

**ASSESSING CANADA'S COMPLIANCE WITH THE CORE
CAPACITIES OF SURVEILLANCE AND RESPONSE OF
THE INTERNATIONAL HEALTH REGULATIONS (2005):
A CASE STUDY OF THE 2008 LISTERIOSIS OUTBREAK**

by

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ABSTRACT

Member states of the World Health Organization are expected to develop and maintain public health systems compliant with the Core Capacities of Surveillance and Response of the International Health Regulations(2005). Compliance with Core Capacities is intended to promote a local response sufficient to control public health emergencies of international concern. The 2008 listeriosis outbreak provided an opportunity to assess Canada's compliance with the IHR(2005). The activities and events of the outbreak were reconstructed using media and government reports, then assessed according to Core Capacities of detection, reporting, response, confirmation and risk assessment. Canada was deemed partially compliant with the IHR(2005) Core Capacities, as they were exhibited during the listeriosis outbreak. Resources and technical capacities of public health exhibited the potential to comply; however, obstacles in public health governance, policy and politics introduced delays in detection, investigation and risk communication of the outbreak, and uncertainty in setting direction for public health.

Keywords: Communicable Disease Control; Public Health; Outbreak; Surveillance; Canada; International Health Regulations; Listeriosis; Health Policy

Subject Terms: Communicable Diseases – foodborne diseases; Public Health – Canada; Public Health – government policy; World Health; Epidemiology

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CHAPTER 1: INTRODUCTION TO THE PUBLIC HEALTH PROBLEM

In August 2008, a deadly outbreak of listeriosis was identified in Canada that would lead to 57 cases and 21 deaths⁽³⁾. Outbreaks of listeriosis are a rare occurrence, but pose a serious public health risk when they do occur, often with case fatality rates upwards of 20%⁽⁴⁾. The case fatality rate of 38% for this particular outbreak far exceeds that of other high profile Canadian outbreaks such as SARS in 2003 (15%) and Walkerton in 2000 (0.04%)⁽⁵⁻⁷⁾. Cases associated with the outbreak were scattered across Canada and were linked to products from a large ready-to-eat meat processing plant in Toronto⁽⁸⁾. The responses mounted by the Canadian Food Inspection Agency (CFIA) and the Public Health Agency of Canada (PHAC) were heavily criticized by the medical community and the media for their delay in confirming the outbreak and slow institution of response measures⁽⁵⁾.

This criticism of the Canadian outbreak detection and response system comes at a time when the country is required to begin strengthening their public health surveillance and response systems to meet the requirements of the World Health Organization's (WHO) newly revised International Health Regulations (IHR). The IHR are designed to encourage the early detection and response to public health emergencies, particularly those that are serious, unusual or unexpected, a threat to international spread, or may lead to international trade or travel restrictions⁽¹⁾.

Assessments of Canadian public health capacities, like the one presented here, are essential to identify gaps and help strengthen Canada's potential to deal with emerging diseases and the international spread of disease in an increasingly globalized environment. The IHR provide a framework by which all countries can improve their public health capacities to limit the international spread of disease. The IHR also represent an international standard, that if met by all countries, will help ensure global public health security. In order to strengthen national public health capacities, there needs to be assessments of both public health policy and current public health practices in each country. This assessment provides the opportunity for current practices in

Canadian public health surveillance and response to be assessed according to the global minimum standard.

The purpose of this report was to assess the 2008 Canadian listeriosis outbreak according to the IHR Core Capacities of Surveillance and Response. The objective of the assessment was to determine if the Canadian response to public health emergencies, particularly foodborne outbreaks, is in line with WHO expectations for detection, reporting, response, confirmation and risk assessment.

CHAPTER 2: BACKGROUND

International Health Regulations

Introduction to the International Health Regulations

The International Health Regulations (IHR or the Regulations) have been the international standard for establishing and maintaining communicable disease surveillance systems for the past 50 years⁽⁹⁾. They are a legally binding international document put forth by the World Health Organization (WHO) and signed by almost all WHO member states. The purpose of the IHR is to provide a globalized legal framework that will help strengthen international defences against modern public health risks by supporting global outbreak alert and response, encouraging international surveillance and promoting transparent international reporting⁽⁹⁾.

History of the International Health Regulations

The first draft of the IHR, published in 1969, used a disease-specific framework that held no consideration for emerging or re-emerging diseases and outlined a prescribed set of 'specified maximum measures' to be implemented in the event of an outbreak of specified diseases⁽¹⁰⁾. The narrow scope of these Regulations and limited situational flexibility eventually led to their revision.

Pressure to revise the IHR (1969) culminated in 1995 at the 48th World Health Assembly. Recent outbreaks of hemorrhagic fever in the Congo and pneumonic plague in India highlighted the inability of the IHR (1969) to adapt to emerging and re-emerging infections and particularly their potential for international spread in an increasingly globalized environment⁽¹¹⁻¹³⁾. Technical reports like the one from the American Academy of Science identifying the risk of emerging infectious diseases provided further pressure for reforms⁽¹⁴⁾. The Severe Acute Respiratory Syndrome (SARS) outbreak in 2003 fuelled the revisions that began in 1995 by highlighting the ease with which emerging pathogens can spread around the globe if not detected and reported in a timely

fashion^(15, 16). This outbreak encouraged the need for a collective and coordinated defence against emerging public health threats not accounted for by the IHR (1969).

International Health Regulations (2005)

The IHR (2005) were built on the principle that timely and transparent notification of public health events, collaborative approaches to risk assessment, effective risk communication and localized responses to public health events would drastically reduce the potential for the international spread of disease⁽⁹⁾.

Under the IHR (2005), any event that may constitute a 'public health emergency of international concern' (PHEIC) is to be reported to the WHO⁽¹⁾. A PHEIC is defined as an "extraordinary event which is determined...to constitute a public health risk to other States through the international spread of disease and to potentially require an international response" and is inclusive of communicable, foodborne, chemical, and environmental events. To assist member states in identifying events that may constitute a PHEIC, the IHR (2005) provide an algorithm known as the 'Decision Instrument'. The Decision Instrument sets parameters for identification of a PHEIC and notification of the WHO. If an event were to meet any two of the following four criteria it is considered to be a PHEIC and thus immediately reportable to the WHO: 1) serious public health impact, 2) unusual or unexpected, 3) potential risk of international spread and 4) potential for restrictions on trade or travel. The annexes of the IHR(2005) also provide examples and conditions for each of these criteria.

Timely and transparent communication is a cornerstone of the IHR (2005). Thus all member states are required to identify a National IHR Focal Point to be available to communicate with WHO on a 24/7 basis. The Focal Point will notify the WHO of any events that may constitute a PHEIC, consult the WHO when external advice is needed and respond to verification requests from the WHO about events occurring within its territories. The previous version of the IHR only allowed the WHO to accept reports of public health events from national Ministries of Health. However, the IHR(2005) provide WHO with the freedom to accept unofficial reports from the media or other non-governmental sources about events and can use them as grounds for beginning a more thorough investigation. This approach improves the timeliness of reporting and allows the WHO to begin collecting information even when Ministries of Health are not forthcoming.

The success of the IHR (2005) in reducing the risk of international public health emergencies depends upon individual countries maintaining adequate disease surveillance and response systems. In order to ensure that countries have sufficient capacities, the IHR (2005) have outlined a series of National Core Capacities for Surveillance and Response (See Appendix A for more details). These core capacities are defined in the areas of detection, reporting, response, confirmation and risk assessment. All member states are expected to develop, strengthen and maintain these Core Capacities of public health using their existing resources. These capacities represent the practical component of the IHR (2005) and provide a framework for the establishment of surveillance and response systems at the community, regional and national levels. The Core Capacities are broadly defined by the IHR (2005) to allow for implementation across the varied health systems of all member states; therefore, each member state is required to translate them into their own national context before determining how to implement them. A Core Capacity Compliance Assessment framework was developed by Kisman et al (unpublished), which defines how Core Capacity compliance should be achieved in Canada and other developed nations. This framework will be used as the basis for assessing Canada's compliance with the IHR (2005) in responding to the listeriosis outbreak.

The IHR (2005) are an international legal agreement, specifying regulations with which all WHO member states are required to comply. However, there are no direct legal or economic enforcement capacities built into the IHR (2005) to punish member states for non-compliance. If a country does not comply with Core Capacities, the IHR (2005) allow for the international distribution of information of the event in question, which may result in a 'tarnished' international image. Furthermore, the WHO has the authority to implement temporary trade or travel restrictions if a public health event is not responded to according to IHR (2005) requirements, which may indirectly result in severe economic consequences. Although the IHR (2005) are considered to be legally binding, outlining regulations with which countries are required to comply, the absence of legal enforcement capacities leaves only indirect consequences for non-compliance.

Compliance with the IHR (2005) requires fulfilment of a number of responsibilities. Member states must designate National IHR Focal Points, perform risk assessments using the PHEIC Decision Instrument, respond to all verification requests from the WHO within 24 hours, develop, strengthen and maintain all core capacities of

surveillance and response, and collaborate with the WHO and other member states on all IHR implementation activities. All member states are required to meet these requirements by a deadline of June 15th, 2012. In the interim, all member states are also required to report on their potential to comply with the IHR (2005) core capacity requirements by June 15th, 2009⁽¹⁷⁾. With the upcoming deadlines, compliance assessments such as the one presented here and the policy compliance assessment currently being performed by PHAC are essential for Canada to fulfil its obligations to the WHO.

Listeriosis

Listeriosis is caused by the bacterium *Listeria monocytogenes*, a Gram positive non spore-forming bacillus⁽¹⁸⁾. *Listeria* is ubiquitous in the environment and is found commonly in soil, decaying vegetation, water and the fecal flora of humans and animals. Despite its ubiquity, 99% of cases are caused by the consumption of contaminated foods⁽⁴⁾. *Listeria* possesses many qualities that allow it to succeed as a foodborne pathogen, such as resistance to high acid and salt, growth in biofilms and the ability to grow at refrigeration temperatures of 4-10°C, and capability of surviving temperatures down to and below freezing⁽¹⁹⁾.

The populations at the highest risk of infection by *Listeria* are pregnant women, newborns, adults over 60 years and individuals with underlying conditions such as malignancies, diabetes mellitus, alcoholism, liver, renal or immune-compromised conditions⁽²⁰⁾. Despite proper handling and refrigeration of foods, *Listeria* can multiply quickly in food, growing from one bacterium to 10⁵, the minimum infective dose, in 40 days at 4°C, or in 15 days at 8°C^(20, 21).

Clinical Presentation

Listeriosis is clinically defined as an invasive disease, causing septicemia, meningitis, cervical infection, stillbirth, encephalitis, diarrhea, bacteremia, perinatal sepsis or focal infections⁽²²⁾. The most common serious clinical presentations are neonatal listeriosis, blood stream infections and meningo-encephalitis⁽¹⁹⁾. Listeriosis has a long incubation period of up to 70 days, often making it extremely difficult to determine the specific source of infection⁽²³⁾. Transmission is almost completely foodborne (99%), but vertical transmission does occur from mother to infant during childbirth⁽²³⁾. Febrile

gastroenteritis with mild gastrointestinal symptoms is commonly associated with *Listeria monocytogenes*, but goes largely unreported⁽²³⁾. This mild presentation is most common in healthy, immunocompetent adults and is most often self-limiting⁽¹⁹⁾.

Listeria is susceptible to ampicillin or trimethoprim-sulphamethoxazole, and can be easily treated if diagnosed early⁽²⁴⁾. Delays in treatment, or attempts to treat immunocompromised individuals have a much higher failure rate and can lead to high case-fatality rates. The case fatality rate for individuals with invasive listeriosis is 20% and can reach 50% for infants or newborns^(20, 23). These extremely high case-fatality rates make listeriosis the most pathogenic of any bacterial food poisoning agent⁽²³⁾.

Epidemiology

Listeriosis is a relatively rare disease, despite the ubiquity of *Listeria* in the environment. Internationally, incidence ranges from 0.6-10.3 cases per million population, where listeriosis is reportable^(23, 25). In Canada, the most recent data from 1999 showed a rate of 2.5 cases per million population⁽²⁶⁾. The United States has traditionally exhibited higher rates than Canada with 4.6 cases per million population in 1999, but rates have been steadily decreasing and are now down to 2.7 cases per million population⁽²⁷⁾. In Europe, the trend has been moving in the other direction with rates increasing over recent years, specifically in people over 60 years of age, who have experienced an increase of 51% in 2006 compared with 2001-2005 rates⁽²⁵⁾. See Table 1 for a summary of listeriosis incidence in Canada, the United States and Europe.

In general, the incidence of *Listeria* infections is grossly underestimated due to the majority of infections causing mild gastrointestinal symptoms in healthy adults⁽²⁰⁾. Under-reporting for invasive listeriosis is estimated to be relatively minimal. Due to the severity of the illness, hospitalization or consultation with a physician will likely occur in the majority of cases⁽⁴⁾.

The vast proportion of listeriosis disease occurs as unlinked cases or small clusters, and rarely as common-source outbreaks⁽⁴⁾. When outbreaks do occur, they are a high priority for investigation due to their infrequency, high case-fatality rate, impact on vulnerable populations and frequent association with processed foods⁽¹⁹⁾. There have only been two high profile outbreaks of listeriosis in Canada, reported in academic literature, one in 1981 in Nova Scotia, linked to contaminated cabbage and one in

Quebec in 2002, linked to soft cheese⁽¹⁹⁾. It is likely that other localized outbreaks have occurred, but these two were the most prominent.

When outbreaks do occur, they are most frequently associated with contaminated ready-to-eat meats or unripened, unpasteurized or raw cheeses⁽¹⁹⁾. A risk assessment performed by the Center for Food Safety and Applied Nutrition in the United States determined that ready-to-eat deli meats pose a 'very high' risk of listeriosis, while pasteurized milk, high fat dairy products, soft, unripened cheese and pate pose a 'moderate' to 'high' risk of listeriosis⁽²⁸⁾. Listeriosis is often linked to processed foods like ready-to-eat meats because the food can become contaminated with low levels of *Listeria* during the processing and then provided with ample time for the bacterium to multiply at low temperatures during storage and distribution. Changes in food production practices and policies over recent years have led to an increased risk of outbreaks; the centralization of food processing facilities means that there are longer storage and travel times, and potential for widespread contamination from a single source⁽²⁹⁾.

Investigation of listeriosis outbreaks is often challenging, requiring considerable time and resources. The long incubation time of *Listeria* makes it very difficult to obtain accurate food histories, requiring persons to recall their food consumption habits over the previous 70 days. Molecular typing of laboratory specimens by pulsed-field electrophoresis (PFGE) has helped to improve the timeliness of outbreak investigations by linking geographically diffuse clusters of cases that may not be otherwise linked through food history surveys and interviews^(19, 30).

Policy

Listeriosis is a nationally notifiable disease in both Canada and the United States and is reportable in most provinces, territories and states. At the national level in Canada, listeriosis was notifiable between 1995 and 1999, then was added back on to the list of Nationally Notifiable Diseases in 2006⁽²³⁾. In Europe, listeriosis is voluntarily reported by physicians⁽²⁵⁾.

The Canadian national standard for the safe allowance of *Listeria* in foods is 100 colony-forming units (CFU) per gram, at the start of a product's life⁽⁵⁾. The Canadian standard is considerably less stringent than that of most others of developed nations. The WHO recommends a maximum tolerance limit of 100 CFU per gram at the end of a

product's life, while the United States does not tolerate any *Listeria* bacteria in its prepared foods⁽⁵⁾.

Despite the permissive standards for allowing *Listeria* contamination in processed foods, the potential severity of listeriosis is well recognized in Canada. Based on the recognition of the public health importance of listeriosis, the Canadian Listeriosis Reference Service (LRS) was developed by Health Canada and the National Microbiology Laboratory in 2001 to investigate all listeriosis cases and to maintain a national collection of isolates⁽³⁰⁾. The purpose of the LRS was to facilitate the identification of geographically dispersed outbreaks, collect surveillance, monitor long-term trends and act in the timely coordination and exchange of information⁽³⁰⁾.

CHAPTER 3: METHODS

This assessment will use the Canadian 2008 listeriosis outbreak as a means to evaluate Canada's compliance with the IHR (2005) Core Capacities of Surveillance and Response. The recent occurrence of this outbreak will allow for current practices of surveillance and response to be assessed alongside the policy and resource compliance assessment currently being performed by PHAC. Together, these studies should provide an insight into Canada's readiness to comply with the IHR (2005).

The outbreak will first be assessed to determine how it qualifies as a PHEIC. The actions undertaken by the Canadian provinces and federal agencies during the course of the outbreak will then be assessed for their compliance with IHR (2005) Core Capacities of surveillance and response.

Reconstructing the Outbreak

In order to evaluate the federal and provincial response to the 2008 listeriosis outbreak, a descriptive timeline of events and activities was constructed. Information on the outbreak was collected primarily from media reports, scholarly journal articles and government sources.

Canadian media was the primary source of information on the outbreak. Article searches were performed of online news sources, CBC News and CTV News, using the search terms 'listeria' or 'listeriosis'. All articles were accepted and reviewed that were relevant to the 2008 outbreak and dated June 2008 to February 2009. Similar searches were also performed for international media sources, BBC News and the New York Times, to determine global interest in the event. ProMed, an internet-based global reporting system used to rapidly disseminate information on outbreaks of infectious disease, was also used to collect additional reports. Media sources were reviewed until similar, or identical articles were collected from multiple sources, indicating that available information was exhausted.

The search terms 'listeria' or 'listeriosis' were used in Medline to search for scholarly journals; all articles dated July 2008 to February 2009 were reviewed. The

Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) websites were both searched for reports, press releases and any other information pertaining to the outbreak. See Appendix B for a complete list of references used to reconstruct the outbreak.

Unofficial information sources, including the media and ProMed were used as the primary sources to reconstruct the activities and events of the outbreak. Canadian federal and provincial government agencies had supplied very few details about the outbreak and CFIA is withholding all outbreak-related files from the public until the completion of a federal inquiry in July 2009⁽³¹⁾. Furthermore, the IHR (2005) allow the WHO to use unofficial reports in their investigation of public health emergencies as grounds to confront a member state about a potential public health emergency occurring within its territories. Media reports, such as the ones reviewed here, may serve as the initial grounds for a WHO investigation into a country's compliance under the IHR (2005) and thus will be used here in a similar manner.

Although the media was an appropriate source of information for this assessment, the utilization of media sources comes with certain inherent limitations. All information on the outbreak that would be required to perform a complete compliance assessment according to the requirements of the IHR(2005) may not be available through media reports. Furthermore, there is no guarantee that the reports are entirely accurate, as they may contain opinions of the author or speculations not reinforced by actual facts. To avoid any potential influence of these biases, an attempt was made to focus on concrete facts that related to specific activities and events, rather than speculation or opinions. Utilization of multiple resources, like CBC News and CTV News, allowed for facts to be verified by more than one source before they were included as a part of the assessment.

Analysis

Public Health Emergency of International Concern Criteria

Before assessing whether the federal and provincial responses to the outbreak were compliant with the IHR (2005), a determination was made as to whether or not the listeriosis outbreak was relevant to the IHR (2005). For an outbreak, or public health event, to be relevant to the IHR (2005), it must meet the criteria of the PHEIC Decision

Instrument (see Figure 1). Information collected from the media, government and scholarly journals, along with background information about the characteristics of listeriosis outbreaks were used to inform the PHEIC assessment. If the outbreak met two of the four PHEIC criteria, it would be considered a 'potential PHEIC' and warrant continued assessment under the IHR (2005).

Core Capacities of Surveillance and Response

Once deemed to constitute a potential PHEIC, the outbreak was analyzed and evaluated further, according to the Core Capacity requirements of the IHR (2005). The descriptive summary of the outbreak, as mentioned above, was qualitatively coded using the subject headings of the Core Capacities of Surveillance and Response, according to the definitions in Appendix A.

Once coding had been completed, the coded sections of the descriptive summary were compared to the core capacity requirements of the IHR (2005), as described by Kisman et al (unpublished), available from the British Columbia Centre for Disease Control website (<http://www.bccdc.org/download.php?item=3694>; accessed March 14, 2009). A matrix was used to organize the coded data into categories according to Core Capacity, then assigned a level of compliance: 'compliant', 'partially-compliant' or 'non-compliant'. An event or activity was considered 'compliant' if it met the requirements of the IHR (2005), 'partially compliant' if the available resources or technical expertise would allow compliance, but were used in a manner that was not fully compliant, and 'non-compliant' if actions were taken that were in opposition with the IHR (2005), or major technical capacities or resources were missing.

Once all information was organized in the matrix, a general measure of compliance (compliant, partially compliant, non-compliant) was assigned to each core capacity. A 'compliant' core capacity was defined as one for which all outbreak events or activities corresponding to the capacity were compliant. A 'partially-compliant' core capacity was defined as one for which some activities were compliant, while others were partially compliant, but there was no direct opposition to the general requirements of the IHR(2005). A 'non-compliant' core capacity was defined as one for which there was one or more aspects of the outbreak that were considered to be non-compliant or in opposition with the requirements of the IHR (2005).

CHAPTER 4: RESULTS

Outbreak Description

The 2008 Canadian listeriosis outbreak was a common source outbreak linked to contaminated ready-to-eat (RTE) meat from a Toronto-area Maple Leaf Foods processing facility with initial cases occurring in early June, detection in late July and confirmation of the outbreak in late August. Over the course of the outbreak, there were a total of 57 confirmed cases and 21 deaths in which listeriosis was the contributing or underlying cause. Incidence of symptom onset began to increase over June and July, peaking at eight cases during the week of August 8th. In August, onset of new cases began to decrease and deaths associated with the outbreak began to increase. The final confirmed case experienced symptom onset during the week of September 21st.

Summary statistics and basic descriptive epidemiological characteristics of the outbreak can be found in Table 2 and an epidemic curve displayed by date of symptom onset in Figure 2. For a detailed description of the outbreak, reconstructed from media sources and government reports, see Appendix C.

The 2008 listeriosis outbreak was deemed to be an event with the potential to constitute a PHEIC, as it met two of four descriptive criteria in the Decision Instrument, as described in Table 3. The outbreak was considered to have a serious public health impact and was unusual or unexpected, but did not pose a significant risk of international spread or international trade or travel restrictions.

Compliance with Core Capacities of Surveillance and Response

Since the 2008 listeriosis outbreak was considered to be an event that may constitute a PHEIC, the activities undertaken in detecting, reporting, responding to, confirming and assessing the event can be evaluated according to the Core Capacities of the IHR (2005). A timeline of outbreak activities and events relevant to the IHR (2005) Core Capacity assessment can be found in Table 4.

Detection

Canadian detection capacities were deemed to be partially compliant with the IHR(2005). Public health policies, systems and infrastructure allow for rapid detection of public health events, but they are not used to their full potential.

Listeriosis is a 'Nationally Notifiable Communicable Disease', thus any cases should be reported to the Public Health Agency of Canada⁽³²⁾. However, there is no legal requirement for national notification of communicable diseases in Canada by the provinces and any reports forwarded to the national level are done so voluntarily⁽³³⁾. The National Notifiable Disease list is intended to outline diseases that should be notifiable across the country, but does not require provinces to report cases to the federal government⁽²⁶⁾. The *Constitution Act 1867* outlines the division of responsibilities between the federal government and the provinces and provides the provinces with the majority of health care and public health responsibilities⁽³³⁾. There are, however, legal mandates for reporting of provincially notifiable communicable disease from the local level to provincial health authorities as outlined in provincial health legislation. Listeriosis is included as a provincially-notifiable communicable disease in all provinces, except Quebec.

Surveillance and detection of individual cases of listeriosis appears to be quite reliable in Canada. The increased number of listeriosis cases from the expected (4 to 8) in June 2008 was rapidly identified in Ontario and detection of additional cases occurred over the following months. Case-based detection and tracking of disease trends indicates that current surveillance systems and detection capacities are compliant with IHR (2005) standards. Furthermore, the establishment of listeriosis case definitions by PHAC during the outbreak and their wide dissemination through national media sources reinforces Canada's potential to comply with detection capacities.

During retrospective analysis of the outbreak, it was determined that there were nearly double the number of cases (18 cases, 9 detected) occurring in June and July that were directly associated with the outbreak but not identified at the time. Detection of these cases in a more timely fashion may have led to a more rapid determination of their association with contaminated meats through an earlier epidemiological investigation. Although case-based detection occurred, it was not sensitive enough for early detection of this outbreak.

Reporting

Reporting capacity during the listeriosis outbreak can be considered partially compliant with IHR (2005) requirements. Similar to detection capacities, reporting infrastructure and policies are in line with the IHR (2005), but they are not always used appropriately.

Toronto Public Health (TPH) was very timely in reporting the cluster of listeriosis cases from a local long-term-care facility to the provincial and federal governments on July 21st, reporting as soon as the cluster was detected. Furthermore, TPH collected laboratory specimens of sandwich meat thought to be associated with the cases and immediately forwarded them to federal laboratories for analysis. Throughout the early stages of the outbreak, TPH was transparent in sharing its information with both provincial and federal authorities and did so in a timely manner. Facilitating this type of communication requires a rapid communication system and adequate personnel resources. With some reports occurring over weekends personnel were likely available to send and receive these reports whenever required. Information sharing between provincial governments and federal authorities can be assumed since information about new cases or deaths appeared to travel rapidly from local to provincial and national authorities.

Although communication systems, personnel and information sharing infrastructure appeared to be compliant with IHR (2005) requirements, data collection was often repeated multiple times at different levels of authority. Toronto Public Health collected information and laboratory samples at the beginning of the outbreak, but when information was shared with provincial and federal authorities, sample collection was performed again by CFIA and the Ontario Ministry of Health and Long-Term Care (OMHLTC). It is reasonable that additional samples may be collected to expand the scope of the investigation, but in this case, it appeared as if samples were recollected to verify a conclusion already reached by TPH. Redundancy in information collection may indicate that despite transparent sharing of information, different levels of public health authority may not readily use data collected and reported from other jurisdictions.

Response

Canada was partially compliant with response capacities, not because of a lack of infrastructure or resources, but because of response delays by public health authorities and unclear definition of responsibility in organizing the responses.

Toronto Public Health responded promptly on a community level once there was suspicion of a listeriosis outbreak due to contaminated foods. TPH responded on August 14th by issuing a warning to all local long-term care facilities not to serve any ready-to-eat meats until further advised. This risk communication action occurred soon after it was known that meat samples from one long-term care facility were contaminated with *Listeria* and on the same day that a conclusive chain of evidence was established, linking Maple Leaf products to cases of listeriosis. On a federal level, CFIA and PHAC took actions to ensure that over 15 000 institutions, retailers and distributors had removed all recalled products from their stock as soon as the recall was initiated, completing the task two weeks later, by August 28th. These actions were timely once it was confirmed that there was widespread contamination of Maple Leaf meats. With relatively few cases of listeriosis, availability of resources to provide diagnosis and treatment were of no concern, and thus fully compliant with IHR (2005) requirements.

Although response and risk communication activities occurred, there were major delays in communication of these actions to the public by federal authorities. PHAC only began to provide guidance to the public through regular updates on the outbreak after August 23rd, when a definitive association had been made between Maple Leaf meats and the increased incidence of listeriosis. Official risk communication began on August 26th, nearly two weeks after August 14th, when TPH warned local long-term care facilities about the risk of contaminated ready-to-eat meats. This delay in official risk communication may have led to widespread anxiety and an overuse of laboratory diagnostics by the public who were concerned they had ingested contaminated meat, as the public was only made aware of the situation through media reports and product recalls.

The unclear designation of responsible authorities and leadership roles in the outbreak also led to the partial compliance of response capacities. PHAC is the National IHR Focal Point for Canada, and should have taken the primary leadership role in the outbreak as soon as it was determined that a national meat distributor was implicated, exhibiting the potential for the outbreak to cross provincial boundaries. Instead, CFIA,

the CEO of Maple Leaf Foods and the Canadian Minister of Agriculture took the primary leadership roles instead of PHAC, who were silent until August 20th, nearly a month after there were suspicions of an outbreak. Public health authorities with the expertise to respond to outbreaks of human illness and foodborne contamination events exist in Canada, but governance structures and communication systems may not be sufficient to allow for their efficient coordination.

Confirmation

Confirmation capacities used during the listeriosis outbreak were partially compliant with the IHR (2005). The infrastructure to perform laboratory and epidemiological analysis was in place across the country and there were sufficient human and physical resources to perform investigations. Although capacities were in place, they were not used efficiently and there were overlaps in investigation activities at different levels of authority. These inefficiencies and overlapping investigations may have delayed important actions and responses.

Confirmation activities were performed at all levels of public health authority during the outbreak. Toronto Public Health began their investigation into the cluster at the long-term care facility using both laboratory and epidemiologic techniques. Investigations continued at the provincial level with OMHLTC performing laboratory analysis of meat samples and forwarding human specimens for genetic typing to the National Microbiology Laboratory (NML). At the federal level, CFIA and PHAC both performed laboratory analysis of meat samples and PHAC continued epidemiological and laboratory analysis of human cases into October. Based on these investigations, the infrastructure and expertise for confirmation of public health events appears to be strong at all levels of authority, constituting the potential for compliance with IHR (2005) capacities.

However, delays were experienced in collecting laboratory results at the provincial and federal levels as it took from the end of July until August 23rd for human specimens to undergo genetic typing at the NML. Ontario Public Health Laboratories possessed the capacity to perform genetic typing within the province, but instead of using available resources, they referred testing to the federal laboratories and a long delay resulted. This delay led to the hesitancy of PHAC and CFIA to confirm the status of the outbreak, as they were waiting for conclusive evidence from human specimen

genetic typing to link the contaminated meat to the human cases. Confirmation delays were also encountered when CFIA was notified of potential contamination of Maple Leaf meats on August 6th, but began their own official investigation on August 12th, appearing to redo the laboratory analysis already performed by TPH. Redoing laboratory tests at the federal level delayed the official confirmation by CFIA of contaminated meat products until August 16th, ten days after TPH first identified the contamination.

Risk Assessment

Capacities to perform public health risk assessments of foodborne outbreaks were demonstrated at local, provincial and federal levels. Toronto Public Health established a conclusive chain of evidence to identify the risk associated with consumption of contaminated Maple Leaf products and communicated this assessment to CFIA and OMHLTC. These actions indicate that a risk assessment was performed by TPH in early August based on outbreak information collected to date. OMHLTC also exhibited the capacity to perform a public health risk assessment through the integration of evidence from June 2008 case reports of listeriosis and historical data of disease trends. Federal authorities, CFIA and PHAC, also performed risk assessments during the outbreak by integrating evidence from epidemiologic and laboratory investigations to confirm the status of the listeriosis outbreak and disseminate public health alerts based on their assessments.

Risk assessment capacities existed at all levels of authority, but they were not sufficient to properly identify the risk of the outbreak in a timely fashion. TPH was quick to perform a risk assessment and concluded that the contaminated meat posed a threat to vulnerable populations in early August. CFIA and PHAC were much slower at coming to the same conclusion, requiring three weeks to reach the same conclusion as TPH. This delay leaves risk assessment capacities partially compliant with IHR (2005) requirements.

To fully assess compliance with IHR(2005), it would have to be determined whether the PHEIC Decision Instrument was used in assessment activities. From the media reports and government statements, it is not possible to determine whether or not this approach was used. However, based on previous research, it could be assumed that the PHEIC Decision Instrument was not used in risk assessment activities. In British Columbia, it was determined that the Decision Instrument is not used in regular risk

assessment activities and there was little familiarity with the IHR (2005) amongst public health professionals (Kisman et al, unpublished). If the situation in British Columbia is applied across the country, risk assessment capacities of the IHR(2005) can be deemed partially compliant due to sufficient technical expertise but inadequate use of the PHEIC Decision Instrument.

CHAPTER 5: DISCUSSION

The 2008 listeriosis outbreak provided an ideal opportunity for the public health reforms that resulted from SARS and the entry into force of the IHR (2005) to be assessed. The Naylor Report, 'Learning from SARS' identified a lack of federal-provincial collaboration, information sharing protocols and timely laboratory testing as the major flaws in the response to the SARS outbreak⁽³⁴⁾. The IHR (2005) have provided further impetus to address these problems, as they encourage timely detection, reporting and a collaborative approach in localized responses to public health emergencies. Five years after the SARS outbreak, Canada had the opportunity to be better prepared for another serious public health event with the newly established PHAC, and more advanced electronic surveillance and reporting tools⁽³⁴⁾. When faced with the listeriosis outbreak, many of the previously encountered problems had been rectified, but there remained gaps that ultimately led to delays and mishandling of the situation.

Assessing the local, federal and provincial response to the listeriosis outbreak according to the IHR (2005) Core Capacity requirements determined that Canada possesses the resources, personnel and infrastructure to comply with the IHR (2005), but does not operationalize its available means to comply with international expectations. As a result, Canada appears to be partially compliant with the IHR (2005).

Due to the unavailability of official government reports on the outbreak and an ongoing federal investigation, media reports and government press releases were relied upon to reconstruct the outbreak and formulate conclusions about Canada's compliance with the IHR(2005). The reliability of the conclusions made on Canada's compliance depends entirely upon the availability of information in the media and the validity of published reports.

Foodborne Outbreaks as PHEIC

Foodborne outbreaks are not overtly included as events that may be considered a PHEIC under the IHR (2005), but they pose great potential to qualify under certain situations⁽³⁵⁾. Annex 2 of the IHR (2005) provides examples of diseases that may qualify

as a PHEIC, but none of them are strictly foodborne pathogens. Although foodborne pathogens are overlooked, the IHR (2005) identifies food contamination as a potential threat to international trade or travel, thus potentially qualifying such events as a PHEIC.

In examining the remaining criteria for a PHEIC, it becomes apparent that food contamination events or foodborne outbreaks could easily qualify as PHEICs. Foodborne events can pose a serious public health threat, particularly in the modern era of centralized food production and widespread, sometimes international, distribution⁽³⁶⁾. These events may also be unusual or unexpected, particularly a national outbreak of a disease like listeriosis that is rarely associated with large-scale outbreaks⁽⁴⁾. Food provides a relatively 'silent' medium through which disease can spread across borders, particularly in the era of globalized food industry⁽³⁷⁾. This potential for international spread is intimately linked to the potential for travel or trade restrictions. In 2003 there was an immediate worldwide ban on Canadian beef after a single case of bovine spongiform encephalopathy was discovered in Alberta⁽³⁸⁾. Even events associated with domestically distributed food could be considered serious, unusual or unexpected under the right conditions⁽³⁵⁾. Furthermore, in a recent survey of past foodborne outbreaks in Australia, it was determined that 7 of 14 outbreaks could be considered reportable to the WHO according to the PHEIC Decision Instrument⁽³⁵⁾. The 2008 listeriosis outbreak met two of the PHEIC criteria, thus qualifying it for assessment under the IHR (2005) Core Capacity requirements, as described in Table 2.

IHR (2005) Core Capacity Compliance and the Listeriosis Outbreak

The responsibility of WHO member states to implement the IHR (2005) rests entirely on the shoulders of the national government. The national government is then responsible for implementing the IHR (2005) in all sectors, ministries and levels of government, as well as ensuring compliant behaviour by all government officials and public health personnel⁽³⁹⁾. For a nation to be successful in implementing the IHR (2005), it must be backed by a strong national public health institute, pursue a collaborative approach to public health problems across all levels of governance and strive for a high degree of timeliness in its surveillance system⁽⁴⁰⁾.

Baker and Fidler (2006) identified five key areas in which nations may face obstacles in complying with the IHR (2005). Technical challenges may arise when

responding to unknown or emerging disease. Resource limitations may affect the response capacities of developing nations, or under-developed regions of developed nations. Governance problems may arise through lack of coordination between levels of authority. Legal or policy hurdles may appear due to constitutional division of health powers. Political issues may develop when dealing with competing health and economic interests of a nation. The Canadian listeriosis outbreak highlighted many of these areas in which Canada is facing obstacles in implementing the IHR (2005).

Technical/Resource

Technical or resource limitations did not pose a problem in Canada's response to the listeriosis outbreak. Lack of resources was never a problem during the outbreak as the relatively small numbers of cases were spread across a large geographical area, placing a minimal burden on the healthcare system and laboratory capacities. Adequate resources were available to facilitate detection of individual cases, reporting of those cases, provision of adequate treatment and confirmation of the outbreak. Technical expertise did not impact Canada's obligations under the IHR(2005) either. Expertise in epidemiology and surveillance analysis was evident at the local, provincial and federal levels, as each level of governance appeared to be able to conduct epidemiological investigations into the outbreak without additional assistance. Local authorities at Toronto Public Health (TPH), provincial authorities at the Ontario Ministry of Health and Long Term Care and federal authorities at the Canadian Food Inspection Agency (CFIA) and PHAC possessed the technical expertise to tailor their investigations specifically towards foodborne outbreaks.

Governance

The health and public health governance structure in Canada places the constitutional authority over most health matters in the hands of the provinces⁽³³⁾. Ambiguity exists over the dividing line of public health responsibility between provincial and federal authorities, which poses problems for inter-provincial outbreaks⁽³³⁾.

A number of governance issues arose during the listeriosis outbreak. Concurrent investigations were performed at both local and federal levels by TPH and CFIA into the possible contamination of Maple Leaf products. A better-coordinated effort could have streamlined their efforts resulting in a more timely federal response. Genetic typing

resources and technical laboratory expertise existed both at the provincial level in Ontario and the federal level at the National Microbiology Laboratory (NML), but all testing was referred to the NML, resulting in a 3-week delay for results to be returned. Coordinating efforts between local, provincial and federal authorities could have saved considerable time in investigating and confirming this outbreak.

Furthermore, PHAC and Agriculture Canada should have assumed the primary leadership role in the outbreak as soon as the outbreak showed potential to cross provincial borders, particularly since the source of the outbreak was a national meat distributor⁽³⁶⁾. The importance of a national public health institute (NPHI) such as PHAC in responding to events according to the IHR (2005) was emphasized by Rodier et al (2007). They stated that an NPHI should be directly involved in all surveillance, investigation, analysis, control and risk communication activities relating to public health threats in order to ensure that the activities undertaken are compliant with the IHR (2005). PHAC only adopted a risk communication role during the later stages of the outbreak and as a result there appeared to be mixed leadership between the provinces and CFIA. Instead of the Chief Public Health Officer serving “as the leading national voice for public health, particularly in outbreaks and other health emergencies”, as was recommended by the Naylor Report and echoed by the IHR (2005), the most prominent figures during the outbreak were the CEO of Maple Leaf Foods and the Federal Agricultural Minister.

These problems associated with public health governance may have led to obstacles in the collaborative investigation of the outbreak and delays in confirming the association between listeriosis and Maple Leaf meats. These issues may have precipitated delays in adequately responding to the outbreak through timely and effective risk communication, thus, governance issues may have led to compliance problems with IHR (2005) core capacities of confirmation and response.

Legal/Policy

There is no legal mandate in Canada that requires local jurisdictions or provinces to report disease events to the federal government⁽³³⁾. The constitutional division of health and public health responsibilities between the provinces and federal government poses a potential problem for federal nations in complying with the IHR (2005)⁽³⁹⁾. The reliance upon voluntary reporting of disease events led to disastrous consequences

during SARS, when Ontario was accused of being less than forthcoming with information about individual cases⁽³⁹⁾. Federal legislation on this issue has not changed since SARS, but transparent reporting was not a problem during the listeriosis outbreak. Case reports from provinces appeared to be timely and there was a sense of collaboration in sharing information about the outbreak.

Reporting laws did not pose a problem for IHR (2005) compliance during this outbreak; however, changes in food inspection policies may have. Collier (2008) identified how recent changes to food inspection policies may have compromised Canada's ability to adequately contain the listeriosis outbreak, indirectly compromising Canada's ability to comply with IHR (2005) core capacities of timely detection and response.

Collier (2008) describes that, on March 31st, 2008, new food inspection policies came into effect in Canada that largely removed food inspectors from food production facilities and encouraged industry self-monitoring, while inspectors took on a predominantly supervisory role. Contamination in a food production facility used to result in plant closure and clean-up supervised by CFIA inspectors. Now, contamination events need not be reported to government inspectors and can simply be addressed by an 'in-house' plan of action. With federal inspectors not being notified of contamination events, delays may occur in discovery of such events by public health authorities. Maple Leaf reportedly identified *Listeria* contamination during the spring, but acted under the new policies and dealt with the event themselves without involving CFIA⁽⁴¹⁾. Once the contamination was publicly identified in August and risk communication began, the number of reported cases increased dramatically. If federal food inspectors would have been made aware of contamination events at an earlier date, enhanced surveillance and risk communication could have been enacted sooner, possibly detecting cases earlier in the outbreak, and implementing responses in a more timely fashion.

Political

Delays in confirmation and response during the listeriosis outbreak may have been related to political issues beyond those of public health concerns. Both PHAC and CFIA were reluctant to confirm the association between Maple Leaf meats and the nationwide outbreak of listeriosis until they possessed unequivocal evidence, both epidemiologic and genetic. TPH had collected enough evidence to implicate Maple Leaf

meats three weeks before the official confirmation was made by PHAC. CFIA was also reluctant to confirm that certain Maple Leaf products were contaminated based on the information collected by TPH, and instead collected their own evidence, which took an additional two and a half weeks (See Table 4). These two delays in confirmation activities also resulted in delayed responses to issue a recall or public warning, possibly for fear of political repercussions.

There was speculation that the Chief Public Health Officer (CPHO) and PHAC may not have been independent enough from other government interests to comment openly on the outbreak until it was fully confirmed, due to the proximity of a forecasted federal election⁽³⁶⁾. The CPHO is employed as a Deputy Minister and is thus required to report through the Minister of Health, and can be replaced at will. As a consequence of this arrangement, the CPHO may not have felt comfortable speaking out before all evidence was collected⁽³⁶⁾. This potential restriction on the freedom of speech of the CPHO and PHAC may have led to delays in confirmation and response to the outbreak, thus jeopardizing compliance with the IHR (2005).

CFIA may also have been reluctant to comment on the contamination of Maple Leaf meats at an earlier date due to its political position promoting both food safety as well as trade and biotechnology⁽³¹⁾. Reluctance to confirm the source of contamination before being completely certain may have stemmed from CFIA's dual political role. These delays in risk communication due to political and economic affiliations may jeopardize Canada's compliance with the core capacities of confirmation and response of the IHR (2005).

CHAPTER 6: CONCLUSION

The surveillance and response capacities exhibited during the listeriosis outbreak provide a current insight into Canada's potential to comply with the IHR (2005). While there still remains three years for Canada and all other WHO member states, to become compliant with IHR (2005) Core Capacities, it is important that areas of partial or non-compliance be identified as soon as possible. Timely assessment is of particular importance because the WHO also requires that all member states submit an assessment of their potential to comply with the IHR (2005) by June 15th, 2009. A national IHR (2005) compliance assessment is currently being conducted by PHAC, but this evaluation will be focused on policies, technical capabilities and resources, rather than the practical aspects of public health. For a nation to be compliant with the IHR (2005), it must possess the necessary capacities, but it must also use them appropriately in practice.

Through an assessment of the activities and events of the listeriosis outbreak, it was determined that Canada possessed sufficient technical capabilities and resources to adequately respond to an urgent public health event according to IHR (2005) requirements. Despite adequate resources and technical capabilities, the events and activities undertaken in the detecting, reporting, confirming, assessing and responding to the outbreak were not fully compliant with IHR (2005) requirements. Detection of cases and clusters of cases was not sensitive, nor timely enough during the early stages of the outbreak. Reporting of some cases was rapid but many cases were only identified in retrospective analyses. Confirmation activities and laboratory investigations were not timely and could have been more efficiently coordinated between public health jurisdictions. Risk assessment and risk communication occurred too late in the outbreak, and leadership roles were unclearly defined.

This assessment has attempted to highlight the barriers to IHR(2005) compliance that exist at all levels of public health in Canada, for the purpose of taking actions to ensure full compliance by June 2012. However, Canada has many structures in place that comply with IHR(2005) requirements. Case-based detection and tracking of historical disease trends to detect outbreaks appears to be well established,

demonstrating Canada's well-established infrastructure of detection capacities. Reporting and communication systems appear to function efficiently as they allow for the rapid sharing of information between local, provincial and federal public health jurisdictions, and there appeared to be complete transparency in information sharing. Public health response infrastructure demonstrated its capacity to rapidly communicate public health alerts and enforce corrective actions. Technical expertise in epidemiological and laboratory capacities is evident and was exhibited at local, provincial and federal levels, providing great potential to comply with both confirmation capacities and risk assessment capacities.

The problems illustrated by the listeriosis outbreak of untimely detection, confirmation and risk communication were not due to an absence of capacities under the IHR (2005), but rather due to barriers in governance, policy and politics. If Canada is to ensure that it is compliant with the Core Capacities for Surveillance and Response, particularly for foodborne events, it must address these barriers by improving coordination between levels of public health governance, adjusting food inspection policies and strengthening the autonomy of PHAC and CFIA to ensure they are free to act first in the public's best interest.

Recommendations to improve coordination between levels of public health governance could include the implementation of a standardized electronic reporting and information-sharing tool, like the Pan-Canadian Public Health Communicable Disease Surveillance and Management Project (PANORAMA), which is currently being evaluated for implementation across Canada. Communication tools like this may limit the repetition of investigations and improve the frequency of communications between public health jurisdictions. Revisions to national food inspection policy may also be warranted by requiring the reporting of any positive tests for foodborne contamination performed by private companies to CFIA inspectors. This change would ensure that federal officials are aware of contamination events that may threaten public health, while maintaining the 'self-monitoring' initiative introduced in recent changes to food inspection policy. Finally, the mandates of both PHAC and CFIA should be revisited to ensure that their primary goal is to act first in the public's best interest, free of influence from political or economic interests. By acting on these recommendations, Canada's strong public health infrastructure, technical capacities and resources could be further reinforced to ensure

that future responses to urgent public health events are fully in line with the Core Capacities of Surveillance and Response of the IHR(2005).

TABLES AND FIGURES

Table 1. Incidence rates of listeriosis (per 1 000 000 persons) in Canada, the United States and Europe

Country	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Canada ¹	2	3.5	2.4	3	1.5	2.6	3.4	2.5								
USA ²					4.6	4.7	5.5	4.6	3.4	2.7	2.6	3.3	2.7	3	3.1	2.7
Belgium ³									4.7	5.6	4.3	7.3	8.6	5.9	6.4	
Denmark ³									7.5	7.1	5.2	5.4	7.6	8.5	10.3	
England-Wales ³									1.9	2.8	2.6	4.5	4	3.5	3.5	
Finland ³									3.5	5.4	3.8	7.9	6.7	6.8	8.5	
France ³								4.5	4.4	3.1	3.6	3.4	3.8	3.5	4.6	
Germany ³										2.6	2.9	3.1	3.6	6.2	6.2	
Netherlands ³											2	3	3	5.6	3.9	
Sweden ³									5.9	7.5	4.4	5.3	4.7	4.4	4.6	
Switzerland ³											3.8	6.1	7.8	9.8	9.1	

Sources: 1 Public Health Agency of Canada ⁽²⁶⁾, 2 CDC FoodNet ⁽²⁷⁾, 3 ⁽²⁵⁾

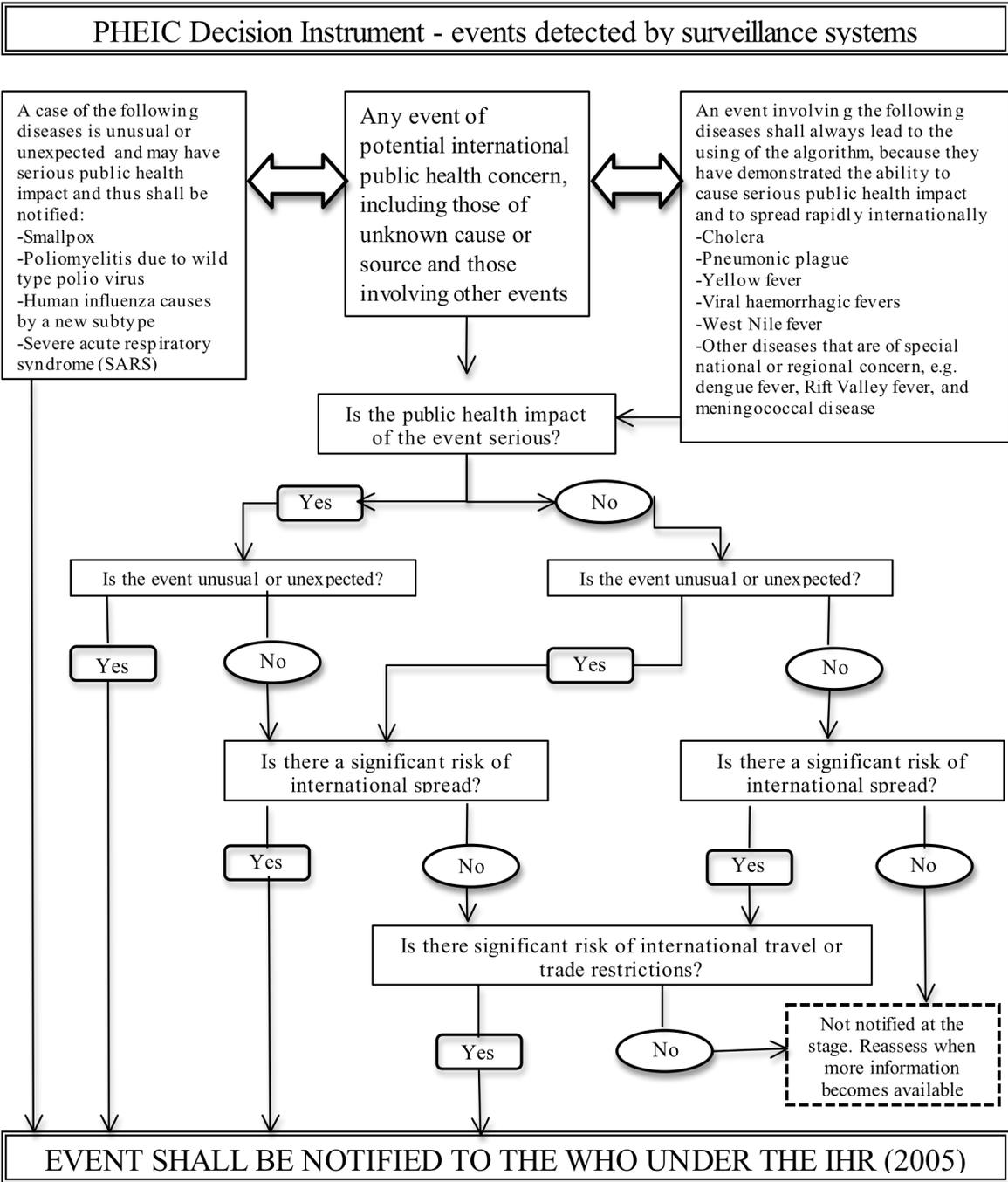


Figure 1. Decision Instrument algorithm of Annex 2 of the International Health Regulations (2005) to be used in assessing public health events for their potential to constitute a ‘Public Health Emergency of International Concern’ (PHEIC). (Adapted from: ⁽¹⁾)

Table 2. Summary statistics of the 2008 Canadian listeriosis outbreak, displayed by province

Province	Confirmed Cases	Deaths*	Population (in 1000's)	Proportion of Canadian Population	Proportion of Total Cases	Proportion of Total Deaths	Attack Rate (per 100 000 persons)	Mortality Rate (per 100 000 persons)	Case Fatality Rate
Ontario	41	15	12,929.00	0.39	0.73	0.75	0.32	0.12	0.37
BC	5	2	4,381.60	0.13	0.09	0.1	0.11	0.05	0.40
Alberta	2	1	3,585.10	0.11	0.04	0.05	0.06	0.03	0.50
Saskatchewan	2	0	1,016.00	0.03	0.04	0	0.20	0.00	0.00
Manitoba	1	0	1,208.00	0.04	0.02	0	0.08	0.00	0.00
Quebec	4	1	7,750.50	0.23	0.07	0.05	0.05	0.01	0.25
New Brunswick	1	1	747.3	0.02	0.02	0.05	0.13	0.13	1.00
Total (Canada)	56	20	33,311.40				0.17	0.06	0.36

*Where listeriosis was the underlying or contributing cause

Table 3. Public Health Emergency of International Concern (PHEIC) assessment of the 2008 Canadian listeriosis outbreak

PHEIC Criteria	PHEIC Guidance Questions	Meets Criteria? (Y/N)	Explanation
Is the public health impact of the event serious?	Is the number of cases and/or number of deaths for this type of event large for the given place, time or population	N	21 deaths and 57 cases over 5 months is not excessive.
	Has the event the potential to have a high public health impact?	Y	Affects vulnerable populations - elderly, infants, pregnant women. Listeriosis has a 10-50% case-fatality rate. Foodborne contamination of a major food distributor - potential for many human cases over a large area. Virulent strain of <i>Listeria monocytogenes</i> .
	Is external assistance needed to detect, investigate, respond and control the current event, or prevent new cases?	N	No need for external assistance
Is the event unusual or unexpected?	Is the event unusual?	Y	Outbreaks of listeriosis are rare (although individual cases are more common).
	Is the event unexpected from a public health perspective?	N	The outbreak was not caused by a disease that had previously eliminated/eradicated - <i>Listeria monocytogenes</i> is common.
Is there a significant risk of international spread?	Is there epidemiological evidence of a link to similar events in other States?	N	No concurrent outbreaks of listeriosis elsewhere in the world.

PHEIC Criteria	PHEIC Guidance Questions	Meets Criteria? (Y/N)	Explanation
Is there a significant risk of international travel or trade restrictions?	Is there any factor that should alert us to the potential of cross-border movement of the agent, vehicle or host?	N	Maple Leaf Foods exports to the US, Mexico and Japan, but the foods produced at the Toronto plant were not exported.
	Have similar events in the past resulted in international restrictions on trade and/or travel?	N	There have not been international trade restrictions based on ready-to-eat meats.
	Is the source suspected or known to be a food product, water or any other goods that might be contaminated that has been exported/imported to/from other states?	N	The meat products produced at the plant were not distributed outside of Canada.
	Has the event occurred in association with an international gathering or in an area of intense international tourism?	N	Did not occur in association with an international gathering.
	Has the even caused requests for more information by foreign officials or international media?	N	Some coverage by international media (BBC/New York Times), but very minimal.

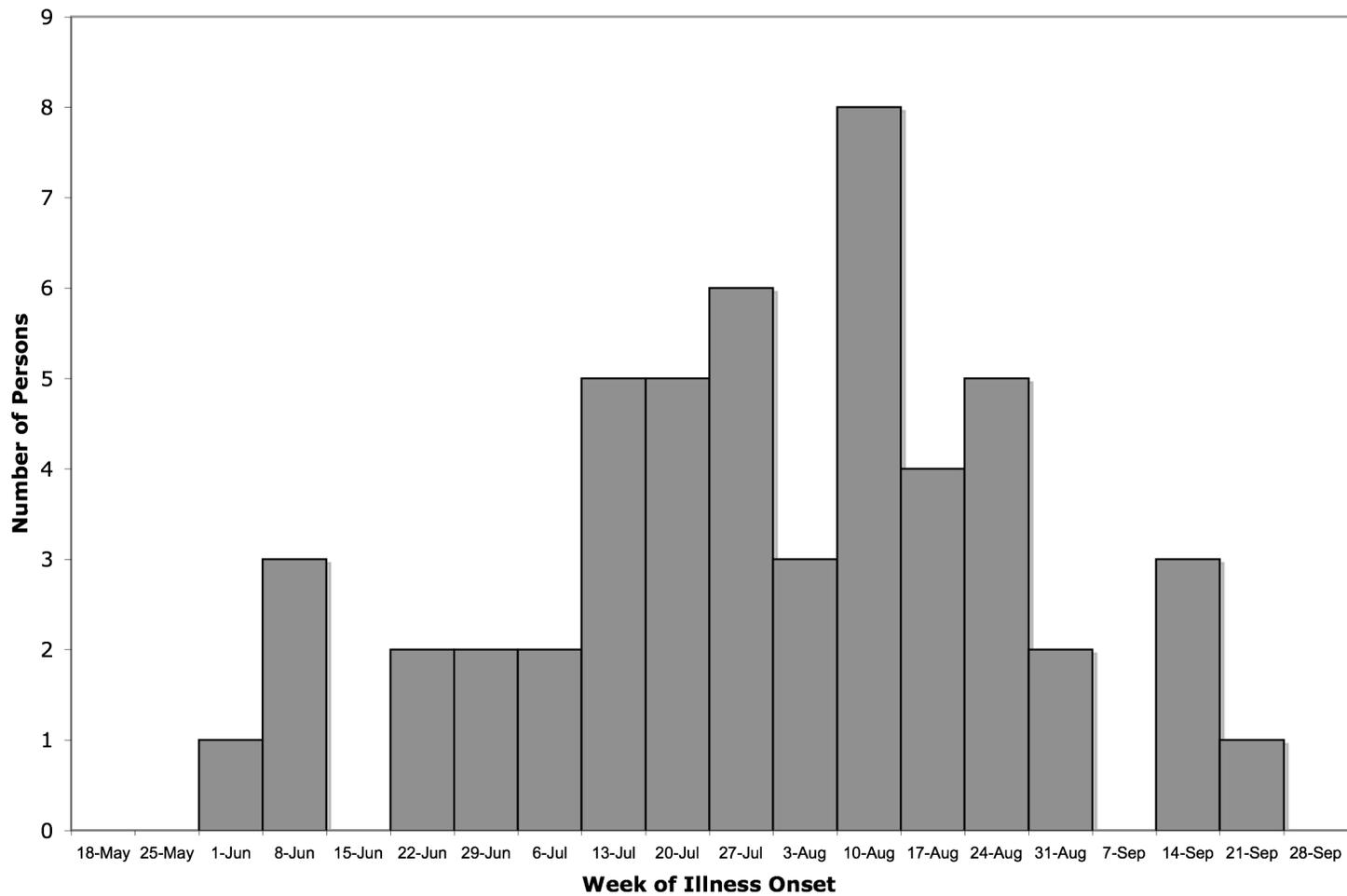


Figure 2. Epidemic curve for 2008 listeriosis outbreak by symptom onset date, or estimated date, as of October 3rd, 2008. (Adapted from: Public Health Agency of Canada, ⁽²⁾)

Table 4. Timeline of selected events in the 2008 listeriosis outbreak relevant to IHR(2005) Core Capacities of Surveillance and Response

Date	Activity/Event	Source (refers to Appendix B)
April-June 2008	Likely timeframe of contamination for Maple Leaf meats at Toronto processing plant	9/3/08 - CTV
June 2008	Ontario public health units detect significant increase in listeriosis reports from historical trends	2/2/09 - CBC
	Ontario CMOH determines there is no cause for concern (risk assessment)	2/2/09 - CBC
	Eight cases retrospectively identified in June associated with the outbreak	PHAC ⁽²⁾
July 2008		
July 16th	TPH receives a report of listeriosis from an LTC facility	9/12/08 - CBC
July 21st	TPH receives second report of listeriosis from same LTC facility	9/12/08 - CBC
	TPH collects samples of ready-to-eat meat from sandwiches of LTC facility and sends them to HC lab for testing (reports to province and federal government)	9/12/08 - CBC
July 24th	Meat samples sent by TPH arrive at HC	9/12/08 - CBC
End of July	OMHLTC begins investigation into possible clustering of listeriosis cases	9/12/08 - CBC
	OMHLTC sends human specimens of listeriosis patients for genetic typing at NML	9/12/08 - CBC
	Total of 11 cases were retrospectively identified in July 2008 (19 total)	PHAC ⁽²⁾
August 2008		
Early August	OMHLTC sends human specimens of listeriosis patients for genetic typing at NML	9/12/08 - CBC
August 5th	Meat samples return from HC lab positive for <i>Listeria</i>	9/12/08 - CBC
August 6th	TPH reports positive test results to CFIA	8/22/08a - CTV
	CFIA returns to LTC facility to take further meat samples	8/22/08a - CTV
August 12th	CFIA begins formal investigation into Maple Leaf products - begins laboratory testing	2/2/09 - CBC

Date	Activity/Event	Source (refers to Appendix B)
August 13th	Maple Leaf places voluntary hold on all products pending results from CFIA	2/2/09 - CBC
August 14th	City of Toronto (TPH) ask LTC facilities to stop serving ready-to-eat meats	8/22/08a - CTV
	TPH gathered sufficient evidence to implicate Maple Leaf in the outbreak (risk assessment)	10/8/08 - CBC
	CFIA declined to issue a public warning based on TPH findings	10/8/08 - CBC
August 16th	CFIA receives lab results (17 of 26 samples were positive for <i>Listeria</i>)	10/9/08 - CBC
August 17th	Maple Leaf begins recall of contaminated meats	2/2/09 - CBC
August 18th	CFIA warns against consumption of certain Maple Leaf products (first public warning)	8/18/08 - CBC
August 20th	PHAC makes first public statement identifying the possible link between cases of listeriosis and Maple Leaf meats	2/2/09 - CBC
August 23rd	OMHLTC receives genetic typing results from NML (forwards to PHAC/CFIA) confirming the identity of the outbreak strain of <i>Listeria</i>	8/23/08 - CTV
	PHAC confirms link between listeriosis outbreak and contaminated Maple Leaf meats	PHAC ⁽⁴²⁾
	Maple Leaf plant is closed	8/28/08a – CBC
August 26th	PHAC begins risk communication by publishing daily updates online	PHAC ⁽⁴²⁾
August 28th	CFIA verified the recall of Maple Leaf products in 15,000 institutions and distributors to date	8/28/08b - CBC
	11 confirmed deaths and 33 confirmed cases to date. Case detection and subsequent deaths continued throughout September and into October.	PHAC ⁽⁴²⁾

Notes: CFIA – Canadian Food Inspection Agency, CMOH – Chief Medical Officer of Health, HC – Health Canada, LTC – Long-term care, NML – National Microbiology Laboratory, OMHLTC – Ontario Ministry of Health and Long Term Care, TPH – Toronto Public Health, PHAC – Public Health Agency of Canada

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APPENDICES

Appendix A – IHR (2005) Core Capacities of Surveillance and Response

Core Capacity requirements for compliance adapted from Kisman et al (unpublished), available from the British Columbia Centre for Disease Control, at <http://www.bccdc.org/download.php?item=3694>.

Detection: Compliance with ‘detection’ capacities of the IHR (2005) requires that events “involving disease or death above expected levels for [a] particular time and place in all areas” of a nation are detected. In order to ensure compliance, notifiable disease lists must be inclusive of all diseases specified in Annex 2 of the IHR(2005), case definitions should be widely available for these diseases, and surveillance systems should allow for detection of these events and be able to identify trends in disease occurrences.

Reporting: Compliance with reporting capacities under the IHR (2005) requires that member states “report all available essential information immediately to the appropriate level of healthcare response. At the community level, reporting shall be to local community health care institutions. At the primary public health response level, reporting shall be to the intermediate or national response level” (IHR, 2005). In order to ensure compliance, a rapid means of communication must be available with personnel available to send and receive reports, information sharing agreements between levels of government and between jurisdictions must be established and laboratory specimens should be submitted for relevant events.

Response: Member states must have the capacity to immediately implement ‘preliminary control measures’ (as defined by Article 18) at a local or community level. To fulfil this capacity, there must be sufficient resources, policies and personnel in place at the local level to immediately implement preliminary control measures. Risk communication is a major component of local and national response and is important to

convey essential information to the public so that a public health event can be properly controlled.

Confirmation: Confirmation capacities under the IHR (2005) require that countries be able to “confirm the status of reported events and to support or implement additional control measures” in a timely manner. To comply with confirmation capacities, laboratory facilities must be available at the provincial and/or federal level to diagnose all IHR-specified conditions, and be able to characterize new or emerging diseases. Furthermore, epidemiological, surveillance analysis and environmental health experts must be available to conduct timely investigations into public health events.

Risk Assessment: IHR (2005) risk assessment capacities require that reported events are assessed immediately, according to the Annex 2 Decision Instrument. In order to comply with this capacity, there must be individuals with expertise in a variety of public health fields at provincial and federal levels, who are familiar with the IHR (2005), have access to all event information and can use the Decision Instrument in their assessment activities. The assessment activities pursued during the listeriosis outbreak were partially compliant with IHR (2005) requirements.

Appendix B – Complete list of references used to reconstruct the 2008 Canadian listeriosis outbreak

Article Title	Date of Publication	Source
CFIA warns against consuming corned beef product	8/18/08	CTV News
Most people unaware of Listeria infection	8/21/08	CTV News
Listeriosis, fatal, meat product - Canada	8/21/08	ProMed
Officials suspected spread of bacteria in July	8/22/08(a)	CTV News
Maritimes outbreak showed listeria can taint food	8/22/08(b)	CTV News
Canada Links a 3rd Death to Bacteria	8/22/08	New York Times
Maple Leaf Foods plant linked to Listeria outbreak	8/23/08	CTV News
Listeriosis linked to 12 deaths: health officials	8/25/08(a)	CTV News
Maple Leaf should rebound from recall: experts	8/25/08(b)	CTV News
Canada Expands Recall of Cold Cuts and Raises Death Toll	8/25/08	New York Times
Listeriosis, fatal, meat product - Canada (02)	8/25/08	ProMed
Class action lawsuit launched over listeria outbreak	8/26/08	CBC News
Sask. Senior diagnosed with listeriosis dies	8/26/08	CTV News
Listeria fears after Canada deaths	8/26/08	BBC News
Federal inspectors not at fault for listeriosis outbreak: agriculture minister	8/27/08(a)	CBC News
Food safety agency allowing producers to police themselves: ex-inspector	8/27/08(b)	CBC News
More legal actions begin against Maple Leaf Foods	8/27/08(c)	CBC News
Inspectors failed to adopt more rigorous U.S. measures	8/27/08	Globe and Mail
How Maple Leaf Foods is handling the Listeria outbreak	8/28/08(a)	CBC News

Article Title	Date of Publication	Source
8 people now dead because of listeriosis: health official	8/28/08(b)	CBC News
Product recall list grows over listeria concerns	8/28/08(c)	CBC News
Ont. urges family doctors to save blood tests for listeriosis patients	8/28/08(d)	CBC News
Listeriosis, fatal, meat product - Canada (03)	8/28/08	ProMed
B.C. death raises listeriosis outbreak toll to 9	8/29/08	CBC News
Ottawa wanted U.S. to accept more lenient meat inspection regime	8/29/08	Globe and Mail
Alberta confirms new Listeria-related death	8/30/08	CTV News
Listeria warning issued for certain B.C. sandwiches	8/31/08	CTV News
PM pledges listeriosis probe as death toll rises to 13	9/3/08	CBC News
Recalled Maple Leaf products found in Montreal	9/3/08	CTV News
Liberals call for Ritz's resignation over listeriosis outbreak	9/4/08	CBC News
Bologna sold in N.L. added to Maple Leaf recall	9/4/08	CTV News
Contaminated slicing machines likely source of listeriosis: Maple Leaf CEO	9/5/08	CBC News
Likely' source of Listeriosis outbreak found	9/5/08	CTV News
Harper sets terms for listeriosis probe	9/6/08	CBC News
Harper sets terms for probe into Listeria outbreak	9/6/08(a)	CTV News
The complete list of recalled foods	9/6/08(b)	CTV News
Listeriosis claims B.C. woman	9/8/08	CBC News
Officials confirm 15th death from listeriosis outbreak	9/10/08(a)	CTV News
Titanium surfaces better at preventing Listeria: study	9/10/08(b)	CTV News
Ottawa listeriosis death linked to outbreak	9/11/08	CBC News

Article Title	Date of Publication	Source
Health officials confirm 16th death from listeriosis	9/11/08	CTV News
Listeria outbreak exposes cracks in public health safety: Ont. labs' head	9/12/08	CBC News
N.B. woman 17th listeria death linked to Maple Leaf products	9/16/08(a)	CBC News
CMAJ slams Conservatives' move to self-monitoring in meat industry	9/16/08(b)	CBC News
Maple Leaf reopens plant at heart of listeria outbreak	9/17/08	CBC News
Ritz sorry for 'tasteless' Listeria comments	9/17/08(a)	CTV News
Maple Leaf reopens plant linked to Listeria outbreak	9/17/08(b)	CTV News
Medical journal slams Tories over listeriosis cases	9/17/08(c)	CTV News
Infant with listeriosis dies in Manitoba	9/18/08	CBC News
Number of Listeria deaths in Canada reaches 18	9/19/08	CTV News
Public Health Officer absent during outbreak: journal	9/20/08	CTV News
Second case of listeriosis confirmed in N.B.	9/24/08	CTV News
Another death linked to the listeriosis outbreak	9/27/08	CTV News
Listeriosis toll reaches 20 with new death in T.O.	10/1/08	CTV News
Listeriosis, fatal, meat product - Canada (04)	10/5/08	ProMed
Policy change delayed alarm signal over listeria, inspectors say	10/6/08	CBC News
Listeriosis is the least of it	10/7/08	CMAJ ⁽⁵⁾
Listeriosis: a primer	10/7/08	CMAJ ⁽²³⁾
Shifting to food industry self-monitoring may be hazardous	10/7/08	CMAJ ⁽⁴³⁾
CFIA told to warn public about tainted meat days before advisory	10/8/08	CBC News
I'd never seen anything like this,' expert says of listeria test results	10/9/08	CBC News

Article Title	Date of Publication	Source
Listeria in meat no surprise: Maple Leaf	10/9/08	CTV News
Maple Leaf Foods assessing Listeria-killing chemical	10/12/08	CTV News
Health Canada approves preservative that could inhibit listeria	10/13/08	CBC News
Meat from Maple Leaf plant given the OK	10/21/08	CTV News
Learning from Listeria: the autonomy of the Public Health Agency of Canada	10/21/08	CMAJ ⁽³⁶⁾
CFIA to launch new listeria testing protocols	11/7/08	CBC News
Listeria files withheld under deluge of access-to-information requests	12/19/08	CBC News
Listeria, food safety brought to public attention in '08	12/23/08	CTV News
Promised listeriosis probe still lacks investigator	1/5/09	CBC News
Promised listeriosis probe still lacks investigator	1/5/09	CTV News
Former Edmonton health chief to investigate listeriosis outbreak	1/20/09	CBC News
Listeriosis investigator accused of conflict of interest	1/21/09	CBC News
CFIA investigates after listeria found in meat from Toronto plant	1/24/09	CBC News
Meat Recall Timeline	2/2/09	CBC News
Listeria monocytogenes outbreak	8/26/2008 - 10/17/2008	PHAC

Appendix C – Detailed description of the 2008 listeriosis outbreak

Outbreak description compiled from media and government reports listed in Appendix B.

June

In June there was a slight increase in reported cases of listeriosis in Ontario; eight cases were reported, whereas four to five are normally expected. This increase was not considered to be significant at the time since there did not appear to be any significant association between cases. Initially, there was no molecular typing performed for any of these cases. Typing occurred later in the outbreak once clustering of cases was detected. Retrospectively, all eight cases were linked to the outbreak, indicating that exposure to *Listeria* must have occurred sometime between April and June 2008.

July

Over the course of July, an additional 11 cases were retrospectively linked to the outbreak, raising the total number of cases to 18. The first set of events that alerted health authorities to the potential of a listeriosis cluster occurred mid-month. Only July 16th, Toronto Public Health (TPH) received a report of listeriosis from a long-term care facility. Five days later, on July 21st, there was another report from the same nursing home. Both cases ended up dying of listeriosis. Clustering of two cases of listeriosis in time and place indicated to TPH that there might be foodborne contamination at the facility. Samples of ready-to-eat meat from sandwiches served at the facility were forwarded to a Health Canada (HC) laboratory for analysis after it was determined that both cases may have been linked by food consumption. Once a possible cluster of cases was identified, the Ontario Ministry of Health and Long Term Care became involved and began a retrospective epidemiologic investigation, looking for genetic clustering of all listeriosis cases. Laboratory specimens of all cases of listeriosis from recent months were sent to the listeriosis Reference Service at the National Microbiology Laboratory (NML) for genetic typing at the end of the month. Samples were sent out-of-province for genetic analysis, despite Ontario Public Health Laboratories possessing adequate capacity to perform the genetic typing themselves.

August

Twenty-two cases of listeriosis experienced symptom onset over the course of August and the first deaths associated with the outbreak began to occur. Investigation into the outbreak continued throughout the month. Toronto Public Health (TPH) received laboratory results from Health Canada, confirming that the sandwich meat collected from the Toronto nursing home that experienced the cluster of cases was indeed contaminated with *Listeria monocytogenes*. These results were received on August 5th, two weeks after they were submitted. On August 6th, TPH notified the Canadian Food Inspection Agency (CFIA) of the test results. Immediately upon receiving notice from TPH, CFIA returned to the long-term care facility to collect additional samples of sandwich meat, both from sandwiches and from unopened packages. Although they were notified immediately after TPH received laboratory results, CFIA did not begin their investigation into the manufacturer of the contaminated meats, Maple Leaf Foods, until August 12th. Once Maple Leaf learned of the investigation, they voluntarily placed an immediate hold on distribution of their products under investigation.

While CFIA was continuing their investigation into Maple Leaf and the long-term care facility, on August 14th TPH had collected what was believed to be sufficient evidence to implicate Maple Leaf ready-to-eat meats in recent cases of listeriosis. Dr. Vinita Dubey, Associate Chief Medical Health Officer cited their chain of evidence consisting of two deaths with listeriosis as the underlying, or contributing cause, with more cases being reported, all epidemiologically linked to Maple Leaf meats of which sandwiches and unopened packages had tested positive for *Listeria monocytogenes*. TPH requested that CFIA issue a public warning about the consumption of the Maple Leaf meats in question. CFIA refused the request, citing that they required further evidence, specifically, the results of the genetic typing of patient laboratory specimens before they would issue a warning. Unable to issue a formal warning, TPH warned all local long-term-care facilities and nursing homes against serving all prepared meats.

August 16th, CFIA received laboratory results for the Maple Leaf products tested for *Listeria*. Twenty-six samples were collected from high-risk locations, like hospitals, long-term-care facilities and AIDS Hospices, and 17 samples tested positive for a virulent strain *L. monocytogenes*. Despite conclusive evidence of contamination, CFIA still refused to issue a warning, citing insufficient evidence.

Upon learning of the positive tests for *L. monocytogenes*, Maple Leaf issued a recall of all offending products on August 17th. Still citing a lack of evidence to conclusively link the contaminated meat and the increased incidence of listeriosis, CFIA issued the first public warning against serving or consuming certain Maple Leaf products. CFIA claimed that there were still no confirmed cases of listeriosis associated with the contaminated products, despite the epidemiologic evidence, as they were waiting for the results of the genetic typing of human specimens.

On August 20th, the Public Health Agency of Canada (PHAC) made their first public announcement about the outbreak, confirming that there was one death and 16 cases of listeriosis directly associated with certain Maple Leaf meats. As a result of this announcement, Maple Leaf expanded their recall to 23 products and closed their Toronto plant implicated in the outbreak. On August 23rd, PHAC fully confirmed the link between the nationwide increase in listeriosis with contaminated meats from Maple Leaf, when genetic typing results of human specimens were finally received from NML. The genetic evidence indicated that four deaths and 21 cases to date were associated with a single strain of *L. monocytogenes*, also isolated from Maple Leaf meats. Genetic typing of *L. monocytogenes* strains took three weeks to complete after being sent to NML by the Ontario Ministry of Health and Long Term Care. These results also arrived two and a half weeks after TPH identified that contaminated Maple Leaf meat from a Toronto long-term care facility was epidemiologically linked to a cluster of two deaths from listeriosis. Following the announcement by PHAC, Maple Leaf expanded their product recall once again to include all 220 products produced at their Toronto facility on August 24th.

PHAC began to publish regular updates on the outbreak once clear case definitions were set. On August 26th, there were 29 confirmed cases, for which the outbreak strain was acquired through the consumption of contaminated Maple Leaf products and 30 suspected cases, for which the individual tested positive for the outbreak strain, but the link to Maple Leaf products was not yet established. In addition to the current cases, there were 6 deaths associated with the outbreak, for which listeriosis, caused by the outbreak strain of *L. monocytogenes*, was the contributing or underlying cause of death. An additional 9 deaths were still under investigation. The cases and deaths to date were located in Ontario, British Columbia and Saskatchewan

Response measures undertaken by PHAC and CFIA to support the Maple Leaf recall included verifying that over 15 000 institutions, distributors and retailers had

removed the recalled products by August 28th. PHAC also attempted to assist in the public response to the outbreak by widely publishing risk factors, signs and symptoms of listeriosis. A request was also forwarded to all family physicians to only submit blood tests for individuals at risk for listeriosis who presented with symptoms in an attempt to limit the burden on public health laboratories and increase the timeliness of essential tests. By August 31st, there had been 11 confirmed deaths and 33 confirmed cases associated with the outbreak, which had just recently been detected in Alberta.

September/October

The outbreak was beginning to decline in September with only 4 cases beginning onset of symptoms of the course of the month, compared to 22 in August, 18 in July and 8 in June. Over the course of the month, additional cases were investigated on Prince Edward Island and in Manitoba. The total number of confirmed deaths associated with the outbreak rose to 20 by October 1st.

On September 5th, Maple Leaf continued their efforts to mitigate the outbreak by identifying the sources of contamination as being two slicing machines. These machines, along with all other machines in their Toronto facility, were disassembled and thoroughly deep cleaned four times before being rested for contamination and reassembled. After sufficient evidence that the source of contamination was eliminated, Maple Leaf reopened their Toronto facility on September 17th, but did not resume distribution until the end of October when meat samples finally began testing negative for *L. monocytogenes*.