Surveillance of laboratory exposures to human pathogens and toxins: Canada 2018

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Abstract

Background: The Laboratory Incident Notification Canada (LINC) surveillance system monitors laboratory incidents reported under the *Human Pathogens and Toxins Act*. The year 2018 marks the third complete year of data.

Objective: To describe the laboratory exposure and laboratory-acquired infection incidents that occurred in Canada in 2018 compared to previous years, and then by sector, human pathogens and toxins involved, number of affected persons, incident type and root causes.

Methods: Laboratory incidents that occurred in 2018 were reported through the LINC system. The number of laboratory incidents, people exposed and laboratory-acquired infections were compared to previous years, then the incidents were analyzed by sector, human pathogen or toxin involved, the type of incident, people exposed, route of exposure and root causes. Microsoft Excel 2016 was used for descriptive analysis.

Results: In 2018, there were 89 exposure incidents to human pathogens and 235 people were exposed. There were five suspected and one confirmed laboratory-acquired infections. This was approximately twice the number of exposure incidents that were reported in 2017 (n=44) and 2016 (n=46). The highest number of exposure incidents occurred in the academic and hospital sectors, and the ratio of incidence to licences was the lowest in the private sector. The majority of incidents (n=50; 56%) involved Risk Group 2 human pathogens that were manipulated in a Containment Level 2 laboratory. Most exposures were related to sharps or procedures and the most common people exposed were laboratory technicians. Human interaction and standard operating procedures were the leading root causes.

Conclusion: Although overall the annual incidence of laboratory exposures in Canada remains relatively low, the incidence was higher in 2018 than in previous years. Whether this is a true increase in incidence or an increase in reporting is not known at this time as baseline estimates are still being established.

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Keywords: laboratory exposures, laboratory incidents, laboratory-acquired infections, human pathogens and toxins, surveillance, Laboratory Incident Notification Canada, Centre for Biosecurity

Introduction

Laboratory work with human pathogens and toxins involves risk of incidents that can cause exposures through accidental or deliberate release. These exposures can affect individuals directly involved in the incident or in proximity. They can potentially be a public health threat if community transmission occurs. Timely reporting of exposure incidents is critical for the prevention of potential outbreaks, as it allows rapid action in response to detected exposures.

In recent years, there has been growing public concern about the potential of a pandemic arising from laboratory-acquired infections as more countries are allowing gain-of-function studies, where researchers are increasing transmissibility and virulence of pathogens such as influenza virus (1,2). Having a strong biosafety and biosecurity regime is essential to address these concerns.

The Public Health Agency of Canada's Centre for Biosecurity is mandated to prevent, detect and respond to public health risks posed by the use of human pathogens and toxins in Canada. The Centre for Biosecurity oversees activities conducted under the *Human Pathogens and Toxins Act* (HPTA) and the *Human Pathogens and Toxins Regulations* (HPTR). In December 2015, the Centre for Biosecurity established a national surveillance system, the Laboratory Incident Notification Canada (LINC), for the mandatory reporting of laboratory incidents involving human pathogens and toxins. Facilities conducting controlled activities with human pathogens and toxins are required to be licensed. One licence can represent multiple containment zones, but a single licence cannot cover different risk groups (RGs). Containment zones can comprise typical laboratory working areas, vaccine production areas or even animal care facilities. Licensed facilities determine how to set up the framework of their licences based on these requirements. Upon registering for a licence, facilities self-identify the one sector that best represents them in terms of organizational structure. The sector choices are academic, hospital, private industry/business, public health or other government.

In accordance with the HPTA/HPTR, facilities conducting controlled activities with human pathogens and toxins must notify the Centre for Biosecurity at the Public Health Agency of Canada without delay of laboratory incidents involving pathogens and toxins at RG2 or higher levels (3). The Centre for Biosecurity provides a response without delay including timely follow-up. This could include biosafety advisories and other alerts regarding emerging trends detected and potential patterns of concern for continuous improvement of biosafety and biosecurity in Canada.

Notifications submitted to the LINC system can include exposure and nonexposure incidents. A laboratory incident can involve a potential or actual exposure to a biological agent, whether it causes a laboratory-acquired infection or not. A non-exposure incident can include inadvertent possession, production or release of a pathogen or toxin; a missing, lost or stolen pathogen or toxin; or a security-sensitive biological agent not received within 24 hours of expected arrival (4). In order to maximize the reporting of these incidents and ensure compliance with the HPTA, the Centre for Biosecurity conducts routine compliance promotion, monitoring and verification activities. It has also been reporting information on laboratory incidents annually to stimulate information sharing, increase awareness and promote reporting (5,6).

This study provides a descriptive summary of laboratory incidents that occurred in Canada in 2018, focussing on data of exposures and laboratory-acquired infections. The objective of this report is to briefly compare exposure incidents to the data from previous years and to describe laboratory exposures by sector, human pathogen and toxin involved, incident type, people exposed, route of exposure and root causes.

Methods

Data sources

The Biosecurity Portal is the "outward facing" portion of the LINC that facilitates notification and reporting of laboratory incidents via the submission of notification reports and follow-up report(s). A Customer Relationship Management system is used as the "inward facing" platform for capturing LINC data that is then exported to Excel for analysis.

For this report, data on laboratory incidents that occurred between January 1 and December 31, 2018 were extracted from the Customer Relationship Management system. Microsoft Excel 2016 was used for the descriptive analysis.

Exposure incidents included those with the potential to cause infection/intoxication and those leading to a confirmed or suspected laboratory-acquired infection involving RG2 to RG4 human pathogens and toxins that are within the scope of HPTA/HPTR. Excluded from the analysis were duplicate entries, and incidents and reports that were not within the scope of HPTA/HPTR, such as incidents involving RG1 human pathogens or pathogens in their natural environment.

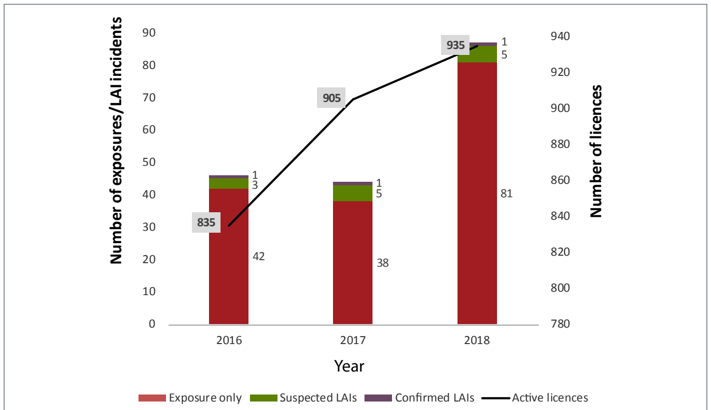
Analysis

Data from reports submitted to the LINC were extracted into Microsoft Excel 2016. The total number of incidents per licence was first compared with reported data from 2017 and 2016. Laboratory incidents were then analyzed by sector, human pathogens or toxins involved, incident type, people exposed, route of exposure and root causes. Some trends were identified through qualitative analysis during compliance monitoring and verification activities.

Results

In 2018, there were 89 exposure incidents to human pathogens, 235 people were exposed and there was one confirmed laboratory-acquired infection. This was approximately twice the number of exposure incidents in 2018 (n=89) than in 2017 (n=44) and 2016 (n=46) (3,4). The number of confirmed laboratory-acquired infections remained the same (n=1) (**Figure 1**). As of December 31, 2018, there were 985 active licences; 461 (47%) were in the private industry sector, 203 (21%) in the hospital sector, 200 (20%) in academia, 94 (9%) in other (non–public health) government sector and 27 (3%) in the public health sector. Overall this represented about a 20% increase in the number of active licences, from 2016 (n=835). There was an increase in the ratio of exposure incidents to active licences in 2018 (1:11) compared to 2017 (1:20) and 2016 (1:18) (data not shown).

Figure 1: Reported exposure, confirmed and suspected laboratory-acquired infection incidents and active licences, Canada, 2016–2018

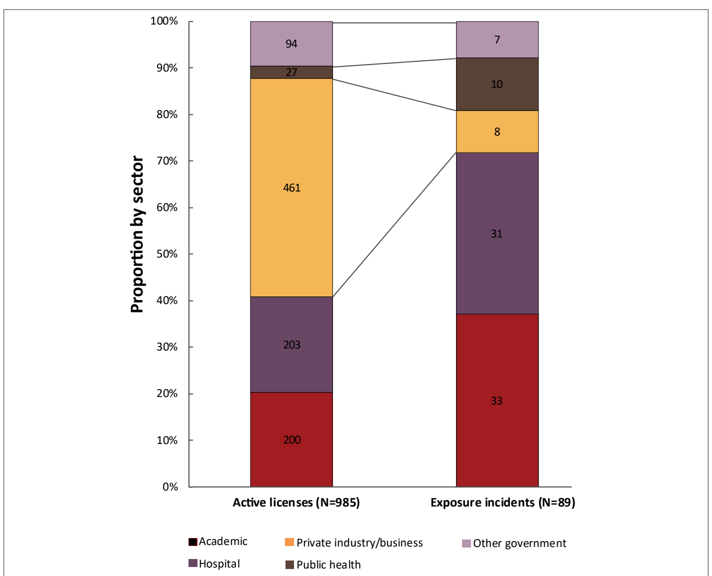


Abbreviation: LAI, laboratory-acquired infection
Sources: Data for 2018 were retrieved from the Laboratory Incident Notification Canada (LINC) system. Data for 2016 and 2017 were retrieved from published reports (5,6)

Exposure incidents by sector

In 2018, the highest number of exposure incidents occurred in the academic (n=33; 37%) and hospital sectors (n=31; 35%) (**Figure 2**). The private sector had the highest proportion of active licenses (n=461; 47%) and a fairly low proportion of exposures reported (n=8; 9%), thus leading to the lowest ratio of incidents to licence (1:58). The public health sector has the highest ratio of incidents to licences with 10 reported exposures and 27 active licences (1:3).

Figure 2: Active licences and exposure incidents by sector, Canada, 2018



Notes: Sectors are self-identified by licensed facilities. "Academic" includes universities, veterinary colleges, colleges, CEGEP (publicly funded pre-university and technical colleges in the province of Quebec) and others; "hospital" includes academic-affiliated and non-academic–affiliated hospitals; "private industry/business" includes animal health, human health, biotechnology, pharmaceutical and the food industry, and pathogen and toxin distributors; "public health" includes federal, provincial, territorial and municipal government laboratories; "other government" includes veterinary/animal health, environmental and other governmental laboratories at the federal, provincial, territorial and municipal level
Source: Laboratory Incident Notification Canada (LINC)

The majority of exposure incidents involving human pathogens and toxins classified as RG2 (n=50) occurred in the academic sector (n=27; 54%); followed by the hospital sector (n=8; 16%); and private sector (n=7; 14%). Exposure incidents with pathogens classified as RG3 (n=32) mostly occurred in the hospital sector (n=20; 63%); followed by the public health sector (n=5; 16%) and academic sector (n=4; 13%) (data not shown).

Human pathogens and toxins

Of the 89 exposure incidents, the majority (n=50; 56%) involved RG2 human pathogens, 32 (36%) involved RG3 pathogens and one (1%) involved a toxin (**Table 1**). A total of 18 (20%) incidents involved security-sensitive biological agents at the RG3 level. The most frequently involved biological agents were bacteria (n=46), viruses (n=17) and fungi (n=10).

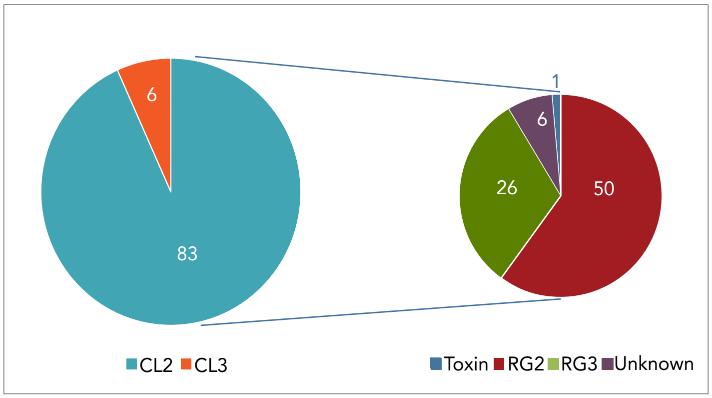
Table 1: Human pathogens and toxins involved in exposure incidents, by risk group level, Canada, 2018

Toxin or pathogen	Non SSBA		SSBA		Total	
	n	%	n	%	n	%
Toxin	1	1	–	–	1	1
RG2	50	77	–	–	50	56
Bacterium	30	46	–	–	30	34
Virus	12	18	–	–	12	13
Parasite	6	9	–	–	6	7
Prion	2	3	–	–	2	2
RG3	14	22	18	100	32	36
Bacterium	4	6	12	67	16	18
Virus	5	8	–	–	5	6
Fungus	4	6	6	33	10	11
Prion	1	2	–	–	1	1
Unknown	–	–	–	–	6	7
Total	65	100	18	100	89	100

Abbreviations: RG, risk group; SSBA, security-sensitive biological agent; –, non-applicable
[a] Toxins are not categorized by risk group. Toxins in the scope of the *Human Pathogens and Toxins Act* (HPTA) can be found in Schedule 1
Note: Percentages rounded to the nearest whole number
Source: Laboratory Incident Notification Canada (LINC)

Most exposure incidents occurred in Containment Level (CL) 2 laboratories (n=83; 93%) and the rest occurred in CL3 (n=6; 7%). Most incidents that occurred in CL2 laboratories involved a RG2 pathogen (n=50; 60%) (**Figure 3**).

Figure 3: Exposure incidents by containment level, and distribution of exposure incidents by risk groups in containment level 2 facilities, Canada, 2018



Abbreviations: CL, containment level; RG, risk group

There were 26 (29%) exposure incidents that involved an inadvertent possession of an RG3 biological agent in a CL2 laboratory (Figure 2). Of those, half (n=13; 50%) involved *Brucella melitensis* (n=7) and *Coccidioides immitis* (n=6) (**Table 2**), and mainly occurred in the hospital (n=11) sector. There was a spike in exposures to *Brucella* species, between March and November. Seven cases were reported, with the majority occurring in July and August. The confirmed laboratory-acquired infection involved *Salmonella enterica* subspecies *enterica* serovar Enteritidis.

Table 2: Numbers of laboratory incidents and exposed individuals by biological agent, Canada, 2018

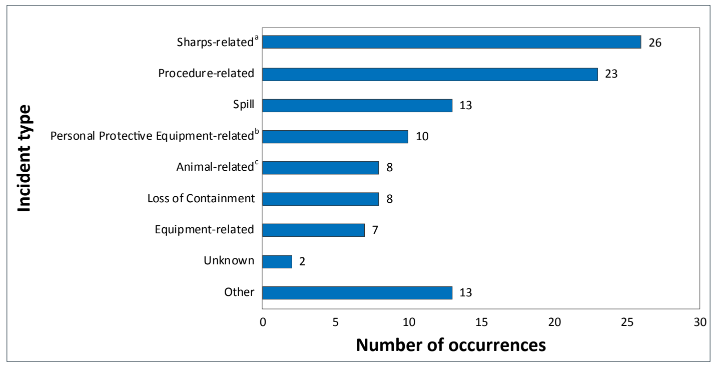
Biological agent	Incidents (N=89)	Exposed individuals (N=235)		
		Exposure only (n=229)	Suspected LAI (n=5)	Confirmed LAI (n=1)
RG2	50	63	4	1
Neisseria meningitidis	5	8	–	–
Staphylococcus aureus	3	3	–	–
Escherichia coli	2	4	–	–
Lymphocytic choriomeningitis mammarenavirus	2	2	1	–
Salmonella enterica	2	1	–	1
Other RG2 incidents	36	45	3	–
RG3	32	159	1	–
Brucella melitensis	7	105	1	–
Coccidioides immitis	6	15	–	–
Francisella tularensis	3	13	–	–
Mycobacterium tuberculosis	3	9	–	–
Other RG3 incidents	13	17	–	–
Toxins	1	1	–	–
Unknown	6	6	–	–

Abbreviations: LAI, laboratory-acquired infection; RG, risk group; –, non-applicable
Source: Laboratory Incident Notification Canada (LINC)

Incident types

There were 110 incident types identified for the 89 exposures reported. The most common types of exposure incidents were related to sharps (n=26; 24%) and procedures (n=23; 21%) (**Figure 4**). During a qualitative exposure incident review, a spike in incidents involving broken glass was identified. This was confirmed during on-site inspection.

Figure 4: Reported exposure incident type, Canada, 2018 (N=110)



Note: More than one incident type can be reported for the same incident
[a] Sharps-related includes needle sticks and other sharp injuries
[b] Personal protective equipment-related includes inadequate or failure of personal protective equipment
[c] Animal-related includes bites and scratches
Source: Laboratory Incident Notification Canada (LINC)

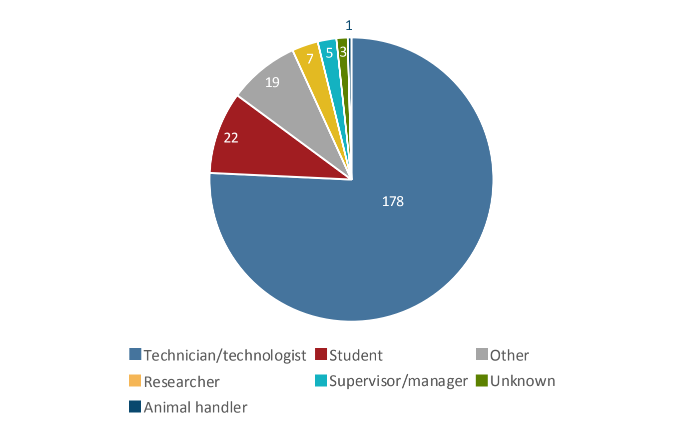
People exposed

In the 89 exposure incidents, 235 people were exposed to a human pathogen or toxin. Of these, five (2%) developed a suspected laboratory-acquired infection and one (0.4%) a confirmed laboratory-acquired infection. All six of the suspected or confirmed laboratory-acquired infections involved only one person exposed per incident.

In most exposure incidents (n=67; 75%), only one person was exposed. In 10 incidents (11%), 2–3 people were exposed and in seven incidents (8%), 4–10 people were exposed. There were missing data from two reports. The remaining incidents (n=3; 3%) involved 10 or more people exposed; these incidents occurred in the hospital sector, where 14, 29 and 53 people were exposed to *Brucella melitensis*.

Of the 235 people exposed, 39 (17%) received first aid treatment and 85 (36%) received prophylaxis within seven days of the incident. In addition, 8 (3%) people received postexposure prophylaxis more than seven days after the incident. The majority of people exposed were laboratory technicians (n=178; 76%) or students (n=22; 9%) (**Figure 5**).

Figure 5: Reported roles of people exposed, Canada, 2018 (N=235)

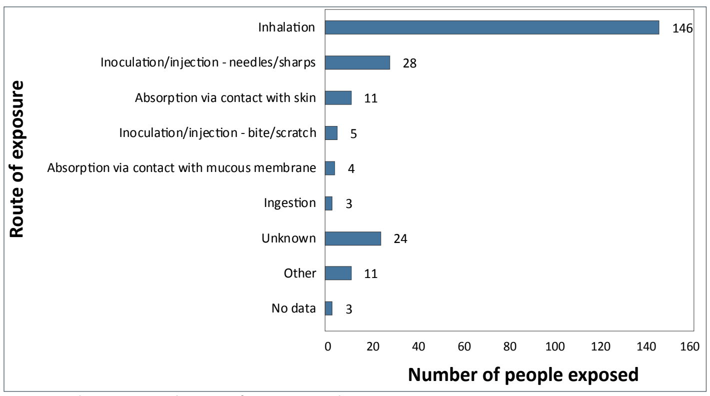


Source: Laboratory Incident Notification Canada (LINC)

Route of exposure

Of the 235 people exposed, the majority were exposed to pathogens or toxins through inhalation (n=146; 62%), while inoculation/injection of needles or sharps was the second most common route of exposure (n=28; 12%) (**Figure 6**).

Figure 6: Reported route of exposure, Canada, 2018 (N=235)



Source: Laboratory Incident Notification Canada (LINC)

Root causes and areas for improvement

In 2018, 233 root causes were identified for the 89 exposure incidents, an average of 2.6 root causes cited per incident. As shown in **Table 3**, human interactions and breaches to the standard operating procedures were the leading root causes (n=53; 23%, n=50; 22% respectively).

Table 3: Root causes and area of improvement reported for exposure incident involving human pathogens or toxins, Canada, 2018 (N=233)

Root cause/area of improvement	Example of areas of concern	Citations 2018	
		n	%
Human interactions	Workload constraints/ pressures/demands	53	23
Standard operating procedure	Procedures were not known /not followed correctly	52	22
Equipment	Equipment was not properly designed/maintained	32	14
Training	Training was not implemented or developed	27	12
Communication	There was no method or system for communication	24	10
Management and oversight	Supervision needed improvement	24	10
Other	Not applicable	21	9

Note: Percentages rounded to nearest whole number
Source: Laboratory Incident Notification Canada (LINC)

Discussion

Altogether, 235 people were exposed to human pathogens and toxins, through 89 exposure incidents. Of these, five incidents led to a suspected laboratory-acquired infection and one to a confirmed infection. Most exposure incidents occurred as a result of sharps and procedure breaches. Human interactions and lack of awareness or compliance with standard operating procedures were the leading root causes.

Although the overall annual reported incidence of laboratory exposures in Canada doubled in 2018 compared to the two previous years, it is not yet known if this rise represents a true increase in incidence or an increase in reporting because baseline estimates are still being established. The Centre for Biosecurity regularly conducts improvements to its LINC surveillance system to facilitate reporting and enhance clarity on regulatory requirements; it is possible that this has contributed to the increase in reporting. Since the LINC is still a fairly new surveillance system, it is likely that organizations will take some time to become accustomed to regulatory reporting requirements.

As in previous years, the number of incidents remained highest in the academic and hospital sectors (5,6). This is expected based on the difference between sectors in the nature of their work. Specifically, the identity of the biological agent is often unknown in hospital/diagnostic laboratories, increasing uncertainty of the risk status and the potential for exposure if the risk is underestimated. Private sector laboratories usually work on samples where the pathogen is already known (e.g. for live vaccine development).

Technicians were involved in the highest number of laboratory exposures, but this might be because they represent the largest proportion of workers manipulating human pathogens and toxins. Technicians are present in all sectors, whereas animal handlers, for example, are not. Of laboratory workers, students had the most exposures incidents after technicians. Anecdotal evidence suggests that students in the academic sector may not be fully aware of or comply with laboratory procedures and safety measures, which may result in the high number of exposure incidents in this population.

Several key findings in this study concur with results reported in the literature: the majority of laboratory-acquired infections occurred in CL2 laboratories; spills and sharps-related occurrences were the most frequently reported types of incident; the main routes of exposure were inhalation and inoculation; and human error and problems with standard operating procedures were the most commonly reported root causes (7,8). The literature also shows that exposure to bacteria is more common than other pathogens (9,10). Specifically, *Brucella melitensis, Coccidioides immitis, Francisella tularensis* and *Mycobacterium tuberculosis* are among the most common biological agents involved in exposures and laboratory-acquired infections (11–13).

Strengths and limitations

The main strength of this study is that it is based on mandatory and standardized reporting and incorporates a review process that includes validation of the self-reported data. This aspect of the surveillance system allows timely and systematic reporting that enables the Centre for Biosecurity to assess the corrective measures that have been put in place by licensed facilities – to identify potential risk factors and to disseminate information. For example, as a result of detecting the spike in incidents involving *Brucella* species in 2018, an email blast was distributed advising facilities to increase biosafety vigilance (*Biosafety and Biosecurity for Pathogens and Toxins eBlast, Laboratory Incidents Involving Brucella species in 2018 – a spike in July, August 2018*). Similarly, stakeholders were notified of the potential risk of sharps-related exposures caused by broken glass and informed of techniques to mitigate the risk (*Biosafety and Biosecurity for Pathogens and Toxins Newsletter, Laboratory Incident Notification (LINC) Program Feature Report: Exposure Related to Broken Glass, October 2018*). Thus, this regulatory and surveillance program enables the early detection of common and emerging risks and the dissemination of information to increase awareness of both the risks and the best mitigation strategies to stakeholders across Canada.

The main limitation of this study is that data may be incomplete, as under certain circumstances laboratory incidents may not be detected or may simply not be reported due to lack of awareness of the requirements or a reluctance to report incidents. This continues to be addressed with the various publications, such as the notification and reporting guideline under the HPTA/HPTR, newsletters and biosafety advisories as well as compliance monitoring and verifications activities that aim to promote reporting and compliance. At this time, we neither have accurate data on the number of licensed facilities that are non-compliant to reporting requirements nor on the number of workers in laboratories. This makes it difficult to draw meaningful conclusions on the significance of ratios of reports by sector.

Next steps

In a number of areas, additional data and analysis would be relevant to the Centre for Biosecurity's activities. For example, to assess if students have an increased risk for exposures it would be useful to identify the number of workers in laboratories across Canada and to review the proportionality of students by both roles and sector. Such information would help the Centre for Biosecurity to better identify risk and allow for more targeted outreach and compliance promotion.

Conclusion

Although the annual incidence of laboratory exposures in Canada remains low, the incidence of laboratory exposures was higher in 2018 than in previous years. It is not yet known if this is a true increase in incidence or an increase in reporting as baseline estimates are still being established. Analysis of the reported exposures serve to inform and update biosafety standards and guidelines for ongoing improvement of biosafety in Canada.

Authors' statement

DC — Incident monitoring, data analysis – original draft, writing, review and editing
LS — Data analysis – original draft, writing, review and editing
SE — Writing – review and editing
FT and MH — Incidence monitoring, writing – review, editing and supervision
EF — Writing – review, editing and supervision

Conflict of interest

None.

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Appendix

Definitions relating to the *Human Pathogens and Toxins Act* (HPTA)

Term	Definitions
Biological safety officer (BSO)	An individual designated for overseeing the facility's biosafety and biosecurity practices.
Containment level (CL)	Minimum physical containment and operational practice requirements for handling human pathogens or toxins safely in laboratory environments. There are four containment levels, from a basic (CL1) to the highest (CL4) level.
Containment zone	A physical area that meets the requirements for a specified containment level. A containment zone can be a single room, a series of co-located rooms or several adjoining rooms. Dedicated support areas, including anterooms (with showers and "clean" and "dirty" change areas, where required), are considered to be part of the containment zone.
Exposure	Contact with, or close proximity to, human pathogens or toxins that may result in infection or intoxication, respectively. Routes of exposure include inhalation, ingestion, inoculation and absorption.
Exposure follow-up report	A tool used to report and document incident occurrence and investigation information for an exposure incident previously notified to the Public Health Agency of Canada.
Exposure notification report	A tool used to notify and document preliminary information to the Public Health Agency of Canada of an exposure incident.
Incident	An event or occurrence involving infectious material, infected animals or toxins that have the potential to result in injury, harm, infection, disease or cause damage.
Laboratory	An area within a facility or the facility itself where biological material is handled for scientific or medical purposes.
Laboratory-acquired infection/intoxication	Infection or intoxication resulting from exposure to infectious material, infected animals or toxins handled or stored in the containment zone.
Licence	An authorization to conduct one or more controlled activities with human pathogens or toxins issued by the Public Health Agency of Canada under Section 18 of the HPTA. One licence can cover many containment zones.
Risk group (RG)	The classification of biological material based on its inherent characteristics, including pathogenicity, virulence, risk of spread and availability of effective prophylactic or therapeutic treatments, that describes the risk to the health of individuals and the public as well as the health of animals and the animal population.
Security-sensitive biological agents (SSBAs)	The subset of human pathogens and toxins that have been determined to pose an increased biosecurity risk due to their potential for use as a biological weapon. Security-sensitive biological agents are identified as prescribed human pathogens and toxins by Section 10 of the *Human Pathogens and Toxins Regulations* (HPTR). This includes all Risk Group 3 and 4 human pathogens that are in the *List of Human and Animal Pathogens for Export Control*, published by the Australia Group, as amended from time to time, with the exception of Duvenhage virus, Rabies virus and all other members of the Lyssavirus genus, Vesicular stomatitis virus, and Lymphocytic choriomeningitis virus. This also includes all toxins listed in Schedule 1 of the HPTA that are listed on the *List of Human and Animal Pathogens for Export Control* when in a quantity greater than that specified in Section 10 (2) of the *Human Pathogens and Toxins Regulations.*
For more definitions, please see the Canadian Biosafety Standard, Second Edition (4)	