



Infection prevention and control lapse involving medical equipment reprocessing at a family medicine clinic in Ottawa, Ontario, 2018

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Abstract

Background: In April 2018, Ottawa Public Health identified a large-scale infection prevention and control (IPAC) lapse spanning 15 years related to inadequate reprocessing of reusable critical medical equipment used in a family medicine clinic.

Objectives: To describe the public health response to, and estimate the risk of hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV) transmission from, this IPAC lapse.

Methods: Patients who underwent a procedure of concern (during which reusable equipment may have been used) at this clinic were identified using Ontario Health Insurance Plan data and individually notified. Testing for HBV, HCV and HIV at the Public Health Ontario Laboratory was recommended, and the odds of infection were estimated.

Results: Of 4,495 patients possibly exposed to improperly reprocessed equipment, 1,496 (33.3%) underwent testing within six months of notification. The prevalence of HBV, HCV and HIV infection in this group was lower than in the general Canadian population. Among patients first diagnosed with HBV after a procedure of concern, the odds of HBV transmission were not increased when the procedure occurred within seven or 28 days of another patient with a positive HBV test result ($OR_{7 \text{ days, age-adjusted}} = 0.59$, 95% CI: 0.14–2.51; $OR_{28 \text{ days, age-adjusted}} = 1.35$, 95% CI: 0.62–2.93). The odds of HCV and HIV transmission could not be estimated because no patient was diagnosed with HCV or HIV after having a procedure of concern within 28 days of another patient with a positive HCV or HIV test result.

Conclusion: We found no evidence of HBV, HCV or HIV transmission associated with this IPAC lapse. However, transmission cannot be ruled out conclusively because only a third of possibly exposed patients underwent testing.

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Introduction

In the ten year period from 2008–2017, the United States (US) Centers for Disease Control and Prevention (CDC) noted 61 healthcare-associated outbreaks of hepatitis B virus (HBV) and hepatitis C virus (HCV) associated with deviations from infection prevention and control (IPAC) best practices (1). More than 115,000 potentially exposed patients were notified as part of these healthcare-associated investigations, and 179 HBV cases and more than 295 HCV cases were identified (1). The majority

(n=58/61 or 95%) of these healthcare-associated outbreaks of HBV and HCV occurred in non-hospital, community-based settings (1). Unfortunately, similar national surveillance data are not available for Canada, and the burden of HBV and HCV infections associated with IPAC lapses across Canada is not known. However, a recent survey of Ontario public health units noted a nearly six-fold increase in IPAC complaints and a near tripling of IPAC lapses from 2015 to 2018 (2).

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The objectives of this article are 1) to describe a large-scale IPAC lapse involving inadequate reprocessing of reusable critical medical equipment at a family medicine clinic in Ottawa, Ontario; 2) to estimate the odds of HBV, HCV and human immunodeficiency virus (HIV) transmission as a result of this lapse; and 3) to illustrate the challenges encountered in the public health response to this lapse.

Background

In Ontario, the mandate and organization of public health units is defined by the *Health Protection and Promotion Act* (3). Ontario currently has a total of 35 public health units: 21 are independent of local municipal government, seven are regional health departments and seven are tied into a single-tier or other municipal administration (4). The *Ontario Public Health Standards* define mandatory public health programs and services (5); further guidance is provided in related Protocols and Guidelines. In 2015, the Ontario Ministry of Health and Long-Term Care amended the *Infection Prevention and Control Practices Complaints Protocol* (6), which mandates public health units to investigate complaints about IPAC practices in a variety of settings including personal service settings (e.g. nail salons, barber shops, tattoo parlours) and facilities in which regulated health professionals (e.g. nurses, physicians, dentists) operate.

Under the *Infection Prevention and Control Complaint Protocol, 2019* (6), public health units are mandated to receive complaints about IPAC practices, investigate these complaints, and take measures to reduce the risk of infection. Following a complaint, a public health inspector and/or nurse typically conduct an inspection of the premises using audit tools and other resources from Public Health Ontario (PHO) (7) and the Provincial Infectious Disease Advisory Committee (8,9) to assess deviations from IPAC best practices. In the *Infection Prevention and Control Complaint Protocol*, an IPAC lapse is defined as a “failure to follow IPAC practices resulting in a risk of transmission of infectious diseases to clients, attendees or staff through exposure to blood, body fluids, secretions, excretions, mucous membranes, non-intact skin, or contaminated equipment and soiled items” (6). A majority of IPAC complaints investigated by public health units involve deviations from or failure to adhere to IPAC best practices that, based on a risk assessment conducted by the unit, do not represent sufficient risk of infection transmission to be considered a lapse. PHO is available to support public health units with complex risk assessments.

If the medical officer of health or designate determines that an IPAC lapse has occurred, it must be disclosed publicly on the public health unit’s website, as per the *Infection Prevention and Control Disclosure Protocol* (10). If an operator (i.e. a person operating a personal service or health care setting) does not either cooperate with the investigation or implement required corrective measures, and the medical officer of health or a public health inspector is of the opinion that a health hazard exists, a

Section 13 order under the *Health Protection and Promotion Act* may be used to stop a practice or the provision of a service, or close a premise.

Methods

Detection of the infection prevention and control lapse

In April 2018, Ottawa Public Health (OPH) received a complaint from a member of the public concerning the cleanliness of a family medicine clinic, including its medical equipment. OPH staff inspected the clinic on the same day that the complaint was received. Several deviations from IPAC best practices were identified involving 1) all steps of reusable critical medical equipment reprocessing; 2) medication storage and administration; 3) laboratory specimen storage and handling; 4) hand hygiene; 5) environmental cleaning; 6) routine practices and additional precautions; and 7) occupational health and safety. These deviations from IPAC best practice were thought to have been present from the inception of the clinic in December 2003, until the time of the complaint in April 2018. Of note, physicians are members of a self-regulated profession; there are no routine inspections of IPAC practices in Ontario medical clinics.

The clinic voluntarily complied with OPH’s requirement to cease performing all invasive medical procedures requiring the use of reusable critical medical equipment until further notice. Compliance with all corrective measures required by OPH was ensured through multiple follow-up inspections.

Risk assessment

In line with the public health mandate under the *Health Protection and Promotion Act*, the risk assessment focused on the potential for transmission of HBV, HCV and HIV, as these infections have the potential to go undiagnosed for several years, leading to poorer health outcomes and to secondary transmission. A query of the integrated Public Health Information System (iPHIS) for reported HBV, HCV and HIV cases residing in the area served by the clinic did not identify an excess of cases compared to the rest of Ottawa or to Canada.

Public Health Ontario qualitatively assessed the risk of infection transmission related to the inadequate reprocessing of reusable critical medical equipment to be “low” for HBV and HCV and “very low” for HIV. Public Health Ontario advised patient notification and testing for HBV, HCV and HIV.

In addition, OPH performed a quantitative risk assessment using published methodology (11,12). OPH’s risk assessment used Canadian population prevalence estimates for HBV (13), HCV (14) and HIV (15), published estimates of the risk of transmission of HBV, HCV and HIV after a percutaneous exposure (16), and assumed a worst-case scenario where the reprocessing was



entirely ineffective; results from this assessment (not shown) were comparable with PHO's qualitative assessment. Had the estimated risk been closer to the 1:1,000,000 threshold for patient notification suggested in the literature (11,12), the OPH *Ethics Framework, 2014* may also have been applied to guide decision-making about patient notification and testing, as it was during OPH's response to an endoscopy clinic IPAC lapse in 2011 (17).

Possibly exposed patients: Definition

A possibly exposed patient was defined as someone who had an Ontario Health Insurance Plan (OHIP) billing record for an invasive medical procedure that may have involved reusable critical medical equipment at the family medicine clinic between its inception in December 2003 and the cessation of invasive procedures in April 2018. Patients were considered "possibly exposed" (rather than exposed) because some invasive procedures may not have involved the use of reusable critical equipment (e.g. a laceration repair could have been done with glue rather than sutures).

Possibly exposed patients: Identification

Over 90,000 unique patients were treated at the family medicine clinic between December 2003 and April 2018. To identify patients who were possibly exposed to reusable critical medical equipment, OPH reviewed the types of procedures performed at the clinic and whether single-use disposable or reusable equipment was typically used. Based on the information obtained from the clinic, OPH concluded that procedures of concern were as follows: removal of skin tags, moles and cysts using a blade or scissors; skin biopsy; incision, drainage and packing of an abscess or cyst; removal of an ingrown nail; laceration repair; removal of sutures or staples; and removal of a foreign body.

In consultation with the clinic, OPH generated a list of billing codes corresponding to the procedures of concern. The OHIP division of the Ontario Ministry of Health and Long-Term Care then extracted and transmitted to OPH all billing claims submitted by the clinic physicians involving one of the procedures of concern where the provider postal code was the same as that of the clinic (the clinic where the lapse occurred was the only clinic in its six-digit postal code area).

Possibly exposed patients: Notification

Patients possibly exposed as a result of this IPAC lapse were notified by mail in July 2018. The notification letter was approved by OPH and sent by the clinic. On the day of the mailout, OPH held a press conference and gave media interviews to disseminate the information to any exposed patients who were not identified in the OHIP billing data (e.g. uninsured patients, uninsured services, billing omissions). A website with detailed information about this lapse was also published on the day of the mailout. That same day, a fax was sent to healthcare system partners, including primary care providers, informing them of the large-scale IPAC lapse, patient notification and recommended

testing, and providing resources to support patient counselling, testing and follow-up. Because the decision to undergo the recommended testing is a personal one, formal reminders were not issued to individual patients. OPH participated in multiple follow-up media interviews about testing uptake and aggregate results several weeks to months after the initial patient notification mailout.

Facilitation of laboratory testing

A Public Health Ontario Laboratory (PHOL) requisition for HBV, HCV and HIV testing pre-filled by one of the clinic physicians was included with every notification letter. This enabled patients to go to any specimen collection centre to have their blood drawn for testing and avoided a medical consultation to obtain a laboratory requisition.

Patients who did not want their results to be sent to the clinic were instructed to consult with their preferred health care provider to obtain a laboratory requisition for testing. A partially-filled PHOL laboratory requisition form (with the tests to be ordered and the special investigation number) was made available on the OPH website for those patients to take to their preferred health care provider.

Laboratory analyses

The PHOL carried out all post notification testing for HBV, HCV and HIV, and all testing was tracked using a special investigation number. Initial serologic testing for HBV, HCV and HIV was performed using the Abbott Architect instrument (Abbott Laboratories, Wiesbaden, Germany) following the manufacturer's instructions. Serum samples that were positive for HCV antibodies were then tested using a second serologic assay (ORTHO[®] HCV Version 3.0 ELISA Test System, Ortho Clinical Diagnostics Inc., Raritan, New Jersey, US) while serum samples testing positive for HIV antibodies underwent further testing using the Geenius[™] HIV 1/2 Confirmatory Assay (Bio-Rad Laboratories, Redmond, Washington, US). Patients with serological tests suggestive of infection underwent DNA/RNA testing and genotyping as part of routine clinical management (cobas[®] HBV and cobas[®] HCV using the Roche 6800 instrument, Roche Molecular Systems Inc., Laval, Quebec, Canada; Abbott RealTime HIV-1 using the Abbott m2000 system, Abbott Molecular Inc., Des Plaines, Illinois US).

In the event that a cluster of two or more cases of HBV, HCV or HIV of the same genotype were detected, additional molecular testing would be sought from the National Microbiology Laboratory. All available post notification testing results were transmitted by the PHOL to OPH one month, three months and six months post-patient notification. In addition, the PHOL also provided all available positive and negative HBV, HCV and HIV serologic and molecular testing results, going as far back as 1996, for any patient who ever had a positive test for HBV, HCV or HIV and was possibly exposed as a result of this IPAC lapse. These data were used to estimate when the infection likely occurred and the possible infectious period.



HBV, HCV and HIV case investigations

HBV, HCV and HIV are provincially-reportable diseases under the *Health Protection and Promotion Act*. As such, all new cases reported to OPH are routinely investigated in accordance with the relevant policies and procedures. Specifically, a public health nurse contacts the diagnosing physician to request that a follow-up form be completed and transmitted to OPH; this form asks about risk factors for infection, follow-up care and contact tracing performed by the health care provider, and provides a checklist for counselling about measures to prevent transmission. If needed, a public health nurse also contacts the case or their next of kin to obtain risk factors, link to follow-up care, complete contact tracing, and provide counselling. Information gathered from the diagnosing physician using the follow-up form and, as needed, from the case, is then entered in the iPHIS.

All patients possibly exposed to this IPAC lapse with evidence of HBV, HCV or HIV infection, diagnosed through post notification testing or previously diagnosed and reported to OPH, were investigated as above. The Nurse manager and the epidemiologist for OPH’s Sexually Transmitted and Bloodborne Infections team then manually reviewed the case investigation files for all HBV, HCV and HIV cases possibly exposed as a result of this IPAC lapse to look for any evidence of clustering or transmission related to the lapse and to identify any competing risk factors for infection.

Statistical analyses

The prevalence of HBV, HCV and HIV infection was estimated among patients who underwent post notification testing. The association between being diagnosed with HBV, HCV or HIV infection after a procedure of concern, and that procedure having occurred within seven days of another procedure involving a patient with a positive test result for the relevant virus predating their own procedure was estimated using odds ratios. Exposure and outcome assessment were based on available laboratory test results and date(s) of procedure(s) of concern. The outcome was HBV, HCV or HIV infection status after the procedure of concern. For the purposes of this analysis, patients were considered exposed if they underwent one or more procedure of concern within seven days following a patient with a positive HBV, HCV or HIV test result predating their own procedure. Patients were considered unexposed if they underwent one or more procedure of concern a) beyond seven days after a patient with a positive HBV, HCV or HIV test result predating their own procedure or b) after a patient who did not have any positive HBV, HCV or HIV test result. The seven day time window used was based on evidence of virus survival (18–22) and the frequency of use and reprocessing of critical instruments (i.e. transmission was only considered for the first person on whom the improperly reprocessed instrument was used; subsequent cycles of reprocessing would be expected to reduce the risk of transmission to effectively zero).

Because HBV and HCV infections can resolve spontaneously, we could not definitely ascertain some patients’ HBV and HCV

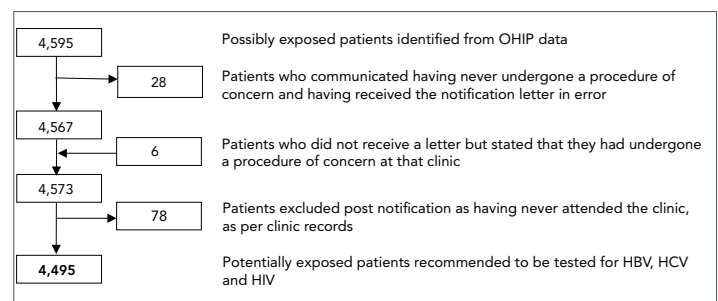
infection status at the time of their procedure. For example, a patient with no previous negative test for hepatitis B who first tested HBcAb-positive and HBsAg-negative (indicating immunity from resolved natural infection) after the lapse notification was considered both as a potential source of infection for another patient who had a procedure of concern within a seven day window, and as potentially having been infected through this procedure of concern. Similarly, because information about HIV viral load was not available (i.e. HIV viral load testing results are not reportable to public health in Ontario), patients with a positive HIV test prior to their procedure of concern were considered infectious at the time of their procedure.

Odds ratio was the measure of association selected because the low uptake of testing did not allow a reliable estimate of infection prevalence and 95% confidence intervals were estimated using the exact method. All analyses were conducted using Stata version 14.2 (StataCorp, US). Sensitivity analyses were conducted using a shorter and longer time window (one and 28 days) and patient-procedure-level data rather than patient-level data.

Results

A total of 4,595 patients were identified from OHIP billing data as having undergone a procedure of concern (**Figure 1**); together, these patients underwent a total of 6,832 procedures of concern. Of those 4,595 patients, 28 contacted OPH after receiving a notification letter to share that they never had a procedure of concern at the clinic, and 78 had never actually attended the clinic based on clinic records. An additional of six patients who had not been identified through OHIP billing data contacted OPH to share that they had undergone a procedure of concern at the clinic. Of the revised total of 4,495 possibly exposed patients, 1,496 (33.3%) underwent the recommended testing for HBV, HCV or HIV at least once within six months after the mailing of the IPAC lapse notification letters.

Figure 1: Identification of patients possibly exposed to this infection prevention and control lapse



Abbreviations: HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; OHIP, Ontario Health Insurance Plan
 Note: Some patients may have received a letter and self-assessed that they had never undergone a procedure of concern and failed to notify Ottawa Public Health or the clinic; these patients are included in this figure as possibly exposed. Some patients may have not received a letter, self-identified as having received a procedure of concern, and sought testing without using the special laboratory requisition containing the investigation tracking number; these patients are not included in this figure



On average, patients who completed the recommended testing tended to be older than those who did not. Completion of recommended testing did not differ based on the timing of the procedure of concern (recent or several years ago) or the number of procedures of concern (Table 1).

Table 1: Characteristics of patients possibly exposed to the infection prevention and control lapse, by completed HBV, HCV and HIV testing status six months following notification (N=4,495)

Patient characteristic	Potentially exposed patients who were tested (N=1,496)		Potentially exposed patients who were not tested (N=2,999)			
	N	%	N	%		
Age group						
0–17 years	142	10	274	9		
18–44 years	410	27	1,414	47		
45–64 years	566	38	884	30		
65 years and older	377	25	426	14		
Data missing	1	<1	1	<1		
Timing of most recent “at risk” procedure						
Less than 12 months ago	144	10	198	7		
12–23 months ago	138	9	256	9		
24–35 months ago	125	8	209	7		
36 months ago or more	1,089	73	2,336	78		
Number of “at-risk” procedures	Mean	Median	Range	Mean	Median	Range
	1.5	1	1–25	1.6	1	1–23

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

Among patients who underwent post notification HBV, HCV and/or HIV testing, there were two new diagnoses of HCV infection (Table 2): one patient was RNA-positive (indicating a chronic infection) and the other was RNA-negative (indicating a resolved infection). The patient with chronic HCV infection was referred by their family physician to an infectious disease specialist for clinical management, and routine public health case investigation found that this patient had other risk factors for HCV infection (i.e. potential vertical transmission or horizontal transmission from household contacts). Post notification testing for HBV and HIV did not yield any new diagnoses of acute or chronic HBV infection or HIV infection.

Overall, among 4,495 patients possibly exposed to improperly reprocessed critical reusable equipment, based on all laboratory testing data available to OPH six months after the patient notification mailout, the prevalence was 0.07%, 95% CI: (0–2.8%) for any HBV infection (chronic or resolved), 0.35%, 95% CI: (0.10–0.80%) for any HCV infection (chronic or resolved) and 0.08%, 95% CI: (0–0.49%) for HIV infection. These results are lower than the estimated prevalence for the Canadian population for HBV (13), HCV (14) and HIV (15,23), and lower than recent estimates for HCV in Ontario (24).

Among patients first diagnosed with HBV infection any time after a procedure of concern, the odds of HBV infection were not increased if the procedure occurred within seven days after another procedure involving someone with a positive HBV test result predating the procedure (OR_{within 7 days} = 0.62, 95% CI: 0.15–2.63). Because patients who underwent post notification testing were older than those who did not, an age-adjusted odds ratio was estimated; the age-adjusted estimated was similar (OR_{within 7 days, age-adjusted} = 0.59, 95% CI: 0.14–2.51). Statistically non-significant results were also obtained when the exposure

Table 2: Number of patients who did and did not undergo a procedure of concern within seven days of a potentially infectious patient, by HBV, HCV and HIV status six months post notification^a

Exposure status	HBV status ^b (N=1,466)			HCV status ^b (N=1,441)			HIV status ^b (N=1,251)	
	Chronic infection	Resolved infection (natural immunity) ^c	Not infected	RNA-positive (chronic infection)	Antibody-positive, RNA-negative/unknown	Not infected	Infected	Not infected
Underwent a procedure of concern within 7 days ^d of another patient with a positive test result ^d for the relevant virus predating their own procedure (exposed)	0	2	153	0	0	78	0	8
Did not undergo a procedure of concern within 7 days ^d of another patient with a positive test result for the relevant virus predating their own procedure (unexposed)	1	26	1,284	5	12	1,346	1	1,242

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

^a Not all patients underwent testing for all three infectious agents; therefore, cell totals are different for each infection

^b The outcome is infection status six-months post notification; cell counts also include patients diagnosed with HBV, HCV or HIV sometime after their procedure of concern and prior to the infection prevention and control (IPAC) lapse notification

^c Case counts for chronic HBV infection and resolved HBV infection were combined in the analysis, given the extended duration of the IPAC lapse and the unknown onset of the infection

^d This time window was based on the likely period of survival of the virus and the frequency of use and reprocessing of critical instruments (transmission was only considered for the first person on whom the improperly reprocessed instrument was used; subsequent cycles of reprocessing would be expected to reduce the risk of transmission to effectively zero)



time window was increased to 28 days ($OR_{\text{within 28 days, age-adjusted}} = 1.35$, 95% CI: 0.62–2.93); analyses could not be performed using the one-day time window due to a numerator of zero.

Similar results were obtained when the analysis was performed at the level of the patient-procedure ($OR_{\text{within 7 days, age-adjusted}} = 0.45$, 95% CI: 0.11–1.85) rather than the patient. The odds of HCV and HIV transmission could not be estimated, because no patient was first diagnosed with HCV or HIV after a procedure of concern that occurred within 28 days after another procedure involving a patient with a positive HCV or HIV test result predating their own procedure.

Discussion

In response to an IPAC complaint, OPH identified an IPAC lapse spanning 15 years and involving inadequate reprocessing of reusable critical equipment in a family medicine clinic. Public Health Ontario qualitatively estimated the risk of infection to be “low” for HBV and HCV and “very low” for HIV. Possibly exposed patients were identified using OHIP billing data; they were then notified, through an individual letter mailout, of their potential exposure as a result of this IPAC lapse, and recommended to be tested for HBV, HCV and HIV. Six months post notification, only 33% of the patients had completed testing; a higher proportion of older patients underwent the recommended testing compared with younger patients. Post notification testing yielded two new diagnoses of HCV infection (i.e. one chronic and one resolved infection); the new case of chronic HCV infection was likely infected through vertical or household transmission. Post notification testing did not yield any new diagnoses of HBV or HIV infection. The prevalence of HBV, HCV and HIV infection among the possibly exposed patients was lower than in the Canadian population. The odds of HBV infection among patients who underwent a procedure within seven or 28 days following another procedure involving a patient with a positive HBV test result predating their own procedure were not increased. The odds could not be estimated for HCV and HIV due to insufficient numbers. Ottawa Public Health’s investigation found no evidence of transmission of HBV, HCV or HIV associated with this IPAC lapse. However, transmission cannot be ruled out conclusively because only a third of possibly exposed patients underwent testing.

Similarly, no evidence of transmission of HBV, HCV or HIV was found during OPH’s investigation of an IPAC lapse at an endoscopy clinic in 2011 involving 6,992 patients (17), 75% of whom underwent post-lapse testing. Also, a review of healthcare-associated HBV and HCV outbreaks reported to the US CDC did not identify any HBV or HCV contamination related to the inadequate reprocessing of reusable critical medical equipment similar to those involved in this IPAC lapse (i.e. equipment used to perform minor surgical procedures) (1). Rather, the most common deviations from IPAC best practices that have resulted in HBV and HCV transmission were related

to point-of-care glucose testing and misuse of multidose vials/injection equipment (1).

Strength and limitations

A major strength of this IPAC investigation was the ability to identify possibly exposed patients from OHIP data. This process could be further enhanced if OHIP data included a clinic-specific identifier as a mandatory field. Other strengths included the centralization of post notification laboratory testing at the PHOL enabling tracking of results, and the access to previous laboratory testing results for possibly exposed patients with a previous positive result for HBV, HCV or HIV. An important limitation of this IPAC investigation was the relatively low uptake of post notification testing, and potential selection bias due to patients self-selecting to undergo testing. Patients who opted to undergo post notification testing were older than those who did not; we attempted to account for this by estimating an age-adjusted OR, which was similar to the crude OR. Except for age (i.e. date of birth), sociodemographic characteristics of patients potentially exposed to this IPAC lapse were not collected or not available, and other factors associated with testing uptake could not be assessed. Furthermore, several factors limited our ability to ascertain exposure status and could have led to exposure misclassification and dilution of the effect: the inability to track which patient had been exposed to a given instrument because an instrument-tracking system (e.g. bar code) was not in place at this clinic; the lack of access to negative HBV, HCV and HIV results for testing completed before the notification (except for patients with a history of a positive test result for the same infection, as negative results are not reportable to public health) and the lack of precise information concerning when patients were first infected with HBV, HCV or HIV; and, whether or not they were infectious when they underwent the procedure of concern.

Conclusion

Findings from large scale IPAC lapse investigations such as these are important to share, so that they may inform the public health response to similar IPAC lapses in the future. Future IPAC lapse investigations would benefit from better outcome and exposure ascertainment, e.g. through access to all HBV, HCV, and HIV testing results (including negative results) from existing laboratory databases. Furthermore, because assessment of the risk of HBV, HCV and HIV infection in relation to an IPAC lapse is an imprecise process, whether a qualitative (25,26) or a quantitative (11,12) risk assessment method is used, provincial surveillance of IPAC lapses and related public health investigations and incorporation of findings from completed investigations would help bolster the evidence basis underlying risk assessments and would help inform decision making about patient notification and testing.

In Ontario, prevention of IPAC lapses is largely beyond the formal mandate of local public health units; that responsibility rests primarily with clinic managers and service providers, health care professional training programs, licensing bodies and



regulatory colleges, as well as the Ontario Ministry of Health and Long-Term Care. That said, following this IPAC lapse, OPH partnered with the College of Physicians and Surgeons of Ontario and PHO to offer a continuing professional development session on IPAC best practices to Ottawa family physicians. OPH also developed and delivered a training session for family medicine residents at the University of Ottawa. Finally, OPH performed an assessment of IPAC learning needs among Ottawa medical and dental clinics (27), with the goal of informing future interventions to improve IPAC practices in these settings.

Authors' statement

Cadieux was the primary author of the manuscript. Friedman contributed to the exposure and outcome assessment and provided feedback on the manuscript. Tilley performed the exposure and outcome assessment and provided feedback on the manuscript. Mazzulli oversaw the laboratory analyses and contributed to the manuscript. McDermaid performed all statistical analyses and contributed to the manuscript.

Conflict of interest

None.

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References

- Centers for Disease Control and Prevention. Viral Hepatitis. Atlanta (GA): CDC; 2018 (Accessed 2019-04-27). <https://www.cdc.gov/hepatitis/outbreaks/pdfs/healthcareinvestigationtable.pdf>
- Cadieux G, Brown C, Sachdeva H. Public health investigation of infection prevention and control complaints in Ontario, 2015-2018. *Can Commun Dis Rep* 2019;45(11):289-95. DOI PubMed
- Ontario Health Protection and Promotion Act, R.S.O. 1990, c. H.7. Ontario; 1990. <https://www.ontario.ca/laws/statute/90h07/v6>
- Association of Local Public Health Agencies. Milestones and History: History of Public Health Units in Ontario. Toronto (ON): alPHa; 2018 (Accessed 2019-10-29). <https://www.alphaweb.org/page/milestones>
- Ontario Ministry of Health and Long-Term Care. Ontario Public Health Standards: Requirements for Programs, Services, and Accountability (Standards). Gov't of Ontario; 2018 (Accessed 2019-09-07). http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/protocols_guidelines/IPAC_Complaint_Protocol_2019_en.pdf
- Ontario Ministry of Health and Long-Term Care. Infection Prevention and Control Complaint Protocol, 2019. Gov't of Ontario; 2019 (Accessed 2019-09-07). http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/protocols_guidelines/IPAC_Complaint_Protocol_2019_en.pdf
- Public Health Ontario. IPAC Checklist for Clinical Office Practice: Core Elements. PHO; 2018 (Accessed 2019-09-07). <https://www.publichealthontario.ca/-/media/documents/checklist-clinical-office-core.pdf?la=en>
- Provincial Infectious Diseases Advisory Committee. (2013). Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices In All Health Care Settings, 3rd edition (Accessed 2019-09-07). <https://www.publichealthontario.ca/-/media/documents/bp-cleaning-disinfection-sterilization-hcs.pdf?la=en>
- Provincial Infectious Diseases Advisory Committee. (2015). Infection Prevention and Control for Clinical Office Practice (Accessed 2019-09-07). <https://www.publichealthontario.ca/-/media/documents/bp-clinical-office-practice.pdf?la=en>
- Ontario Ministry of Health and Long-Term Care. (2019). Infection Prevention and Control Disclosure Protocol (Accessed 2019-09-07). http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/protocols_guidelines/Infection_Prevention_and_Control_Disclosure_Protocol_2019_en.pdf
- Weber DJ, Rutala WA. Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Am J Infect Control* 2013 May;41(5 Suppl):S67-71. DOI PubMed
- Rutala WA, Weber DJ. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infect Control Hosp Epidemiol* 2007 Feb;28(2):146-55. DOI PubMed
- Rotermann M, Langlois K, Andonov A, Trubnikov M. Seroprevalence of hepatitis B and C virus infections: Results from the 2007 to 2009 and 2009 to 2011 Canadian Health Measures Survey. *Health Rep* 2013 Nov;24(11):3-13. PubMed
- Trubnikov M, Yan P, Archibald C. Estimated prevalence of hepatitis C virus infection in Canada, 2011. *Can Commun Dis Rep* 2014;40(19):429-36. DOI PubMed
- Public Health Agency of Canada. Summary: Estimates Of HIV Incidence, Prevalence And Proportion Undiagnosed In Canada, 2014. Ottawa (ON): PHAC; 2015 (Accessed: 2019-10-29). http://publications.gc.ca/collections/collection_2016/aspc-phac/HP40-147-2015-eng.pdf



16. U.S. Public Health Service. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. *MMWR Recomm Rep* 2001 Jun;50 RR-11:1–52. [PubMed](#)
17. Willmore J, Ellis E, Etches V, Labrecque L, Osiowy C, Andonov A, McDermaid C, Majury A, Achonu C, Maher M, MacLean B, Levy I. Public health response to a large-scale endoscopy infection control lapse in a nonhospital clinic. *Can J Infect Dis Med Microbiol* 2015 Mar-Apr;26(2):77–84. [DOI PubMed](#)
18. Bond WW, Favero MS, Petersen NJ, Gravelle CR, Ebert JW, Maynard JE. Survival of hepatitis B virus after drying and storage for one week. *Lancet* 1981 Mar;1(8219):550–1. [DOI PubMed](#)
19. Ciesek S, Friesland M, Steinmann J, Becker B, Wedemeyer H, Manns MP, Steinmann J, Pietschmann T, Steinmann E. How stable is the hepatitis C virus (HCV)? Environmental stability of HCV and its susceptibility to chemical biocides. *J Infect Dis* 2010 Jun;201(12):1859–66. [DOI PubMed](#)
20. Doerrbecker J, Friesland M, Ciesek S, Erichsen TJ, Mateu-Gelabert P, Steinmann J, Steinmann J, Pietschmann T, Steinmann E. Inactivation and survival of hepatitis C virus on inanimate surfaces. *J Infect Dis* 2011 Dec;204(12):1830–8. [DOI PubMed](#)
21. Kamili S, Krawczynski K, McCaustland K, Li X, Alter MJ. Infectivity of hepatitis C virus in plasma after drying and storing at room temperature. *Infect Control Hosp Epidemiol* 2007 May;28(5):519–24. [DOI PubMed](#)
22. Painsil E, Binka M, Patel A, Lindenbach BD, Heimer R. Hepatitis C virus maintains infectivity for weeks after drying on inanimate surfaces at room temperature: implications for risks of transmission. *J Infect Dis* 2014 Apr;209(8):1205–11. [DOI PubMed](#)
23. Public Health Agency of Canada. Summary: Estimates of HIV incidence, prevalence and Canada's progress on meeting the 90-90-90 HIV targets, 2016. Ottawa (ON): PHAC; 2018 (Accessed on: 2019-11-09). <https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/diseases-conditions/summary-estimates-hiv-incidence-prevalence-canadas-progress-90-90-90/pub-eng.pdf>
24. Bolotin S, Feld JJ, Garber G, Wong WW, Guerra FM, Mazzulli T. Population-based estimate of hepatitis C virus prevalence in Ontario, Canada. *PLoS One* 2018 Jan;13(1):e0191184. [DOI PubMed](#)
25. Patel PR, Srinivasan A, Perz JF. Developing a broader approach to management of infection control breaches in health care settings. *Am J Infect Control* 2008 Dec;36(10):685–90. [DOI PubMed](#)
26. Centers for Disease Control and Prevention. Steps for Evaluating an Infection Control Breach. Atlanta (GA); CDC; 2012 (Accessed 2019-04-27). https://www.cdc.gov/hai/outbreaks/steps_for_eval_ic_breach.html
27. Cadieux G, Bhatnagar A, Schindeler T, Prematunge C, Perron D, Willmore J. Assessment of the infection prevention and control learning needs of Ottawa community-based healthcare providers. *Can J Infect Control* 2019;34(3):135–40. <https://www.researchgate.net/publication/337735988>