Ninth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

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English only

Item 11 of the provisional agenda
Consideration of issues identified in the review of the operation of the Convention as provided for in its Article XII and any possible consensus follow-up action

Laboratory Incidents Notification Canada (LINC) Program Overview

Submitted by Canada

I. Background

1. Working with human pathogens and toxins (HPTs) in laboratory settings carries risks of exposure for laboratory personnel. With these risks in mind, the Centre for Biosecurity (CB) within the Public Health Agency of Canada (PHAC) enacted the Human Pathogens and Toxins Act (HPTA) and the Human Pathogens and Toxins Regulations (HPTR) in 2015.

2. The Laboratory Incident Notification Canada (LINC), a biosafety surveillance system, was put in place following the coming into force of the HPTA and HPTR to account for laboratory-acquired infections (LAI). This system mandates the timely reporting of laboratory incidents, at the federal level, involving Risk Group (RG) 2, 3, and 4 HPTs. This act mandates the timely reporting of laboratory incidents involving Risk Group (RG) 2, 3, and 4 HPTs. Regulated parties' licence holder or biological safety officer (BSO) must submit notification reports of laboratory exposure incidents using different standardized forms by logging into their account in PHAC's Biosecurity Portal, the external face of the electronic surveillance system, accessible online.

II. Notification reports of laboratory exposure incidents

3. The Exposure Report (ER) form captures the incident type, its description, location, dates of occurrence and reporting, exposure occurrence type, main activity, the biological agent involved and decontamination/disinfection methods and explanations. A follow-up report must also be provided to PHAC within 15-days for incidents involving a security sensitive biological agent (SSBA1), or 30-days for incidents involving non-SSBA pathogens. The follow-up report should additional details regarding the incident, including the results of the investigation of the incident and any corrective measures taken to mitigate or prevent a reoccurrence, if there was secondary transmission, number of secondary cases, risk ratings and risk, type of safeguards, investigation status and root cause analysis, corrective actions, and biosafety improvements. Details on each affected person in the incident are also captured.

4. Non-exposure reports (NERs) are also provided to PHAC by a license holder or BSO for incident types involving inadvertent possession, production, or release of an HPT;

[1] 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 Regulation.

missing, lost, or stolen biological agent(s); or SSBAs not received within 24 hours of expected arrival. A member of the LINC team reviews the NER to ensure that it is complete, that there are no on-going concerns or exposure risks, and/or to answer questions and provide guidance and tools to deal with the incident where appropriate.

5. Lastly, the Biosecurity Portal captures Other Reports (ORs). These reports include changes affecting biocontainment, prohibiting access to part of a facility for SSBAs, and risk group reduction/change of the pathogens used in the laboratory, which may lead to changes or amendments to their associated licence.

6. Reports involving exposure and non-exposure laboratory incidents reported to the Biosecurity Portal are first reviewed for accuracy and completeness and then shared with CB Inspectors, to review and determine whether any follow-up is required. Further, LINC data are extracted, cleaned and used to create summaries on a monthly and quarterly basis. The data are also used to produce an annual overview report of all laboratory incidents for publication in the Canada Communicable Disease Report (CCDR). The published report describes the distribution of laboratory incidents, focusing on exposures and LAIs and comparing exposure incidents with those of previous years, laboratory exposures by sector, type of pathogens and toxins, occurrence type, activity, number of people exposed (their regular role, education, years of laboratory experience and route of exposure) and root causes.

III. Lessons Learned

7. Though the LINC surveillance system allows for an almost real-time identification of causes of incidents and potential areas of improvement in laboratory safety, there are still limitations and areas for improvement. These include:

- **Possible under-reporting**: The magnitude and significance of under-reporting is currently unmeasured and is a confounder in the laboratory incident analysis and research. This is an on-going issue that is addressed by continually encouraging stakeholders through newsletters and biosafety advisories to report, as well as by conducting various compliance and monitoring activities;
- **Variability in the level of details provided**: In the reporting forms filled by stakeholders, there exists variability in the level of detail that the reporter provides. Changes to the phrasing of the reporting questions and possibly the addition of comment fields, outlining what specific details should be written in their incident descriptions, may help with these inconsistencies and with providing better data for qualitative analysis;
- **Workforce size**: LINC does not capture laboratory workforce size or distribution of roles within laboratories. However, licences are currently used as a proxy for workforce size;
- **Capturing of near misses**: The HPTA and HPTR do not mandate licensed stakeholders to report near misses. However, having information on the occurrence and frequency of near misses can also help with overall mitigation strategies;
- **RG1 pathogens and toxins:** Laboratories working with RG1 pathogens and toxins are not under the purview of the HPTA and HPTR, and are therefore not obliged to report any laboratory exposure incidents. However, CB has tried to address this issue by asking, with limited success, for voluntary reporting of exposure incidents involving RG1.

8. Overall, the lessons learned pave the way for enhanced biosafety and oversight in laboratory settings. More engagement and promotion activities with stakeholders in terms of laboratory best practices, such as yearly training and updates on laboratory standard operating procedures will likely also play a significant role in mitigating LAIs.