not participate in the DAD, the database captures approximately 75% of all acute care hospitalizations in Canada. Population denominators were obtained from Statistics Canada population estimates (12). In September 2017, the number of new prescriptions filled for anti-HCV therapy was extracted from the IQVIA CDH CompuScript database (formerly IMS Health) (13) by month and year, as well as province and age group for the period spanning September 2011 to August 2017. This database is created from a panel survey of over 5,700 pharmacies, representing more than 60% of all retail pharmacies in Canada. The products used to treat HCV are listed in **Appendix 1**. The baseline projection of hospitalization levels by birth cohort were taken from the 2014 Schanzer et al. study (6).

Data analysis

Annual trends

To assess the impact on an annual basis, we limited the comparison of the actual number of annual hospitalizations with the baseline scenario to birth cohorts for which we had sufficient data to estimate the baseline projection (persons born between 1925 and 1989, but aged less than 90 years). We computed 95% confidence limits corresponding to the standard error of the difference between actual and predicted values for the pre-DAA period (2004–2011). We also calculated the ratio of the annual number of hospitalizations divided by the baseline projection for the same year. During the pre-DAA period, the ratio was expected to track close to 1.0, and then start to decline as first- and then second-generation DAAs started to reduce the risk of hospitalization. Logistic regression was used to assess trends in the inpatient fatality rate and proportion of hospitalizations associated with HCC.

Age group

To assess the impact by age group, we compared the annual number of hospitalizations with a recorded diagnosis of HCV and CLD in the hospital discharge abstract for 2016/17 with the baseline projections for 2016/17 for each 5-year birth cohort.



The average age at hospitalization was calculated for each birth cohort by year. The error bars corresponding to the 95% confidence intervals (CIs) were based on the Poisson distribution typically used for count data.

New prescriptions

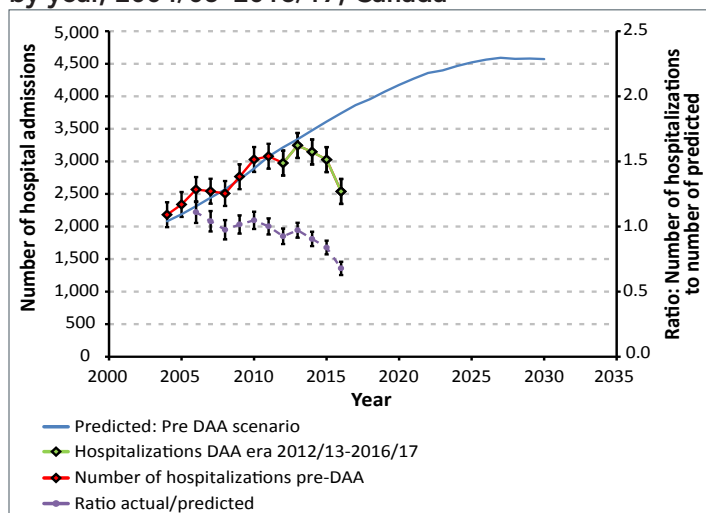
We plotted the monthly number of new prescriptions in Canada as a time series. The ratio of new prescriptions to hospitalizations was calculated by calendar year and by age group from the IQVIA data extract. New prescriptions for Quebec were excluded from the ratio calculation.

Results

Annual trends

The annual number of hospitalizations associated with HCV and CLD tracked the projected numbers closely during the pre-DAA period (Figure 1, red curve compared to blue curve). A statistically significant reduction compared with the baseline was first observed in 2014/15 (green curve compared to blue curve). The largest reduction occurred in 2016/17, 32% (95% CI: 27%–37%), with 2,538 HCV and CLD hospitalizations compared with the predicted 3,740.

Figure 1: Trends in annual hospitalizations associated with hepatitis C virus infection and chronic liver disease, by year, 2004/05–2016/17, Canada^a



Abbreviation: DAA, direct-acting antiviral

^a Excluding Quebec

Legend: Historical rates from 2004–2010 by age and birth cohort (red curve) were used to create the pre-DAA scenario baseline (blue curve). First-generation DAAs became available in 2012/13, with the impact monitored annually to 2016/17 (green curve). A statistically significant reduction compared to baseline first occurred in 2014/15, with a sharper reduction for 2016/17 following the availability of interferon-free DAAs in 2015. The ratio of the number of hospitalizations to the baseline projection is represented by the dashed purple curve

The inpatient mortality rate for HCV and CLD declined from 15.7% in 2003 to 13.0% in 2016 (Table 1), corresponding to an annual average percent change (AAPC) of –1.2% (95% CI: –2.0% to –0.4%). After controlling for the aging of the hospitalized HCV cohort, the rate of decline was stronger (AAPC: –1.9%; 95% CI: –2.6% to –1.1%). The proportion of HCV and CLD hospitalizations with an HCC diagnosis increased from 11% to 25% for an AAPC of 6.4% (95% CI: 5.0%–7.9%). After controlling for age, the AAPC was 4.0% (95% CI: 2.9%–5.1%). This trend was evident in the baseline period (2003–2010) with an AAPC of 6.6% (95% CI: 4.8%–8.6%).

Table 1: Number of hospitalizations associated with hepatitis C virus infection and chronic liver disease by fiscal year, 2003/04–2016/17, all ages included, Canada^a

Year	Hospitalizations (n)	Deaths (n)	Mortality rate (%)	HCC cases (n)	HCC ^b (%)
2003/04	2,115	331	15.7	226	10.7
2004/05	2,182	334	15.3	264	12.1
2005/06	2,338	341	14.6	321	13.7
2006/07	2,569	421	16.4	388	15.1
2007/08	2,542	395	15.5	420	16.5
2008/09	2,527	404	16.0	438	17.3
2009/10	2,774	384	13.8	551	19.9
2010/11	3,041	415	13.6	594	19.5
2011/12	3,092	459	14.8	622	20.1
2012/13	2,979	446	15.0	619	20.8
2013/14	3,255	464	14.3	742	22.8
2014/15	3,152	457	14.5	631	20.0
2015/16	3,040	428	14.1	669	22.0
2016/17	2,554	333	13.0	633	24.8

Abbreviations: HCC, hepatocellular carcinoma; n, number; year, fiscal year

^a Excluding Quebec

^b The proportion of hepatitis C virus–chronic liver disease hospitalizations with a diagnosis of hepatocellular carcinoma

Source: CIHI Discharge Abstract Database (11)

Age group

In Figure 2a, the actual number of hospitalizations are compared with the projected baseline levels for 2016/17. The largest declines in the number of hospitalizations in 2016/17 occurred in the birth cohorts with the highest baseline estimates (1950–54 and 1955–59). The ratio of the observed to projected number of hospitalizations in Figure 2b shows that the largest relative declines were observed among patients born before 1960 (age 55 years or older), at 40% below expected. Conversely, for patients aged 45 years or less, a ratio of one suggests that treatment has not resulted in significant short term reductions to the risk of hospitalization.



Figure 2a: Annual number of hospitalizations associated with hepatitis C virus and chronic liver disease compared with baseline estimates, by age^a, 2016/17, in Canada^b

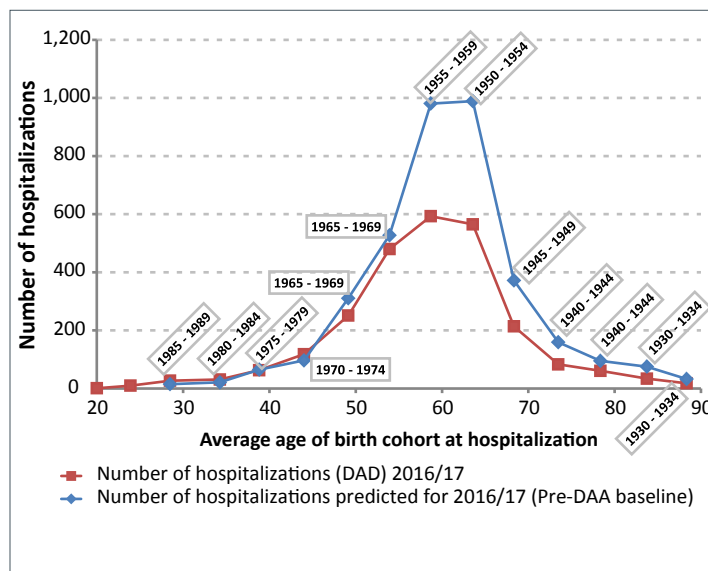
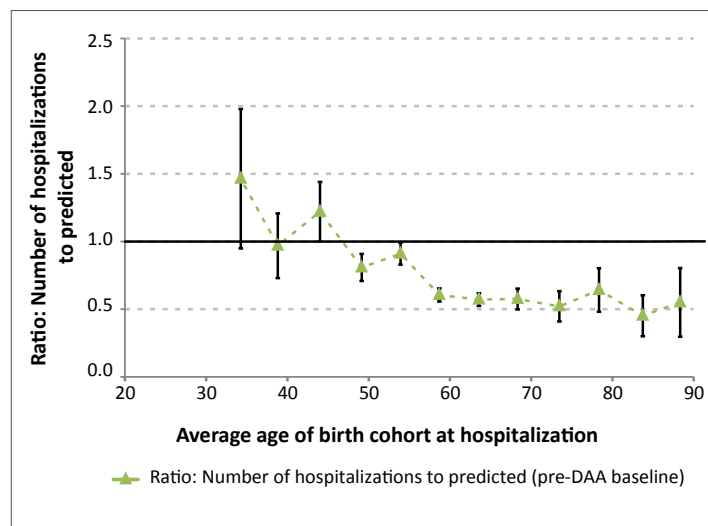


Figure 2b: Ratio of the actual number of hospitalizations to the pre-DAA baseline projection by age^a, 2016/17 in Canada^b

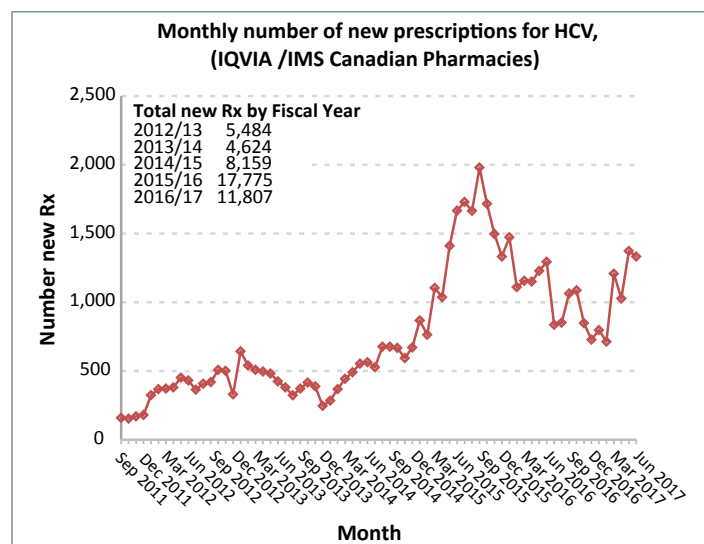


Abbreviations: #, number; DAA, direct-acting antiviral; DAD, Discharge Abstract Database; HCV, hepatitis C virus
^a The approximate age on the x-axis corresponds to the average age at time of hospitalization for each 5-year birth cohort. The labels in Figure 2a correspond to the birth cohort. The error bars for the ratio of the actual number of hospitalizations to baseline (Figure 2b) correspond to the 95% confidence interval calculated for count data
^b Excluding Quebec
 Source: Discharge Abstract Database (11)

New prescriptions

New prescriptions peaked in 2015 (Figure 3), shortly after the introduction of second-generation DAAs, increasing from 5,484 in 2012 to 17,775 in 2015. The age distribution of new prescriptions was similar to the age distribution of hospitalizations, though the treated group was slightly younger

Figure 3: Monthly number of new prescriptions for hepatitis C virus, in Canada



Abbreviations: HCV, hepatitis C virus; Rx, prescriptions
 Data source: IQVIA CDH CompuScript (formerly IMS Health) (13)

than those hospitalized, as seen by the ratio of new prescriptions to hospitalizations for each year and age group (Table 2).

Table 2: Ratio of the number of new prescriptions to the number of hospitalizations, 2012–2016, all ages included, Canada^a

Calendar Year	Age group (years)					Total
	19–29	30–39	40–49	50–59	60+	
2012	1.9	4.8	0.3	1.7	0.9	1.3
2013	4.4	4.6	1.6	1.6	1.0	1.5
2014	8.2	4.5	2.0	2.0	1.6	1.9
2015	10.5	10.1	1.7	5.6	4.9	5.0
2016	7.4	8.7	5.1	4.8	4.1	4.7

^a Excluding Quebec

Discussion

There was a slight reduction in hospitalizations for HCV-related chronic liver disease diagnoses in Canada in 2014/15 and 2015/16 compared with the baseline projection. In 2016/17, the reduction in hospitalizations was modest following a significant increase in the uptake of treatment with the introduction of second-generation DAAs in 2015. This reduction is nevertheless impressive considering that the burden was expected to increase. By using baseline projections from a previous study, we were able to monitor early progress in reductions in the HCV and CLD burden by age group. Persons with an HCV infection born before 1960 (55 years or older in 2016) appear to have benefited the most from DAAs in the near-term, with a 40% reduction in hospitalizations in 2016 compared with the projected baseline. The largest reduction in the number of hospitalizations occurred in the birth cohorts with the highest baseline estimates (1950–54



and 1955–59). A large change for the younger cohorts was not observed despite a proportionally higher uptake of treatment. This likely reflects differences in the disease stage of patients who received treatment. Patients receiving treatment in the early stages of fibrosis would be at a very low risk of hospitalization for advanced liver disease in the short term, while more substantial benefits for this group would be expected over the longer term.

A decline in the inpatient mortality rate was observed over the full study period (2003–2016), as was an increase in the proportion of hospitalizations with HCC. Despite some controversy about the possibility that DAAs may increase the risk of HCC, more recent data clearly show that, like interferon-induced sustained virologic response, viral clearance with DAAs reduces but does not eliminate the risk of HCC (14). Rather, a strong increase in both mortality and HCC risk with age has been noted for patients with a chronic HCV infection (10). Emerging data confirm that while achieving sustained virologic response largely prevents hepatic decompensation in patients with cirrhosis and even improves liver function in those who are treated after initial decompensation, the risk of HCC remains a major concern (9). Recent declines in the number of inpatient deaths and the number of HCC hospitalizations are encouraging, though these numbers are too small and the time period too short to assess the statistical significance of the impact of the second-generation DAAs on mortality and HCC.

Strengths and limitations

The main strength of this study is the use of hospitalization data compared with a baseline projection to provide a more timely assessment of the early impact of DAAs than would be possible with vital statistics data (8). The larger number of annual events provides the statistical power to detect an impact earlier than mortality data. The baseline projection corresponding to the hypothetical absence of DAA therapy (6) provided a more accurate assessment of the impact of the new therapies than would be available from a simple trend analysis. This approach allowed us to control for variation in exposure to HCV infection in different birth cohorts, and due to the slow natural progression of disease, the number of early hospitalizations was a good predictor of the number of future events. As well, this approach did not require the many estimates, data points or assumptions needed to model the full complexity of disease progression. The comparison with the hypothetical baseline rather than previous levels allowed us to assess the potential early benefits of the intervention and control for the anticipated increase in burden.

There are also several limitations to consider. We were unable to assess trends in the number of HCC hospitalizations, as the numbers were small and we did not have a readily available baseline estimate to take into account the increasing underlying burden. As a population level study, patient-specific information such as the disease history, patient care and exposure category that could help refine projections of the future burden under various scenarios of ramped-up treatment and screening was not available. As we used the presence of an HCV and CLD diagnostic code in any of the diagnostic fields in the DAD database to identify HCV and CLD hospitalizations, there is a risk of bias due to under-ascertainment. The HCV diagnosis was likely not included in the discharge record for all hospitalizations of patients diagnosed with an HCV infection. The number of new prescriptions does not necessarily correspond to the number of

treatment courses, as physicians may not include all renewals for the full treatment course on one script. In addition, the quality of the prescription data from IQVIA has not been fully assessed. Unfortunately, Quebec does not participate in the DAD, so the hospitalization results are not national. Many of these limitations could be overcome through data linkage projects.

Next steps

With a potentially curative treatment available, the research focus has shifted from measuring and predicting burden of illness to documenting the impact of treatment on long term outcomes. Challenges in monitoring the impact of DAA at a population level amid an otherwise growing burden remain, as does concern about the access to treatment, the HCV-associated HCC burden (15,16) and the impact of sustained virologic response on the future HCC burden (9,10,14). Reductions in HCV-related compensated or decompensated cirrhosis or HCC should be detectable well ahead of reductions in hospitalization. As such, if these data were available in a timely manner, these trends would be better indicators of progress. One Canadian study used linked health data to characterize patients who developed HCV-related decompensated cirrhosis or HCC between 2007 and 2011 (16). Samji et al. defined a late diagnosis as having been diagnosed with HCV within the previous two years (16). They found that the proportion of late diagnoses was substantially reduced over the (pre-DAA) study period and that illicit drug use (as identified in the medical records) and regular physician visits were protective against a late HCV diagnosis (16). The capacity to monitor these trends and the characteristics of persons developing cirrhosis or HCC will greatly assist in monitoring progress and guiding public health efforts in further reduction of the burden.

Researchers affiliated with the [Canadian Network on Hepatitis C](#) (CanHepC) program (17) are conducting a number of additional studies that aim to link a cohort of people diagnosed with HCV with other administrative health databases (15,16). Linkage requires various approvals and safe-guards to maintain patient confidentiality. Though true data-sharing is not likely feasible, these researchers are planning to coordinate definitions across provinces so that results will be comparable. Significant progress has been made in Ontario (at the Institute for Clinical Evaluative Sciences), British Columbia and Quebec, and additional statistics related to late presentation and the cascade of care for patients with an HCV diagnosis is forthcoming. Preliminary research compared the number of new prescriptions from IQVIA Institute for Human Data Science with preliminary data on the number of DAA treatment courses in British Columbia and found that one treatment course accounts for approximately 1.4 new prescriptions (*Personal communication. NZ Janjua, February 7, 2018*).

Conclusions

Canada has had a modest decrease in HCV and CLD hospitalizations following the switch to second-generation DAAs. However, liver disease burden associated with chronic HCV is still high and progression to HCC following sustained virologic response in cirrhotic patients remains a concern. As it is preferable to treat patients with chronic HCV infection before cirrhosis has developed, it will likely be many years before the full benefit of DAA treatment can be observed. The observed trends are also consistent with the emerging data that patients



with much more advanced liver disease can be safely and effectively treated. Identifying and monitoring leading indicators such as disease stage at sustained virologic response along with measures of the cascade of care will be helpful in monitoring progress toward the elimination of the disease burden associated with HCV. Linked health administrative databases created to monitor the disease burden in the new treatment era should provide additional insight with the linkage of treatment history and disease stage to individual outcomes.

Authors' statement

DS – Conceptualization; methodology; writing – original draft; validation, statistical analysis
 JA – Writing – review and editing
 MGR – Writing – review and editing
 LP – Writing – review and editing
 KT – Writing – review and editing
 JCK – Clinical expertise; data for validation and comparison with other studies; writing – review and editing
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 JF – Clinical expertise; data for validation and comparison with other studies; writing – review and editing

Conflict of interest

JF has collaborated on research projects with Abbvie, Gilead, Janssen and Merck and has consulted for Abbvie, Gilead and Merck.

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Appendix 1

Rx for HCV by DIN product and combined molecule (CDH CompuScript)		
Product	Combined molecule abbreviation	DIN
DAKLINZA	DACLATASVIR	2444747, 2444755
EPCLUSA	SOFOSBUVIR:VELPATASVIR	2456370
GALEXOS	SIMEPREVIR	2416441
HARVONI	LEDIPASVIR:SOFOSBUVIR	2432226
HOLKIRA PAK	DASABUVIR:OMBITASVIR:PARITAPREVIR:RITONAVIR	2436027
IBAVYR	RIBAVIRIN	2425890, 2425904, 2439212
INCIVEK	TELAPREVIR	2371553
PEGASYS	PEGINTERFERON ALFA 2A	2248077, 2248078
PEGETRON	INTERFERON ALFA 2B:RIBAVIRIN	2246026, 2246027, 2246028, 2246029, 2246030
PEGETRON REDIPEN/CLEARCL	INTERFERON ALFA 2B:RIBAVIRIN	2254581, 2254603, 2254638, 2254646
SOVALDI	SOFOSBUVIR	2418355
TECHNIVIE	OMBITASVIR:PARITAPREVIR:RITONAVIR	2447711
VICTRELIS	BOCEPREVIR	2370816
VICTRELIS TRIPLE	BOCEPREVIR:PEGINTERFERON ALFA 2B:RIBAVIRIN	2371448, 2371456, 2371464, 2371472
ZEPATIER	ELBASVIR:GRAZOPREVIR	2451131



Awareness and knowledge of hepatitis C among health care providers and the public: A scoping review

S Ha^{1*}, K Timmerman¹

Abstract

Background: The Global Viral Hepatitis Strategy aims to eliminate hepatitis as a public health threat by 2030. The hepatitis C virus (HCV) can be difficult to detect as infection can remain asymptomatic for decades. Individuals are often neither offered nor seek testing until symptoms develop. This highlights the importance of increasing awareness and knowledge among health care providers and the public to reach the viral hepatitis goals.

Objectives: To conduct a scoping review to characterize current awareness and knowledge among health care providers and the public regarding HCV infection, transmission, prevention and treatment and to identify knowledge gaps that public health action could address.

Methods: A literature search was conducted using Embase, Medline and Scopus to find studies published between January 2012 and July 2017. A search for grey literature was also undertaken. The following data were extracted: author, year of publication, study design, population, setting, country, method of data collection, and knowledge and awareness outcomes. Commentaries, letters to the editor and narrative reviews were excluded.

Results: Nineteen studies were included in this review. The definition of awareness and knowledge varied across studies; at times, these terms were used interchangeably. Health care providers identified injection drug use or blood transfusions as routes of HCV transmission more frequently than other routes of transmission such as tattooing with unsterile equipment and sexual transmission. Among the general public, misconceptions about HCV included believing that kissing and casual contact were routes of HCV transmission and that a vaccine to prevent HCV was available. Overall, there was a lack of data on other high-risk populations (e.g., Indigenous, incarcerated).

Conclusion: Continued public and professional education campaigns about HCV could help support HCV risk-based screening and testing. Future research could assess the awareness of other populations at increased risk and include consistent definitions of awareness and knowledge.

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Keywords: awareness, knowledge, hepatitis C, scoping review, health care providers

Background

Hepatitis C virus (HCV) causes inflammation of the liver, which can become chronic. Chronic HCV infection can be asymptomatic for decades before symptoms appear. Globally, about 71 million people have chronic HCV infection (1). Chronic HCV infection is not easy to detect; even when symptoms are present, they are often nonspecific (e.g., fatigue) (2). Chronic HCV infection can lead to cirrhosis or liver cancer. Approximately half a million people die each year from HCV-related liver diseases (3).

In 2011, about 220,000-246,000 individuals were living with chronic HCV infection in Canada and approximately 44% were unaware of their infection (4). Over the past few years, there have been significant advances in HCV treatment, and infection is now curable. Previous treatment regimens consisted of peg-interferon and ribavirin, which involved longer treatment durations and more side effects. The new interferon-free direct acting antiviral (DAA) treatments have been found to be highly effective and have fewer side effects. Currently, most provincial and territorial formularies cover these new treatments and



Canada has started to witness a decrease in hospitalizations associated with HCV infection and chronic liver disease (5).

In 2016, the 69th World Health Assembly adopted the Global Health Sector Strategy on Viral Hepatitis with the goal of eliminating both hepatitis B and C as a public health threat by 2030 (6). The goal is to have 90% of viral hepatitis B and C diagnosed and 80% of eligible people with chronic hepatitis B virus (HBV) and chronic HCV infection treated (6). Awareness and knowledge of hepatitis C is an important first step in the elimination strategy. The identification of HCV through screening and testing is essential for patients to make appropriate lifestyle changes and to begin treatment.

Limited awareness of and knowledge about HCV have been identified as the key barriers to health care providers offering hepatitis C testing and for patients seeking testing (7). This lack of awareness and knowledge leads to continued HCV transmission and missed prevention and treatment opportunities. In an effort to improve risk-based screening in Canada and to reduce the number of people who are unaware of their infection, it is important to understand current awareness and knowledge of HCV among health care providers and the public alike.

The objectives of this review are to summarize health care providers' and the general public's awareness and knowledge of the natural history of HCV and HCV transmission, prevention and treatment, and to identify knowledge gaps in both groups that public health action could address.

Methods

We worked with a research librarian to conduct a literature search in Embase, Medline and Scopus for published studies on awareness and knowledge of HCV among health care providers and the public. We also completed a search for grey literature (i.e., reports available on public domains) using Google. The following search terms were used: hepatitis C, HCV, awareness, and knowledge. Studies were included in the review if they were published between January 2012 and July 2017; published in English or French; conducted in Canada or similarly economically developed and well-resourced countries; and focused on the public or health care providers. We restricted the search years to the last five years to capture the most recent information. Commentaries, letters to editors and case studies were excluded. Outcomes of interest included HCV awareness and knowledge, which are defined in various ways based on the study.

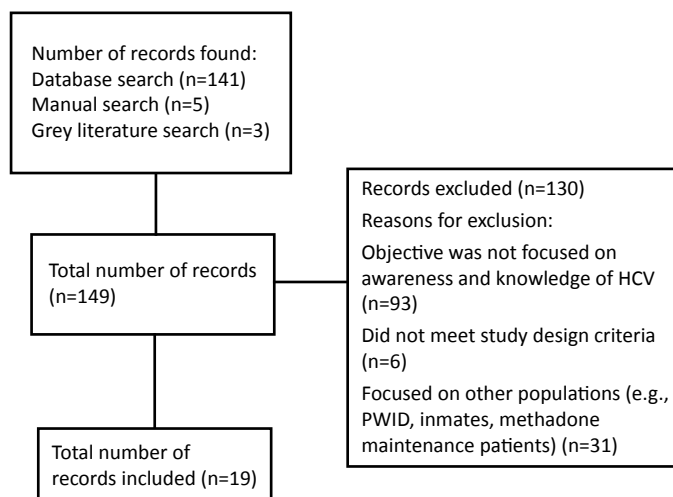
After screening the titles and abstracts of potentially relevant articles, we reviewed the full texts of included studies. We developed data extraction forms and extracted data on the following: author, year of publication, study design, population, setting, country, method of data collection, and knowledge and awareness outcomes.

As a scoping review a qualitative analysis of the findings was completed and the results were summarized into themes but we did not conduct a detailed assessment of overall quality or risk of bias.

Results

The literature search identified 141 potentially relevant articles on HCV awareness and knowledge of health care providers and the general public. A manual search of the reference lists identified five additional references. An additional three reports were identified through the grey literature search. After the title and abstract screening and the full text review, 19 studies were included in this review (Figure 1).

Figure 1: Flowchart of study selection process



Abbreviations: HCV, hepatitis C virus; n, number; PWID, people who inject drugs

Awareness and knowledge were at times used interchangeably in the included studies. Awareness was defined as either awareness of one's own HCV infection, diagnosis or seropositivity or awareness of the existence of HCV, the risk factors or availability of treatment. Knowledge could include the natural history and consequences of HCV, HCV risk factors and transmission routes, or vaccine and treatment availability. Consequently, the results are reported based on how the studies themselves defined awareness and knowledge.

Characteristics of included studies

The majority of the included studies were conducted in the United States (US; n=8), followed by Canada (n=5) and Australia (n=3). The remainder of the studies were from Germany, Italy, Japan and Netherlands. Most of the studies (n=13) targeted the general population and less than one-third (n=5) focused on health care providers; one study included both populations. Participants were recruited from a variety of settings including hospitals, outpatient clinics, primary care clinics, emergency departments and online panels. Data collection methods most often included questionnaires completed online, in-person or by phone. (For more details about the included studies, please refer to **Appendix 1.**)

Of the studies that focused on health care providers, job categories included physicians, nurses, residents, dental students and specialists (i.e., hepatologists and gastroenterologists). Of the studies that focused on non-health care providers,



population groups included HCV-infected people with or without HIV coinfection, men who have sex with men (MSM), immigrants, the general public and adults born between 1945 and 1965 (Table 1).

Table 1: Summary of included studies

Characteristics	Number of studies (n) ^a
Country	
US	8
Canada	5
Australia	3
Netherlands	2
Germany	1
Italy	1
Japan	1
Other	3
Health care providers	
Physicians	3
Nurses	3
Specialists (e.g., hepatologist, gastroenterologist)	2
Medical students	1
Other	1
Non-health care providers	
People living with HCV with or without HIV coinfection	4
Men who have sex with men (MSM)	3
General public	2
People born between 1945–1965	2
Immigrants	1
Other	1

Abbreviations: HCV, hepatitis C virus; HIV, human immunodeficiency virus

^aSome studies included more than one population or country

Awareness

There were six studies on awareness of hepatitis C (11,12,14,17,18,24). The types of awareness varied across these studies: awareness of risk factors, of treatment, of one's own infection and of the existence of HCV. Four studies included findings on awareness of HCV by the general public (11,12,14,17), one on awareness of HCV by MSM (18) and one on awareness of treatment by Canadian health care providers (24).

Two studies found that the general public had some awareness (defined as the knowledge that something exists) of hepatitis C (11,17). Compared with the public (27%), Canadian-born baby boomers (33%) were more likely to be aware that injection drug users have an increased risk of HCV compared with the general public (27%) (14). However, results from the United States' National Health and Nutrition Examination Survey (NHANES) indicated that fewer than half of Americans who had HCV infection were aware of their infection (12). Two studies found

that the general public was not clear about the differences between hepatitis A, B and C (11,19).

Knowledge

All of the included studies assessed knowledge of HCV. Knowledge was measured using a series of yes/no/don't know or true/false statements, or one's perceived knowledge level. Knowledge was assessed in the following topics: natural history of HCV, transmission routes, the availability of a vaccine and the availability of treatment.

The natural history of HCV and its consequences

Three studies included information on health care providers' knowledge of the natural history and consequences of HCV (16,25,26). In a convenience study of Canadian physicians, 35% reported "knowing a lot" about symptoms associated with HCV (16). In a small study of dental students from Bulgaria, 80% reported knowing that infection with hepatitis B virus (HBV) or HCV may be asymptomatic (26). In addition, residents, physicians, nurse practitioners and physician assistants working in emergency departments in the US were reported to have high knowledge scores regarding the manifestations of HCV (percentage not reported) (25).

Eight studies included information on the public's knowledge about the natural history of HCV (8,9,11,13,14,16,17,19). Two Canadian studies found that 83–90% of participants knew that people with HCV could be unaware of an existing infection (14,16). Similarly, over half (57%) of US baby boomers knew that HCV can lead to liver cancer and 61% believed that someone with HCV infection can present with no symptoms (8). One study reported that one-third of MSM knew that HCV infection could lead to liver cancer (31%) and liver failure (37%)(18). Conversely, in an international study with immigrants from Asia, it was reported that there was confusion about the different types of hepatitis infections and uncertainty about the natural history of the infection (19).

Knowledge of transmission

Two studies reported on health care providers' knowledge of HCV transmission (22,26). The majority of health care providers in the studies identified the main routes of transmission as blood transfusions, exposure to blood during sexual activity and sharing needles while injecting drugs (22,26). A small percentage (12%) of nurses working in hemodialysis clinics in Italy believed, incorrectly, that HCV can be transmitted through kissing, and 19% did not know that getting a tattoo could be a means of HCV transmission (22).

Ten studies reported information on knowledge of HCV transmission among the general public (8,10-12,14-17,19,21). One Canadian study reported that the most frequently known HCV transmission routes were blood transfusions, unsafe/unprotected intercourse and injection drug use/sharing of needles (14). Few Canadians identified other routes of transmission such as sharing personal hygiene items (7%), getting tattoos and body piercings (4%), exposure to risk factors while travelling in foreign countries where HCV may be endemic (4%), and mother-to-child transmission through pregnancy (1%) (14). Furthermore, approximately 54–62% of the general population in Canada knew that HCV is transmitted mainly through blood-to-



blood contact (16). In four studies, a small percentage of the general public indicated that HCV can be transmitted through kissing or casual contact (8,12,14,21).

Knowledge of treatment

Two recent studies, published after the new interferon-free DAA therapies became available, focused on knowledge of the curability of HCV (8,24).

Among health care providers, specialists (i.e., hepatologists, gastroenterologists, hepatology nurses) scored higher on knowledge statements about HCV treatment than general practitioners (GPs) (23,24). Of the 10 primary care physicians surveyed, seven were unsure or not aware of the new interferon-free DAAs and were not sure about the mechanisms of action (24).

In the US, 51% of baby boomers presenting to emergency departments correctly believed that HCV is curable and 77% had knowledge of new medications available to treat HCV (8). However, three studies detected a misconception among the general public about the availability of a vaccine to prevent HCV (11,15,21). About one half of the Canadians interviewed (50%) in one study believed there was a vaccine to prevent HCV (14). In two US studies, 42% of American baby boomers and 60% of African-American baby boomers believed there was a vaccine to prevent HCV (8,11).

A summary of the findings is shown in Table 2.

Table 2: Summary of findings on awareness and knowledge of hepatitis C virus among health care professionals and the general public

Outcomes	Key Findings
Awareness	Public: The general public was aware of HCV and main risk factors (14) MSM had high awareness of HCV treatment (18)
Knowledge	Health care providers: Specialists were more up-to-date on new HCV treatments than primary care physicians (24) Health care providers knew less about some routes of HCV transmission (e.g. unsafe tattooing practices or piercings) compared with the main routes (i.e., injection drug use) (22,26) Public: The general public had misconceptions around risk factors for transmission of hepatitis C (e.g., casual contact, saliva, kissing) (11,12,14,16,19) There were also misconceptions about the availability of a vaccine (8,14,16) Overall, there was little knowledge about the interferon-free DAA hepatitis C treatment (8,9,13,14,16)

Abbreviations: DAA, direct acting antivirals; HCV, hepatitis C virus; MSM, men who have sex with men

Discussion

To the best of our knowledge, this is the first scoping review that provides a snapshot of what health care providers and the general public know about HCV. Overall, health care providers know about the most common transmission routes and risk factors, whereas specialists are more up-to-date on treatments than primary care physicians (23,24). The general public is aware of HCV; however, some people do not know the difference between hepatitis A, B and C; there are misconceptions around routes of transmission; and some incorrectly believe that an HCV-preventable vaccine exists.

There are some limitations to consider when interpreting our findings. First, there was a lack of standard definitions for knowledge and awareness and the terms were often used interchangeably. Second, only a few studies captured awareness and knowledge of interferon-free DAA treatments. Finally, the findings were based on cross-sectional studies, which only capture data of a study population at a single point in time.

Future research could include assessment of high-risk populations (e.g., Indigenous peoples or incarcerated populations); incorporate clear and consistent definitions of awareness and knowledge; and assess factors that may be associated with differences in awareness and knowledge (e.g., rural versus urban settings, and socioeconomic status). Additional research on health care providers’ knowledge of HCV could also help tailor future knowledge translation and exchange products.

In conclusion, increasing health care providers’ and the general public’s awareness of and knowledge about HCV can facilitate the discussion about whether HCV testing should be considered. The findings and gaps identified in this review can help inform future interventions and public health campaigns to do with HCV and support the Global Health Sector Strategy on Viral Hepatitis.

Authors’ statement

SH – Conceptualization, methodology, writing (final draft), data curation, validation, formal analysis, writing, reviewing and editing, supervision, project administration, visualization
KT– Conceptualization, methodology, reviewing and editing, supervision, project administration, visualization

Conflict of interest

None.

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Appendix 1: Description of included studies (n=19)

Author(s), year of publication / Country	Study design / Population / setting	Method of data collection	Outcome / Findings
General public (n=14)			
Allison et al. (2016) (8) US	Cross-sectional study Baby boomers (1945–1965) (n=915) Urban emergency department	Structured interview within six weeks of HCV antibody test to assess knowledge	Knowledge <ul style="list-style-type: none"> Most participants were familiar with the natural history and complications of HCV Most participants were familiar with the risk factors for HCV Some participants had misconceptions about transmission (i.e., kissing) More than half of participants thought that HCV-preventable vaccines existed Many lacked the knowledge about the curability of HCV
CATIE (2015) (9) Canada	Cross-sectional study People living with HCV (n=326) Medical clinics offering HCV infection care	Self-administered questionnaire (paper and online)	Knowledge <ul style="list-style-type: none"> 23% reported knew a lot about hepatitis C Younger respondents, men and Indigenous people were more likely to report lower levels of knowledge about hepatitis C 20% reported knowing a lot about treatment Younger respondents and Indigenous people were more likely to report lower levels of knowledge about hepatitis C
Chen et al. (2013) (10) US	Cross-sectional study HCV infection and HIV/HCV coinfection (n=292) Outpatient clinic	Cross-sectional survey and pre- and post-educational surveys	Knowledge <ul style="list-style-type: none"> Overall, HCV knowledge was limited, with less than 50% of the questions answered correctly No differences between the mono-infected and coinfecting groups regarding HCV knowledge score or the subscales representing HCV disease and transmission Coinfected participants had a higher mean HCV treatment knowledge score compared with mono-infected participants
Crutzen & Goritz (2012) (11) Germany and Netherlands	Cross-sectional study General public in Germany (n=1989) and Netherlands (n=668) Online panel	Two large-scale surveys administered to online panels	Awareness <ul style="list-style-type: none"> High awareness of hepatitis A, B and C (no percentage values/scales provided) Knowledge <ul style="list-style-type: none"> Knowledge was very low in both countries (slightly above 50% correct answers) People are aware of the existence of similarities and differences between HAV, HBV and HCV, but they know less about the transmission, consequences and prevention of these infections
Denniston et al. (2012) (12) US	Cross-sectional study General public who tested positive for HCV (n=32,847) NHANES 2001–2008 data	Phone interview	Awareness <ul style="list-style-type: none"> Less than half of those who were HCV-positive were aware of their infection Knowledge <ul style="list-style-type: none"> Respondents answered most knowledge questions correctly, ranging from 57.1% to 95.7% correct Lower proportion of respondents correctly answered questions related to the transmission of HCV through kissing, sexually and vertically (i.e. mother to child) Responses about vertical transmission had the highest proportion of “don’t know” responses (33.7%)
Eguchi & Wada (2013) (13) Japan	Cross-sectional study Japanese working population (n=3,129) Online	Self-administered questionnaire (online)	Knowledge <ul style="list-style-type: none"> 19% believed that HBV/HCV is the cause of liver cancer in 90% of cases 39% believed that people who have HBV/HCV may develop hepatic cirrhosis or liver cancer at age 40–60 years 39% believed that treatment can cure HBV/HCV and prevent liver damage



Appendix 1: Description of included studies (n=19) (continued)

Author(s), year of publication / Country	Study design / Population / setting	Method of data collection	Outcome / Findings
General public (n=14) (continued)			
EKOS Research Associates Inc. (2012) (14) Canada	Cross-sectional study General public (≥16 years old) (n=2,000) Survey panel	Phone interview	<p>Awareness and knowledge</p> <ul style="list-style-type: none"> • Awareness was not clearly defined • 13% of Canadians believed they are very knowledgeable about HCV • 23% believed that HCV infection can be cured; 55% did not know/gave no response • 50% believed that a vaccine is available to prevent HCV; 24% did not know/gave no response • 36% indicated that HCV can be transmitted through blood transfusions • 25% indicated that HCV can be transmitted through unsafe/unprotected intercourse • 23% indicated that HCV can be transmitted through injection drug use/sharing needles • <10% indicated that HCV can be transmitted the following ways: casual contact (e.g., kissing, hugging, shaking hands); from mother to child during pregnancy; tattoos, body piercing; sharing personal hygiene items • 25% did not know/had no response of how HCV can be transmitted
Hopwood et al. (2016) (15) Australia	Cross-sectional study Gay and bisexual men living with HIV and/or HCV (n=474) Online study	Self-administered questionnaire	<p>Knowledge</p> <ul style="list-style-type: none"> • HCV knowledge was moderate to good • 44% believed that being HIV positive makes it more likely to get HCV during sex between men • Respondents wanted information on how to avoid transmitting HCV to sexual partners (46%); complementary therapies for HCV (42%); how HIV/HCV coinfection affects health (42%); and how HIV and HCV treatments affect each other (40%) • The majority of men said their GP or specialist (85%) or the Internet (69%) were their primary sources of HCV information. Fewer men reported that they had accessed information via hepatitis organizations (52%); other health care workers (38%); and friends (23%)
Ipsos (2012) (16) Canada	Cross-sectional study General population (≥18 years) (n=1,000) (Setting unknown: information not available)	Self-administered questionnaire (online)	<p>Knowledge</p> <ul style="list-style-type: none"> • 90% indicated that someone can have hepatitis C and not know it • 62% of Gen Y (18–29 years), 60% of Gen X (30–46 years) and 54% of baby boomers (47–67 years) knew that HCV is primarily transmitted via blood-to-blood contact • 23% of Gen Y (18–29 years), 14% of Gen X (30–46 year) and 18% of baby boomers (47–67 years) knew of the curability of HCV infection
Lambers et al. (2013) (17) Netherlands	Observational study HIV-positive and HIV-negative MSM (n=539) Various (recruitment campaigns, media, word of mouth)	Self-administered questionnaire (paper)	<p>Awareness</p> <ul style="list-style-type: none"> • 74.1% of respondents were aware that HCV can be transmitted during sex between men; 47.2% were aware that HIV-positive men are more likely to report HCV sexual transmission • 57.5% were aware that there is treatment for HCV; 35.6% were aware that HCV treatment could cure the infection • 23.0% were aware of spontaneous clearance of HCV without treatment <p>Knowledge</p> <ul style="list-style-type: none"> • Participants had the highest knowledge scores for HCV transmission and HIV/HCV coinfection • Participants had lowest scores for natural history of HCV, testing and prevention, and treatment



Appendix 1: Description of included studies (n=19) (continued)

Author(s), year of publication / Country	Study design / Population / setting	Method of data collection	Outcome / Findings
General public (n=14) (continued)			
Lea et al. (2016) (18) Australia	Cross-sectional study MSM (n=405) Various (social media advertisements, community organization websites)	Self-administered questionnaire (online)	Awareness <ul style="list-style-type: none"> 70% of HIV-negative and 80% of HIV-positive MSM were aware of HCV More than half of HIV-negative (55%) and HIV-positive MSM (63%) were aware of the existence of HCV treatment Knowledge <ul style="list-style-type: none"> 31% knew that HCV could lead to liver cancer 37% believed that HCV could lead to liver failure
Owiti et al. (2015) (19) Australia, Canada, Mexico, the Netherlands, US	Systematic narrative review Predominantly Asian immigrants (n=51) ^a (Setting unknown: information not available)	Information not available	Knowledge <ul style="list-style-type: none"> There were misconceptions regarding the different types of hepatitis (A, B, C) There was uncertainty around the natural history of hepatitis (e.g., liver damage) and confusion about cause (hormones, stress) One of the studies reviewed reported lack of knowledge of effective HCV treatment There was low level of knowledge of main transmission risk factors, especially sexual contact (horizontal transmission) and childbirth (vertical transmission) Cause and transmission were incorrectly attributed principally to lifestyle activities and cultural practices around food
Pundhir et al. (2016) (20) US	Cross-sectional study Patients (≥18 years) with HCV infection and with or without HIV coinfection (n=292) Primary care clinic	Self-administered questionnaire (online and paper)	Knowledge <ul style="list-style-type: none"> Respondents believed that if their doctor does not talk about hepatitis C, it must not be important to treat Respondents perceived long wait times to see a specialist for treatment as indicating that it was not important to treat HCV knowledge was not associated with appointment-keeping behaviour
Rashrash et al. (2016) (21) US	Cross-sectional study African-American baby boomers (b. 1945–1965) (n=137) Hospital and wellness centre	Cross-sectional survey using audio computer-assisted self-interviewing	Knowledge <ul style="list-style-type: none"> The average knowledge score was low (48.7%). Areas of high knowledge: <ul style="list-style-type: none"> 66.4% correctly identified that HCV can be transmitted via blood 81.8% correctly identified that HCV can be transmitted through needle sharing Areas of low knowledge: <ul style="list-style-type: none"> 45.3% correctly identified that HCV does not affect the bladder 21.2% correctly identified that HCV could not be transmitted via saliva 12.4% correctly identified that there was a vaccine available
Health care providers (n=6)			
Bianco et al. (2013) (22) Italy	Cross-sectional study Nurses (n=326) Hemodialysis units	Self-administered questionnaire	Knowledge <ul style="list-style-type: none"> 49.8% correctly identified all modes of HCV transmission Most nurses correctly identified the following certain transmission routes: receiving blood transfusion from an infected donor (93.9%); having sex with an HCV-positive partner (91.4%); and sharing needles while injecting drugs (90.7%) 11.5% believed that HCV could be transmitted through kissing 19.2% did not indicate that getting a tattoo was a mode of transmission 21.4% incorrectly believed that avoiding breastfeeding can reduce the risk of HCV transmission 70.8% believed that HCV could be spread via patient-to-patient contact
Ipsos (2012) (16) Canada	Cross-sectional study GPs/Family practitioners (n=300) (Setting unknown: information not available)	Information not available	Knowledge <ul style="list-style-type: none"> 96% of GPs agreed that many HCV-infected people are not aware of their infection 35% of GPs know a lot about symptoms associated with HCV infection 10% of GPs know a lot about available treatments 43% correctly identified that hepatitis C is curable; 22% were unsure



Appendix 1: Description of included studies (n=19) (continued)

Author(s), year of publication / Country	Study design / Population / setting	Method of data collection	Outcome / Findings
Health care providers (n=6) (continued)			
McGowan et al. (2013) (23) Canada, Central/ Eastern Europe, Latin America, Western Europe, Nordic countries, Asian/Pacific countries, Middle East/Africa, US	Cross-sectional study Physicians providing HCV treatment (n=697) International market research database	Phone interview or self-administered online questionnaire	Knowledge <ul style="list-style-type: none"> Overall, a greater proportion of hepatologists knew about HCV treatment than GPs Most physicians understood that different genotypes require different treatment durations Most physicians understood that treatment should be discontinued in patients who fail to achieve an early virologic response The majority of physicians incorrectly believed that HCV RNA levels correlate with liver disease severity The majority of physicians also incorrectly believed that non-responders should receive maintenance therapy 40% of providers believed that they have adequate knowledge of treatment guidelines
Naghdi et al. (2017) (24) Canada	Cross-sectional study Primary care physicians, specialists, hepatology nurses and nurse practitioners (n=163) Convenience sample through provider organizations	Self-administered questionnaire (online)	Knowledge <ul style="list-style-type: none"> 78% of primary care physicians were not comfortable initiating hepatitis C therapy 70% of primary care physicians expressed discomfort about switching patients from one therapy to another Compared with primary care physicians, hepatologists, gastroenterologists, hepatology nurses and nurse practitioners expressed greater comfort in monitoring patients' current therapy 22% of primary care physicians had low awareness of current coverage for HCV treatment
Rotte et al. (2013) (25) US	Observational study Residents, physicians, nurse practitioners, physician assistants (n=78) Emergency departments	Self-administered questionnaire (online)	Knowledge <ul style="list-style-type: none"> Knowledge of HCV consequences was high (percentage not provided) 81% were unaware of medications that can cure HCV are available 58% were aware of the CDC HCV-related guidelines 42% were worried about contracting HCV while working in the emergency department 67% were more worried about contracting HCV from a needle-stick injury than HBV or HIV 71% agreed that rapid HCV testing would be beneficial to their patients 40% denied that health care providers with HCV could transmit HCV to a patient
Todorova et al. (2015) (26) Bulgaria	Cross-sectional study Dental medicine students (n=96) Faculty of Dental Medicine, Medical University of Varna, Bulgaria	Self-administered questionnaire	Knowledge <ul style="list-style-type: none"> 41.6% had a good knowledge of HBV/HCV (score of 8/10) Aware of possible routes of transmission: <ul style="list-style-type: none"> 90.6% knew about broken skin or blood transmission 62.5% knew about broken skin or saliva 87.5% knew about needle injury Intact skin in contact with saliva (87.5%) and intact skin in contact with intact skin (90.6%) were correctly considered as not dangerous for HBV/HCV transmission and respectively 80% knew that HBV/HCV carriers may look healthy and not show symptoms

Abbreviations: CDC, Centers for Disease Control and Prevention; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; Gen, generation; GP, general practitioner; MSM, men who have sex with men; NHANES, National Health and Nutrition Examination Survey; n, number; RNA, ribonucleic acid; US, United States

* A number of studies were included in the systematic review



Barriers to and facilitators of hepatitis C virus screening and testing: A scoping review

N Shehata¹, T Austin^{1*}, S Ha¹, K Timmerman¹

Abstract

Background: As part of the global effort to eliminate hepatitis C virus (HCV), it is important to understand the barriers to and facilitators of HCV screening and testing.

Objective: To examine the barriers and facilitators experienced by health care providers offering HCV screening and testing and patients seeking HCV testing.

Methods: A literature search was conducted using Embase, Medline and Scopus databases to collect studies published between January 2012 and July 2017. We extracted the following data: author, year of publication, study design, population, setting, country, method of data collection, and knowledge and awareness outcomes.

Results: A total of 16 articles were identified. Barriers to HCV screening and testing among patients included low self-perceived risk of acquiring HCV, perceived stigma and fear of a positive result. Facilitators of HCV screening and testing, as reported by patients, included increased knowledge of transmission and manifestations of HCV infection and having HCV testing included as part of routine care with or without HIV testing. Barriers to offering HCV screening and testing included time constraints, lack of specific knowledge about HCV and discomfort in asking about risk behaviours. Facilitators of offering HCV screening and testing included testing reminders and working in locations with a higher HCV caseload.

Conclusion: Lack of knowledge and fear of stigma and discrimination remain barriers to HCV testing at the patient level and lack of time, knowledge and discomfort in asking about risk behaviours remain barriers to offering HCV testing by health care providers. This identifies potential areas for future public health action.

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Keywords: barriers, facilitators, screening, testing, hepatitis C

Introduction

In 2016, the 69th World Health Assembly approved the Global Health Sector Strategy to eliminate hepatitis C virus (HCV) and hepatitis B virus as a public health threat by 2030 (1). This goal has been made possible as a result of the availability of the new interferon-free direct acting antiviral (DAA) therapies, which are highly effective in stopping the progression of liver disease and eliminating the virus (2).

One of the challenges with diagnosing HCV infection is that it is often asymptomatic. Screening and testing for HCV infection is a fundamental step in identifying those who are unaware of their infection. Furthermore, the diagnosis of HCV infection can help reduce the burden of disease and limit transmission to those at increased risk of infection and those at risk of reinfection (3). The more people with HCV infection are treated, the less transmission and the fewer new cases. Thus screening

and testing is critical to achieving the World Health Assembly's targets.

In 2011, it was estimated that 44% of people who were living with chronic HCV infection in Canada were unaware of their infection (4). Current Canadian HCV screening guidelines recommend screening of individuals at increased risk of infection (5). People at high risk include individuals with current or past history of injection drug use, HIV-positive gay/bisexual men who have sex with men, incarcerated populations, people experiencing homelessness, individuals exposed to previous health care procedures or personal services where there is a lack of infection prevention control, and individuals who were born, travelled, or resided in countries with high HCV prevalence (6).

The objective of this scoping review is to examine the current barriers to and facilitators of HCV screening and testing from the perspectives of both patients and health care providers.



Methods

In this scoping review, we sought to examine the barriers to and facilitators of HCV testing among health care providers, patients and individuals other than injection drug users at risk of HCV infection. The rationale for this was that barriers to and facilitators of HCV screening and testing among people who inject drugs are well-documented (7). In addition, people who inject drugs tend to have high testing rates (5). Yet, few studies have examined the barriers to and facilitators of HCV screening and testing among other at-risk populations including where there may be a hidden burden.

We conducted a literature search for studies published between January 2012 and July 2017 to capture the most recent studies in the changing landscape of HCV screening and testing. We searched Embase, Medline and Scopus using the search terms "hepatitis C" or "HCV" and "screen" or "test" and "barriers" or "facilitators." (Search strategy available upon request)

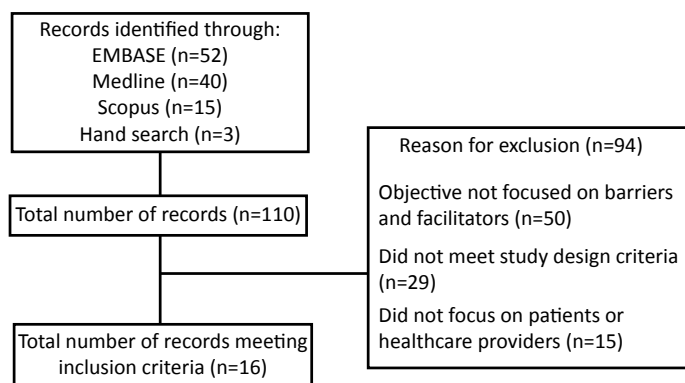
Studies were included if they were published between January 2012 and July 2017; published in English or French; focused on populations other than people who inject drugs; and conducted in well-resourced countries. Letters to the editors, narrative reviews and commentaries were excluded. Key populations were not determined *a priori* but rather emerged from the results of the search.

Once the articles were identified, title and abstracts were screened for relevance. We extracted data on the study population, location of study, study design, outcomes and results.

Results

Of the 126 articles identified in the search, 16 studies focused on the barriers to and facilitators of HCV screening and testing (Figure 1).

Figure 1: Search strategy flow diagram



Abbreviation: n, number

Most of the studies examined both health care provider and patient populations. Health care providers included general practitioners, clinical representatives from hospitals, newly qualified doctors, medical students, resident physicians and nurses (8-14). Patient groups included adults born between 1945

and 1965; patients attending sexually transmitted infections (STI) clinics, outpatient clinics or primary care facilities; youth and adults working in HIV/HCV prevention; immigrant and migrant populations; and sex workers (10,12,13,15-23).

Most of the studies were conducted in the United States (n=9), followed by Canada (n=2), United Kingdom (n=2), Australia (n=1), France (n=1) and Scotland (n=1). Study designs included observational studies, cross-sectional studies and qualitative interviews.

Barriers for health care providers

We identified three primary categories of barriers to health care providers offering HCV screening and testing: time constraints, lack of HCV specific knowledge and discomfort with discussing HCV. These barriers were reported across all specialities (i.e., by emergency department nurses, general practitioners, new medical residents) and settings (i.e., in emergency rooms, community health centres, primary care and STI clinics).

Time constraints

Time constraints—more specifically, limited consultation times, competing priorities and lengthy pre- and post-test counselling procedures—were commonly cited barriers to HCV screening and testing (8,10-13). As a result, health care providers—especially general practitioners—did not routinely ask patients about HCV risk factors (8,21). HCV is also often accorded a low priority due to its slow progression compared with other health conditions that may need to be addressed during an appointment (8,11,15).

Lengthy counselling procedures also emerged as a barrier to health care providers offering HCV testing. In a study conducted in an American teaching hospital, 75% of patients in a hospital setting were not screened because the medical resident circumvented the screening process (21).

Lack of specific knowledge

Health care providers demonstrated a general understanding of HCV risk factors but recognized the need for improving their knowledge of who to test (8,11). In a study conducted in Scotland, health care providers also reported limited knowledge about counselling, to whom and where to refer diagnosed patients and protocols for testing (11). Lack of knowledge of screening guidelines was also a barrier (12).

Lack of comfort

Most health care providers understand the importance of addressing risk factors and diagnosing HCV; however, many reported difficulties in raising the subject with their patients (9). This was especially true if the patient did not have regular contact with the provider and patient-provider rapport was limited. Providers reported that they were more comfortable offering testing after they had built a rapport with their patient and had learned about patients' history and risk factors (8).

Location of practice was an important factor that contributed to health care providers' comfort with HCV screening and testing. In regions with high prevalence of HCV infection, health care providers were more comfortable with offering testing. In contrast, health care providers who worked in regions with low HCV infection prevalence were less likely to encounter cases of



HCV and were less likely to be comfortable with offering a test (8).

Patient barriers to testing

Common patient barriers to seeking HCV testing include lack of knowledge; low perceived risk of infection; fear, stigma and discrimination; and limited access to health care services.

Lack of knowledge

Lack of knowledge about HCV including risk factors, routes of transmission, manifestations and outcomes of untreated infection were frequently reported as barriers to patients seeking HCV testing. Knowledge gaps are evident among patients of all levels of risk. In addition, HIV/HCV stakeholders believed that health care providers' reluctance to discuss HCV contributed to youth and adults' reluctance to seek or discuss testing (18).

Low perceived risk of infection

Lack of knowledge about HCV leads to low self-perceived risk of infection, which in turn leads to under- and undiagnosed cases of HCV infection. Patients frequently reported not being at risk for HCV infection or not having any risk factors (11,15,19). Moreover, patients who had had a previous HCV test were more likely to not seek testing again (19).

Fear, stigma and discrimination

In a Canadian qualitative study, youth and adult HIV/HCV-prevention stakeholders reported that stigmatizing perceptions and negative attitudes about HIV/HCV persist and are a significant barrier to patients seeking testing (18). Other studies have also reported patients—particularly immigrant and migrant populations—fearing a positive HCV diagnosis and the associated stigma and discrimination as barriers to HCV screening (19,20,22).

Limited access to the health care system

Limited interactions with the health care system, lack of a primary care provider and an unstable socioeconomic status were all identified in the literature as barriers to HCV testing reported by patients. Adults born between 1945 and 1965 have reported cost of testing, lack of health insurance, limited access to hepatology clinics and long wait times for appointments as barriers to HCV screening (13,19). Language barriers and lack of culturally sensitive health services limit migrant populations' access to HCV testing (20,22,23).

Health care provider facilitators

Two key facilitators to health care providers offering HCV screening and testing are awareness and knowledge of HCV risk factors and reminders through electronic medical record (EMR) flags.

Awareness and knowledge of risk factors

Awareness and knowledge of HCV risk factors can help health care providers facilitate HCV screening and testing. In a study conducted by McLeod et al. (2017) in Scotland, general practitioners reported almost always offering an HCV test to patients with abnormal liver function test results when they are aware of the risk factors (11).

Electronic medical record flags

A common facilitator of offering HCV screening and testing were reminders. Such reminders could decrease missed opportunities for testing. Health care providers mentioned computerized prompts built into EMRs, based on the patient's health history and risk factors, as a method of being reminded (8,9). This could help ensure that patients who had not been previously offered a test or who had previously declined a test not miss other opportunities for testing. Although one study described "electronic medical record flag fatigue" (where health care providers receive too many reminders) (10), other studies noted health care providers' forgetfulness as a barrier to screening and suggest EMR flags as a solution (8).

Patient facilitators

A key facilitator of seeking HCV testing is awareness and knowledge of HCV.

Awareness and knowledge

Enhanced patient education emerged as an important facilitator of HCV testing. Education, either directly (i.e., health care providers informing patients about the risks of HCV infection) or through awareness campaigns (e.g., television advertisements, poster and public health campaigns), lets patients know the risk factors, routes of transmission and other general information on HCV, which could make them more likely to seek testing (8,19,20).

Table 1 summarizes the key barriers to and facilitators of HCV screening and testing. Details of the included studies are shown in **Appendix 1**.

Table 1: Summary of the key barriers to and facilitators of HCV screening and testing

Population	Barriers	Facilitators
Health care providers	<ul style="list-style-type: none"> Time constraints Lack of HCV-specific knowledge Lack of comfort discussing HCV Lack of awareness and knowledge of HCV screening recommendations 	<ul style="list-style-type: none"> HCV screening recommendations Electronic medical record flags
Patients	<ul style="list-style-type: none"> Lack of knowledge Low perceived risk of infection Fear of a positive diagnosis Stigma and discrimination Language barriers among migrant populations Lack of culturally sensitive health services Cost of testing Confidentiality Lack of health insurance 	<ul style="list-style-type: none"> Awareness and knowledge of HCV Previous HIV testing

Abbreviations: HCV, hepatitis C virus; HIV, human immunodeficiency virus



Discussion

This scoping review presents a high-level snapshot of the barriers to and facilitators of health care providers offering HCV screening and testing and of patients seeking HCV testing. Barriers experienced by health care providers included time constraints, lack of specific knowledge about HCV and lack of comfort discussing HCV. Common barriers for patients were: lack of knowledge, low perceived risk of infection, fear of a positive diagnosis, stigma and discrimination, and limited access to the health care system. Facilitators for health care providers to screen were: electronic medical record flags and awareness and knowledge of HCV. Facilitators for patients to request screening were: awareness and knowledge of HCV. Given the estimated prevalence of undiagnosed cases of HCV infection, results of this scoping review are important for raising awareness of factors that facilitate and hinder HCV testing.

This review has two limitations. First, as a result of the variation in time and place of the studies, some refer to first-generation DAAs, while others refer to second generation DAAs. Although the review focused on barriers to and facilitators of HCV testing, it is important to note the treatment landscape when interpreting findings, particularly considering that some barriers (i.e., cost of treatment, fear of a positive result) may be linked to the availability of treatment.

Second, there are some limitations inherent to the methodological designs of the included studies. For example, seven of the studies were cross-sectional designs, which are only able to capture data at a specific point in time. Other limitations, such as sampling bias may also be applicable to some of the included studies.

The results from this review align with previous research and add to the literature on HCV screening and testing, particularly the barriers and facilitators. A strength of this review is the focus on populations other than injection drug users, including other at-risk populations (i.e., migrants, and sex workers), as well as the general public. Future research could include assessing the barriers to and facilitators of hepatitis C testing in special populations (e.g., Indigenous communities, remote/isolated regions) where the diagnostic and treatment environments of testing are unique.

Conclusion

Understanding the barriers to and facilitators of HCV screening and testing can inform public health actions to improve risk-based screening and reduce the number of individuals unaware of their HCV infection. Informed patients and health care providers who are given the means to address stigma and discomfort around HCV could help advance the goal of HCV eradication.

Authors' statement

NS – Writing (first draft – background and methods), data curation (extraction)

TA – Data curation (verification), formal analysis, writing (final draft), review and editing

SH – Conceptualization, methodology, writing (final draft), data curation, validation, formal analysis, reviewing and editing, supervision, project administration, visualization
KT – Conceptualization, methodology, reviewing and editing, supervision, project administration, visualization
NS and TA contributed equally to this article.

Conflict of interest

None.

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Appendix 1: Characteristics of included studies on barriers to and facilitators of testing for hepatitis C virus (n=16)

Author(s), year of publication / Country	Study design / Setting / Population (n)	Barriers	Facilitators
Allison et al. (2016) (15) US	Cross-sectional study Emergency department Adults born between 1945 and 1965 (n=81)	<ul style="list-style-type: none"> Low perceived risk of HCV infection Fear of needles and not wanting to have additional blood tests Hepatitis C is a lower priority among patients 	<ul style="list-style-type: none"> Acceptability of HCV testing and novel testing methods
Aparicio et al. (2012) (16) France	Observational study Outpatient clinic Adults attending outpatient clinics (n=272)	<ul style="list-style-type: none"> Previous testing with a negative result was a barrier to testing 	<ul style="list-style-type: none"> Including information about screening in the welcome package for newcomers (immigrants) Physicians and nurses offering screening to patients presenting to the hospital for any medical concern
Datta et al. (2014) (8) United Kingdom	Mixed-methods study Six national health service practices in Bristol, United Kingdom Patients at risk of developing HCV (n=3,765) GPs (n=17)	<ul style="list-style-type: none"> Difficulty discussing risk factors with patients Forgetting to address HCV HCV is a lower priority due to its slow progression Competing priorities (i.e., limited consultation time) Difficulty building rapport with patients 	<ul style="list-style-type: none"> When patients disclose risk factors Awareness and knowledge of HCV risk factors Working in a setting where there is a high prevalence of HCV
Duerme et al. (2016) (9) US	Cross-sectional study Clinical representatives (n=27) ^a Hospital	<ul style="list-style-type: none"> Limited provider capacity 	<ul style="list-style-type: none"> Hospital's electronic health record system had an age-based screening alert for high-risk patients
Feldman et al. (2017) (17) US	Cross-sectional study STI clinic Patients attending an STI clinic (n=357)	<ul style="list-style-type: none"> Patients with previous HIV screening were more likely to have been screened for HCV 	None reported
Gahagan et al. (2015) (18) Atlantic Canada	Scoping review and qualitative interviews Nova Scotia Health Research Foundation Youth (ages 15–24 years) and adult HIV/HCV-prevention stakeholders (n=48)	None reported	<ul style="list-style-type: none"> Stigmatizing perceptions and negative attitudes about HIV/ HCV Lack of understanding regarding the importance of targeted testing among health care providers contributed to youth's reluctance to discuss or seek testing
Goel et al. (2015) (10) US	Observational study (retrospective) Primary care setting Primary care patients (n=37,223) Health care providers not specified	<ul style="list-style-type: none"> Time constraints Competing priorities EMR fatigue 	<ul style="list-style-type: none"> EMR flags to screen baby boomers Screening by nonphysicians (i.e., nurses) may be helpful
Grannan (2017) (19) US	Cross-sectional study Federally qualified health centre Adult participants recruited from a federally qualified health centre (n=111)	<ul style="list-style-type: none"> Patients did not think they were at risk or reported no risk factors Previous HCV test Cost of testing Fear of a positive result Providers did not tell patients that they needed testing 	<ul style="list-style-type: none"> Being in the baby boomer cohort (born between 1945 and 1965) prompted testing Awareness and knowledge of HCV risk factors
Guirgis et al. (2012) (20) Australia	Cross-sectional study Hospital liver clinic Migrants (n=60)	<ul style="list-style-type: none"> Language barriers to accessing health care and not understanding medical terminology Cultural barriers to accessing health care Fear of discrimination/stigma Perceived health risk Privacy/confidentiality issues Financial concerns 	<ul style="list-style-type: none"> Availability of a screening program (i.e., maternity, immigration, prison, schools, blood donations) Greater awareness and education More culturally sensitive health services



Appendix 1: Characteristics of included studies on barriers to and facilitators of testing for hepatitis C virus (n=16) (continued)

Author(s), year of publication / Country	Study design / Setting / Population (n)	Barriers	Facilitators
McLeod et al. (2017) (11) Scotland	Cross-sectional study (pre and post survey) Primary care setting Newly qualified doctors and medical students (n=233 pre survey; n=217 post survey)	<ul style="list-style-type: none"> Patients not identifying themselves as being at risk Poor awareness of HCV among clients HCV not being a priority for clients Lack of time for pre- and post-test counselling Insufficient staff with appropriate skill for counselling Poor awareness of HCV among staff Limited knowledge to whom and where to refer diagnosed patients Limited knowledge of testing protocols and who to test 	<ul style="list-style-type: none"> Most general practitioners would always/almost always offer HCV testing to patients with abnormal liver function tests Awareness and knowledge of HCV risk factors
Patil et al. (2016) (21) US	Observational study (retrospective) A teaching community hospital Chart review of adults born between 1945 and 1965 (n=2,534) Number of internal medicine respondents not specified	<ul style="list-style-type: none"> Internal medical residents circumvented the screening test Inaccurate date of birth recorded in the resident admission note Patients had altered mental status and could not give consent Screening test ordered but not sent to laboratory 	None reported
Seedat et al. (2014) (22) United Kingdom	Qualitative study Migrant community Migrant community health care leads (n=20)	<ul style="list-style-type: none"> Accessibility of health care services for migrant communities Low awareness of services available Stigma and discrimination Fear of a positive result Screening services are not migrant friendly/ lack of cultural sensitivity Lack of entitlement to free health care Confidentiality issues 	None reported
Socias et al. (2015) (23) Vancouver, BC	Observational study Female sex workers (n=705)	<ul style="list-style-type: none"> Language barriers to health services Participants with higher number of clients Immigrants living in Canada 	None reported
Szeto et al. (2014) (12) US	Observational study (retrospective) Primary care setting Adults born between 1945 and 1965 (n=395) Resident physicians (n=45)	<ul style="list-style-type: none"> Lack of awareness and knowledge of screening guidelines Time constraints to care for patients with complex medical history 	None reported
Taylor et al. (2016) (13) US	Descriptive study Hospital Adults born between 1945 and 1965 (n=2,327)	<ul style="list-style-type: none"> Time constraints (i.e., nurses found the informed consent process too onerous) Lack of health insurance among patients Limited access to hepatology clinics, long waits for new appointments, difficulty navigating the referral process 	None reported
White et al. (2016) (14) US	Cross-sectional study Emergency department Emergency department nurses (n=65) and patients (n=491)	<ul style="list-style-type: none"> Nurses frequently misperceived how patients experience HCV screening, assuming patients are uncomfortable with it 	None reported

Abbreviations: BC, British Columbia; EMR, electronic medical record; GP, general practitioner; HCV, hepatitis C virus; HIV, human immunodeficiency virus; STI, sexually transmitted infection; US, United States

* n refers to the number of hospitals



Hepatitis C virus infection in Saskatchewan First Nations communities: Challenges and innovations

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Abstract

Hepatitis C virus (HCV) infection has become a major public health issue in Canada, and especially in Saskatchewan First Nations (FNs) communities. One of the challenges in eliminating hepatitis C in Canada is accessing hard-to-reach populations, such as FNs people living on reserves. In Canada, HCV is a notifiable disease but complete and timely surveillance of HCV data is not always possible in remote communities. In addition, national surveillance data are insufficient for determining the number of cases of hepatitis C among FNs populations, because many provinces do not collect information according to ethnicity. Statistics for FN communities are available federally through the First Nations and Inuit Health Branch (FNIHB) in partnership with the communities and the province. There are multiple factors associated with the high rates of HCV in FNs communities, including barriers in accessing preventive services, early diagnosis and treatment. These access issues are largely attributable to issues with geographical remoteness, transportation, education and awareness, and a health care system designed around urban health. New and innovative ways of delivering information and services, such as the mobile hepatitis C clinic (Liver Health Days) and the community-driven Sexually Transmitted Bloodborne Infections (STBBI) Know Your Status program, are proving invaluable in remote FNs communities. Extending these in-community and community-driven programs to other FNs communities and to the prison population could be invaluable in working towards the World Health Organization elimination goals of hepatitis C virus for all.

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Introduction

Approximately 170 million people worldwide are chronically infected with hepatitis C virus (HCV) (1-6). In Canada, 250,000 to 275,000 are chronically infected with HCV and an upward trend of both infection and HCV-associated liver diseases was reported nationally (1-3,7-12). Until recently an estimated 15,800 persons were living with cirrhosis and 5,500 with liver failure in 2017. It has been estimated that from 2007 to 2027, the number of prevalent cases of cirrhosis will increase from 15,814 to 17,570 and carcinoma will increase from 338 to 379 cases (13). The impact of HCV and the sequelae of hepatitis C infection on the health of Canadians are considerable in terms of the impact of chronic liver failure, liver transplant and early death (13).

Injection drug use is the most common risk factor for hepatitis C (7-10,13-17). Two hard-to-reach populations at high risk for hepatitis C are First Nations (FNs) people and people in prison. FNs people in Canada are seven times more likely to be infected with HCV compared with those in the non-FNs population: it has been estimated that 34,900 (or 3.0%) of FNs people were HCV-infected and 6,300 (18.7%) of incarcerated persons were HCV-infected (13,14,18-20). Saskatchewan (SK) has the highest burden of HCV infection in FNs people (1-12,21-23).

There are multiple factors associated with this high burden, including access to testing, health care providers and treatment (9,10,21,22). These access issues predominantly relate to geographical remoteness, issues with transportation, education and awareness, and a health care system designed around urban health (1,2,8-12,21-23).

There are significant limitations in HCV surveillance; and despite this, a continuous and rising burden of HCV has been documented in Saskatchewan FNs communities as well as correctional facilities where FNs people are over represented (1-5,11,12). Furthermore, 21%–44% of those chronically-infected are not aware of their HCV status (2,24,25).

In recent years, new curative Direct Acting Agents (DAA) have revolutionized HCV treatment and have brought hope of possible elimination of HCV and associated liver diseases. But to deliver these promising treatments, individuals with HCV have to be accessed, identified, educated and properly treated. This paper highlights the burden of HCV in Saskatchewan, identifies challenges and barriers to care, and outlines ways Saskatchewan has been working to improve access to prevention and treatment services to promote liver health among FNs living on reserves.



HCV and Saskatchewan First Nations people

Saskatchewan is a rapidly-growing province of over a million people. There are 70 distinct FNs in Saskatchewan and a total of 156,828 registered FNs people living in 84 geographically-isolated and geographically-dispersed communities. The community sizes range from 113 to 10,000 people. More than 50% of FNs people living on reserves in Saskatchewan, and 14% of these reserve communities are geographically isolated. Based on the population projection of Statistics Canada, one in every five people in Saskatchewan could be aboriginal by 2036 (7-10).

In addition to geographical isolation, FNs people in Canada also suffer from a high incarceration rate; estimated to be 1,024 per 100,000 or almost nine times higher for FNs people than for non-FNs people (14). While FNs people made up only 15% of the general population in Manitoba and Saskatchewan, they accounted for 64% of the provincial jail admissions in Manitoba and 76% in Saskatchewan in 2000–2001 (14). At the same time, data suggests that FNs people are at increased risk for human immunodeficiency virus (HIV) and HCV infection and are infected at a younger age than non-FNs people. The high degree of mobility of FNs people between inner cities and rural areas may bring the risk of HIV and HCV to even the most remote communities (3,14,18-20,24).

In addition, FNs people are over-represented in groups at high risk for HIV infection, in particular among injection drug users (IDUs). In Saskatchewan, a 2005 cross-sectional survey by Hennink et al. found that HCV is acquired relatively soon after IDUs begin injecting drugs (11). Within five years of beginning to inject, 50%–80% of IDUs were infected with HCV. As a result, many IDUs who become infected with HIV are already infected with HCV. Similarly Klein et al. found that HIV-HCV co-infected persons remained at markedly increased risk for death, despite treatment with antiretroviral therapy (15). A Canadian cohort study found that Aboriginal ethnicity and the female sex were associated with increased rates of HCV clearance, while HIV co-infection and illicit drug use were associated with decreased clearance rates (3). To further complicate identification and treatment of HCV-infected individuals, approximately 50%–85% of those who remain infected will progress to chronic infection but may be asymptomatic for decades.

The challenges

HCV surveillance

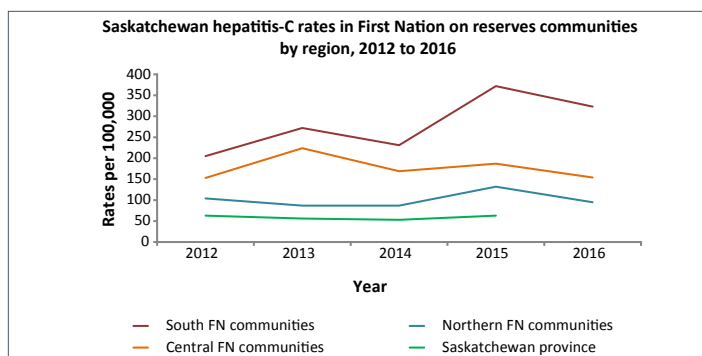
In Canada, HCV is a notifiable disease. Complete and timely surveillance of HCV data is essential for early identification and response to HCV outbreaks to minimize transmission and to implement evidenced-based prevention strategies. But in FNs communities, complete and timely surveillance is not always possible. In addition, national surveillance data are insufficient for determining the number of cases of hepatitis C among FNs populations, largely because many provinces do not collect information according to ethnicity (1-5,7-15). As a result, information regarding ethnicity has been confined to population groups already at high risk for acquisition of blood borne pathogens (such as prison inmates and IDU) (3). Although FNs

peoples are considered to bear the highest burden, there is a paucity of data.

Some statistics for FN communities are available federally through the First Nations and Inuit Health Branch (FNIHB) in partnership with the communities and the province. According to FNIHB-Health Canada, Saskatchewan Region, in 2015 the reported HCV new seropositive rates for FNs on-reserve communities were 372.0, 186.7, and 129.0 cases per 100,000 population in southern, central and northern FNs communities respectively. In 2015, these rates were six times, three times and two times higher than the provincial HCV rate (62.7 cases per 100,000), respectively.

In 2016, reported rates continued to increase, with the HCV new seropositivity rates of 401.2 cases per 100,000, 211.6 cases per 100,000 and 130.0 cases per 100,000 for the southern, central and northern communities, respectively (see **Figure 1**). HCV rates also increased markedly in the southern Saskatchewan FNs communities in the past years.

Figure 1: Saskatchewan hepatitis C rates in First Nations on reserves, by region, 2012 to 2016



Abbreviation: FN, First Nation

In 2016, the majority of the HCV cases in Saskatchewan FNs communities were males (66%) and many (33%) of the HCV cases diagnosed were 30–39 years of age (7-10). This is in contrast to Canadian data where the age range of HCV cases is older (3,25).

Access to HCV treatment and prevention programs

Access to testing is not available in some of FN communities in Saskatchewan and many do not have access to primary care (7-10,13-17,26). Furthermore for FNs on reserves, if the diagnosis is made off reserve where a local address is used, then the burden on reserves will be under represented. Mobility also leads to significant difficulty in locating patients and hence many are lost to follow up. Indeed, many do not get a confirmatory viral load diagnosis and many are not even aware of their infection.

Non-Insured Health Benefits (NIHB) program in Health Canada was one of the first plans to cover direct acting antiviral treatment for HCV for FNs and Inuit patients. Significant barriers related to poverty, communication and remoteness for FNs on reserves have impeded access to any curative therapy. Treatment requires access to fibroscan or staging of liver disease typically available in tertiary care centres only, as well as an HCV



treatment provider, who is available predominantly in major urban centres. Further, untreated viremia, combined with limited access to harm reduction services, only continues to exacerbate the rates through on-going active transmission.

Liver transplantation is problematic, as access to specialized hepatitis clinics and treatment is limited in Saskatchewan and a growing number of patients are referred to the Edmonton liver transplant program (20,22,23,27-29). In Saskatchewan only 28 patients have received liver transplants since 2008 and 225 are currently on the waiting list for a transplant (22,23,26).

The innovations

Preventive services

The FN communities are at various stages in terms of capacities and their response to the increasing HCV (and HIV) rates. Currently there are 21 harm reduction (including needle exchange programs) sites operating on reserves in Saskatchewan. These programs are linked to screening, mental health and addiction services and other family support programs. The FNIHB-Saskatchewan Region (Indigenous Services Canada), is working closely with all partners to support communities adapting Sexually Transmitted and Bloodborne Infection (STBBI) Know Your Status models of care.

The culturally grounded Know Your Status model was initially implemented by two Saskatchewan FN communities, and involves 1) community engagement, education, prevention and harm reduction and 2) clinical management surveillance and evaluation. Key personnel of the Know Your Status program include those specializing in community health, harm reduction outreach, lab services, primary care, infectious disease, prevention and awareness, and cultural support (7-10,21,26,30). The Know Your Status proved to be a highly effective model of HIV care for on reserve communities. In 2015 it achieved the United Nations goal of 90/90/90 (90% of people living with HIV know their status (31), 90% of people who know their status are accessing treatment and 90% of people on treatment have a suppressed viral load) (7-10,21,26,30). In partnership with Saskatchewan FNs, similar programs are currently being rolled out to more than 50 other communities. This model of care is now being extended to include HCV and other STBBIs.

To support the 84 FN communities across Saskatchewan, there are currently 12 nursing stations on reserves in the north, 23 sites operating in south central communities that offer HIV/HCV Point of Care Testing and 13 specialized mobile nursing or outreach teams across Saskatchewan that provide program support.

Mobile hepatitis C clinics

There has been a change in approach to address hepatitis C in FN communities in Saskatchewan over the past two years. A partnership has been established between public health, FN communities, FN leaders, labs and clinical providers to bring testing and care directly to remote FN communities through the use of mobile hepatitis C clinics, which brings testing, education, fibroscans and DAA treatment directly to the Saskatchewan FN communities.

These mobile clinics are multidisciplinary in nature. These clinics are advertised in advance and invite community members with HCV or those who engage in risk behaviours to attend. They provide one-on-one educational and in depth counselling sessions. Testing and assessment of patient's health/liver conditions are also undertaken and, where indicated, plans are made for integrated care and referral for community-based treatment the same day. Moreover, awareness and expertise developed locally has allowed communities to take ownership of this comprehensive approach to HCV infection, its underlying risk factors and the health of their members by providing culturally-sensitive and accessible care in a team-based model.

These mobile in-community HCV clinics have been named "Liver Health Days". They have not only attracted the interest of FNs people affected with HCV but have also improved treatment uptake, health outcomes and adherence rates. The number of these mobile clinics is increasing as more FN communities take ownership and leadership in the prevention programs. Community leadership, staff (e.g., community health nurses, registered nurses and nurse practitioners) trained in liver health and cultural safety in the provision of HCV care are the key ingredients of success in this regard. Culturally safe or appropriate care means that all members of the health care system are aware of the history and impact of intergenerational trauma and the current challenges (such as racism) that FN people experience when trying to access health care, and that they do everything possible to ensure that the care they provide is respectful, comprehensive and holistic.

Injection drug use (IDU) and addressing determinants of health

As IDU is a primary risk factor for acquiring and for the transmission of HCV, addressing drug addiction and associated mental health issues are critical to the HCV response. Monitoring drug and addiction trends at the community level is an effective tool. While offering community-based services for HCV infection, awareness of factors that promote resilience and addressing determinants of health such as intergenerational trauma from a history of colonization and residential schools, racism, overcrowding, education and literacy, social exclusion and gender inequality, could help FN people access to health care services (16,17).

Discussion

The HCV has become a major global public health issue that is reflected in the rising burden of HCV in Saskatchewan FN people on reserves. Until recently, FN people living on reserves in Saskatchewan have not been accessing treatment. Recent community-based programs innovations, such as the mobile hepatitis C clinic and the community-driven HIV/HCV Know Your Status program, which offer onsite testing/counselling, harm reduction services, diagnostics and treatment, are becoming invaluable in addressing the HCV situation on FN reserves (7-10,21,26,30,32).

In 2016, Canada, along with member states of the World Health Organization, adopted the first global strategy on viral hepatitis with a goal to eliminate viral hepatitis as a major public health



threat by 2030 and that everyone living with viral hepatitis has access to safe, affordable and effective treatment (33). The strategy identified underdiagnosis as a key barrier to eliminating HCV (2,6,34). Adopting best practices and innovative models that engage clients in prevention, early diagnosis and treatment of HCV is critical to stopping the transmission in all settings, whether it is on or off reserve. Given the high level of HCV in IDU, attention has focussed on this subgroup of the population. A recent meta-analysis of strategies effective at reducing HCV sero-conversion found that employing a combination of interventions was most effective at reducing HCV transmission among IDU (24,25,32,35-41) before the onset of cirrhosis (fibrosis stage F0-F3) have fewer long term HCV-related complications than those who achieve sustained virologic response (SVR) after the onset of cirrhosis (fibrosis stage F4) (2,4). Early intervention has been found to be effective not only in preventing progression of liver disease but also in stopping the spread of infection in communities.

Next steps

Based on the success of Saskatchewan's STBBI Know Your Status approach, expansion of similar community-designed and culturally appropriate programs to other FN reserves across Saskatchewan will help to improve treatment and stop transmission of HCV. This could have the added benefit of improving surveillance information and providing good outcome data.

Partnerships between on and off reserve programs are needed to optimize care and provide outreach support and awareness campaigns across various national and provincial jurisdictions. It will be important to address attitudes that may interfere with the prevention, treatment and care activities, and to reduce HCV- and HIV-related stigma and discrimination across the spectrum of services.

Due to the alarmingly high levels of HCV in prison inmates, particularly in the FN inmates, targeted HCV initiatives by and for FN inmates are needed in Saskatchewan. The FN HCV programs already present at the community level could be linked to care in prisons. Interventions targeting modifiable risk factors, such as substance use, smoking, proper adherence to antiretroviral therapy and timely provision of HCV therapy could substantially reduce complications and lower death rates.

Further research is needed to evaluate the extent and the determinants associated with HCV infection, obtain population-based estimates of HCV prevalence and incidence in the Saskatchewan FN population, develop FN community-led programs to prevent new infection, better understand HCV infection, and implement more effective methods of addiction management in HCV-positive patients.

Conclusion

There are multiple factors associated with the high rates of HCV in FN communities, including barriers to access preventive services, early diagnosis and treatment. These access issues predominantly relate to remoteness, transportation, education and awareness and a health care system designed around urban health. Instigation of new and innovative ways of delivering information and services, such as the mobile hepatitis C clinic

and the community-driven STBBI Know Your Status model of care, are proving invaluable in remote FN communities. Extending these programs to other FN communities and to the prison population, which often has a disproportionately high population of both FN individuals and HCV-infected individuals, could prove to be invaluable in addressing HCV infection and helping Canada meet the global goal of HCV elimination.

Authors' statement

Dr. Skinner and Dr. Khan collaborated with Chief Cote and all the content reflected in this article come from the programs delivered in direct partnership with First Nations communities.

Conflict of interest

None.

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A summary of the Pan-Canadian framework on sexually-transmitted and blood-borne infections

Centre for Communicable Diseases and Infection Control^{1*}

Abstract

Sexually-transmitted and blood-borne infections (STBBI) remain a significant health concern in Canada and around the world. To guide Canada's efforts to reduce the health impact of STBBI and to contribute to global efforts, a PanCanadian framework was developed and has been endorsed by federal, provincial and territorial ministers of health. The framework sets out an overarching and comprehensive approach to address STBBI. It has an integrated approach given the shared common risk factors, transmission routes, and affected populations. The framework establishes a vision for Canada where STBBI are rare and people living with STBBI receive the care and support they need. The success of the framework will be measured against the global STBBI targets and progress towards these strategic goals: reduce the incidence of STBBI in Canada; improve access to testing, treatment, and ongoing care and support; and reduce stigma and discrimination that create vulnerabilities to STBBI. The framework is composed of four interconnected pillars that span the continuum of STBBI care: prevention, testing, initiating care and treatment, and ongoing care and support. The framework recognizes that the creation of an enabling environment that includes interrelated legal, social, cultural, physical, and structural conditions supports successful STBBI programs, policies and actions. Through this framework, Canada is unifying and communicating a common approach to addressing STBBI while respecting the flexibility required by jurisdictions and sectors to address different needs and priorities. As outlined in the Pan-Canadian framework, federal, provincial, and territorial governments will develop indicators and targets for Canada that will permit them to measure Canada's progress and guide their respective priorities for all pillars of the framework.

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Keywords: sexually-transmitted and blood-borne infections, framework, Canada

Introduction

Sexually-transmitted and blood-borne infections (STBBI) remain a significant health concern in Canada even though they are largely preventable, treatable and, in many cases, curable. Rates of certain STBBI continue to rise in Canada and global momentum to eliminate new infections is building. To this end, Canada has endorsed the United Nations Sustainable Development Goals, as well as the Joint United Nations Programme on HIV/AIDS (UNAIDS), and the World Health Organization's (WHO) global health sector strategies to address HIV, viral hepatitis and sexually-transmitted infections. These goals and strategies call on countries to work towards the elimination of STBBI as a public health concern by 2030 (1).

To guide Canada's efforts to reduce the health impact of STBBI and to contribute to global efforts, a Pan-Canadian framework titled '*Reducing The Health Impact of Sexually-Transmitted and Blood-Borne Infections in Canada by 2030: A Pan-Canadian Framework for Action*' was developed by the Public Health Agency of Canada and has been endorsed by federal, provincial and territorial ministers of health (2). This article is a summary of the full report.

The state of STBBI in Canada

In Canada, the number of newly diagnosed HIV and hepatitis C virus (HCV) infections has remained relatively stable nationally in recent years, though there are variations at the regional level and among specific communities. An estimated 65,000 people were living with HIV in Canada at the end of 2014, of whom an estimated 20% were unaware of their status (2). Gay, bisexual and other men who have sex with men represented approximately 2.5% of the male population (15 years and older) and yet accounted for almost 50% of those living with HIV infection and more than 50% of new infections in Canada in 2014 (3). As of 2011, an estimated 221,000 to 246,000 Canadians had a chronic HCV infection, of whom an estimated 44% were unaware of their status (4).

The numbers of newly diagnosed chlamydia, gonorrhea, and syphilis infections have also increased consistently since the mid-1990s, despite numerous public health interventions designed to prevent, diagnose, and treat these infections (5). Between 2005 and 2014, there was a 49% increase in the reported rate of chlamydia, a 61% increase in the reported rate of gonorrhea and a 95% increase in the reported rate of syphilis (6).

Canada has made progress in areas such as improving access to innovative treatments, creating strong surveillance



systems to monitor infections, and building the capacity of community-based organizations. However, despite having the tools and having made some progress, there continues to be an unacceptable number of new infections in Canada. The time is right for Canada to foster a new approach to reduce new infections, improve health outcomes, and contribute to global efforts.

An integrated approach

In 2016 and 2017, concrete actions that could have a significant impact on rates of STBBI in Canada were identified through online surveys and in-person meetings with a broad range of partners and stakeholders, including people living with HIV and hepatitis, people from key populations, representatives of First Nations, Inuit and Métis communities and organizations, clinicians and other health professionals, community-based and civil society organizations, researchers, provincial and territorial governments, and representatives of the pharmaceutical industry. This input informed the framework through an iterative process.

The framework sets out an overarching and comprehensive approach to address STBBI. Canada has been evolving towards an integrated approach given the shared common risk factors, behaviours for transmission, and transmission routes across STBBI, as well as the key populations affected by them. At the same time, it is recognized that infection-specific approaches are still appropriate in certain circumstances or communities. It is expected that partners and stakeholders across the country will look to the framework to inform their work. A collaborative approach will be required to succeed since one sector alone is not enough to reduce the health impact of STBBI.

Pan-Canadian framework on STBBI

The framework establishes a vision for Canada where STBBI are rare and people living with STBBI receive the care and support they need. The success of the framework will be measured against the global STBBI targets and progress towards these targets will support the following broader strategic goals for Canada:

- Reduce the incidence of STBBI in Canada
- Improve access to testing, treatment, and ongoing care and support
- Reduce stigma and discrimination that create vulnerabilities to STBBI

A set of guiding principles were adopted within the framework to help inform the collective action required to address STBBI in Canada (Table 1).

The framework is composed of four interconnected pillars that span the continuum of STBBI care:

- **Prevention** promotes sexual health knowledge, changes attitudes and behaviours, as well as supports the uptake of existing and emerging prevention interventions (e.g. HIV pre-exposure prophylaxis, vaccines);
- **Testing** promotes normalized routine offer of tests, new point-of-care testing, and addresses barriers to access testing;
- **Initiation of care and treatment** promotes timely care and treatment and the uptake of new medications for all populations; and

Table 1: Guiding principles of the 2018 Pan-Canadian Framework to reduce to reduce STBBI (2)

Guideline principle	Definition
Meaningful engagement of people living with HIV and viral hepatitis and key populations	People living with HIV and viral hepatitis and key populations are meaningfully engaged in the development and implementation of policies and programs that affect them.
Moving towards truth and reconciliation	Policies and programs to address STBBI among Indigenous Peoples are developed by and with First Nations, Inuit and Métis peoples through a relationship grounded in mutual respect and rooted in an understanding and recognition of and responsiveness to the ongoing impacts of colonization, health and social consequences of residential schools, structural inequities and systemic racism.
Integrated approach	Interventions and programs are designed to address the complexity and interrelated nature of risk factors and transmission routes for STBBI while recognizing that disease-specific approaches may be appropriate in some cases.
Cultural relevance	Policies and programs to address STBBI reflect and respect cultural realities and practices while ensuring the safety of individuals and communities.
Human rights	All people, regardless of their sexual orientation, race, culture, gender, abilities, or personal practices, are important and their human rights are recognized, respected and promoted.
Health equity	All people, regardless of sex, gender, race, income, sexual orientation, geographic location, status, age or culture, have equitable access to quality information and services from qualified health professionals and other front-line providers.
Multi-sectoral approach	Multi-sectoral and multi-disciplinary approaches to prevention and care are embraced to improve collaboration and ensure interventions acknowledge the whole individual and their wellness needs.
Evidence-based policy and programs	Interventions and programs are consistently developed with, and guided by, the most recent surveillance data, research and other evidence.

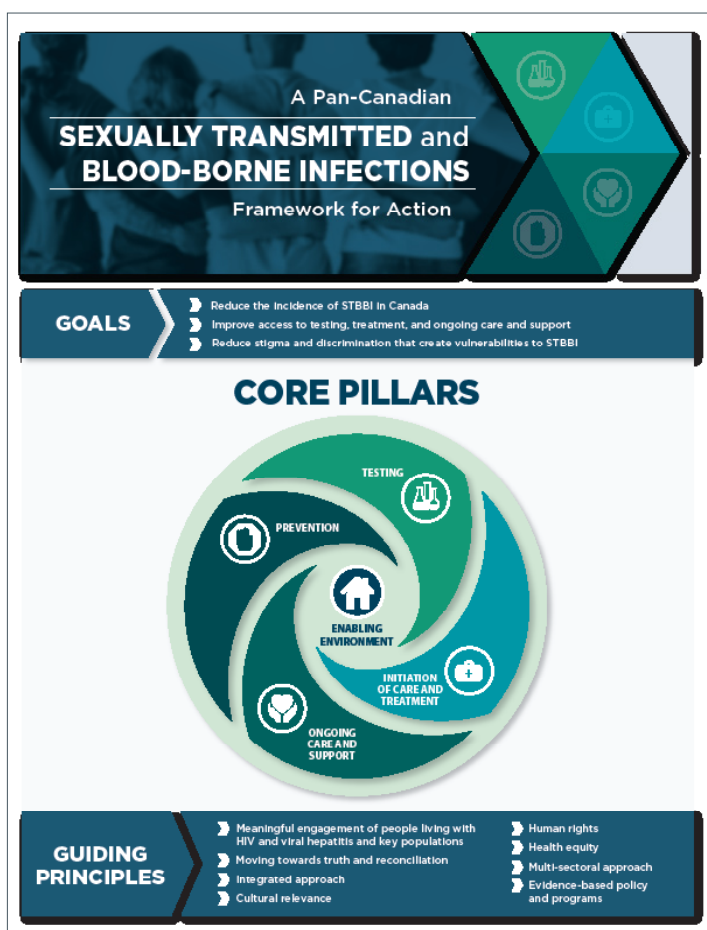
- **Ongoing care and support** promotes efforts to retain and reengage into care those who have been affected by STBBI, and includes the development of “wrap-around”, interdisciplinary, multi-sectoral care models that incorporate STBBI services into primary care.

Further to the core pillars, the framework recognizes that the creation of an *enabling environment* is critical to the success of the actions under all core pillars of the framework. An enabling environment creates the conditions needed to ensure equitable coverage, to increase the uptake of services, and to improve the quality of health services. This includes interrelated legal, social, cultural, physical, and structural conditions that support successful STBBI programs, policies, and actions. An outline of the framework is noted in Figure 1.

The framework identifies 26 opportunities for action spanning across the pillars including the enabling environment that can be used to inform actions by people from key populations such as: Indigenous leadership/communities, civil society, health professionals, professional associations and licensing bodies, the private sector, and all levels of government. Lastly, the framework also recognizes surveillance, research, knowledge mobilization, and monitoring and evaluation as being important cross-cutting activities.



Figure 1: A Pan-Canadian Framework to reduce health impact of STBBIs in Canada



Conclusion and next steps

Through the Pan-Canadian framework, Canada is unifying and communicating a common approach to addressing STBBI while respecting the flexibility required by jurisdictions and sectors to address different needs and priorities. Federal, provincial, and territorial governments will develop indicators and targets for Canada that will permit them to measure Canada's progress and guide their respective priorities for all pillars of the framework.

The Government of Canada is developing an implementation plan that will identify specific actions to be undertaken by

the federal government over the next five years that will help contribute to the elimination of STBBI and to achieve the strategic goals as set out in the framework.

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Community outbreak of invasive group A streptococcus infection in Ontario, Canada

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Abstract

Background: Outbreaks of invasive group A streptococcal infection (iGAS) have historically occurred in institutional settings. Increasingly, community-based outbreaks have been reported, often among marginalized populations, yet few guidelines exist for managing iGAS outbreaks in such settings.

Objective: To describe the ongoing outbreak of iGAS in Middlesex-London, Ontario, and the challenges that arose while applying current guidelines to a marginalized population in a community setting.

Methods: The outbreak investigation included all iGAS cases in Middlesex-London with an onset date from April 1, 2016 to February 28, 2018. Clinical specimens were submitted to provincial and federal laboratories for typing. Public health management of the outbreak involved environmental health inspections, contact tracing, chemoprophylaxis of close contacts, swabbing to determine colonization rates of *Streptococcus pyogenes*, and communicating with stakeholders and the public.

Results: A total of 156 confirmed cases of iGAS corresponding to 147 individuals were reported in less than two years. More than 60% of cases occurred in men (n=91) and almost half (n=71) of the total number of cases were persons who used drugs (PWUD) and/or were under-housed. Of the PWUD cases, 58 of 65 (89%) used injection drugs. Key challenges in controlling this outbreak included reaching PWUD and under-housed people; completing a case history and contact list; facilitating completion of treatment; dealing with concurrent infections such as human immunodeficiency virus (HIV) and hepatitis C virus (HCV); and optimizing environmental health conditions. Guidelines were adapted so contacts who shared drugs or injection drug equipment with a known iGAS case would be offered chemoprophylaxis regardless of the clinical severity of the case. To optimize treatment completion, a single-dose of azithromycin for individuals in close contact with PWUD and/or under-housed cases was given. Cases with macrolide-resistant strain *emm9* have recently emerged.

Conclusion: The application of institution-based guidelines for iGAS outbreaks has been ineffective in controlling this particular community outbreak. There is a need for guidelines on managing outbreaks of iGAS in the community especially when an outbreak involves marginalized populations.

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Keywords: invasive group A streptococcus, outbreak, community, marginalized population, persons who use drugs

Introduction

In May 2016, a community outbreak of invasive group A streptococcus (iGAS) was declared by the Medical Officer of Health of the Middlesex-London Health Unit, a rural-urban Ontario community with fewer than 500,000 people. Despite applying current Canadian guidelines for institutional outbreaks—which were adapted for this community outbreak—the outbreak is ongoing. The purpose of this report is to describe this community outbreak: the epidemiology of reported cases, the public health response and the challenges that arose when attempting to apply the institutional-based guidelines.

Background

Group A streptococci (GAS) are human bacterial pathogens that colonize the throat or skin and may be present in asymptomatic carriers. This gram-positive bacteria can cause a broad spectrum of disease that can be noninvasive or invasive. Noninvasive disease includes pharyngitis (e.g., strep throat), impetigo, scarlet fever and cellulitis (1,2). Invasive group A streptococcal infections (iGAS) occur when the pathogens infect normally sterile sites, such as the blood, cerebrospinal fluid, joints, pleural or pericardial fluid (1,3). **Text box 1** summarizes the Ontario Ministry of Health and Long-Term Care provincial case definition for a laboratory-confirmed case of iGAS (3). Although uncommon



Text box 1: Definition of a laboratory-confirmed case of invasive group A streptococci^a

Isolation of group A streptococcus (*Streptococcus pyogenes*) or DNA detection by nucleic acid amplification test (NAAT) from a normally sterile site (e.g., blood, cerebrospinal fluid, joint fluid, pleural fluid, pericardial fluid) with or without evidence of clinical severity, OR

Isolation of group A streptococcus from a nonsterile site (e.g., skin) with evidence of severity. Clinical severity is defined as one of the following:

- Streptococcal toxic shock syndrome (STSS), which is characterized by hypotension (systolic blood pressure <90 mm Hg in adults or <5th percentile for age for children) and at least two (2) of the following signs:
 - renal impairment (creatinine >177 µmol/L for adults);
 - coagulopathy (platelet count ≤100,000 mm³ or disseminated intravascular coagulation);
 - liver function abnormality (AST (SGOT), ALT (SGPT) or total bilirubin ≥2x upper limit of normal for age);
 - adult respiratory distress syndrome (ARDS);
 - generalized erythematous macular rash that may desquamate; OR
- Soft tissue necrosis, including necrotizing fasciitis or myositis or gangrene; OR
- Meningitis; OR
- Death; OR
- A combination of any of these conditions.

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; DNA, deoxyribonucleic acid; SGOT, serum glutamic-oxaloacetic transaminase; SGPT, serum glutamic pyruvic transaminase

^a According to the Ontario Ministry of Health and Long-Term Care Infectious Disease Protocol (http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/gas_cd.pdf)

compared to noninvasive GAS infection, iGAS is associated with significant morbidity and mortality, as the bacteria can cause severe sequelae such as pneumonia, meningitis, necrotizing fasciitis, sepsis and streptococcal toxic shock syndrome (4,5). For GAS isolates, the M protein (encoded by the *emm* gene) is a significant virulence and epidemiologic factor that impacts the pathogen's ability to evade the human immune response to infection (6).

Historically, outbreaks of iGAS have occurred in long-term care facilities (7-10), hospitals (8) and child care centres (11-14). The Public Health Agency of Canada's 2006 *Guidelines for the Prevention and Control of Invasive Group A Streptococcal Disease* focus on managing disease in these facilities (15). Subsequent provincial protocols (3,16) and recommendations (17) have also focused on these settings.

However, recent outbreaks of both noninvasive and invasive GAS disease have been reported in community settings, often in marginalized populations. For example, there have been reports of GAS outbreaks in a homeless shelter in Toronto, Ontario (18), a homeless population in Alaska, United States (US) (19), persons who use drugs (PWUD) in England and Wales (20), and a population with a high prevalence of PWUD, alcohol abuse and homelessness in Thunder Bay, Ontario (21).

The Canadian guidelines for institutional iGAS outbreaks include a retrospective chart review, identification of close contacts, alerting contacts to signs and symptoms, strict enforcement of standard infection control practices and a 10-day chemoprophylaxis of close contacts of a confirmed severe case (15). However, these guidelines are difficult to implement in marginalized populations.

In 2004, the United Kingdom's Health Protection Agency released interim guidelines for the management of community-acquired cases of iGAS (22). While the guidelines acknowledge that cases occurring in homeless shelters can present a challenge for public health action, the recommendations do not include additional measures for marginalized populations. For example, there are no measures addressing barriers to accessing primary health care, to reaching those affected (e.g., those with no personal phone number and with no fixed address), or to getting full disclosure regarding contacts or challenges in completing a 10-day course of treatment (16).

Methods

Outbreak detection and investigation

Between January 2015 and March 2016, the average monthly incidence of iGAS in the Middlesex-London Health Unit was 1.73 cases per month overall, and 0.47 cases per month among PWUD and/or under-housed individuals. In a 25-day period spanning April and May 2016, five cases of iGAS were reported to the Middlesex-London Health Unit, all who were PWUD; this amounted to more than two standard deviations (SD) of the monthly mean for overall cases (2 SD + mean = 3.80) and for PWUD and/or under-housed cases (2 SD + mean = 1.50). Due to the potential for iGAS to have severe clinical outcomes (including death), the Middlesex-London Health Unit declared a community outbreak of iGAS in its jurisdiction on May 12, 2016.

The outbreak case definition included all cases of laboratory-confirmed iGAS in Middlesex-London with an accurate episode date on or after April 1, 2016. The accurate episode date is the earliest recorded date of symptom onset, date of lab specimen collection or date reported to public health. This article includes cases reported to the Middlesex-London Health Unit up to and including February 28, 2018.

In Ontario, molecular typing is not routinely conducted on iGAS specimens. As part of the outbreak investigation, laboratory specimens were sent to the Public Health Ontario Laboratories for pulsed-field gel electrophoresis (PFGE) typing and to the National Microbiology Laboratory for *emm* typing.

Contact tracing

Contact tracing focused on individuals in close contact with iGAS cases, defined according to the Public Health Agency of Canada's *Guidelines for the Prevention and Control of Invasive Group A Streptococcal Disease* (15) (summarized in **Text box 2**). Middlesex-London Health Unit staff attempted to contact all the close contacts identified to alert them to the signs and symptoms of iGAS, to advise them to seek medical attention should they develop any clinical signs of iGAS and to determine whether chemoprophylaxis might be warranted.

Risk factor assessment

Anyone who reported illicit drug use (e.g., opioids, cocaine, methamphetamines) during the six months preceding the diagnosis was considered a "PWUD"; exclusive users of marijuana were excluded. "Under-housed" was defined as an individual with no fixed address, living in a homeless shelter or group home or couch-surfing (i.e. temporarily staying with friends). To better understand whether drug use practices may be contributing to iGAS transmission, an enhanced drug

**Textbox 2: Definition of close contacts of iGAS cases (15)**

- Household contacts of a case who have spent at least 4 hours/day on average in the previous 7 days or 20 hours/week with the case;
- Non-household contacts who shared the same bed with the case or had sexual relations with the case;
- Contacts who had direct mucous membrane contact with the oral or nasal secretions of a case (e.g., mouth-to-mouth resuscitation, open mouth kissing) or had unprotected direct contact with an open skin lesion of the case;
- Injection drug users who shared needles with the case.

Abbreviation: iGAS, invasive group A streptococcal

questionnaire was developed, with input from community partners, for PWUD iGAS cases. The questionnaire was piloted in April 2017 and administered between May 1, 2017, and January 31, 2018 (available upon request).

Environmental health inspections

To assess the living conditions at premises linked to cases, Middlesex-London Health Unit public health inspectors performed site visits to unlicensed rooming houses (a house or building where multiple tenants share kitchen and/or washroom facilities and each tenant pays individual rent) and a licensed lodging home. Site visits to local homeless shelters were also conducted to determine client interaction, facility sanitation and cleaning, the use of laundry and shower facilities, and the availability of health care services for clients.

Data analysis

A case line-list was extracted from the integrated Public Health Information System (iPHIS) and imported into Microsoft Excel (version 2010; Microsoft Inc, Redmond, Washington, US). The line-list included information on age, sex, address, episode date and laboratory test results. Additional information contained in the internal Middlesex-London Health Unit Infectious Disease Control database (e.g., drug use, housing, existing conditions,

symptoms, clinical severity) were added to the spreadsheet. Analyses were conducted in Microsoft Excel and STATA/SE (version 14.0; StataCorp, College Station, Texas, US). Rate ratios (RR) and Pearson chi-squared test (or Fisher exact test) were used to assess the difference in proportions between groups.

Results

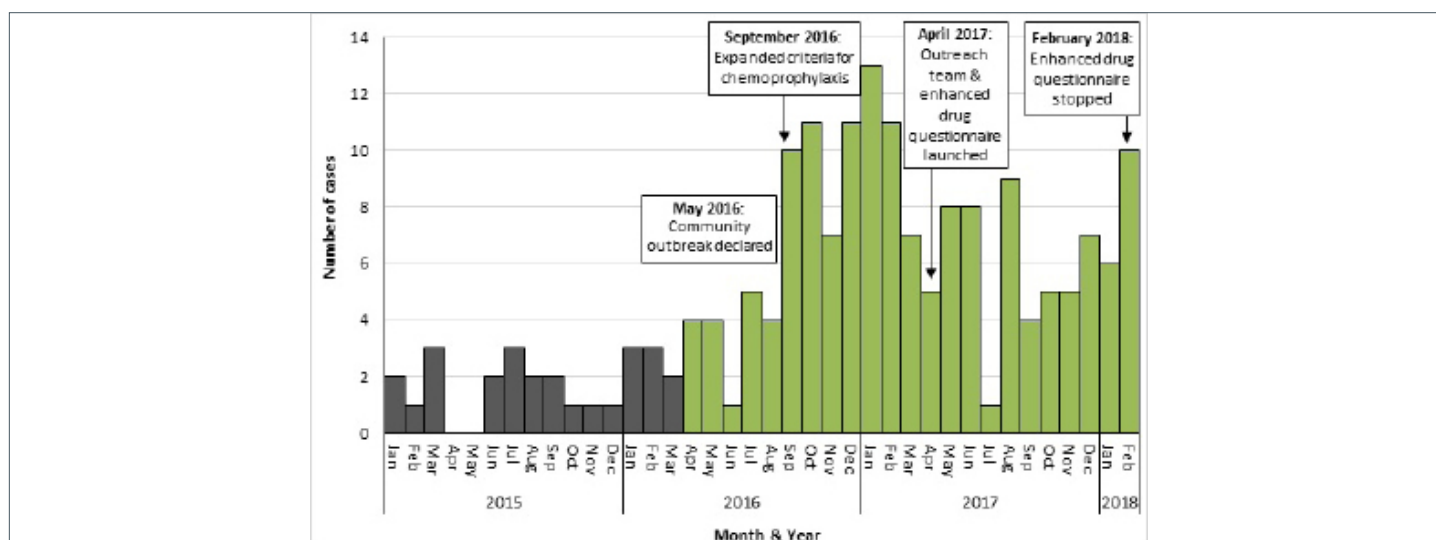
A total of 156 confirmed iGAS cases with an accurate onset date between April 1, 2016, and February 28, 2018, were reported to the Middlesex-London Health Unit. This corresponded to 147 people because nine individuals had two separate episodes during the 23-month period. One individual with a recent case of iGAS was identified as a potential close contact of another case (i.e. the contact may have been the index case); otherwise, no secondary cases of iGAS were reported among close contacts. **Figure 1** shows an epidemic curve of cases by month of onset from January 1, 2015, to February 28, 2018.

The cases were between three and 98 years of age (median: 47); there were more male (91/147; 61%) than female cases (**Table 1**).

Cases of iGAS were reported among two different groups of people. In the first group, approximately half the cases (48%; 71/147) were marginalized populations defined as PWUD and/or under-housed. Of those, 29 (41%) were exclusively PWUD, six (8%) were exclusively under-housed and 36 (51%) were both. Among the PWUD and/or under-housed cases (n=71), most were in the 30-39 year age group (20/71; 28%). In addition, 52 (73%) were co-infected with the hepatitis C virus (HCV) and 15 (21%) with the human immunodeficiency virus (HIV). Nearly all the cases (14/15; 93%) with HIV were co-infected with HCV. For those who were not aware of their HCV or HIV status, testing performed at the time of treatment for iGAS resulted in newly diagnosed cases of HCV (n=8) and HIV (n=3), with care for these conditions initiated at the hospital.

The second group consisted of people who were neither PWUD nor under-housed (n=76). Approximately 22% were aged 50–59 years and represented the largest age group (17/76). Slightly

Figure 1: Cases of invasive group A streptococcal infection in Middlesex-London, Ontario, by month of onset (January 1, 2015–February 28, 2018)^a



^a Includes cases reported up to March 20, 2018

Legend: Green bars denote cases included in the outbreak investigation (from April 1, 2016, onwards). Grey bars denote cases with an onset date prior to the outbreak



Table 1: Characteristics of cases of invasive group A streptococcus infection Middlesex-London, Ontario, from April 1, 2016 to February 28, 2018 (n=147 people)^a

Characteristics	n (%) ^b	Rate per 100,000
Sex		
Male	91 (62)	21.4
Female	56 (38)	13.0
Age group in years		
0–9	6 (4)	8.1
10–19	2 (1)	1.3
20–29	21 (14)	13.1
30–39	27 (18)	25.1
40–49	25 (17)	18.6
50–59	33 (23)	24.9
60–69	16 (11)	16.9
70–79	8 (5)	18.1
80–89	7 (5)	15.4
90–99	2 (1)	19.6
Risk factors		
PWUD use ^c	65 (44)	N/A
Injection drug use	58 (40)	N/A
Homelessness or under-housed	42 (29)	N/A
PWUD use and/or under-housed	71 (48)	N/A
Known HCV positive	60 (41)	N/A
Known HIV positive	15 (10)	N/A

Abbreviations: HCV, hepatitis C viral infection; HIV, human immunodeficiency virus; N/A, not applicable; n, number; PWUD, persons who use drugs

^a For individuals with two infections during the period (n=9), only the first episode was included

^b Does not add up to exactly 100% due to rounding to the nearest whole number

^c PWUD denotes cases who reported illicit drug use (e.g., opioids, cocaine, methamphetamines) in the previous six months; exclusive users of marijuana were excluded

over 10% (8/76) were HCV positive and none were HIV positive. Overall, this group was almost seven times less likely to have HCV compared with the PWUD and/or under-housed cases (95% confidence interval [CI]: 3.56–13.60). However, the odds of having a clinically severe disease were higher (RR: 1.85; 95% CI: 1.18–2.89). The odds of having necrotizing fasciitis (RR: 3.08; 95% CI: 1.18–8.06) and of requiring treatment in the intensive care unit were also higher (RR: 2.22, 95% CI: 1.21–4.08) (Table 2).

Drug practices among PWUD

The enhanced drug questionnaire was completed by 69% (18/26) of the PWUD cases who were reported to the Middlesex-London Health Unit between May 1, 2017, and January 31, 2018. These cases were between 18 and 56 years of age (median: 35.50), and 61% were male (11/18). The majority of cases (94%; 17/18) reported injection drug use while 78% (14/18) reported using hydromorphone within the last six months. With regard to specific drug use practices, 47% (8/17) reported reusing personal injection drug equipment; 24% (4/17) reported sharing injection drug equipment; 71% (12/17) reported reusing a cooker or wash; and 47% (8/17) reported using the “shake-and-bake” method (i.e. no heat) to prepare drugs for injection.

Table 2: Clinical features of invasive group A streptococcal infections in Middlesex-London, Ontario, by drug use and/or under-housed status, April 1, 2016–February 28, 2017 (n=156 cases)

Clinical features ^a	PWUD and/or under-housed n (%) ^b	Neither PWUD nor under-housed n (%) ^b	Rate ratio (95% CI)
Wound infection and/or cellulitis	50 (63)	37 (48)	1.32 (0.99–1.75)
Pneumonia	9 (11)	10 (13)	0.88 (0.38–2.04)
Clinically severe disease ^c	20 (25)	36 (47)	0.54 (0.35–0.85)
Necrotizing fasciitis	5 (6)	15 (19)	0.32 (0.12–0.85)
Other soft tissue necrosis	6 (8)	10 (13)	0.58 (0.22–1.53)
Streptococcal toxic shock syndrome (STSS)	8 (10)	17 (22)	0.46 (0.21–1.00)
Meningitis	1 (1)	1 (1)	0.97 (0.06–15.31)
Admitted to the ICU	12 (15)	26 (34)	0.45 (0.24–0.83)
Death (within 7 days of diagnosis)	4 (5)	6 (8)	0.65 (0.19–2.21)
Total	79	77	N/A

Abbreviations: CI, confidence interval; ICU: intensive care unit; N/A, not applicable; n, number; PWUD, persons who use drugs

^a Not mutually exclusive; cases may have had one or more of the listed clinical features. Hence percentages add up to more than 100

^b Rounded off to the nearest whole number

^c Evidence of clinical severity as defined in the Ontario Ministry of Health and Long-Term Care's Infectious Disease Protocol (http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/gas_cd.pdf)

When asked about using an alcohol swab or wipe on the skin before injecting, 76% (13/17) reported “never” or “sometimes” and 24% (4/17) reported “always.”

emm types and PFGE groups

As of March 22, 2018, the Middlesex-London Health Unit had emm typing for 71% (111/156) of cases and PFGE grouping for 60% (94/156). To date, 13 emm types have been identified (Table 3). Among the non-PWUD/under-housed cases, the most prevalent subtype was emm1 (29%; 14/49). Among the PWUD and/or under-housed cases, the most predominant subtypes were emm81 (44%; 27/62), emm74 (29%; 18/62) and emm9 (17%; 11/62). A review of clinical records for cases with emm9 found that all were macrolide-resistant (Personal communication. M John, 7 February 2018, London Health Sciences Centre).

Public health response

The Middlesex-London Health Unit communicated with a wide range of community partners, which included homeless shelters, needle exchange facilities, first responders and other service providers, to raise awareness of the risks of iGAS and its signs and symptoms. Information was disseminated through a variety of materials, such as the Middlesex-London Health Unit's



Table 3: Distribution of *emm* types of cases of invasive group A streptococcal infection in Middlesex-London, Ontario, by drug use and/or under-housed status, April 1, 2016–February 28, 2018^a

<i>emm</i> type	PWUD and/or under-housed n (%)	Neither PWUD nor under-housed n (%)
<i>emm</i> 1	1 (2)	14 (29)
<i>emm</i> 4	0	6 (12)
<i>emm</i> 5	0	1 (2)
<i>emm</i> 6	0	1 (2)
<i>emm</i> 9	11 (18)	5 (10)
<i>emm</i> 12	0	2 (4)
<i>emm</i> 28	0	2 (4)
<i>emm</i> 73	2 (3)	2 (4)
<i>emm</i> 74	18 (29)	6 (12)
<i>emm</i> 77	2 (3)	0
<i>emm</i> 81	27 (44)	7 (14)
<i>emm</i> 87	1 (2)	0
<i>emm</i> 89	0	3 (6)
Total	62	49

Abbreviations: N/A, not applicable; n, number; PWUD, persons who use drugs

^a Includes results received by the Middlesex-London Health Unit by March 20, 2018 (111/156; 71%)

physician newsletter, notices to community partners and posters in needle exchange facilities, shelters and clinics that serve PWUD and/or under-housed clients.

The Middlesex-London Health Unit also continued to promote harm reduction practices to prevent transmission (e.g., not sharing needles, using alcohol swabs at the injection site, not licking skin or needle tip before injecting, heating drugs before injecting) and encouraged clinical referrals to treat possible strep throat, cellulitis or wound infections. Meetings with stakeholders were also organized to provide updates about the outbreak and discuss strategies to detect cases early on and initiate referrals for wound care (e.g., training on how to spot wounds that require medical attention).

Environmental health inspections

Site visits to unlicensed rooming houses uncovered unsanitary living conditions, large quantities of needle waste, infestations of bedbugs and cockroaches, and structural defects (e.g., broken fixtures, exposed electrical wiring, holes in the walls). As a result, a number of directives were issued by the public health inspectors that included pest control, environmental cleaning and safe collection and disposal of needle waste.

Health unit investigators noted that a large number of shelter clients had visible open wounds on their faces and forearms. At the shelter associated with the highest number of cases, shared spaces were regularly cleaned and clients had access to shower and laundry facilities; however, emergency beds were found to be in close proximity to each other. A lodging home that had two cases of iGAS and one case of GAS was found to have satisfactory sanitation conditions.

Adapting strategies for contact tracing and chemoprophylaxis

In September 2016, the Middlesex-London Health Unit expanded its criteria for chemoprophylaxis to include contacts who shared drugs or injection equipment with a known iGAS case, regardless of the case's clinical severity. The possibility of offering chemoprophylaxis broadly to local homeless shelter clients was considered in order to reduce asymptomatic carriage rates. However, more than half of the under-housed cases (22/42) did not report spending time in homeless shelters, and cases associated with shelters were scattered in time and across different shelters and involved at least four different *emm* types. Consequently, the decision was made to not move forward with this intervention, considering the limited reach, the resources that would have been required to implement it and the potential health risks. In April 2017, the Middlesex-London Health Unit revised its antibiotic chemoprophylaxis recommendations to offer single-dose azithromycin to individuals who had had close contact with PWUD and/or under-housed cases as the recommended 10-day regimen was potentially difficult for this vulnerable population to complete.

During the outbreak, the Middlesex-London Health Unit Outreach Team was launched to help identify and provide street-level support to people who were under-housed or used drugs. The goal was to help reduce the transmission of infection among this population. The Outreach Team located, engaged with and educated clients, and linked them to care, treatment and basic needs programs (e.g., housing, Infectious Disease Care Program). Initially, the Team also administered the enhanced drug questionnaire to PWUD cases, but stopped doing so because of the significant resources required to administer the survey and its similarity to another project. Moreover, findings from the initial questionnaires failed to add new insights about drug injection practices.

Discussion

This 23-month outbreak of iGAS in a rural/urban community in Ontario has affected two distinct populations and is yet to be controlled. Although the number of reported iGAS cases reached a peak in January 2017, the monthly case counts continue to be higher than the previous 5-year monthly average. Reason(s) for the increased incidence of iGAS in the Middlesex-London Health Unit remains unclear. Unlike outbreaks reported in Toronto, Ontario (18), Montréal, Quebec (23) and Anchorage, Alaska (19), few epidemiologic links have connected the cases reported in the Middlesex-London Health Unit (e.g., matching isolate strains, presence in the same location). For example, 13 different *emm* types have been reported to date and cases have been distributed across different locations within the health unit. While nearly half of the cases have involved PWUD and under-housed individuals, the incidence rate has also increased among seemingly unrelated individuals living in stable housing and with no history of drug use. Findings from studies in the United States (24) and United Kingdom (25) have also found that cases among people who inject drugs tend to have less clinically severe infections than among people who do not inject drugs.

There were a number of challenges in applying the existing *Guidelines for the Prevention and Control of Invasive Group A Streptococcal Disease*. For example, although criteria have been developed to trigger action when iGAS occurs in a long-term care facility, hospital or child care centre (e.g., one severe case of iGAS in a child attending a child care centre) (15), criteria have not been developed for cases or clusters within a community.



A number of cases who were PWUD and/or under-housed were difficult to locate or could not be tracked down for investigation and follow-up (e.g., no phone, no fixed address). When cases were contacted, interviews were often challenging: some individuals were reluctant or refused to speak to public health and/or hospital staff, especially about their drug use and practices. Contact tracing for PWUD cases was often difficult as many individuals were reluctant or unwilling to disclose the name of their needle-sharing partners. Some cases who were either too ill or not sufficiently cogent to respond required multiple interview attempts.

In addition, possible adaptations of the guidelines for the community—such as routine testing to determine GAS and iGAS colonization rates or more widespread chemoprophylaxis in an under-housed population—have yet to be evaluated to determine effectiveness (26). For example, current guidelines identify first-generation cephalosporins (e.g., cephalexin) as the preferred antibiotic for iGAS chemoprophylaxis (15). This regimen requires a 10-day treatment, which may be difficult for PWUD and/or under-housed individuals to complete. To control an iGAS outbreak at six homeless service sites in Anchorage, Alaska, public health authorities offered a single-dose regimen (azithromycin) to clients, staff and volunteers (19). In Canada, azithromycin is not recommended as a first- or second-line treatment because evidence shows that it may select for macrolide resistance more strongly than either erythromycin or clarithromycin (15,27).

For the current outbreak, it is unclear whether chemoprophylaxis has been effective in preventing secondary cases. Expanding the criteria for the chemoprophylaxis of contacts and offering a single-dose regimen (azithromycin) did not appear to have resulted in any direct reduction in the incidence of iGAS. Furthermore, the emergence of macrolide-resistant *S. pyogenes emm9* strains may indicate greater selective pressure after these adaptations to the guidelines were implemented. To prevent further development of antimicrobial resistance, the Middlesex-London Health Unit will explore alternatives to azithromycin for chemoprophylaxis of contacts who may have trouble adhering to a 10-day regimen. Alternatives could include injectable penicillin or directly observed therapy with outreach workers.

The data included in this report are subject to a number of limitations. Because disease investigations were largely based on case interviews, the information is subject to recall and self-reporting bias. As drug use, precarious housing and other potentially high-risk behaviours (e.g., sexual activities) were likely underreported, some cases may have been misclassified during the investigation. As well, *emm* and PFGE typing data for cases were incomplete; due to communication and procedural issues, a number of specimens were not forwarded from the hospital laboratory to the provincial laboratory for molecular testing.

Other clusters of iGAS are currently being investigated across Ontario and each have somewhat different epidemiologic characteristics (i.e. different *emm* types, different affected populations). Information about the current outbreak in Middlesex-London as well as the clusters occurring elsewhere may help public health officials understand the reason(s) for the increase in the incidence of iGAS, and determine potential public health interventions that may be effective in preventing and mitigating future outbreaks. Trends in antimicrobial resistance also need to be monitored.

Conclusion

There are unique challenges to controlling iGAS outbreaks in the community, especially when they involve marginalized populations. There is a need for specific guidelines for managing outbreaks of iGAS in the community—including among marginalized populations. Until then, public health efforts will continue to focus on contact tracing to identify those at a higher risk of acquiring iGAS in order to be able to prevent new cases or to treat infections at an early stage, and thus prevent further transmission.

Authors' statement

CD conceived the first draft of this manuscript. CD, KK and MP analyzed the data. CD, CB, VN and GH were involved in the outbreak investigation and public health management. All authors contributed to the development and revision of this manuscript.

Conflict of interest

None.

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HEPATITIS C IN CANADA



1% OF CANADIANS HAVE BEEN INFECTED WITH **HCV** IN THEIR **LIFETIME** (2011)¹

OF THOSE

43% are found in **former and current persons who inject drugs**



while

35% are found in **foreign-born populations**¹



Up to **246,000** Canadians are living with **CHRONIC HEPATITIS C VIRUS (HCV) INFECTION** (2011)¹



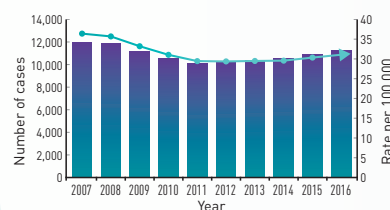
An estimated **44%** are **unaware** of their infection

AVERAGE ANNUAL RATES OF REPORTED HCV CASES PER 100,000 (2012–2016)³

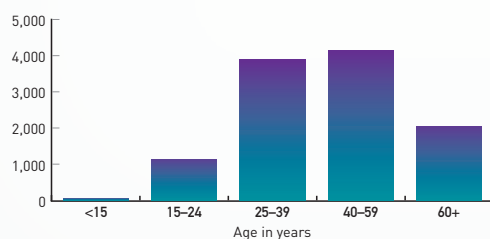


1 in 4 prevalence of HCV among **FEDERAL INMATES** (2005–2012)²

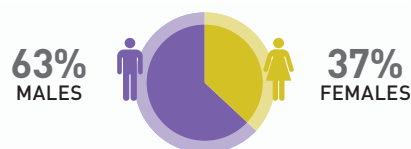
TRENDS IN REPORTED HCV CASES (2007–2016)³



NUMBER OF REPORTED HCV CASES BY AGE (2016)³



REPORTED HCV CASES BY SEX (2007–2016)³



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