January 3, 2019 • Volume 45-1

CCDR

CANADA COMMUNICABLE DISEASE REPORT

CHALLENGES IN INFECTION CONTROL

Public Health Agency of Canada
Agence de la santé publique du Canada

Canada

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CANADA COMMUNICABLE DISEASE REPORT

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Pedicures are one type of personal service where infectious disease transmission can occur. Photo by Shutterstock (https://www.shutterstock.com/image-photo/pedicure-treatment-beauty-salon-close-concept-634850564)

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ISSN 1481-8531 / Cat. HP3-1E-PDF / Pub. 180681

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OVERVIEW

Infection prevention in personal services settings: Evidence, gaps and the way forward

A Popalyar[1], J Stafford[2], T Ogunremi[1], K Dunn[1]*

Abstract

Background: Personal services is a continuously evolving industry that encompasses a variety of aesthetic treatments and personal enhancement services. Personal services are an important public health concern because delivery of service may pose potential health risks for both clients and workers. To date, there is a lack of evidence on the specific infection risks involved with personal services and the magnitude of these risks. While guidance and regulation of personal services settings do exist, they appear in varying degrees and complexity across Canada.

Objectives: To summarize relevant literature on the risk of infections related to personal services; conduct an environmental scan of current provincial and territorial guidance and regulations; identify key risk mitigation measures; and summarize gaps and challenges.

Methods: A working group of national experts in the field of infection prevention and control was established for consultation on key issues. A narrative literature review was conducted to summarize findings from relevant articles. Key questions and a literature search strategy were developed and articles were screened and critically appraised for eligibility. An environmental scan of key guidelines was also conducted to identify relevant legislation and guidance. Findings from both the narrative review and environmental scan were summarized to inform guidance and identify gaps.

Findings: The review of the literature identified factors associated with increased risk of infection including inadequate training of personal services workers and non-compliance with established infection prevention principles. The environmental scan demonstrated that some guidelines have been developed by provincial/territorial ministries of health utilizing basic, generally accepted infection prevention principles. The established body of evidence that informs infection prevention and control recommendations is valid for health care settings; however, there are factors to consider in extracting and applying such guidance to personal services settings. Major gaps and challenges remain in supporting both the advancement of infection prevention guidance and the development of enhanced regulatory frameworks, applicable to personal services settings in Canada.

Conclusion: This review involved a comprehensive examination of relevant literature and provides a summary of issues addressing the risk of infection in personal services settings. There is a paucity of high quality evidence to support guidance, and findings reveal the need for further investigation and enhanced awareness of public health risks associated with personal services. Nonetheless, these findings can inform future research and the development of infection prevention and control guidelines and recommendations for such settings.

Suggested citation: Popalyar A, Stafford J, Ogunremi T, Dunn K. Infection prevention guidance for personal services settings: Evidence, gaps and the way forward. Can Commun Dis Rep 2019;45(1):1-11. https://doi.org/10.14745/ccdr.v45i01a01

Keywords: personal services, infection, prevention, risk mitigation

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Introduction

Personal services is a continuously evolving industry that encompasses a variety of aesthetic treatments and personal enhancement services, from non-invasive (such as hair and nail services) to invasive procedures such as microneedling and other body modification procedures. Many of these services intentionally or accidentally penetrate the body's defences, posing an infection risk to clients and personal services workers.

There is little information on the infection risks specifically associated with these services. In addition, there is no national surveillance system related to complications of the personal services industry in Canada. While guidance and regulation of personal services settings do exist, the degree and complexity varies across Canada. With a lack of evidence related to disease acquisition in personal services settings, general principles of infection prevention are applied; these may not be directly applicable to the industry.

The objectives of this article are to summarize the available relevant literature on the risk of infections related to personal services; conduct an environmental scan of current provincial/territorial ministry of health guidance and regulations; outline generally accepted infection prevention principles relevant to personal services settings; and summarize major gaps and challenges. This article is intended to bring greater awareness from a public health perspective and be a resource for those considering the development of guidelines or regulations in this area.

A review of practice guidelines, recommendations, position papers, produced by personal services and/or public health professional associations or by educational programs is beyond the scope of this article.

Methods

Expert Working Group

In 2013, an expert working group was established to inform the Public Health Agency of Canada (PHAC) of issues associated with personal services and to provide infection prevention guidance for this setting. Expertise from the field included public health nurses and inspectors and infection prevention and control professionals from Nova Scotia, New Brunswick, Ontario, Manitoba and Alberta. The expert working group reviewed findings from the literature search and environmental scan.

Literature review

A narrative literature review was conducted to determine and summarize findings from relevant studies on the risk of infections related to personal services and inform the development of guidance. Key questions addressed prevalence, infection risk factors and infection prevention strategies for the three categories of personal services: piercing; other invasive services; and non-invasive services. The Health Library (Health Canada) undertook a comprehensive literature search using PubMed, Embase, Global Health, Ovid MEDLINE, Ovid MEDLINE Daily and Ovid OLDMEDLINE databases for studies published from January 1999 to December 2016.

The search was limited to studies in English and French with no filters applied, which would limit retrieval by study design. The full texts of all retrieved studies were manually screened to identify studies that reported on the receipt of one or more of the following categories of services:

- Body modification (i.e., ear/body piercing, body/eyeball tattooing, micropigmentation, scarification, tongue splitting, beading, jewellery implants, ocular jewellery, branding)
- Injections (i.e., fillers)
- Cosmetology (i.e., aesthetics, hair dressing/barber services, shaving, microdermal abrasion, facials, artificial nails, manicures, pedicures, make-up, face painting, waxing, electrolysis); and/or
- Other personal services (i.e., health spa/skin clinic, mud/steam bath, laser service including hair removal/skin resurfacing, massage, tanning, aromatherapy, teeth whitening, colonic irrigation, flotation tanks/water therapy)

AND the development of one or more of the following:

- Skin/soft tissue infection
- Bloodborne infection (e.g., hepatitis B, hepatitis C, HIV, other); and/or
- Systemic infection (e.g., endocarditis, septicemia, other)

Environmental scan

An environmental scan of ministry of health websites was conducted to identify provincial and territorial guidelines, standards and regulations to do with personal services.

Guiding principles for infection prevention and control, as applicable to personal service settings, were identified and summarized.

Summary of findings

Expert Working Group

Challenges and gaps identified by public health inspectors and infection prevention and control professionals highlighted the need for increased awareness as well as improved guidance and regulations.

Literature review

Of the 729 papers identified for preliminary screening, 555 were reviews or abstracts and were therefore excluded. A further 92 papers did not meet the search criteria outlined in the scope. A critical appraisal of the remaining 82 studies was accomplished using the PHAC *Infection Prevention and Control Guidelines Critical Appraisal Tool Kit* (1), and a further 31 papers were eliminated due to flaws in methodology (n=16) or analysis of results (n=15). This resulted in a total of 51 papers on the risk of infections related to personal services.

Risk of infection and transmission

The risks identified in the literature were quite varied. Information relevant to infection risks and the magnitude of these risks specific to Canadian personal services settings were limited however, a number of studies identified factors associated with increased risk of infection in personal services settings in other countries:

- Inadequate training and skill level of personal services workers (resulting in poor infection prevention control practices) (2,3)
- Poor or non-compliance with generally established infection prevention practices (resulting in individual cases or wider outbreaks of infection) (4–7)

Specific findings related to breaches or non-compliance with recommended infection practices include:

- Improper glove use (8)
- Improper cleaning of the environment (9,10)
- Improper cleaning, disinfection and sterilization of tools or equipment (2,7,8,10–20)
- Use of non-sterile instruments for invasive procedures (8,17–20)
- Use of contaminated water, ink, supplies or equipment (6,7,21–32)
- Pre-existing health status of the clients (33–39)
- Failure to provide adequate after care instructions (40,41)
- Deficiencies in the physical layout and inadequate infection prevention and control practices, including lack of hand washing facilities and/ or with no potable water (8)

Studies showed that infections associated with personal services may be bacterial (38,42–46), viral (47–52) or fungal (53). The risk for transmission of bloodborne viruses within personal services settings is impacted by knowledge of and/or adherence to effective, established infection prevention practices (54–58). Specific risk factors associated with exposure to bloodborne infections during personal services procedures include:

- Potential contact with blood when sharps containers are not placed within reach, leading to unnecessary handling of contaminated sharps and injuries; improper disposal of sharps, by, for example, repackaging used sharps or discarding them in the regular garbage
- Cross-contamination of instruments and surfaces
- Re-use of disposable instruments and equipment such as razors and styptic pencils
- Inadequate disinfection and sterilization of equipment
- Inadequate management of cuts and abrasions on personal services workers
- Inconsistent hand hygiene and glove use
- Lack of knowledge about appropriate procedures and routes of transmission of bloodborne pathogens
- Lack of vaccine-induced protection (e.g., for hepatitis B)

Environmental scan

The environmental scan was limited to provincial/territorial ministry of health websites to identify relevant legislation, regulations and approved guidelines, practices and standards. Guidance and regulations for personal services settings exist in varying degrees and complexity across Canada (**Table 1**). A review of practice guidelines, recommendations, position papers, etc. produced by personal services and/or public health professional associations or by educational programs was beyond the scope of the scan.

Table 1: Summary of published provincial and territorial personal services guidelines, standards, protocols, acts and regulations

Province/ territory	Guidelines, standards, protocols and/or other	Acts, regulations and/ or bylaws
Newfoundland and Labrador	N/A	*Personal Services Act*, 2012 (59)
Prince Edward Island	Guidelines for Tanning Salon Owners and Operators, 2011 (60)[a]	*PEI Public Health Act*, 2018 (61)
Nova Scotia	Salon and Spa Compliance Handbook, no date (62)	*Safe Body Art Act*, 2011 (63) *Health Protection Act*, 2016 (64) *Safe Body Art Regulations*, 2018 (65)
New Brunswick	N/A	*New Brunswick Bill 56 Public Health Act*, 1998 (66)
Quebec	Tattooers and Piercers: Protect Your Client and Yourself Against HIV and Hepatitis B and C,1999 (67)	N/A

Table 1 *(continued)*: **Summary of published provincial and territorial personal services guidelines, standards, protocols, acts and regulations**

Province/ territory	Guidelines, standards, protocols and/or other	Acts, regulations and/or bylaws
Ontario	Infection Prevention and Control Best Practices for Personal Services Settings, 2009 (68) Infection Prevention and Control Disclosure Protocol, 2018 (69) Infection Prevention and Control Complaint Protocol, 2018 (70) Personal Service Settings Guideline, 2018 (71) The Ontario Public Health Standards: Requirements for Programs, Services, and Accountability, 2018 (72)	*Health Promotion and Protection and Promotion Act, Ontario Regulation 136/18: Personal Service Settings*, 2018 (73)
Manitoba	Personal Services Facility Guideline, 2013 (74)	N/A
Saskatchewan	Personal Service Facility Best Management Practices, 2014 (75)	*The Health Hazard Regulations*, 2002 (76)
Alberta	Health Standards and Guidelines for Tattooing, 2002 (77) Health Standards and Guidelines for Body and Ear Piercing, 2002 (78) Health Standards and Guidelines for Barbering and Hairstyling, 2002 (79) Health Standards and Guidelines for Esthetics, 2002 (80) Health Standards and Guidelines for Electrolysis, 2002 (81)	*Public Health Personal Services Regulation*, 2003 (82)
British Columbia	Guidelines for Personal Services Establishments, 2017 (83) Guidelines For Body Modification, 2017 (84) Guideline for Personal Services Offered at Tradeshows, 2016 (85) Guidelines for Floatation Tanks, 2016 (86) Laser Hair Removal Devices: Safety Guidelines for Owners/ Operators, 2005 (87) Microblading Services in Personal Service Establishments – Fact Sheet for Operators, 2017 (88)	*Public Health Act, Regulated Activities Regulation*, 2011 (89)

Table 1 *(continued)*: **Summary of published provincial and territorial personal services guidelines, standards, protocols, acts and regulations**

Province/ territory	Guidelines, standards, protocols and/or other	Acts, regulations and/or bylaws
Yukon	Personal Service Premises Inspection Model, 2013 (90)	*Public Health Act – Personal Service Establishment Regulations*, 1984 (91)
Northwest Territories	Standards for Personal Service Establishments, 2012 (92)	*Public Health Act – Personal Services Establishment Regulations*, 2013 (93)
Nunavut	N/A	*Public Health Act*, 2016 (94) *Barber Shops and Beauty Salons Regulations*, 1990 (95)

Abbreviation: N/A, not applicable
[a] Limited focus on infection prevention control

General risk mitigation measures

The scope of personal services is very broad and different services and settings may require different infection prevention guidance. Generally accepted key measures that minimize infection risk are summarized in **Table 2**. Consistent application of infection prevention practices and precautions help prevent the acquisition and transmission of infections. The general infection prevention principles outlined in Table 2 are not comprehensive and are based on core infection prevention principles as identified in the PHAC guideline: *Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings* (96).

Gaps and challenges

Following the review of findings from the narrative review and environmental scan as well as discussions with the expert working group, a number of gaps and challenges were identified. These are summarized in **Table 3.**

Table 2: General infection prevention principles to mitigate risk of exposure to infections in personal services settings

Risk Mitigation Measure	Additional Context
Administrative controls	• Provide an infrastructure of protocols and practices intended to prevent the risk of infection to personal services workers and clients in personal services settings • Administrative controls include infection prevention policies and procedures; education and training (along with readily available resources such as instructions and manuals); proper use of equipment and instruments; monitoring compliance with infection prevention practices; appropriate occupational health and safety practices (e.g., worker immunization); and documentation and record keeping (e.g., records of disinfection and sterilization) in accordance with municipal and/or provincial/territorial standards and legislation
Risk assessment	• Must be performed before undertaking any personal service activity to evaluate the risk of infection or cross-contamination associated with an activity and to implement appropriate prevention measures • Includes determining the potential for contact with blood, body fluids and non-intact skin for the worker or client, exposure to mucous membranes and exposure to contaminated equipment or surfaces
Hand hygiene	• Single most important measure for preventing the transmission of microorganisms in all settings • Should be performed (as recommended in the PHAC *Hand Hygiene Practices in Healthcare Settings* guideline and local or provincial/territorial guidelines) using either an alcohol-based hand rub or liquid soap and water if hands are visibly soiled (97) • Gloves are not a substitute for hand hygiene
Environmental cleaning and disinfection	• Helps reduce the contamination of surfaces, decreasing the risk of transmission of microorganisms that may lead to infections in clients or workers • Manufacturer's directions for use and contact times for cleaning and disinfection products must be followed • Low-risk surfaces (e.g., tables covered with a single-use towel, hairdressing chairs or sinks for hair washing) are less likely to contribute to an infection as they typically come into contact only with intact skin. These surfaces should be cleaned immediately when they become visibly soiled and at least once per day (98) • Higher-risk surfaces (e.g., manicure/pedicure tables not covered with a single-use towel, counters used to prepare materials, equipment for procedures or foot baths) are more likely to be contaminated from contact with non-intact skin and blood and/or other body fluids. These surfaces should be cleaned and disinfected between clients and when surfaces are visibly soiled (98)
Single-use devices and products	• Single-use devices and products should be used wherever possible and, where applicable, lot numbers and expiry dates should be checked prior to use • Single-use devices and products must be discarded after one use: they must not be reprocessed, reused or kept in the personal services setting for future use with either the same client or a different client
Reprocessing reusable devices	• Level of reprocessing required for a specific reusable device depends on the device's intended use and the risk of infection to the client • All reusable devices require meticulous cleaning prior to disinfection or sterilization • Reusable devices used in the provision of services to clients must be reprocessed according to manufacturer instructions for cleaning, disinfection and/or sterilization and should adhere to the most current reprocessing standards from the Canadian Standards Association. In the absence of specific manufacturer's instructions, decisions around reprocessing should be based on provincial/territorial best practice recommendations (96) or determined based on Spaulding's classification (99)

Abbreviation: PHAC, Public Health Agency of Canada

Table 3: Gaps and challenges both related to infection prevention and outside the scope of infection prevention

Gap/Challenge related to:	Context
Related to infection prevention	
Setting	**Health care guidelines and standards for infection prevention are not directly applicable to personal services settings** • Personal services settings serve a healthier client base compared to most health care settings • Personal services settings are often small businesses; feasibility of implementing guidelines/standards is an important consideration • The physical layout and design of these settings can contribute to infection prevention issues. Personal services are no longer only offered in traditional commercial settings; they now include mobile, home-based, mall kiosk and special-event settings. There are limited guidelines and standards in this industry to address these issues directly. Where guidelines and standards do exist, they are mostly developed from the perspective of permanent commercial settings (e.g., stores in retail spaces) and may not be applicable to alternate settings
	Limited and poor quality literature and data on risk of infection and the burden of illness associated with personal services settings • No Canadian research published for infection prevention in personal services settings; data obtained from poor quality evidence such as case reports
	Recommendations for cleaning and disinfection, including recommendations for products used to clean and disinfect, exist in varying degrees and complexities • Practices for cleaning and disinfection are inconsistent • Availability and purchase of standardized disinfection products can be a challenge in community practice • A similar challenge exists for antiseptic products. Some settings wish to use alternative products that may not be appropriate for antisepsis

Table 3 *(continued)*: **Gaps and challenges both related to infection prevention and outside the scope of infection prevention**

Gap/Challenge related to:	Context
Related to infection prevention *(continued)*	
Infection prevention education and training	**Education and training of workers on infection prevention is not feasible (or enforceable) in many personal services settings**
	Workplace and practice audits by personnel trained in infection prevention are often not available to personal services settings
Outside the scope of infection prevention	
Legal infrastructure	**A consistent definition of personal services across jurisdictions is difficult to achieve** as this is a continuously evolving industry. Lists of procedures that can be offered in these settings exist; however they are quickly outdated and are inconsistent across jurisdictions
	Jurisdictional guidance and/or regulation regarding acceptable procedures and standards may be limited for non-regulated workers. There are questions around the type of procedures acceptable for delivery by personal services workers versus delivery by health care professionals
	Health care professionals are providing services in medical spa settings; this has created a grey area for public health inspectors. While the practice of the personal services worker falls under the jurisdiction of the professional regulatory body, the service delivery setting itself can require public health inspection if located outside the mandate of a health authority
Client safety	**Chemicals and devices used in personal services settings can cause injuries such** as those associated with the application of energy (e.g., lasers, fat freezing, cryotherapy chambers, plasma pens) and injections (e.g., mesotherapy). Health care organizations have protocols, procedures, and oversight in place to ensure devices and products are used safely and to address any injuries; many personal services settings do not have this type of infrastructure
	Health Canada licences medical devices, products and chemicals that can be sold in Canada, but **other substances that may not be licensed for use in Canada are available for purchase internationally via the internet**
	The public do not consistently have access to inspection reports that would assist them in their choice of personal services setting
Worker skill and knowledge	**There is uncertainty regarding scope of practice**, in particular for workers without a professional regulatory body
	Many workers do not have formal standard education and training in the services they provide. They may be self-taught or learn from another worker
	Most personal services settings require a license to operate, but not all workers have their practice regulated by a professional college/association

Discussion

There are concerns about infection prevention in the personal services industry. This article describes some of the concerns from a public health perspective, based on published studies and an environmental scan of guidelines and regulations available on provincial/territorial ministry of health websites. In addition, the gaps and challenges presented are a preliminary list of major issues as identified by the external expert working group, and do not encompass the full breadth or complexity of issues faced by public health in general.

There were notable limitations with the results of the literature review, in terms of comparability and applicability of available evidence to the Canadian context of personal services settings. This includes challenges with the quality of evidence, and limitations to extraction of data from case reports, self-reports, laboratory sampling, medical records and survey questionnaires. General principles and core elements for infection prevention are available from an established and recognized body of evidence that informs recommendations for practice in health care settings; however, there are challenges when applying measures from one setting to another. When extracting specific guidance for health care settings and adapting to personal services settings, some measures may not be relevant or directly apply.

This industry continues to evolve, with emergence of new procedures and services across a range of personal settings. The majority of publications and reports available focused on tattooing and piercing; however, a number of areas of personal services have no published information. Examples include body modification (tongue splitting, branding and scarification), nail salons and laser device uses for body enhancement. There is a need for further investigation to reflect the broad range of services and risks for exposure and transmission of infections in the Canadian context.

The feasibility of implementing infection prevention standards can be a challenge for alternate small business settings. The physical layout and design of these settings can contribute to infection prevention issues, there is limited evidence and data on the risk of infection in these settings, practices for cleaning and disinfection are inconsistent, and worker education and training on infection prevention are also limited depending on available resources.

In relation to the legal infrastructure, difficulties in defining personal services spill over into jurisdictional and regulatory issues and create grey areas in public health. Client safety is a major concern, particularly in the use of chemicals and devices in personal services settings. There is a need for standardized and consistent education and training of personal services workers.

While some organizations, such as the National Collaborating Centre on Environmental Health and the Canadian Institute of Public Health Inspectors, continue to examine and make efforts toward addressing issues related to personal services, further work is needed in this area. Canadian studies on infection prevention in personal services settings is recommended to provide information on the transmission pathways and risk of infections, and allow for assessment of burden of illness related to personal services settings in Canada. A continuously evolving industry also requires keeping an eye out for new services while working on legislation, regulation, guidelines, licensing and public education.

Conclusion

Personal services is a continuously evolving industry that encompasses a variety of aesthetic treatments and personal enhancement services, including procedures that range from non-invasive to more invasive, with associated risk of infection to clients and workers. This overview includes a summary of current regulations and guidelines across provincial and territorial jurisdictions. Findings were informed by the contribution of experts in the field, in addition to results from the narrative review and environmental scan.

Despite limitations to evidence on the specific infection risks associated with these services, reports and publications do indicate contributing factors and findings that can be used to inform risk mitigation strategies. At the current time, there is no established surveillance system for data related to complications associated with the personal services industry in Canada. This summary identifies gaps and challenges to bring greater awareness from a public health perspective, and opportunities to address public health concerns through policy, regulation and guidelines, in an effort to promote and monitor best practices for the health of Canadians.

Authors' statement

AP – Data review, writing – original draft, review and editing
JS – Data collection, data analysis and interpretation, writing – review and editing
TO – Writing – review and editing
KD – Conceptualization, writing - review and editing, supervision and project administration

Conflict of interest

None.

Contributors

The authors would like to thank the following members of the expert working group for their subject matter expertise, contributions to the project that informed this article, and their input on former drafts of this article.

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Acknowledgements

The authors thank Laurie O'Neil and Christine Weir for their project leadership, expertise on infection prevention and control, and for conducting initial literature reviews in consultation with members of the expert working group. The authors would like to thank Heidi Pitfield for subject matter expertise, review and contribution to discussions on the manuscript.

Funding

This work was supported by the Public Health Agency of Canada.

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Effectiveness of hand hygiene practices in preventing influenza virus infection in the community setting: A systematic review

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Abstract

Background: Hand hygiene is known to be an effective infection prevention and control measure in health care settings. However, the effectiveness of hand hygiene practices in preventing influenza infection and transmission in the community setting is not clear.

Objective: To identify, review and synthesize available evidence on the effectiveness of hand hygiene in preventing laboratory-confirmed or possible influenza infection and transmission in the community setting.

Methods: A systematic review protocol was established prior to conducting the review. Three electronic databases (MEDLINE, Embase and the Cochrane Library) were searched to identify relevant studies. Two reviewers independently screened the titles, abstracts and full-texts of studies retrieved from the database searches for potential eligibility. Data extraction and quality assessment of included studies were performed by a single reviewer and validated by a second reviewer. Included studies were synthesized and analyzed narratively.

Results: A total of 16 studies were included for review. Studies were of low methodological quality and there was high variability in study design, setting, context and outcome measures. Nine studies evaluated the effectiveness of hand hygiene interventions or practices in preventing laboratory-confirmed or possible influenza infection in the community setting; six studies showed a significant difference, three studies did not. Seven studies assessed the effectiveness of hand hygiene practices in preventing laboratory-confirmed or possible influenza transmission in the community setting; two studies found a significant difference and five studies did not.

Conclusion: The effectiveness of hand hygiene against influenza virus infection and transmission in the community setting is difficult to determine based on the available evidence. In light of its proven effectiveness in other settings, there is no compelling evidence to stop using good hand hygiene practice to reduce the risk of influenza infection and transmission in the community setting.

Suggested citation: Moncion K, Young K, Tunis M, Rempel S, Stirling R, Zhao L. Effectiveness of hand hygiene practices in preventing influenza virus infection in the community setting: A systematic review. Can Commun Dis Rep 2019;45(1):12-23. https://doi.org/10.14745/ccdr.v45i01a02

Keywords: community, hand hygiene, hand sanitizer, handwashing, influenza infection, influenza transmission, systematic review

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Introduction

Hand hygiene is a commonly recommended infection prevention and control measure to reduce the risk of influenza infection and transmission in health care and community settings. Routine hand hygiene protocols that indicate the use of soap and running water to wash hands (1) and/or alcohol-based hand sanitizers to rub hands (1,2) are effective at physically removing influenza virus from human hands.

Hand hygiene practices have been found to be effective in reducing infection and transmission of healthcare-associated pathogens in the health care setting (3); in reducing non-pathogen-specific gastrointestinal and respiratory illnesses in the community setting (4–7); and for disinfection, removal of contaminants and reduction of the incidence of hospital-acquired infections in the health care setting (3).

Less frequently studied has been the degree of protection against influenza virus infection and transmission afforded by hand hygiene practices in the community setting. An initial scoping search of the literature identified two systematic reviews that came to different conclusions. A review of randomized controlled trials found that hand hygiene as a co-intervention with facemask use in the community setting was efficacious against laboratory-confirmed influenza infection or influenza-like illness, but hand hygiene alone was not (8). Another review of intervention trials and observational studies found evidence of a reduction in influenza infection with hand hygiene interventions in schools, but no effect on secondary transmission of influenza in households in the community that had already experienced an index case (9).

A systematic review was undertaken to identify, review and synthesize the latest evidence on the effectiveness of hand hygiene as an intervention in preventing laboratory-confirmed or possible influenza infection and transmission in the community setting. The term "possible influenza infection" was defined as non-laboratory-confirmed cases, including influenza-like illness or an acute respiratory illness.

Methods

The systematic review parameters, search strategy and analysis plan were established prior to the conduct of the review. Hand hygiene was defined as handwashing, hand antisepsis and actions taken to maintain healthy hands and fingernails (10). The search strategy (**Appendix 1**) was developed in collaboration with a research librarian. MEDLINE, Embase and the Cochrane Library electronic databases were searched from inception until June 5, 2017 using search terms for influenza and hand hygiene. Searches were restricted to articles published in English or French.

Studies were included for review if they met the following criteria:

- They were conducted in a community setting, which is defined as a non-health care, open setting without confinement and without special care for the participants (e.g., school, workplace, household) (8)
- They were observational studies that assessed hand hygiene as an exposure of interest (e.g., observed or reported hand hygiene practice) or clinical trials that could include combinations of education, promotion and provision of products to do with hand hygiene, but assessed a hand hygiene intervention that could be reasonably expected to exert an independent influence
- They assessed the impact of hand hygiene on:
    - laboratory-confirmed or possible influenza infection or
    - laboratory-confirmed or possible influenza transmission

Studies were excluded if they met one or more of the following criteria:

- They were conducted in the health care setting only
- They assessed a multicomponent intervention for which hand hygiene could not be reasonably expected to exert an independent influence
- They were not clinical research studies (e.g., literature reviews, editorials, opinion pieces or news stories, or non-human or in vitro studies)

Study selection was completed independently by two reviewers. Reference lists of included studies and relevant secondary research articles retrieved through the search were also searched to identify relevant publications. One reviewer (KM) performed data extraction and quality appraisal and a second reviewer performed validation (LZ). Data were extracted on study design, population, setting, hand hygiene intervention (i.e., from clinical trials) or practice (i.e., from observational studies) and outcomes of interest. Study quality was assessed using the Cochrane Collaboration Risk of Bias Tool for randomized controlled trials (RCTs) (11) and the Effective Public Health Practice Project Quality Assessment Tool for observational designs (12). Disagreements between the two reviewers were resolved by discussion and reaching a consensus.

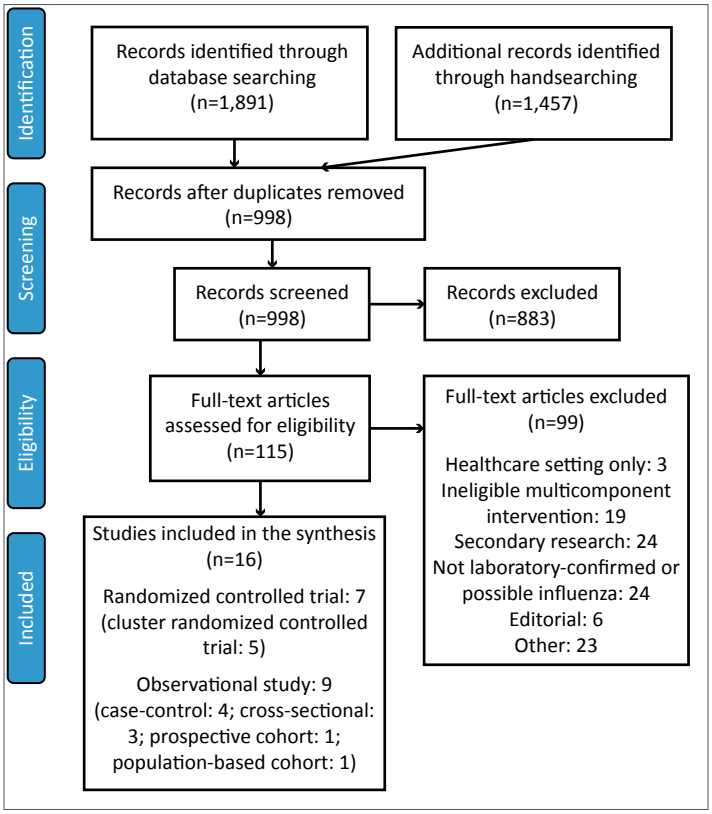
Narrative data synthesis and analysis were planned to summarize the direction, size and statistical significance of reported effect estimates for various study-defined outcomes and to explore

overall patterns in the data extracted from included studies. If possible, meta-analyses were planned to assess the association of hand hygiene with influenza outcomes by income level of country of study, study design, setting, intervention evaluated and outcome assessed.

Results

After database searching, handsearching and removal of duplicates, 998 records remained. After screening, 115 records were identified for full-text review. When all inclusion and exclusion criteria were applied, 16 studies—seven RCTs and nine observational studies—were available for review. **Figure 1** summarizes the study selection process.

Figure 1: Flow diagram of the study selection process



Abbreviation: n, number

RCTs assessed using the Cochrane Collaboration Risk of Bias Tool were all found to be at a high risk of bias (13–19). Observational studies assessed using the Effective Public Health Practice Project Quality Assessment Tool found seven of nine observational studies as weak in quality (20–26) and two as moderate in quality (27,28). The reviewers made a post-hoc decision to not perform a meta-analysis as the limited number of included studies were not adequate for grouping by the study characteristics of interest.

RCTs on hand hygiene interventions

Of the seven included RCTs, six assessed the provision of hand sanitizer or soap with instructions on their use (13–16,18,19). One RCT delivered an internet-based intervention educating and promoting handwashing without provision of any hand sanitizer or soap to participants (17). None of these RCTs reported the instructions or education given to participants on handwashing or hand antisepsis in sufficient detail to compare the appropriateness of these interventions to best practices.

Observational studies on hand hygiene practices

Of the nine included observational studies, four collected self-reported handwashing frequency (23,26–28). Of the remaining five studies, one study dichotomized observed handwashing behaviour as observed or not observed (20) and one as frequent or infrequent (21). These studies did not specify or report the use of handwashing criteria in estimating handwashing frequency or counting handwashing events. Two studies assessed self-reported quality of hand hygiene practice, that is, good or poor (22), and optimal or suboptimal (25), and of these, one defined optimal hand hygiene practice according to published best practices (22). Another study collected self-reported information on adoption of various non-pharmaceutical interventions, including washing hands more often and hand sanitizer use (24).

Hand hygiene and influenza infection

Nine studies evaluated the effectiveness of hand hygiene interventions or practices in preventing laboratory-confirmed or possible influenza infection in the community setting, including two RCTs (15,17), one cohort study (27), three case-control studies (21,23,28) and three cross-sectional studies (20,22,25).

Study findings were mixed; six of nine studies found that some form of hand hygiene intervention or practice reduced laboratory-confirmed (23,28) or possible (17,20,22,25) influenza infection, while three studies found hand hygiene to be not statistically significantly associated with a decrease in influenza infection (15,21,27). For the two RCTs, one found a significant association between handwashing and decreased risk of influenza-like illness (15) and the other found no effect on self-reported clinically diagnosed influenza for a workplace hand sanitizer intervention (13). For the observational studies, which relied on self-reported (22,23,25,27,28) or observed (20,21) hand hygiene practice, most found statistically significantly lower likelihood of possible infection (20,22,23,25,28). The limited number of heterogeneous studies did not allow for more granular qualitative analysis of findings. The results are summarized in **Table 1**.

Table 1: Summary of evidence related to the effectiveness of hand hygiene practices in preventing laboratory-confirmed or possible influenza infection in the community setting

Study	Sample size (n)	Hand hygiene intervention or reported practice/ control intervention	Main outcome measure	Relevant key findings
Randomized controlled trial				
Hubner et al., 2010 (15)	134 (intervention: 67; control: 67)	Instruction to use an alcohol-based hand disinfectant at least five times daily only at work, with disinfectant provided Control: No instruction or disinfectant provided	Self-report of clinically diagnosed influenza	Intervention and control groups did not differ in likelihood of clinically diagnosed influenza (OR: 1.02, 95% CI: 0.20–5.23)
Little et al., 2015 (17)	20,066 (intervention: 10,040; control: 10,026)	Access to web-based intervention providing information about the importance of influenza and the role of HW Control: No access to the web-based intervention	ILI	Participants in the intervention group had a decreased risk of reported ILI in the past four months (aRR: 0.80, 95% CI: 0.72–0.92) and in the past month (aRR: 0.85, 95% CI: 0.77–0.94) compared to the control group
Cohort study				
Merk et al., 2004 (27)	4,365	Self-reported HW frequency	Self-reported ILI and ARI	Adults who washed their hands ≥5 times per day and those who washed their hands two to four times per day did not statistically significantly differ in incidence of ILI (aRR: 1.10–1.48) and ARI (aRR: 1.08–1.22)
Case-control study				
Doshi et al., 2015 (21	486 (case: 145; control: 341)	Observed household level HW behaviour (frequent/infrequent)	Laboratory-confirmed influenza	Household level HW with soap and water was not statistically significantly associated with laboratory-confirmed influenza (aOR: 1.06, 95% CI: 0.90–1.24)
Liu et al., 2016 (23)	200 (case: 100; control: 100)	Self-reported HW frequency	Laboratory-confirmed influenza	HW statistically significantly decreased the likelihood of laboratory-confirmed influenza (by 54% per unit increase in HW score; aOR: 0.46, 95% CI: 0.29–0.74)
Torner et al., 2015 (28)	478 (case: 239; control: 239)	Self-reported HW frequency	Laboratory-confirmed influenza	Children who reported washing their hands ≥5 times a day had a statistically significantly lower likelihood of laboratory-confirmed influenza compared to those who did not (aOR: 0.62, 95% CI: 0.39–0.99). The use of alcohol-based HS (aOR: 1.54, 95% CI: 0.8–2.66) and HW after touching contaminated surfaces (aOR: 0.62, 95% CI: 0.29–1.31) were not statistically significantly associated with laboratory-confirmed influenza
Cross-sectional study				
Adesanya et al., 2016 (20)	28,596	Observed HW behaviour (observed/not observed)	Parent-reported ARI	Children who were observed to not wash their hands had an increased likelihood of having ARI symptoms compared to children who were observed to wash their hands (aOR: 1.66, 95% CI: 1.33–2.07)
Hashim et al., 2016 (22)	468	Self-reported hand hygiene practice (good/poor)	Self-reported respiratory illness (ILI and non-ILI)	Hajj pilgrims with self-reported good hand hygiene practice had a statistically significantly lower likelihood of developing respiratory illness compared to those who did not report good hand hygiene practice (OR: 0.41, 95% CI: 0.20–0.85)
Wu et al., 2016 (25	13,003	Self-reported HW or HS use (optimal/suboptimal)	Self-reported ILI	Optimal hand hygiene (definition not provided) was found to be statistically significantly associated with a lower likelihood of reporting ILI (OR: 0.87, 95% CI: 0.80–0.94)

Abbreviations: aOR, adjusted odds ratio; ARI, acute respiratory illness; aRR, adjusted rate ratio; CI, confidence interval; HS, hand sanitizer; HW, handwashing; ILI, influenza-like illness; n, number; OR, odds ratio; ≥, superior or equal to

Hand hygiene and influenza transmission

Seven studies assessed the effectiveness of hand hygiene practices in preventing laboratory-confirmed or possible influenza transmission in the community setting, including five RCTs (13,14,16,18,19), one cohort study (24), and one case-control study (26). A majority of these studies assessed influenza transmission in the community setting by estimating secondary attack rates (SARs) at the household level (e.g., the proportion of susceptible individuals who became ill) for laboratory-confirmed or possible influenza (13,14,16,18,19).

Five of seven studies did not find a statistically significant association between hand hygiene intervention or practice and influenza transmission (13,14,16,18,24). An RCT found a statistically significant difference in SARs for influenza-like illness across handwashing, handwashing and facemask, and control interventions (0.17, 0.18 and 0.09, respectively), but not in SARs for laboratory-confirmed influenza (19). A case-control study found that handwashing at least three times per day was statistically significantly associated with reduced likelihood of household transmission of pandemic influenza A (H1N1) (26).

In four of five cluster RCTs conducted at the household level, hand hygiene intervention was implemented after the identification of the index case (13,14,18,19). Two of these four studies assessed a subgroup of households where the intervention was implemented within a defined period after the onset of symptoms in the index case (e.g., less than 36 or 48 hours); one of the two studies did not find a statistically significant difference between hand hygiene and control groups (14) while the other study found mixed results, depending on influenza type and determination of influenza (19). Four of five cluster RCTs did not find statistically significant differences in SARs for laboratory-confirmed or possible influenza between hand hygiene and control groups (13,14,16,18) and one found mixed results depending on outcome (19). The results are summarized in **Table 2**.

Table 2: Summary of evidence related to the effectiveness of hand hygiene practices in preventing laboratory-confirmed or possible influenza transmission in the community setting

Study	Sample size (n)	Hand hygiene intervention or reported practice/ control intervention	Main outcome measure	Relevant key findings
Randomized controlled trial				
Cowling et al., 2008 (13)	198 households (hand hygiene: 36; FM: 35; control: 127)	Hand hygiene intervention: Same education as control intervention plus hand hygiene education (potential efficacy of proper hand hygiene in reducing transmission and instructions) and provision of HS and soap FM intervention: Same education as control intervention plus FM education and provision of FMs to each household member Control: Healthy diet and lifestyle education with respect to illness prevention for household contacts and symptom alleviation for the index subject	SARs for clinical (three definitions) or laboratory-confirmed influenza	SARs for clinical and laboratory-confirmed influenza did not statistically significantly differ across the intervention arms. The likelihood of secondary infection in a household contact was statistically similar between the hand hygiene intervention and control groups for clinical (OR: 0.80–0.86) and laboratory-confirmed (OR: 1.07) influenza
Cowling et al., 2009 (14)	407 households (hand hygiene: 136; hand hygiene and FM: 137; control: 134)	Hand hygiene intervention: Same education as control intervention plus hand hygiene education (potential efficacy of proper hand hygiene in reducing transmission and instructions) and provision of HS and soap Hand hygiene and FM intervention: Same education as control and hand hygiene interventions plus FM education and provision of FM to each household member Control: Healthy diet and lifestyle education with respect to illness prevention for household contacts and symptom alleviation for the index subject	SARs for clinical (two definitions) and laboratory-confirmed influenza	SAR for clinical and laboratory-confirmed secondary cases did not statistically significantly differ across the intervention arms. The likelihood of secondary infection in a household contact was statistically similar comparing the hand hygiene intervention group for clinical (OR: 0.92–0.81) and laboratory-confirmed (OR: 0.57) influenza and the hand hygiene plus FM intervention group for clinical (OR: 1.25–1.68) and laboratory-confirmed (OR: 0.77) influenza to the control group

Table 2 *(continued)*: **Summary of evidence related to the effectiveness of hand hygiene practices in preventing laboratory-confirmed or possible influenza transmission in the community setting**

Study	Sample size (n)	Hand hygiene intervention or reported practice/ control intervention	Main outcome measure	Relevant key findings
Randomized controlled trial *(continued)*				
Larson et al., 2010 (16)	509 households (HS: 169; HS and FM: 166; control: 174)	HS intervention: Educational materials and HS to be carried by individual household members to work or school HS and FM intervention: Educational materials, HS, FMs and instructions on FM use Control: Educational materials regarding the prevention and treatment of URI and influenza	ILI and laboratory-confirmed influenza SARs for URI, ILI and laboratory-confirmed influenza	Intervention and control groups did not differ in rates of ILI or laboratory-confirmed influenza SARs for URI, ILI and laboratory-confirmed influenza were similar across interventions (HS: 0.144; HS and FM: 0.124; and control: 0.137) Restricting outcomes to ILI and laboratory-confirmed influenza, SARs were similar across interventions (HS: 0.020; HS and FM: 0.018; and control: 0.023)
Ram et al., 2015 (18)	377 households (HW: 193; control: 184)	HW education and promotion and provision of HW station with soap and water after illness onset in the index case Control: Standard practice	SARs for ILI and laboratory-confirmed influenza	SAR ratios for ILI (1.24, 95% CI: 0.93–1.65) and laboratory-confirmed influenza (2.40, 95% CI: 0.68–8.47) comparing intervention to control households were not statistically significant
Simmerman et al., 2011 (19)	465 households (HW: 155; HW and FM: 155; control: 155)	HW intervention: HW education and soap dispenser HW and FM intervention: HW education, soap dispenser and FMs Control: Nutritional, physical activity and smoking cessation education	SARs for ILI and laboratory-confirmed influenza	SARs for ILI were statistically significantly different across interventions (HW: 0.17; HW and FM: 0.18; and comparison: 0.09; p=0.01). However, SARs for laboratory-confirmed influenza were not statistically significantly different across interventions (HW: 0.23; HW and FM: 0.23; and control: 0.19; p=0.63). Other analyses for influenza transmission found similar associations for ILI and laboratory-confirmed influenza outcomes comparing intervention and control groups
Cohort study				
Loustalot et al., 2011 (24)	2,030	Self- and proxy-reported household-level hand hygiene behaviour (HW frequency and HS use)	Reported ILI in household	Households with at least one reported case of ILI did not statistically significantly differ in reported HW frequency (p=0.34) or HS use (p=0.37) compared to households without ILI
Case-control study				
Zhang et al., 2013 (26)	162 households (case household: 54; control household: 108)	Self-reported HW frequency	Laboratory-confirmed influenza	HW ≥3 times per day was statistically significantly associated with reduced likelihood of household transmission of pandemic influenza A (H1N1) (OR: 0.71, 95% CI: 0.48–0.94)

Abbreviations: CI, confidence interval; FM, facemask; HS, hand sanitizer; HW, handwashing; ILI, influenza-like illness; n, number; OR, odds ratio; SAR, secondary attack rate; URI, upper respiratory infection; ≥, superior or equal to

Discussion

The present systematic review identified 16 studies that assessed the impact of hand hygiene intervention or practice on influenza infection or transmission in the community setting. Two-thirds of studies suggested hand hygiene practices may help prevent influenza infection. Most studies that looked at influenza transmission, however, had non-statistically significant results. Most studies had design elements associated with the potential for bias. The studies were too heterogeneous in design for meta-analysis. Our findings were similar to the two other systematic reviews conducted on this issue despite methodological differences in study selection. Whereas we found both positive and negative studies, the Wong et al. review (8) found that hand hygiene intervention alone was not efficacious against laboratory-confirmed influenza and the Warren-Gash et al. review (9) found some evidence of influenza risk reduction with hand hygiene intervention, depending on the community setting. Warren-Gash et al. also found no evidence of effectiveness of hand hygiene on secondary transmission of influenza in households that had already experienced an index case (9).

Limitations

There are a number of important limitations to consider when interpreting the findings of this review. In general, the majority of studies investigated outcomes that were not specific to influenza virus infection, but were influenza-like illness and acute respiratory illness, which could be caused by other respiratory viruses. Findings from lower income settings (e.g., rural Bangladesh) may not be generalizable to high-income settings and vice versa. Moreover, in controlled clinical trials conducted in high-income settings, there may already be high baseline levels of hand hygiene practice rendering intervention and control groups more similar irrespective of hand hygiene intervention. The effectiveness of hand hygiene interventions is dependent on mode of influenza transmission and may be attenuated when the mode of transmission is not through contact. The present review restricted its scope to hand hygiene interventions independent of other public health measures; therefore, these interventions may not be reflective of real-world, multicomponent public health measures. Finally, a search of the grey literature was not undertaken, so some studies may have been missed.

There were also limitations inherent to both types of study. Some of the included RCTs lacked statistical power (13,15,16). None of the included RCTs presented information on hand hygiene interventions in sufficient detail to allow the comparison of these interventions to best practices. Possible non-compliance with the intervention and contamination of control participants may underestimate possible effects of hand hygiene. Adoption of effective hand hygiene practice may take longer than the intervention period of a clinical trial. For RCTs investigating influenza transmission in households with an index case, it is possible that the hand hygiene intervention was implemented too late in the course of illness of the index case to be effective in preventing intra-household transmission. In household studies, direct and indirect protection conferred by hand hygiene practice for more susceptible individuals (e.g., children) cannot be readily assessed due to a lack of information on hand hygiene practice collected at the individual level.

For the included observational studies, where hand hygiene practices were either self-reported or observed, measurement of hand hygiene practice may be influenced by response bias (e.g., social desirability bias), recall bias or the observer effect (29). Although most observational studies collected exposure data on self-reported handwashing frequency, these studies did not specify or report the use of criteria for counting handwashing events; therefore, optimal and suboptimal hand hygiene practices cannot be differentiated in the overall reported handwashing frequency. Observational studies may also be susceptible to residual confounding, selection bias and other biases that may further complicate the interpretation of findings. Although the cross-sectional studies included for review found statistically significant results (20,22,25), the cross-sectional design cannot determine whether the reported hand hygiene behaviour preceded influenza illness.

Implications and next steps

These numerous limitations of the existing body of evidence highlight the difficulties of conducting research on this topic in the community setting for both experimental and observational designs (8,9,30). Hand hygiene is a non-invasive, non-pharmaceutical intervention without adequate comparator interventions (31). There are also challenges in conducting RCTs with appropriate sample sizes to establish the relative importance of hand hygiene (6). In the community setting, it is also difficult to implement interventions and assess outcomes.

In light of the robust body of evidence on the benefits of hand hygiene practices with respect to general infectious disease prevention and control (7), the mixed results and limitations of current studies, there is no compelling evidence to stop using good hand hygiene practice to reduce the risk of influenza infection and transmission in the community. Hand hygiene practices are non-invasive and have broad applicability as an infection prevention and control intervention with no demonstrated evidence of harm.

Further research would help to clarify whether, and under what circumstances, hand hygiene interventions in the community are effective in preventing influenza infection and transmission.

Conclusion

Available evidence on the effectiveness of hand hygiene practices in preventing influenza infection and transmission in the community is inconsistent and insufficient in both quality and quantity. However, in light of its efficacy in general infectious disease prevention and control, there is no compelling evidence to stop using good hand hygiene practice to reduce the risk of influenza infection and transmission in the community.

Authors' statement

KM – Conceptualization, methodology, analysis, writing – original draft, review and editing
KY – Methodology, analysis, writing – review and editing
MT – Analysis, writing – review and editing
SR – Analysis, writing – review and editing
RS – Methodology, analysis, writing – review and editing
LZ – Conceptualization, methodology, analysis, writing – review and editing

Conflict of interest

None.

Acknowledgements

The authors would like to thank the members of the Canadian Pandemic Influenza Preparedness Task Group for their valuable comments. The authors gratefully acknowledge the contributions of Stella Chen, Lindsay Colas, Lisa Glandon, Kevin Leung, Lisa Paddle, Sharon Smith and Jill Williams to the systematic review.

Funding

This work was supported by the Public Health Agency of Canada.

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Appendix 1: Electronic database search strategy and results

Set #	Searches	Results
MEDLINE		
1	hand hygiene/ or hand disinfection/	5,680
2	(hand? adj3 (hygien* or wash* or disinfect* or sanitiz* or antiseptic* or steriliz* or decontaminat* or clean*)).tw.	7,433
3	handwash*.tw.	1,661
4	1 or 2 or 3	10,550
5	exp residence characteristics/ or exp schools/ or workplace/ or exp "Non-Medical Public and Private Facilities"/	280,888
6	(communit* or domicile? or domestic or residential or neighborhood? or household? or home? or family or families or school* or college? or universit* or "education* setting*" or student? or daycare? or childcare or workplace? or workspace? or worksite? or employee? or "public setting?" or "non healthcare setting*" or "non health care setting*").tw.	2,148,929
7	((work or job or public) adj3 (setting? or location? or site? or place?)).tw.	15,472
8	5 or 6 or 7	2,296,190
9	influenza, human/ or exp influenzavirus a/ or exp influenzavirus b/	63,179
10	(influenza* or flu or h1n# or h2n# or h3n# or h5n# or h6n# or h7n# or h9n# or h10n#).tw.	110,315
11	common cold/ or respiratory tract infections/ or rhinitis/ or sinusitis/ or fever/ or cough/ or pharyngitis/ or sneezing/ or myalgia/ or headache/ or vomiting/ or diarrhea/	201,878
12	("common cold" or "respiratory infection*" or "respiratory virus*" or "respiratory tract infection*" or "respiratory illness*" or fever* or cough* or "sore throat" or "runny nose" or "nasal congestion" or sneezing or malaise* or myalgia or headache* or "muscle ache*" or vomit* or diarrhea or diarrhoea).tw.	419,905
13	9 or 10 or 11 or 12	616,262
14	4 and 8 and 13	717
15	limit 14 to (english or french)	674
16	15 and "Editorial" [Publication Type]	2
17	15 and "Newspaper Article" [Publication Type]	1
18	15 not (16 or 17)	671
19	hand hygiene/ or hand disinfection/	5,680
20	(hand? adj3 (hygien* or wash* or disinfect* or sanitiz* or antiseptic* or steriliz* or decontaminat* or clean*)).tw.	7,433
21	handwash*.tw.	1,661
22	19 or 20 or 21	10,550
23	influenza, human/ or exp influenzavirus a/ or exp influenzavirus b/	63,179
24	(influenza* or flu or h1n# or h2n# or h3n# or h5n# or h6n# or h7n# or h9n# or h10n#).tw.	110,315
25	common cold/ or respiratory tract infections/ or rhinitis/ or sinusitis/ or fever/ or cough/ or pharyngitis/ or sneezing/ or myalgia/ or headache/ or vomiting/ or diarrhea/	201,878
26	("common cold" or "respiratory infection*" or "respiratory virus*" or "respiratory tract infection*" or "respiratory illness*" or fever* or cough* or "sore throat" or "runny nose" or "nasal congestion" or sneezing or malaise* or myalgia or headache* or "muscle ache*" or vomit* or diarrhea or diarrhoea).tw.	419,905
27	23 or 24 or 25 or 26	616,262
28	22 and 27	1,349
29	limit 28 to (english or french)	1,249
30	29 and "Editorial" [Publication Type]	15
31	29 and "Newspaper Article" [Publication Type]	3
32	29 and "Comment" [Publication Type]	32
33	29 not (30 or 31 or 32)	1,203
34	33 not 18	538

Appendix 1 *(continued)*: **Electronic database search strategy and results**

Set #	Searches	Results
Embase		
1	hand washing/ or hand disinfection/	11,298
2	(hand? adj3 (hygien* or wash* or disinfect* or sanitiz* or antiseptic* or steriliz* or decontaminat* or clean*)).tw.	10,307
3	handwash*.tw.	1,863
4	1 or 2 or 3	16,007
5	community/ or community living/ or household/ or home/ or exp school/ or workplace/ or building/	456,912
6	(communit* or domicile? or domestic or residential or neighborhood? or household? or home? or family or families or school* or college? or universit* or "education* setting*" or student? or daycare? or childcare or workplace? or workspace? or worksite? or employee? or "public setting?" or "non healthcare setting*" or "non health care setting*").tw.	2,757,553
7	((work or job or public) adj3 (setting? or location? or site? or place?)).tw.	19,320
8	5 or 6 or 7	2,899,020
9	exp influenza/ or exp influenza virus/	88,859
10	(influenza* or flu or h1n# or h2n# or h3n# or h5n# or h6n# or h7n# or h9n# or h10n#).tw.	126,819
11	common cold/ or respiratory tract infection/ or fever/ or rhinitis/ or sinusitis/ or coughing/ or sore throat/ or rhinorrhea/ or nose obstruction/ or pharyngitis/ or sneezing/ or myalgia/ or headache/ or vomiting/ or diarrhea/	737,993
12	("common cold" or "respiratory infection*" or "respiratory virus*" or "respiratory tract infection*" or "respiratory illness*" or fever* or cough* or "sore throat" or "runny nose" or "nasal congestion" or sneezing or malaise* or myalgia or headache* or "muscle ache*" or vomit* or diarrhea or diarrhoea).tw.	562,610
13	9 or 10 or 11 or 12	1,087,580
14	4 and 8 and 13	1,092
15	limit 14 to (english or french)	1,041
16	15 and "Editorial" [Publication Type]	6
17	15 not 16	1,035
18	hand washing/ or hand disinfection/	11,298
19	(hand? adj3 (hygien* or wash* or disinfect* or sanitiz* or antiseptic* or steriliz* or decontaminat* or clean*)).tw.	10,307
20	handwash*.tw.	1,863
21	18 or 19 or 20	16,007
22	exp influenza/ or exp influenza virus/	88,859
23	(influenza* or flu or h1n# or h2n# or h3n# or h5n# or h6n# or h7n# or h9n# or h10n#).tw.	126,819
24	common cold/ or respiratory tract infection/ or fever/ or rhinitis/ or sinusitis/ or coughing/ or sore throat/ or rhinorrhea/ or nose obstruction/ or pharyngitis/ or sneezing/ or myalgia/ or headache/ or vomiting/ or diarrhea/	737,993
25	("common cold" or "respiratory infection*" or "respiratory virus*" or "respiratory tract infection*" or "respiratory illness*" or fever* or cough* or "sore throat" or "runny nose" or "nasal congestion" or sneezing or malaise* or myalgia or headache* or "muscle ache*" or vomit* or diarrhea or diarrhoea).tw.	562,610
26	22 or 23 or 24 or 25	1,087,580
27	21 and 26	2,512
28	limit 27 to (english or french)	2,370
29	28 and "Editorial" [Publication Type]	68
30	28 not 29	2,302
31	30 not 17	1,267

Appendix 1 *(continued)*: **Electronic database search strategy and results**

Set #	Searches	Results
Cochrane Library		
1	[mh ^"hand hygiene"] or [mh ^"hand disinfection"]	363
2	(hand? near/3 (hygien* or wash* or disinfect* or sanitiz* or antiseptic* or steriliz* or decontaminat* or clean*)):ti,ab,kw	154
3	handwash*:ti,ab,kw	217
4	1 or 2 or 3	544
5	[mh ^"residence characteristics"] or [mh schools] or [mh ^workplace] or [mh "Non-Medical Public and Private Facilities"]	3,578
6	(communit* or domicile? or domestic or residential or neighborhood? or household? or home? or family or families or school* or college? or universit* or (education* next setting*) or student? or daycare? or childcare or workplace? or workspace? or worksite? or employee? or (public next setting?) or "non healthcare setting" or "non health care setting" or "non healthcare settings" or "non health care settings"):ti,ab,kw	101,164
7	((work or job or public) near/3 (setting? or location? or site? or place?)):ti,ab,kw	248
8	5 or 6 or 7	101,724
9	[mh ^"influenza, human"] or [mh "influenzavirus a"] or [mh "influenzavirus b"]	1,830
10	(influenza* or flu or h1n? or h2n? or h3n? or h5n? or h6n? or h7n? or h9n? or h10n?):ti,ab,kw	7,611
11	[mh ^"common cold"] or [mh ^"respiratory tract infections"] or [mh ^rhinitis] or [mh ^sinusitis] or [mh ^fever] or [mh ^cough] or [mh ^pharyngitis] or [mh ^sneezing] or [mh ^myalgia] or [mh ^headache] or [mh ^vomiting] or [mh ^diarrhea]	13,353
12	("common cold" or (respiratory next infection*) or (respiratory next virus*) or (respiratory next tract next infection*) or (respiratory next illness*) or fever* or cough* or "sore throat" or "runny nose" or "nasal congestion" or sneezing or malaise* or myalgia or headache* or (muscle next ache*) or vomit* or diarrhea or diarrhoea):ti,ab,kw	77,363
13	9 or 10 or 11 or 12	82,910
14	4 and 8 and 13	86
15	[mh ^"hand hygiene"] or [mh ^"hand disinfection"]	363
16	(hand? near/3 (hygien* or wash* or disinfect* or sanitiz* or antiseptic* or steriliz* or decontaminat* or clean*)):ti,ab,kw	154
17	handwash*:ti,ab,kw	217
18	15 or 16 or 17	544
19	[mh ^"influenza, human"] or [mh "influenzavirus a"] or [mh "influenzavirus b"]	1,830
20	(influenza* or flu or h1n? or h2n? or h3n? or h5n? or h6n? or h7n? or h9n? or h10n?):ti,ab,kw	7,611
21	[mh ^"common cold"] or [mh ^"respiratory tract infections"] or [mh ^rhinitis] or [mh ^sinusitis] or [mh ^fever] or [mh ^cough] or [mh ^pharyngitis] or [mh ^sneezing] or [mh ^myalgia] or [mh ^headache] or [mh ^vomiting] or [mh ^diarrhea]	13,353
22	("common cold" or (respiratory next infection*) or (respiratory next virus*) or (respiratory next tract next infection*) or (respiratory next illness*) or fever* or cough* or "sore throat" or "runny nose" or "nasal congestion" or sneezing or malaise* or myalgia or headache* or (muscle next ache*) or vomit* or diarrhea or diarrhoea):ti,ab,kw	77,363
23	19 or 20 or 21 or 22	82,910
24	18 and 23	127
25	24 not 14	41

Invasive group A streptococcal infection outbreaks of type *emm*118 in a long-term care facility, and of type *emm*74 in the homeless population, Montréal, Quebec

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Abstract

Background: Two invasive group A streptococcus (iGAS) infection outbreaks occurred in Montréal in 2016 and 2017; one in a long-term care facility (type *emm*118) and one in the community, primarily involving homeless people (type *emm*74).

Objective: To describe two recent iGAS outbreaks in Montréal and highlight the challenges in dealing with these outbreaks and the need to tailor the public health response to control them.

Methodology: All cases of iGAS were investigated and the isolates were sent to the laboratory for *emm* typing. In both outbreaks, cases of superficial group A streptococcus (GAS) infection were identified, through 1) systematic case detection accompanied by screening for asymptomatic carriers among residents and employees of the long-term care facility and 2) sentinel surveillance among homeless people. Visits were made to community organizations providing homeless services (including shelters) and social networks were analyzed to establish whether there were any links among cases of GAS infection (both invasive and noninvasive) and locations frequented. In both outbreaks, recommendations were made to service providers regarding enhancement of infection prevention and control measures.

Results: In the long-term care facility, five cases of type *emm*118 iGAS were identified over a 22-month period, one of which resulted in death. All residents were screened and no carriers were identified. Among the employees, 81 (65%) were screened and four carriers were identified. Of those, one was a carrier of type *emm*118 GAS. All carriers were treated, and subsequent follow-up sampling on three carriers (including the one with *emm*118) was negative.

In the community, 23 cases of type *emm*74 iGAS were detected over a 16-month period, four of which resulted in death. Half of the cases (n=12) were described as homeless, and six others were users of services for the homeless. Sentinel surveillance of superficial infections yielded 64 cultures with GAS, chiefly on the skin, including 51 (80%) of type *emm*74. An analysis of the social networks revealed the large number and variety of resources for the homeless used by the cases. Visits to the community organizations providing homeless services revealed the heterogeneity and precariousness of some of these services, the difficulties encountered in applying adequate health and hygiene measures, and the high degree of mobility amongst those who use these services.

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Conclusion: The detection and control of iGAS outbreaks in both long-term care establishments and among community organizations providing homeless services are very complex. An outbreak of iGAS can develop in the background over a long time and be easily overlooked despite cases being admitted to the hospital. *Emm* typing and systematic research of previous cases of iGAS are essential tools for the detection and characterization of outbreaks. Close cooperation among public health agencies, clinical teams, community organizations and laboratories is essential for proper monitoring and the reduction of GAS transmission in the community and health care settings.

Suggested citation: Pilon PA, Savard N, Aho J, Caron J, Urbanek A, Paré R, Le Guerrier P, Savard C, Hammond-Collins K, Dung Tran C, Allard R, Domingo MC. Invasive group A streptococcal infection outbreaks of type *emm*118 in a long-term care facility, and of type *emm*74 in the homeless population, Montréal, Quebec. Can Commun Dis Rep 2019;45(1):24-31. https://doi.org/10.14745/ccdr.v45i01a03

Keywords: invasive, infection, group A streptococcus, long-term care facility, homeless population

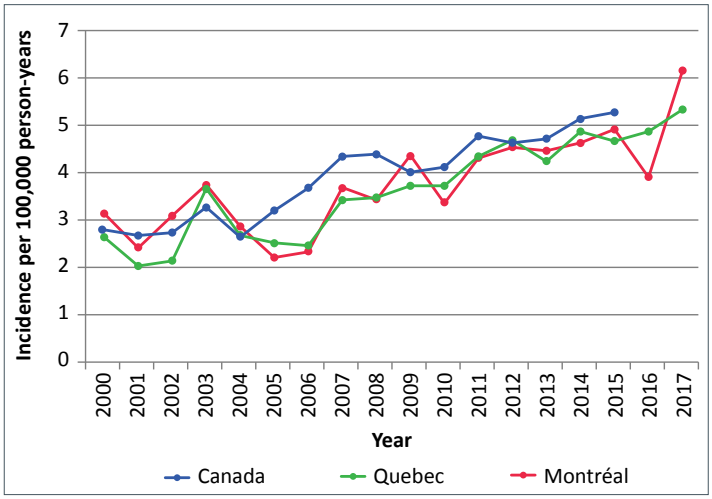
Introduction

The β-hemolytic group A streptococcus (GAS) (*Streptococcus pyogenes*) is a bacterium that is transmitted primarily through droplet inhalation or via skin contact. Sites such as the oropharynx and skin can be asymptomatically colonized. There is a spectrum of infections that can be caused by GAS, ranging from benign infections, such as pharyngitis or impetigo, to invasive infections, such as bacteremia, necrotizing fasciitis or streptococcal toxic shock syndrome (1). The sequencing of a portion of the *emm* gene, which codes for a virulence factor called the M protein, allows the identification of 220 distinct strains, called *emm* types (2).

The risk factors for invasive GAS (iGAS) infections include advanced age, skin lesions or breaks, viral respiratory infections, some chronic diseases such as diabetes, immunosuppression, use of intravenous drugs and excessive use of alcohol (1,3–5).

In Quebec, iGAS is a notifiable disease. The Direction régionale de santé publique (DRSP) [Regional Public Health Department], Centre intégré universitaire de santé et de services sociaux (CIUSSS) du Centre-Sud-de-l'Île-de-Montréal handles such reports for a population base of approximately two million people. Cases of iGAS reported by labs and physicians are systematically investigated by the DRSP to identify the severity of the infection, the associated risk factors and any close contacts who might benefit from prophylaxis as per provincial recommendations (6). Since 2010, isolated strains from sterile sites have been sent to the Laboratoire de santé publique du Québec (LSPQ) [Quebec Public Health Laboratory], then to the National Microbiology Laboratory (NML), which does the *emm* gene typing. An antibiogram is performed to test for sensitivity to penicillin, ceftriaxone, erythromycin, clindamycin and vancomycin. Surveillance statistics show that the incidence of iGAS is on the rise in Montréal, the province of Quebec as a whole and across Canada (**Figure 1**) (6–9).

Figure 1: Incidence of invasive group A streptococcal infections for Montréal, the province of Quebec and Canada, 2000–2017



Sources: Public Health Agency of Canada. Number of invasive cases of group A streptococcal infections reported between 1994 and 2015 – Notifiable diseases online (consulted February 21, 2018); Institut national de santé publique du Québec. *Rapport hebdomadaire/annuel des maladies à déclaration obligatoire d'origine infectieuse* [Weekly/Annual Report of Infectious Notifiable Diseases] (consulted February 21, 2018)

In 2016 and 2017, the DRSP detected two outbreaks of iGAS in very different populations: in residents of a long-term care facility; and in a homeless population. The goal of this article is to describe these two outbreaks and to illustrate the challenges encountered and the need to tailor responses to the specific affected populations.

Outbreak in a long-term care facility

Background

Due to a combination of host- and environment-related factors, elderly people in a long-term care environment are at higher risk of contracting and dying from iGAS (10,11). Several iGAS outbreaks, occurring mostly over periods of a few months,

have been reported in this type of setting within Canada and elsewhere in the world (3,12–15).

In Quebec, the recommendation is to conduct a 30-day surveillance after any iGAS case is reported in a long-term care resident. If the iGAS case is severe (meningitis, pneumonia, soft-tissue necrosis, toxic shock or death), antibiotic prophylaxis is given to all close contacts and a retrospective investigation is conducted for the previous 30 days (6). If a high number of cases are identified, the recommendation is to look for asymptomatic carriers and carry out a prospective surveillance of invasive and noninvasive GAS infections (6,7).

Methodology

Detection of the outbreak

In July and August 2016, two cases of type *emm*118 iGAS were reported to the DRSP by a long-term care facility that accommodated approximately 200 residents. The public health investigator noted that other cases of iGAS had occurred in the same long-term care facility over the two previous years. The period covered by the investigation was therefore expanded beyond the routinely recommended 30-day retrospective period.

Definition of a case

A confirmed case of iGAS is defined as being a long-term care facility employee or resident in whom type *emm*118 GAS was isolated from a normally sterile site any time after January 1, 2014. Asymptomatic carriers or superficial GAS infections are defined as being an employee or resident in whom type *emm*118 GAS was isolated from a non-sterile site (oropharynx, wound) any time after January 1, 2014.

Search for cases

All cases of iGAS reported to the DRSP by this long-term care facility were reviewed. Lab results positive for GAS (as of January 1, 2014) for residents of the long-term care facility and patients of its referring hospital were retrospectively reviewed to identify cases of iGAS that may not have been reported as well as cases of noninvasive GAS infection. Active surveillance began in August 2016 and continued until April 2017 to detect type *emm*118 GAS, whether invasive or not.

Screening for asymptomatic carriers was proposed to all residents and health care staff via throat swabs and, if applicable, wound swabs. This screening offer started in the summer of 2016 and continued for 12 weeks.

Microbiological analyses

The NML performed *emm* typing of isolates from both sterile and non-sterile sites. While awaiting the results of *emm* typing, the LSPQ conducted pulsed-field gel electrophoresis (PFGE) on isolates taken from iGAS cases to confirm similarities between invasive strains.

Data analysis

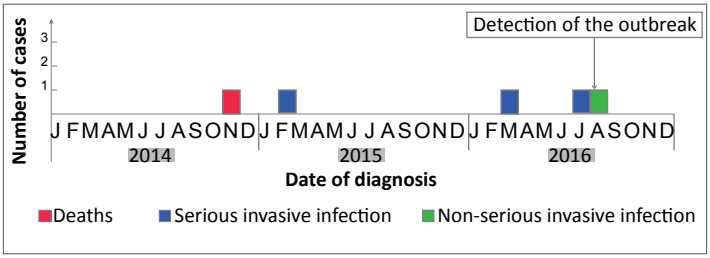
The descriptive analyses and the epidemic curve were derived using Microsoft™ Excel 2010 software.

Results

Five confirmed cases of type *emm*118 iGAS were identified via the systematic review of cases reported to the DRSP. Pulsed-field gel electrophoresis analyses indicated the same profile for these strains. All type *emm*118 isolates were sensitive to all antibiotics tested. A review of patient records in the facility and prospective surveillance revealed no additional cases.

All cases of type *emm*118 iGAS were found in men 71 to 84 years of age. All had comorbidities, notably kidney failure, chronic obstructive pulmonary disease, immunosuppression or cirrhosis. None had any chronic wounds, skin infections or skin diseases. Four cases presented a serious infection (one death from streptococcal toxic shock and three cases of pneumonia) and one case presented with bacteremia. All of the cases occurred between November 2014 and August 2016 (**Figure 2**). No close contacts between cases of type *emm*118 iGAS were identified.

Figure 2: Epidemic curve of cases of invasive type *emm*118 group A streptococcal infection in a Montréal long-term care facility, 2014–2016 (n=5)



All residents were screened. None of them were GAS carrier. Among employees, 81/125 (65%) were tested: four were GAS carriers, one of whom was *emm*118-positive. This particular person was working in the facility when the five cases of iGAS were reported. All employees who were carriers were withdrawn from work for the first 48 hours of treatment (10 days of oral penicillin V, amoxicillin or cefadroxil). The success of the treatment was ascertained by an oropharyngeal culture from three of the four employees, including the carrier of the *emm*118 strain (6). No further cases were identified in the subsequent six months.

Outbreak in a homeless population

Background

Due to a combination of risk factors, homeless individuals are at greater risk of iGAS (16,17). They are over-represented among reported cases in Montréal (*unpublished data*), although no outbreak had been previously documented among this

population in Montréal. Elsewhere, outbreaks of iGAS have been reported among intravenous drug users (18–23) and, more recently, among homeless populations (24–28).

Methodology

Detection of the outbreak

Between March and May 2017, the DRSP received reports of two cases of iGAS at the same shelter. These two instances led to a review of all cases reported among homeless people in 2017. A greater number of cases (n=7) had occurred in this population since January 2017, compared with the same period in the preceding year (n=3). The first five cases for which the *emm* type was identified were of *emm*74 type. This *emm* type had not previously been reported in Montréal.

Definition of cases

An iGAS outbreak case was defined as a person living in Montréal, with isolation of type *emm*74 GAS from a normally sterile site between March 1, 2017 and July 31, 2018. An outbreak case with superficial (noninvasive) infection was defined as being a person identified by the sentinel surveillance initiated during the outbreak and having at least one culture from a non-sterile site testing positive for type *emm*74 GAS.

Investigation of cases

Following detection of the outbreak, the iGAS cases were again investigated to identify which homeless services and shelters were used during the month preceding the appearance of symptoms or, if accurate timing was impossible, the generally frequented places. For new cases, several investigations were conducted in person with the cases, in order to obtain more comprehensive information about their risk factors, places frequented and close contacts.

Surveillance of noninvasive infections

A sentinel surveillance of cases of superficial infection was initiated in July 2017. The main clinical teams working with the homeless population were asked to look for any wounds that seemed infected, to swab these wounds for culture and to fill out a short survey documenting the homeless services and shelters used in the two preceding weeks. The cultured GAS strains were sent to the LSPQ, then to the NML for *emm* typing.

Data analysis

Descriptive statistics and the comparison with sporadic cases of iGAS in Montréal were performed with IBM Cognos Business Intelligence™ 10.2.2 software (International Business Machines Corp., Armonk, New York, US), Microsoft Excel 2010 and Stata™ 15 (StataCorp, College Station, Texas, US). Social networks were analyzed using the Pajek 5.04 application. The resulting network includes cases of iGAS, their close contacts as defined in Quebec guidelines (6), the cases of superficial GAS infection detected via sentinel surveillance and the places frequented (i.e., shelters and other residential locations, day centres, clinical services for the homeless and gathering places).

Intervention

The DRSP worked in close cooperation with the *Service régional en itinérance* [Regional Homeless Service], clinical teams working with the homeless, and several dozen community agencies that operate shelters, day centres and other services for the homeless.

In June, an alert was sent out to the health care network and recommendations for basic hygiene measures were forwarded to community organizations providing services to the homeless. Recommendations focused on the early detection of infected wounds, swabbing them for culture and on their treatment. In July the sentinel surveillance system for monitoring wounds was established.

Throughout June and July, the DRSP visited nine shelters and three day centres to assess the situation and issue more specific recommendations to decrease the transmission of infections, to facilitate hygiene and cleanliness, and to control infestations by ectoparasites, as these could lead to wounds initiated from scratching. In October, follow-up visits were conducted to evaluate the implementation of recommendations and to distribute a reader-friendly information poster to inform people using these homeless services of the ways they can protect themselves. As recommended by provincial guidelines (6), antibiotic prophylaxis for people who had close contact with severe cases of iGAS was offered whenever possible.

Results

The first iGAS case of this outbreak occurred in March 2017. The outbreak was declared over on July 31, 2018, after eight consecutive months with no excessive cases of iGAS among homeless services users. The outbreak had 23 cases of iGAS, 19 of which were reported between March and November 2017. The cases of iGAS included 14 men and nine women from 34 to 80 years of age (median=54).

The most common clinical presentations were soft-tissue infections (n=14, including five cases of necrotizing fasciitis) and bacteremia (n=7). All were hospitalized, eight went into toxic shock and four died. Half of the cases (n=12) were homeless when the infection occurred, six were not homeless but had used homeless services, and three had an epidemiological link to this population. Two subjects had no links to this population. Twelve people consumed excess alcohol and three used intravenous drugs.

The outbreak's iGAS cases were significantly different from the sporadic cases reported in Montréal during the same period (**Table 1**). All of the *emm*74 iGAS isolates were sensitive to all of the antibiotics tested.

Table 1: Comparison of cases from the invasive type *emm*74 group A streptococcal infections with other cases from the same period

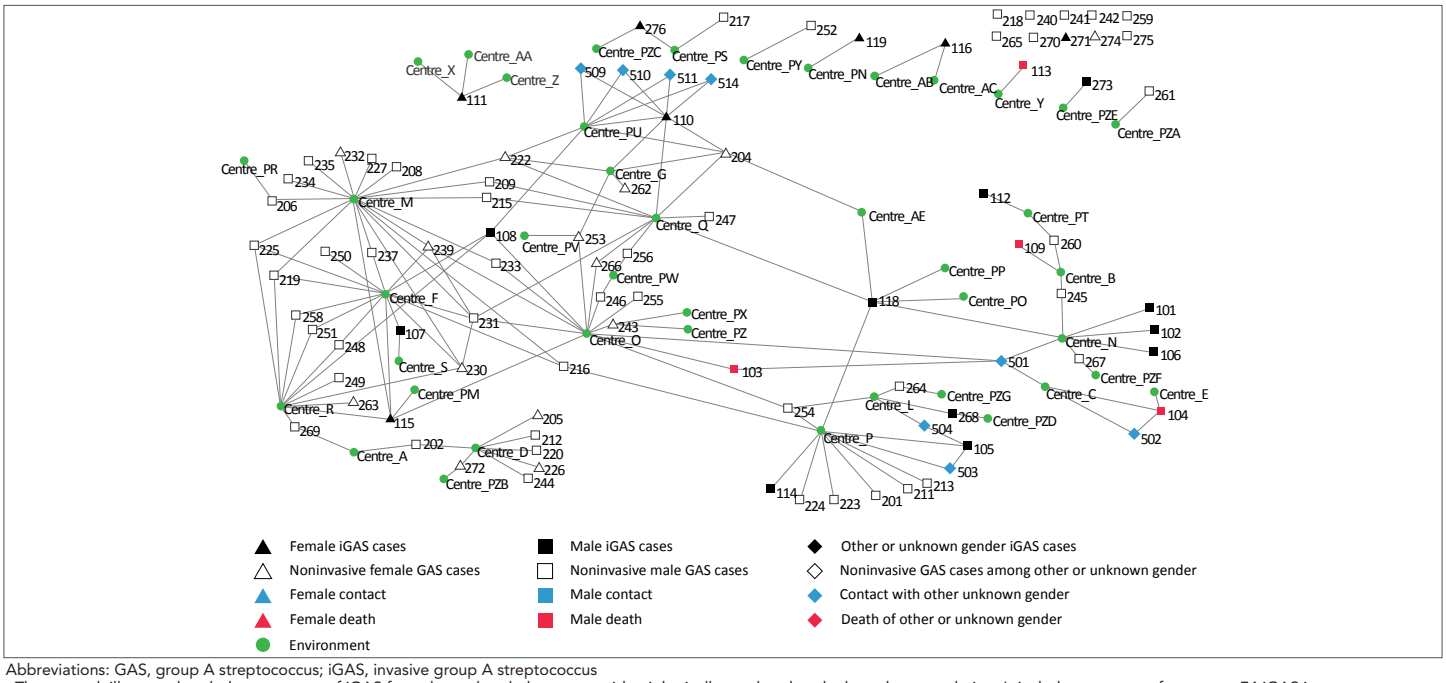
Characteristics	Type *emm*74 March 2017 to July 2018		Other *emm* type or unknown March 2017 to July 2018		*P* value[a]
	N=23	%	N=167	%	
Median age (years)	54	N/A	46	N/A	N/A
Male	14	60.9	93	55.7	0.662
Hospitalized	23	100.0	153	91.6	0.225
Death	4	17.4	10	6.0	0.072
Infection types					
Soft tissue[b]	14	60.9	64	38.3	0.045[d]
Respiratory[c]	3	13.0	28	16.8	1.000
Bacteremia	7	30.4	35	21.0	0.295
Toxic shock	8	34.8	19	11.4	0.007[d]
Risk factors					
Homelessness	12	52.2	8	4.8	<0.001[d]
Drugs	4[e]	17.4	11	6.6	0.090
Alcoholism	12	52.2	17	10.2	<0.001[d]
Diabetes	5	21.7	20	12.0	0.195
Chronic pulmonary diseases	6	26.1	11	6.6	0.008[d]

Abbreviations: N/A, not applicable; N, total number; <, inferior to
[a] Fisher's exact test for comparison of cases of invasive group A streptococcal infections type *emm*74 and those of other or unknown *emm* type
[b] Soft tissue infections include soft tissue necrosis, fasciitis, myositis and/or cellulitis or erysipelas
[c] Respiratory infections include pneumonia or other pulmonary manifestation and/or pharyngitis/tonsillitis
[d] Statistically significant (α = 0.05)
[e] Including intravenous and oral drugs

Of a total of 156 specimens submitted, sentinel surveillance detected 63 wounds and one throat that had been infected or colonized by GAS, of which 51 (80%) were type *emm*74. An analysis of the social networks revealed eight components, the chief of which linked 68% of iGAS cases and 81% of superficial infection cases (**Figure 3**). Some locations had been frequented by a greater number of cases (four cases of iGAS for one location, 17 noninvasive cases for another), but no single environment was directly linked with a majority of cases.

For the nine severe cases of iGAS who used homeless services or were epidemiologically related, only four close contacts could be identified for antibiotic prophylaxis. The community organizations had been alerted to the importance of prevention measures, but the necessary resources were not always available, which introduced some variability with respect to the application of prevention and treatment measures. The main challenges encountered were the frequency of housekeeping, the cleaning of beds and bed linens, the laundering of clothing and the availability of a change of clothing. Noteworthy improvements were observed in some organizations during follow-up visits.

Figure 3: Analysis of social networks for cases of invasive and noninvasive *emm*74[a] type group A streptococcal infections



Abbreviations: GAS, group A streptococcus; iGAS, invasive group A streptococcus
[a] The network illustrated excludes two cases of iGAS from the outbreak that were epidemiologically unrelated to the homeless population. It includes one case of type *emm*74 iGAS in a non-Montrealer who was epidemiologically related to the homeless population

Discussion

Managing these two iGAS outbreaks in two very different contexts identified both common and context-specific challenges. Detecting the outbreak proved to be a challenge in both contexts. For the long-term care outbreak, the length of time between cases led to a 21-month delay between the appearance of the first case and the detection of the outbreak. For the outbreak among the homeless population, detection was more timely but could have been delayed had two related cases not been reported in the same shelter. The absence of specific surveillance by *emm* type was a limiting factor in the detection of both outbreaks.

The long-term care outbreak was characterized by its long-lasting nature and the presence of the same *emm* type in an employee. In the absence of close contact among the different cases of iGAS, the most likely assumption is transmission via an asymptomatic carrier, possibly the *emm*118 GAS-positive employee, although this person could also have been a secondary case, with the primary case being an unidentified carrier. The work of long-term care personnel in identifying and dealing with similar future outbreaks could be facilitated with the development of an operational protocol for screening, treatment and follow-up of screened employees. The DRSP's recommendation to long-term care facility was to continue prospective surveillance of GAS infections for a minimum of six months after the last identified case, even though the optimal timing for prospective surveillance is currently unknown (29). Of note, no further cases of iGAS infection were detected at the long-term care facility during this additional surveillance period. Enhancement of infection prevention and control measures, and detection and treatment of the *emm*118 GAS carrier, may have contributed to this outcome, as it has been reported in other outbreaks (5,12,29,30).

For the homeless population outbreak, analysis of the social network and sentinel surveillance revealed that the outbreak was not limited to one specific setting. Rather, the strain involved was found to be circulating throughout the homeless population. This population is inherently mobile: homeless people can sleep in different places and call upon different resources, which would account for widespread transmission. This mobility creates a daunting challenge in terms of intervention. Other challenges encountered included limited human and financial resources available for the application of recommendations regarding hygiene and cleanliness, mental health issues among the users, which make it difficult to apply personal hygiene measures and treat infestations, the difficulty of accessing proper care and the wide variety of community organizations involved. In addition, there is no way of assessing the effectiveness of the public health interventions and distinguishing their effect from the natural evolution of the outbreak.

These iGAS outbreaks have identified the need for improved detection methods. *Emm* typing of iGAS and systematic search for previous cases of iGAS are essential tools for detecting and characterizing outbreaks. These outbreaks have also prompted the development of more effective ways of collaboration between clinical partners, community organizations and laboratories to pave the way for setting-specific interventions. The development of intervention strategies to identify and control iGAS outbreaks in vulnerable populations, whether in the community or in a health care setting, is especially relevant in a context where the incidence of iGAS is on the rise in Canada.

Authors' statement

All the authors — PAP, NS, JA, JC, AU, RP, PLG, CS, KHC, CDT, RA, and MCD — have contributed to managing different aspects of either or both of the outbreaks.

The authors — JA, PAP and RP — wrote the first versions of the manuscript on the long-term care facility outbreak and the others authors — CDT, RA and MCD — have contributed to the final version by providing precisions, feedback and suggestions.

The authors — NS and PAP — wrote the first versions of the manuscript on the outbreak in the homeless population and the other authors —JC, AU, PLG, CS, KHC and MCD — have contributed to the final version by providing precisions, feedback and suggestions.

Conflict of interest

None.

Acknowledgements

We thank the investigators who investigated the cases, in particular Mr. Guy Lapierre, nurse, for his vigilance and his excellent work as well as the staff of the *Direction régionale de santé publique* for data collection. We thank Ms. Johanne Sicotte and Mrs. Annie Parisien from the infection prevention and control team and Ms. Manon Aubé in occupational health at the establishment to which the long-term care facility was attached for their indispensable collaboration.

We thank the Service régional en itinérance et activités communautaires of the *Centre intégré universitaire de santé et de services sociaux* (CIUSSS) *du Centre-Sud-de-l'Île-de-Montréal*; the clinical staff of the shelters, the clinical care team of the *CIUSSS du Centre-Sud-de-l'Île-de-Montréal* and of the *CIUSSS-du-Centre-Ouest-de-l'Île-de-Montréal*, the hospital laboratories (Centre Hospitalier Universitaire de Montréal, McGill University Health Centre) and Doctors of the World who participated in sentinel surveillance; and staff and services who work with the homeless population and who have worked closely on the implementation of public health recommendations.

We also thank the following people who contributed to the work at some point: Dr. Carole Morissette, Ms. Maryse Lapierre, Dr. Marie Munoz-Bertrand, Dr. Marie-Jo Ouimet, Ms. Manon

Dugas, Ms. Karyne Daigle, Ms. Deboray Bonney, Ms. Mélanie Tailhandier, Mrs. Mireille Carpentier, Mr. Chérif Trabelsi, Dr. David Kaiser, Mrs. Isabelle Rouleau and Dr. Richard Massé.

Finally, we thank Ms. Cindy Lalancette of the Laboratoire de santé publique du Québec for the analysis of pulsed-field gel electrophoresis profiles; Dr. Irene Martin and staff of the National Microbiology Laboratory for their collaboration in laboratory analysis.

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West Nile virus illness in Ontario, Canada: 2017

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Abstract

Background: In Canada, the annual incidence rates of West Nile virus (WNV) illness have fluctuated over the last 15 years. Ontario is one of the provinces in Canada that have been the most affected by WNV and, as a result, has implemented robust mosquito and human surveillance programs.

Objective: To summarize and discuss the epidemiology of WNV illness in Ontario, Canada in 2017, with comparisons to previous years.

Methods: Case data were obtained from the provincial integrated Public Health Information System. Provincial and public health unit (PHU)-specific incidence rates by year were calculated using population data extracted from intelliHEALTH Ontario.

Results: In 2017, the incidence of WNV illness in Ontario was 1.1 cases per 100,000 population, with 158 confirmed and probable cases reported by 27 of the province's 36 PHUs. This is the highest rate since 2013, but less than the rate in 2012 (2.0 cases per 100,000 population). Incidence rates in 2017 were highest in Windsor-Essex County and in PHUs in eastern Ontario. While the seasonality is consistent with previous years, the number of cases reported between July and September 2017 was above expected. Most cases were in older age groups (median: 58 years old) and males (59.5% of provincial total); cases with severe outcomes (neurological complications, hospitalizations, deaths) were also disproportionately in older males.

Conclusion: WNV illness continues to be an ongoing burden in Ontario. The increase in the number of cases reported in 2017, and the increased number of PHUs reporting cases, suggests changing and expanding risk levels in Ontario. Continued mosquito and human surveillance, increased awareness of preventive measures, and early recognition and treatment are needed to mitigate the impact of WNV infections.

Suggested citation: Wijayasri S, Nelder MP, Russell CB, Johnson KO, Johnson S, Badiani T, Sider D. West Nile virus illness in Ontario, Canada: 2017. Can Commun Dis Rep 2019;45(1):32-7. https://doi.org/10.14745/ccdr.v45i01a04

Keywords: *Culex*, mosquito, surveillance, epidemiology, public health, climate, West Nile virus

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Introduction

West Nile virus (WNV) is a mosquito-borne pathogen of public health concern in Canada. The virus was first identified in North America in 1999, with the first human case of WNV illness in Canada confirmed in Ontario in 2002 (1,2). The virus has since become endemic to Canada, with the annual number of cases reported nationally fluctuating over the last 15 years (reaching a high of 2,215 cases in 2007 and a low of five cases in 2010) (3). Cases have been reported in all ten provinces since 2002, with the majority occurring in the prairie and central provinces (4). Ontario (which represents approximately 38.7% of the Canadian population) has reported cases of WNV illness every year since 2002, with epidemics reported in 2002 and 2012 (2,5,6).

In Ontario, *Culex* mosquitoes are primarily responsible for WNV transmission to humans (7). Mosquito development, and the rate of virus replication inside the mosquito, is heavily driven by temperature and geography – they are most active in warmer temperatures and urban environments where catch basins with standing water are widespread (6,7). In 2016, the majority of WNV-positive mosquito pools in Ontario were reported in the Golden Horseshoe and urban areas of southwestern and

southeastern Ontario (7). Studies have identified a strong relationship between the number of WNV-positive mosquito pools and the number of confirmed human cases reported each year, highlighting the usefulness of mosquito surveillance in early detection and risk assessment (6,8).

While the majority of cases are asymptomatic, or do not seek medical attention due to mild symptoms, a fraction of those infected develop severe outcomes, including neuroinvasive disease (9,10). Neuroinvasive disease that can present as meningitis, encephalitis or acute flaccid paralysis are difficult to treat and are associated with high morbidity, mortality and long-term sequelae (9,10). Considering that WNV infection can lead to severe illness, and that treatment is only supportive, public health efforts have focused on early detection through mosquito and human surveillance, promotion of preventive measures and increasing awareness (9). An understanding of WNV epidemiology is therefore necessary to inform such public health efforts.

The objective of this report is to summarize and discuss the epidemiology of WNV illness in Ontario, Canada in 2017, with comparisons to previous years.

Methods

Population and surveillance case definitions

During the 2017 surveillance period, there were 36 public health units (PHUs) in Ontario that provided local health services within their jurisdictions (11). Under the *Health Protection and Promotion Act*, all PHUs are responsible for case management and reporting of diseases of public health significance in Ontario (12). PHUs classify and report confirmed and probable WNV illness cases using the provincial surveillance case definitions and disease classifications (13).

Data source

PHUs report WNV illness cases to the province using the web-based integrated Public Health Information System (iPHIS). PHU reports include information on case demographics, exposures, symptoms, hospitalizations and deaths. Details for confirmed and probable cases of WNV illness with episode dates from 2005 to 2017 were extracted from iPHIS. Episode date is an approximation of illness onset, based on the first available date in the following hierarchy: symptom onset, specimen collection, laboratory result or report date.

Analyses

Descriptive analyses were conducted using SAS 9.3 and Microsoft Excel 2010. Case-level data from iPHIS were used to describe the geographic trends, seasonality, age and sex distributions and clinical outcomes of WNV illness cases in Ontario reported in 2017. To eliminate the skewing effect of the WNV epidemic in 2012, the epidemic year was excluded from historical averages, and four-year historical averages (2013–2016) were used as comparators to 2017 (6). Provincial incidence rates (2005–2016) and PHU-specific incidence rates (2017) were calculated per 100,000 population per year using provincial and PHU population estimates (2005–2016) and projections (2017) obtained from Statistics Canada via intelliHEALTH Ontario. Given the uncertainties with assigning exposure locations, cases reporting travel outside the province during the incubation period were not excluded from the analyses. ESRI ArcGIS™ v10.3 (ESRI, Redlands, California, United States) was used to map WNV illness incidence rates by PHUs for 2017. Rates were grouped into classes using manual classification methods.

Ethics statement

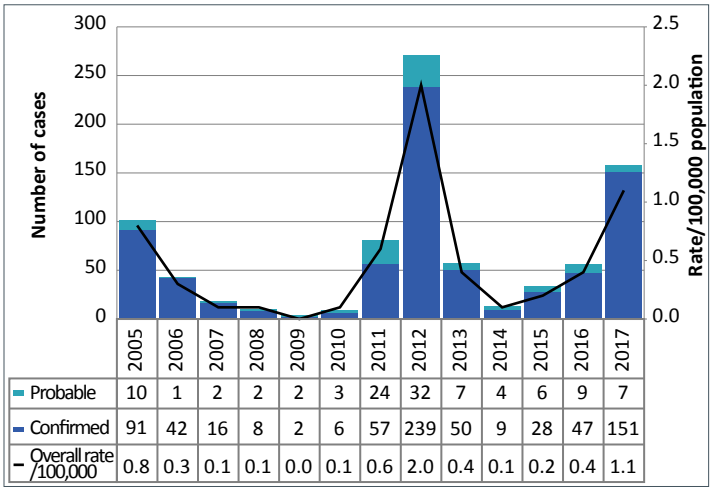
This manuscript reports on routine surveillance activities and not research, and therefore research ethics committee approval was not required. Data are available upon request via Public Health Ontario at http://www.publichealthontario.ca/en/About/Pages/privacy.aspx.

Results

Overall

In 2017, 158 confirmed and probable WNV illness cases were reported in Ontario, well above the four-year historical average of 40 cases per year. This is the second highest number of cases reported in a single year since 2005, with the number of cases increasing annually since 2014 (**Figure 1**). The incidence rate of WNV illness in Ontario in 2017 was 1.1 cases per 100,000 population, an almost three-fold increase from 2016 (0.4 cases per 100,000 population), but below the incidence rate in 2012 (2.0 cases per 100,000 population).

Figure 1: Number of confirmed and probable West Nile virus illness cases and incidence (per 100,000 population), by year, in Ontario, Canada, 2005–2017



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Probable	10	1	2	2	2	3	24	32	7	4	6	9	7
Confirmed	91	42	16	8	2	6	57	239	50	9	28	47	151
Overall rate /100,000	0.8	0.3	0.1	0.1	0.0	0.1	0.6	2.0	0.4	0.1	0.2	0.4	1.1

Geographic distribution

Twenty-seven PHUs reported WNV illness cases in 2017. This is higher than in the previous four years (2013–2016), during which 13 to 15 PHUs reported cases per year. Of the total cases reported in Ontario in 2017, the majority of cases were reported by Toronto (28/158 cases, 17.7%), followed by Ottawa (20/158 cases, 12.7%) and Windsor-Essex County (20/158 cases, 12.7%). Increases in Ottawa (7.5 times its four-year historical average) and Windsor-Essex County (5.7 times its four-year historical average) were particularly notable (**Table 1**).

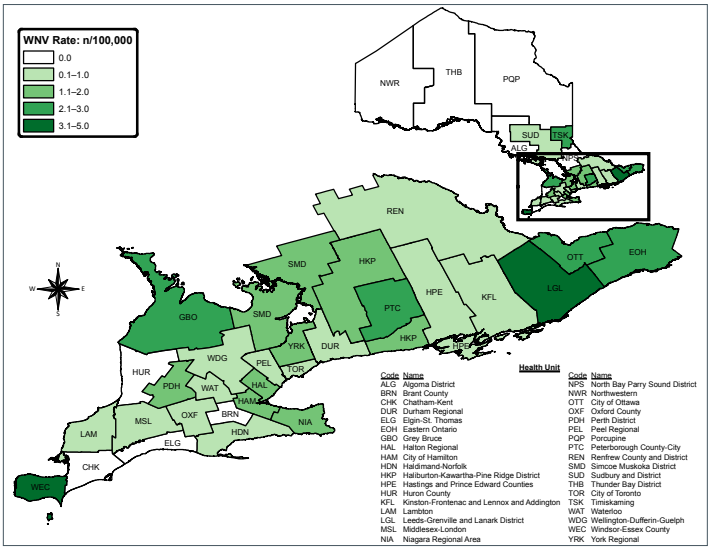
Table 1: Number of confirmed and probable West Nile virus illness cases reported in 2017, compared to four-year historical averages (2013–2016), by public health unit[a], Ontario, Canada

Health Unit	2017		2013-2016
	n	%[b]	Four-year average
Toronto	28	17.7	12.5
City of Ottawa	20	12.7	2.7
Windsor-Essex County	20	12.7	3.5
York Region	12	7.6	1.5
Peel Region	10	6.3	4.3
Niagara Region	8	5.1	5.7
Simcoe Muskoka District	7	4.4	1.3
City of Hamilton	6	3.8	3.7
Halton Region	6	3.8	1.5
Leeds, Grenville and Lanark District	6	3.8	0.0
Eastern Ontario	5	3.2	1.0
Grey Bruce	4	2.5	0.0
Durham Region	3	1.9	0.0
Haliburton, Kawartha, Pine Ridge	3	1.9	0.0
Peterborough County-City	3	1.9	0.0
Waterloo Region	3	1.9	0.0
Kingston, Frontenac, Lennox & Addington	2	1.3	0.0
Sudbury and District	2	1.3	1.0
Wellington-Dufferin-Guelph	2	1.3	1.0
Haldimand-Norfolk	1	0.6	0.0
Hastings & Prince Edward Counties	1	0.6	0.0
Lambton County	1	0.6	1.0
Middlesex-London	1	0.6	2.0
Oxford County	1	0.6	1.0
Perth District	1	0.6	0.0
Renfrew County and District	1	0.6	1.0
Timiskaming	1	0.6	0.0
Total (Ontario)	158	100.0	40.0

Abbreviation: n, number
[a] Public health unit refers to the individual's health unit of residence at the time of illness onset and not necessarily the location of exposure. Location of disease acquisition cannot be attributed to public health unit. Only public health units that reported cases in 2017 are included in this table (n=27)
[b] Percent (%) is the proportion of total cases reported in Ontario in 2017 (n=158)

Windsor-Essex County also had the highest incidence rate (4.9 cases per 100,000 population) in Ontario in 2017. High incidence rates were also observed in several low population health units in the eastern region of Ontario, including Leeds, Grenville and Lanark District (3.5 cases per 100,000 population), Timiskaming (3.0 cases per 100,000 population) and Eastern Ontario (2.4 cases per 100,000 population) (**Figure 2**). Of cases reporting an exposure in 2017, 9.2% (13/141) reported travel outside the province during the incubation period.

Figure 2: Incidence of West Nile virus illness (per 100,000 population) in 2017, by public health unit[a], Ontario, Canada



Abbreviations: n, number; WNV, West Nile virus
[a] Public health unit refers to the individual's health unit of residence at the time of illness onset and not necessarily the location of exposure. Location of disease acquisition cannot be attributed to public health unit

Seasonality

The majority of cases occurred between July and September 2017, with the highest proportion of cases reported in August (57.6%) (**Figure 3**). The seasonal distribution of cases in 2017 was similar to previous years, peaking in August; however, monthly case counts were more than four times the average of the previous four years for July (observed 19 cases, expected four) and August (observed 91 cases, expected 17).

Figure 3: Number of confirmed and probable West Nile virus illness cases reported in 2017, compared to four-year historical averages (2013–2016), by episode month, Ontario, Canada

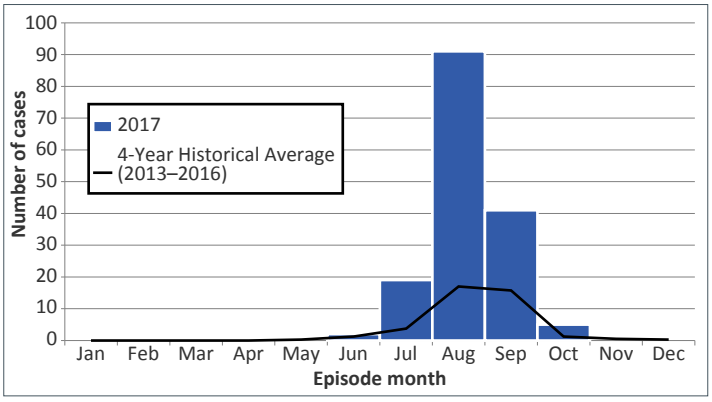
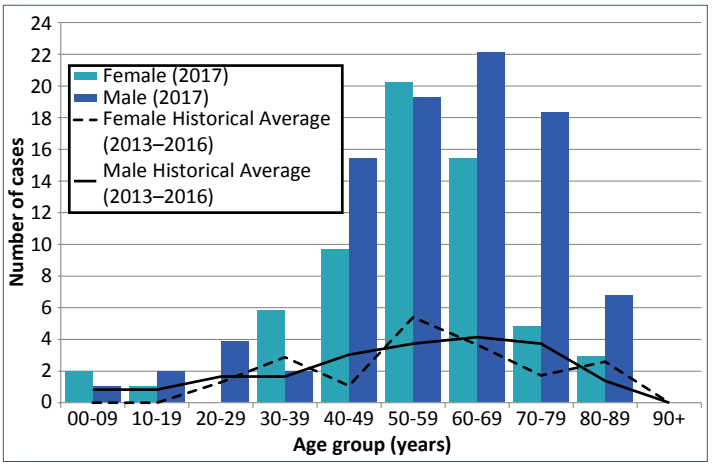


Figure 4: Number of confirmed and probable West Nile virus illness cases reported in 2017 compared to four-year historical averages (2013–2016), by age group[a] and sex, Ontario, Canada



[a] Age group refers to the age group (in years) of the individual at the time of illness

Age and sex distribution

Cases of WNV illness in 2017 ranged from five to 89 years old, with most cases in older age groups (median: 58 years old) and males (59.5% of provincial total) (**Figure 4**). In particular, 50.6% of the cases reported in 2017 were 50–69 years old and 51.3% were males over 45 years old. Overall, the age distribution in 2017 follows patterns observed in the previous four years. However, the male to female ratio was higher in the older age groups, particularly in the 40–49 (1.6 times), 60–69 (1.4 times), 70–79 (3.8 times) and the 80–89 (2.3 times) year age groups.

Clinical outcomes

Of the 158 cases reported in 2017, 38.6% (61 cases) presented with neurological complications, 37.3% (59 cases) presented with non-neurological syndrome, and 2.5% (four cases) were asymptomatic; illness presentation was not specified for 21.5% (34 cases) (**Table 2**). Hospitalization was indicated for 38.6% of cases reported in 2017 (61/158), of which 72.1% (44/61) presented with neurological complications and 14.8% (9/61) presented with non-neurological syndrome; illness was not specified for the remaining 13.1% (8/61). The median age of hospitalized cases was 65 years old (range: 5–80 years old), and 68.9% (42/61) were male. Of the 158 WNV illness cases reported in 2017, nine died (case fatality rate: 5.7%), with WNV illness reported as the underlying or contributing cause for six cases (66.7%). The median age of the nine fatal cases was 79 years old (range: 54–89 years old) and six (66.7%) were male. In comparison, the number of deaths reported between 2013 and 2016 ranged from zero to six per year.

Table 2: Number and proportion of confirmed and probable West Nile virus illness cases, by severity of illness and year, in Ontario, Canada, 2013–2017

Severity of Illness	2013		2014		2015		2016		2017	
	n	%	n	%	n	%	n	%	n	%
Clinical Illness (all cases)	57	100	13	100	34	100	56	100	158	100
Asymptomatic	3	5.3	1	7.7	1	2.9	4	7.1	4	2.5
Non-neurological syndrome	22	38.6	3	23.1	12	35.3	13	23.2	59	37.3
Neurological complications	17	29.8	6	46.2	14	41.2	32	57.1	61	38.6
Unspecified illness	15	26.3	3	23.1	7	20.6	7	12.5	34	21.5
Hospitalization[a]	19	33.3	4	30.8	13	38.2	27	48.2	61	38.6
Death[b]	2	3.5	0	0.0	0	0.0	6	10.7	9	5.7

Abbreviation: n, number

[a] Percent (%) refers to the proportion of total annual cases that were reported as hospitalized due to their disease at the time of data extraction; underreporting of hospitalizations may occur in the integrated Public Health Information System (iPHIS), particularly if the case was hospitalized after follow-up by the public health unit, or if the case was hospitalized for other reasons when they acquired West Nile virus

[b] Percent (%) refers to the proportion of total annual cases for which a death was reported. Deaths were counted if the case was reported as having died due to their disease at the time of data extraction; variations in follow-up may exist among public health units in determining outcomes for all reportable diseases as well as how the deaths are entered in the type/cause of death fields in iPHIS

Discussion

The number of WNV illness cases reported in Ontario in 2017 was higher than the previous four years. This trend corresponds to trends in WNV-positive mosquito pools identified in Ontario (14). The seasonality of WNV illness in 2017 was also typical of patterns observed in previous seasons in Ontario and the United States (2,15). However, while the distribution of WNV illness in urban areas of Ontario (Toronto, Ottawa, Windsor-Essex County, York Region and Peel Region) is consistent with mosquito surveillance previously conducted in the province, increases in WNV illness cases were also observed in low population, rural PHUs in eastern Ontario (6,16). The age and sex distribution of cases reported in 2017 were also similar to previous years, with older age groups and males disproportionately affected. The majority of cases with severe clinical outcomes (neurological complications, hospitalizations and deaths) were also older and mostly male, consistent with previous findings that increasing age and being male are risk factors for severe WNV illness outcomes and long-term sequelae (15,17).

Implications and next steps

While the cause of the increase is not immediately clear, there may some contributing factors. Ontario experienced a relatively warmer (above historical average) 2016–2017 winter, followed by average spring and early summer temperatures (18). The warmer winter temperatures allowed for increased survival of overwintering *Culex* mosquitoes and an increased number of WNV-positive mosquitoes in the spring and summer to start the transmission cycle (19,20). This is consistent with the observation that, while the increase in 2017 was above expected, average temperatures in spring and early summer were not high enough to allow for quicker mosquito development and virus amplification to reach levels similar to 2012 (20,21).

In terms of next steps, there are several public health implications. The 2017 surveillance period highlights the important role of robust and comprehensive surveillance data in WNV prevention and control efforts. Given that temperature is a driving factor in mosquito development and virus amplification, monitoring temperature in conjunction with ongoing mosquito and human surveillance is necessary for early detection and to assess the fluctuating risks of WNV transmission. Mosquito surveillance conducted over several years, particularly in the eastern PHUs, is needed to determine if risk levels are changing in this region and in the province. Such surveillance data are essential to informing targeted public health actions, such as increasing awareness and education related to preventive measures and early recognition, particularly in the older portions of the population and those at risk of severe disease.

Limitations

As with most passive surveillance systems, the true incidence of disease is underreported due to a variety of factors, such as disease awareness, health care seeking behaviours and variations in clinical testing. Therefore, the incidence of WNV illness is likely underestimated, and skewed toward cases with severe clinical symptoms and outcomes. Given that the majority of WNV cases are asymptomatic or have mild symptoms, and are likely not captured by surveillance, estimating the true burden of WNV infections in the province is particularly challenging. The Public Health Agency of Canada has estimated that 18,000–27,000 WNV infections in Canada may have gone unreported or were unrecognized between 2002 and 2013 (4). As well, the geographic distributions presented in this report are based on the PHU of residence of the case at the time of illness onset and are not necessarily the location of exposure. Exposure locations reported in iPHIS (including travel-related exposure) are not sufficient to determine location of acquisition.

Conclusion

The number of WNV illness cases reported in Ontario has risen in recent years. While variations in vector biology, weather and human activity make predicting the extent and impact of WNV challenging, it is expected that as ambient temperature increases, the number of WNV illness cases in Ontario and Canada may increase. Continued and strengthened mosquito and human surveillance, public health action to increase awareness of preventive measures, and clinical care focused on early recognition and treatment, will all help to mitigate the impact of WNV illness in Canada.

Authors' statement

SW – Conceptualization, methodology, analysis, interpretation, writing original draft, review and editing
MPN, CBR – Conceptualization, methodology, analysis, interpretation, writing original draft (parts), review and editing
KOJ, SJ, TB, DS – Methodology, analysis, interpretation, review and editing

Conflict of interest

None.

Acknowledgements

The authors thank Ontario's public health units for their continued commitment to West Nile virus illness case management, surveillance and reporting.

Funding

This work was supported by Public Health Ontario.

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Canadian Pandemic Influenza Preparedness: Antiviral strategy

B Henry[1,2] on behalf of the Canadian Pandemic Influenza Preparedness Task Group

Abstract

Antiviral medications are the only influenza-specific pharmaceutical intervention that can be used to mitigate the impact of a pandemic until a vaccine becomes available. The *Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector* (CPIP) outlines how federal, provincial and territorial governments will work together to ensure a coordinated and consistent health sector approach to pandemic influenza preparedness and response. This article summarizes Canada's pandemic influenza antiviral strategy as described in the recently updated CPIP Antiviral Annex. The antiviral strategy builds on lessons learned during the 2009 H1N1 pandemic. Key elements of the strategy include ensuring equitable, timely and coordinated access to antivirals through government stockpiles; having regulatory mechanisms in place that facilitate timely access to antivirals; providing timely and evidence-based clinical guidance; maintaining effective stockpile management practices; and monitoring antiviral utilization, effectiveness and safety. Since the CPIP is an evergreen document, this Annex will be updated as new information warrants.

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Suggested citation: Henry B on behalf of the Canadian Pandemic Influenza Preparedness Task Group. Canadian pandemic influenza preparedness: Antiviral strategy. Can Commun Dis Rep 2019;45(1):38-43. https://doi.org/10.14745/ccdr.v45i01a05

Keywords: influenza, pandemic, antivirals, public health

Introduction

Antiviral drugs are an integral component of Canada's pandemic preparedness and response plan. Antivirals are the only influenza-specific pharmaceutical countermeasure that can be used to mitigate the impact of an influenza pandemic in the 4–6 months prior to vaccine availability, using the current egg-based vaccine production technology. The 2009 influenza pandemic was the first time the government stockpiles of antivirals were deployed and presented an opportunity to test Canada's antiviral strategy. The widespread use of antiviral drugs during the pandemic contributed greatly to the evidence base on antiviral safety and effectiveness.

Canada's renewed antiviral strategy is outlined in the updated *Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector* (CPIP) Antiviral Annex (1,2). The CPIP Antiviral Annex provides technical advice for federal, provincial and territorial (FPT) ministries of health and other government departments that have roles in providing health care to select populations. It describes the specific roles and responsibilities of those involved in providing equitable, coordinated and timely access to antivirals for eligible people living in Canada via FPT stockpiles, enabling regulatory mechanisms, provision of clinical guidance, stockpile management and the monitoring of antiviral use, safety and effectiveness.

The Canadian Pandemic Influenza Preparedness Task Group recently updated the CPIP Antiviral Annex to incorporate the experience gained during the 2009 pandemic and to reflect Canada's pandemic goals of minimizing serious illness, death and societal disruption. The CPIP Antiviral Annex should be read in conjunction with the main body and other technical annexes of the CPIP as they are intended to be used together.

This article summarizes Canada's antiviral strategy as outlined in the CPIP Antiviral Annex. It is part of a series outlining Canada's approach to pandemic influenza preparedness (3–7).

Objectives of Canada's Pandemic Antiviral Strategy

The objectives of the antiviral strategy are to support Canada's pandemic goals by:

- Maintaining and providing timely access to a supply of antivirals
- Reducing the severity and duration of disease through early treatment of influenza cases
- Controlling outbreaks of pandemic influenza in closed health care facilities (e.g., long-term care homes) and other closed facilities (e.g., prisons) and settings (e.g., remote and isolated communities) where residents are at higher risk of severe outcomes of influenza
- Possibly reducing transmission of the influenza virus by reducing the level and duration of viral shedding; and
- Reducing the impact of influenza-related absenteeism in the workplace due to worker illness or family caregiving

Canadian context

During an influenza pandemic, eligible people will be provided with antivirals by the health authority of the province or territory in which they reside. Some federal departments such as Department of National Defence, Global Affairs Canada, and Correctional Service Canada also have a role in providing and/or administering antivirals to specific populations. Each jurisdiction has its own health care delivery model and will determine how antiviral drugs will be made available during a pandemic.

Canada's vast and variable geography and diverse population can present challenges to the delivery of antivirals during a public health emergency. Pandemic plans need to take into consideration the impact of adverse weather conditions, long distances from pharmacies and lack of systems that allow timely access to antivirals. As such, pre-positioning of antivirals is an important consideration for provinces and territories with remote and isolated communities.

The diversity of Canada's population means that jurisdictional pandemic plans need to take into consideration language, culture, ethnicity and religious or spiritual beliefs so that all populations and communities can understand how best to access antiviral treatment in a timely manner.

Key elements of the antiviral strategy

Timely access

Timely access to antivirals is fundamental to Canada's antiviral strategy. Studies conducted during the 2009 influenza pandemic demonstrated that antiviral treatment is most effective when started as early as possible within 48 hours of the onset of symptoms (8,9). The experience identified a number of challenges to providing timely access to antivirals including the triggers for releasing antivirals from stockpiles; logistical issues in distribution; and timeliness of clinical guidance.

There are also unique planning and ethical considerations for individuals whose needs may not be fully addressed by standard services and resources (e.g., those who are culturally or socially isolated, have low income, are recent immigrants). Providing timely treatment requires delivery models that provide rapid access to clinical assessment and make antiviral drugs available through multiple distribution routes (10). The CPIP Antiviral Annex identifies a variety of options for jurisdictions to assess to expedite antiviral treatment including telephone assessment; expanding prescribing authority (e.g., registered nurses or pharmacists); identifying mechanisms for access in communities with limited or no access to health care workers; and providing advance prescriptions.

The CPIP Antiviral Annex demonstrates how other components of Canada's pandemic preparedness and response are integral to the antiviral strategy including: epidemiological surveillance to inform antiviral decision-making, laboratory surveillance of circulating strains and virus susceptibility to antiviral drugs, health care services to provide access to influenza assessment and antiviral treatment, and timely communications for the public and health care providers on antiviral drug access.

Antiviral supply

At present, there is no domestic source of influenza antiviral manufacturing in Canada. To ensure timely and equitable access to antiviral drugs across Canada, FPT governments maintain supplies of antivirals, primarily in two stockpiles:

- The National Antiviral Stockpile (NAS), which is the collective name for the antiviral stockpiles held by each province and territory. In the event of a pandemic, eligible people will be provided with antivirals by the province or territory in which they live. The 2009 influenza pandemic marked the first time the provinces and territories released stock from the NAS
- The National Emergency Strategic Stockpile (NESS) is a federal stockpile of emergency pharmaceuticals and medical supplies, including antivirals. The NESS antiviral stockpile is intended to provide surge capacity to provinces and territories if their own NAS supply is depleted. The NESS target size for antiviral holdings is the equivalent of 2.5% population coverage

Following the 2009 influenza pandemic, Canadian experts and decision-makers reviewed the use, size and composition of the NAS. The review included a systematic review of the literature

on the safety and effectiveness of neuraminidase inhibitors for seasonal, pandemic and novel influenza; a scan of the antivirals licensed for sale in Canada; an update on the global status of antiviral drug resistance; international stockpiling practices; and mathematical modelling on the optimal size of the NAS. The following is a summary of the final recommendations:

- At the time of an emerging pandemic, the NAS will be used primarily for early treatment, with limited use for post-exposure prophylaxis. Real-time advice will be provided on the use of antivirals, based on available data, to optimize the use of the stockpile
- The size of the NAS should range between 17.14% and 23.19% population coverage. This is based on the projected number of people in Canada that would need treatment in an influenza pandemic with high clinical severity and moderate to high transmissibility. Each province and territory makes its own decision on the size of antiviral stockpile to hold
- The NAS should include oseltamivir (adult and pediatric doses) and other antivirals with different resistance profiles to mitigate the risk of oseltamivir resistance. At this time, the only licensed antiviral meeting this criterion is zanamivir. The recommended proportion of zanamivir is between 18% and 25% of the NAS

These recommendations were endorsed by the Public Health Network Council in 2017 and are expanded upon in the CPIP Antiviral Annex. The NAS and the NESS both currently hold the antivirals oseltamivir and zanamivir, which belong to the neuraminidase inhibitors drug class. FPT governments procure antivirals for their respective pandemic stockpiles through joint supply contracts with antiviral manufacturers. Maintaining stockpiles is a key element of the antiviral strategy because without them there is no guarantee of sufficient supply from commercial markets alone, given that demand for antivirals globally could be high, especially in a more severe pandemic.

Regulatory mechanisms for emergency access

Health Canada has the authority for licensing drug products, including antiviral drugs, in Canada. In a pandemic, circumstances could arise in which licensed antivirals are not available to adequately treat specific individuals or groups. Such circumstances may include seriously ill patients who are not responding to therapy with licensed antivirals or for certain age groups for which the licensed antivirals are not indicated for use. Health Canada has the legal means to make certain drugs available expediently in a public health emergency. Available mechanisms include an interim order issued by the federal Minister of Health, authorization under Regulations for Extraordinary Use New Drugs, the Special Access Program, a regulatory pathway to enable Access to Drugs in Exceptional Circumstances and authorization of the use of investigational drugs in clinical trials.

Stockpile management

The 2009 influenza pandemic experience highlighted the need for well-established antiviral stockpile management practices, including storage, distribution and inventory management.

Storage

In the interpandemic period, the NAS and NESS are held centrally by each FPT jurisdiction in temperature-controlled warehouses or hospital pharmacies.

It is critical that antiviral drugs be stored and transported in a manner that minimizes exposure to conditions (e.g., temperature, humidity and light) that can reduce the drugs' integrity, quality and efficacy for use during a pandemic. Therefore, antivirals need to be handled according to Good Manufacturing Practices and requirements set out by the manufacturer. The responsibility for maintaining the required storage conditions lies with each party involved in the transportation and storage chain, including dispensing locations.

Distribution

Effective distribution logistics are crucial to provide timely access to antivirals in a pandemic. Logistics are determined by each province and territory. At the time of a pandemic, jurisdictions will leverage existing distribution systems to distribute the stockpiled antivirals from the central storage facilities to the dispensing locations, while factoring in the environmental impact and geographic conditions. Dispensing locations may include one or more of the following options: community pharmacies; district health authorities; hospitals; community health centres; remote nursing stations; influenza assessment centres; and correctional facilities. To facilitate timely access to antivirals, provinces and territories may also consider delegating prescribing authority to other health care providers, such as registered nurses and pharmacists.

The trigger for releasing antivirals from the NAS for distribution will be based on each jurisdiction's risk assessment, taking into consideration anticipated timing and impact of the pandemic, as well as the need to ensure access to antivirals from the start of a pandemic virus activity. In some parts of the country, such as in remote and isolated communities, antivirals may need to be pre-positioned (i.e. in advance of pandemic virus activity or even in the interpandemic period) to ensure timely access.

Inventory management

Real-time inventory management is necessary to track antiviral stockpile capacity and to anticipate shortages. FPT collaboration on real-time data on antiviral holdings and rate of depletion will be important to have by way of a reporting process. Currently, there is no standardized way to collect NAS inventory data. In the 2009 influenza pandemic, each province and territory developed its own method of tracking antiviral distribution and utilization, which included leveraging existing administrative

drug formulary systems in retail pharmacies combined with paper-based reporting.

Clinical recommendations for antiviral use

Guidance for practitioners on the use of antiviral drugs for seasonal influenza is routinely provided by experts from the Association for Medical Microbiology and Infectious Disease Canada (11). Virus-specific guidance for clinicians on the recommended use of antivirals will be provided at the time of an emerging pandemic. The guidance will be based on a risk assessment using the available epidemiology of the pandemic and available scientific evidence, and can be expected to evolve as new information becomes available. Existing scientific expertise will be leveraged to develop clinical guidance and ongoing assessments. The CPIP Antiviral Annex identifies the relevant information to be included in clinical guidance and includes an example of such guidance from the 2009 pandemic.

At the time of a pandemic, guidance may also be provided on the use of antivirals to control outbreaks of pandemic influenza in closed facilities and settings where residents are at higher risk of severe outcomes from influenza. If an antiviral supply shortage is anticipated, antiviral use will be prioritized based on a prioritization framework that is included in the CPIP Antiviral Annex.

Antiviral safety monitoring

Plans to monitor the safety of antivirals during an influenza pandemic are based on current drug safety monitoring practices. In the event of an influenza pandemic, Health Canada's Marketed Health Products Directorate will conduct post-market safety surveillance aimed at monitoring, identifying and assessing possible safety issues related to antivirals, developing risk mitigation measures and providing timely communications on potential safety issues identified for these products.

It is expected that reporting adverse reactions will also be based on the current reporting practices. This requires drug manufacturers reporting serious and unexpected adverse reactions that come to their attention to Health Canada. Adverse reaction reports from health professionals and consumers are submitted on a voluntary basis either directly to Health Canada or through the manufacturer.

Antiviral resistance monitoring

As with seasonal influenza, it is important to have in place a surveillance program to detect antiviral drug resistance during an influenza pandemic. The novel or pandemic influenza virus strain's susceptibility to antivirals will be tested on an ongoing basis by the National Microbiology Laboratory (NML). Plans call for provincial laboratories to submit a proportion of influenza virus specimens to the NML for antiviral drug resistance testing, as well as testing of samples from clinical situations in which drug resistance is suspected. Information on antiviral susceptibility during the interpandemic period is summarized on a weekly basis in FluWatch reports (12). More information on plans for laboratory testing in a pandemic is available in the CPIP Laboratory Annex (13).

Risk management approach

Canada's pandemic antiviral strategy is subject to numerous risks, including the possibility that the pandemic influenza strain is or becomes resistant to the stockpiled antivirals. The CPIP Antiviral Annex incorporates the CPIP new risk management approach to support scalable and flexible pandemic planning, identifying antiviral-specific risks and events and the proposed mitigation. **Table 1** provides an example of how the CPIP risk-based approach is applied to the antiviral strategy.

Table 1: Risks affecting the antiviral strategy, their implications and potential mitigation or response

Factor/event	Implications	Potential mitigation/ response
Supply of antivirals becoming depleted	• Will not be able to treat as many people as anticipated (will impact on pandemic objectives) • Health care provider and public distress • May not be able to ensure equitable access	• Activate measures for surge capacity (e.g., expedited purchases through contracts or advance purchase agreements, NESS, interjurisdictional loans) • May need to prioritize antiviral use
Shortage of some specific formulations or products	• Unable to provide optimal treatment regimens	• Monitor NAS/NESS holdings closely to allow for timely restocking • Activate measures for surge capacity, including procurement of needed formulations if available • Combine other strengths or compound suspensions to obtain required dose(s) • Adjust recommendations and prioritize use
Viral resistance to stockpiled antiviral drugs	• Dramatic reduction of available supply of effective antivirals • Resistance to all antivirals would effectively remove antiviral treatment option • Some groups may be disproportionately impacted, e.g., zanamivir not authorized in young children	• Include antivirals with different resistance profiles in NAS • Adjust antiviral recommendations and prioritize use • Procure effective antivirals, if available • If there is resistance to oseltamivir, consider authorizing lower age for zanamivir diskhaler use • Engage rapid clinical research into effective regimens

Abbreviations: NAS, National Antiviral Stockpile; NESS, National Emergency Strategic Stockpile

Discussion

Canada's pandemic influenza preparedness and response require a multifaceted approach. Antiviral drugs are an essential component, being the only pharmaceutical intervention until vaccine becomes available.

Central to Canada's pandemic antiviral strategy is the ability to provide timely access to a secure government controlled supply of safe and effective antivirals. Since the 2009 influenza pandemic, the antiviral strategy has been strengthened through updated recommendations for the NAS; identification of best practices in stockpile management; new regulatory pathways to make certain drugs available expediently; strategies to provide timely clinical guidance in a pandemic; and plans for safety surveillance for antiviral drugs in a pandemic. In addition, antiviral drug susceptibility is monitored on an ongoing basis by the NML. The risks to the antiviral strategy have been identified and mitigation strategies proposed for jurisdictions to consider in their pandemic planning.

Canada's antiviral strategy is subject to change based on advances in antiviral drug research and development. Since the CPIP is an evergreen document, the Antiviral Annex will be updated as required.

The Antiviral Annex also demonstrates the importance and linkage of other pandemic preparedness components to the antiviral strategy including surveillance, laboratory monitoring, access to health care services, and timely communication strategies. The Annex outlines how all levels of government have a crucial role in ensuring timely and equitable access to antivirals for Canadians at the time of an influenza pandemic.

Authors' statement

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Conflict of interest

None.

Acknowledgements

Many thanks to the Public Health Agency of Canada's Immunization Programs and Pandemic Preparedness Division, for their contribution to the preparation of this summary: E Henry (Director), L Paddle, S Smith, A Rousseau, J Williams, F Lalonde and R Stirling.

Funding

The work of the Canadian Pandemic Influenza Preparedness Task Group is supported by the Public Health Agency of Canada.

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Reference

1. Canada Communicable Disease Report Editorial Team. CCDR has adopted the Creative Commons CC BY 4.0 license. Can Commun Dis Rep 2019;45(1) 44.

Suggested citation: Canada Communicable Disease Report Editorial Team. CCDR announces new online manuscript submission capacity. Can Commun Dis Rep 2019;45(1):44

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CANADA COMMUNICABLE DISEASE REPORT

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