Evidence Base for Best Practices

for Public Health Laboratories

and their Networks

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AUTHORS

Dr. Judy Isaac-Renton (Team Leader)
Public Health Laboratory Director, PHSA Laboratories Discipline Head, and BCCDC Site Director
Professor, Department of Pathology and Laboratory Medicine, UBC
Co-Chair, Canadian Public Health Laboratory Network
Co-Chair, BC Provincial Infection Control Network

Bruce Gamage
Infection Control Consultant, BCCDC Laboratory Services

Dr. Swee Han Goh
Senior Scientist, BCCDC Laboratory Services
Clinical Associate Professor, Department of Pathology and Laboratory Medicine, UBC

Dr. Linda Hoang
Medical Microbiologist, BCCDC Laboratory Services
Assistant Professor, Department of Pathology and Laboratory Medicine, UBC

Dr. Mel Krajden
Director, BC Hepatitis Services, BCCDC
Medical Microbiologist, BCCDC Laboratory Services
Associate Professor, Department of Pathology and Laboratory Medicine, UBC

Dr. Muhammad Morshed
Head, Zoonotic and Emerging Pathogens, BCCDC Laboratory Services
Clinical Associate Professor, Department of Pathology and Laboratory Medicine, UBC

Dr. Corinne Ong
Senior Scientist, BCCDC Laboratory Services
Assistant Professor, Department of Pathology and Laboratory Medicine, UBC

Dr. Martin Petric
Clinical Virologist, BCCDC Laboratory Services
Professor, Department of Pathology and Laboratory Medicine, UBC

Edward Ratnarajah
Director, Emergency Management Support and Operations, BCCDC and BCCDC Laboratory Services
Chief Biohazard, Biocontainment/Biosafety

Amelia Trinidad
Head, Quality Management, BCCDC Laboratory Services
(Chief Technologist, PHSA Laboratories BCCDC Site)

Other Contributors
Yin Chang
Dr. Vicki Foerster
Kit Johnson
Julia Kingsbury
Margaret Litt
Dr. Malcolm Steinberg

EXECUTIVE SUMMARY

There is an increasing need for a strong and responsive public health system. To this end, core functions in public health have been established by BC's Ministry of Health. With respect to public health laboratories in particular, the purpose of this report is to provide an evidence base for the core functions of public health laboratories and their networks.

As distinct from regional acute care or private laboratories, public health laboratory programs are specialized in population-focused ways. They are required to be responsive to outbreaks and their investigations; they must respond to change quickly, e.g., react to new pathogens; they must have experts that lead, coordinate, train, and perform surge capacity services; they must be nodes for the province's microbiology network, acting as the link to the National Microbiology Laboratory (NML); they must carry out clinical and environmental testing for surveillance and outbreak management, responding to special requests for unique testing and follow-up; and they must be skilled in biosafety, biohazard containment, and bioterrorism response.

A public health laboratory must be in top form at all times, employing a Quality Management System (QMS) to ensure competent performance. Structured planning, continuous review and analysis, and ongoing process improvements mean that evolving "Best Practices" are adopted. Originally resulting from system-wide failures in public health laboratories in the United States, recent expert opinion derived core functions of public health laboratories are considered to be Best Practices for the unique roles of public health laboratories, including:

1) Communicable disease surveillance, prevention, and control
2) Outbreak and emergency response to communicable diseases
3) Environmental health and food safety
4) Reference testing, specialized screening, and diagnostic testing
5) Biosafety, biocontainment, and biohazard response
6) Integrated data management
7) Policy development and evaluation
8) Laboratory improvement and regulation (quality assurance)
9) Training and education of health care and public health workers
10) Public health related research and development.

This report presents the evidence behind the development of the 10 core functions for public health laboratories. Indirect evidence for the importance of meeting and sustaining these core functions is provided through specific examples of successes and failures. Many will be very familiar to the reader through media exposure, e.g., SARS, West Nile virus, Walkerton water contamination, and anthrax bioterrorism.

As new public health challenges arise, the effectiveness of response of the public health system will depend in part on the ability of BC's public health laboratory network to work to Best Practice standards. Based on the evidence, the authors recommend that Best Practices in public health laboratories be sustained by:

- Strengthening the public health laboratory network through enhanced partnerships with other types of microbiology laboratories within the jurisdiction by building on current networking.
- Strengthening specific provincial public health laboratory core functions and specific nodes/functions in the national public health system.
- Enhancing efficiencies and effectiveness through clearly defined roles and responsibilities regarding service/program core functions within laboratory networks.
- Supporting the need for leadership in fundamental areas, particularly in information management and QMS development.

ABBREVIATIONS AND ACRONYMS

APHL	Association of Public Health Laboratories [United States]
BC	British Columbia
BCCDC	BC Centre for Disease Control
CCHSA	Canadian Council on Health Services Accreditation
CDC	Centers for Disease Control [United States]
CL-3	Containment Level 3
CPHLN	Canadian Public Health Laboratory Network
CSA	Canadian Standards Association
HCAI	health care acquired infection
HIV	human immunodeficiency virus
ISO	International Organization for Standardization
LRN	Laboratory Response Network [United States]
NML	National Microbiology Laboratory
PFGE	pulsed field gel electrophoresis
PHSA	Provincial Health Services Authority
PICNet	Provincial Infection Control Network
PLCO	Provincial Laboratory Coordinating Office
PPE	personal protective equipment
QMS	quality management system
RT-PCR	reverse transcriptase polymerase chain reaction
SARS	severe acute respiratory syndrome

Evidence Base for Best Practices for Public Health Laboratories and their Networks

TABLE OF CONTENTS

1.0 REPORT CONTEXT AND OBJECTIVES

The public health system is integral to health care at many levels and, in fact, the approach in public health is considered to be more a system than the traditional medical model. Public health laboratories and their provincial, national, and international networks are a fundamental component of a public health system. They provide a framework for using a population health lens to guide the various services provided, not just by public health laboratories but by all laboratories.

In March 2005, a British Columbia (BC) Ministry of Health Services document, *Public Health Renewal in British Columbia: An Overview of Core Functions in Public Health,* established core functions in public health (BCMOHS 2005). In order for the Ministry to evaluate the core functions of the province's public health laboratories in an ongoing cycle of improvement, performance improvement measures based on an evidence review are needed. The purpose of this report is to provide an evidence base for the core functions of public health laboratories and their networks. In addition, to illustrate the essential nature of public health laboratory services, examples of the impacts and costs of failures in public health laboratory systems are presented.

2.0 BACKGROUND

Approach taken by this report

Laboratories provide essential information to physicians for patient management. The BC Laboratory Services Review (Bayne, 2003) reported that *"laboratory tests make up about 70% of the objective data reported in a patient's health record and some estimate that 60 to 70% of diagnoses are based on pathology tests"*. Laboratories are also integral to the operation of the public health system. In particular, public health laboratories and their networks are a key component of public health infrastructure.

This report first presents an overview of the roles of different types of laboratories. Following this introductory section, the report reviews the evidence base for "Best Practices" for public health laboratories in the following sections:

- Laboratory quality management as Best Practices
- Core functions of public health laboratories as Best Practices
- Impacts and costs of public health laboratory failures.

Laboratories and laboratory networks

Laboratories impact many decisions in patient care and population health. The information they provide is necessary for: accurate diagnosis to rule in or rule out various illnesses, selection of therapies, therapeutic monitoring, population level epidemiology data to monitor trends and outcomes, and molecular fingerprinting or other forms of typing of organisms for national and international surveillance and response.

In this section of the report, laboratories and laboratory networks will be defined under the following headings to allow for a common understanding:
2.1 Similarities and differences amongst laboratories
2.2 Roles of community sector laboratories in public health
2.3 Roles of acute care laboratories in public health
2.4 Roles of public health laboratories
2.5 Laboratory networks
2.6 Change drivers

2.1 Similarities and differences amongst laboratories
Although functions may differ, all medical laboratories share several common platforms. For example, they carry out their responsibilities in the same recognized areas (explored further in Appendix A): pre-examination, examination, post-examination, and value-added. Each type of laboratory then defines these areas in the context of its particular stakeholders, clients, and jurisdictions.

Differences among laboratories are also important – as important in laboratories as physician specialists are to patient care in the medical model – because various types of laboratories have unique and specialized roles. A public health laboratory is one type of specialized medical laboratory. A certain level of redundancy amongst laboratories is also needed for instances where vulnerable areas may risk collapse and ongoing services (business continuity) are critical.

Medical laboratories within a network may focus on different disease areas. For example, if a care provider suspects that a patient or population is being affected by an infectious agent, the laboratory-scientific discipline required will be microbiology. On the other hand, patients with suspected cancer will be diagnosed by laboratory experts in a discipline such as anatomical pathology. Acute care hospital laboratories often have wider spectrums of disciplines within their laboratories than other types of laboratories whereas public health laboratories focus primarily on microbiology.

Data considerations are important. Public health assessment requires that patient-specific data be collected in order to manage the care of individual patients, but there is also a need to bring together comprehensive information to allow for tracking of population outcomes and co-morbidities. In particular, the needs of vulnerable populations must be recognized and acted upon. A balance must be achieved between the benefits of protecting the privacy and confidentiality of the individual and the benefits of comprehensive population-level information that is synthesized and devoid of unique identifiers.

2.2 The roles of community sector laboratories in public health
Private sector ("for profit") medical laboratories generally carry out routine, relatively simple tests, operating at a community level of patient care. In some jurisdictions, funding may drive the type of testing offered. These laboratories are linked to public health through the BC *Health Act Communicable Disease Regulation* (www.qp.gov.bc.ca/statreg/reg/H/Health/4_83.htm). They are also linked through a reference testing network because public health laboratories act as microbiology reference laboratories in most provinces and states throughout North America.

2.3 The roles of acute care laboratories in public health
Acute care laboratories perform both routine and complex tests, depending on regional factors and the needs within each health authority and, like community laboratories, are linked to public health through public health legislation and the reference testing network. Acute care microbiologists are also infection control officers who work closely with regional infection control practitioners.

2.4 The roles of public health laboratories

What role does a public health laboratory have in comparison to that of a private laboratory or acute care? The distinction is illustrated in a Journal of Clinical Microbiology commentary (McDade & Hausler, 1998)*:*

> *"Private laboratories may test a stool specimen from a person with an enteric illness and culture it for a pathogenic bacteria from which a given species may be recovered. In doing so, this laboratory has provided the necessary information to ensure appropriate patient management is provided. In contrast, public health laboratories subtype pathogen isolates using molecular microbiology-based techniques to determine whether the patient's illness is sporadic or if other persons in the community have been infected with the same strain. In turn, the sub-typing information is often transmitted to a common national [or international] database in order to assess for common infections across geographical boundaries."*

In BC, public health reference laboratories (rather than private laboratories) actually perform the majority of this work, emphasizing the need for a highly trained and equipped laboratory core of technical, scientific, and medical staff.

Programs at public health laboratories, as distinct from regional acute care or private laboratories are:

- Population focused.
- Networked to allow provision of comprehensive services, including specialized reference testing.
- Established with capacity to respond to outbreaks and investigations.
- Partnered with stakeholders to create new knowledge using an appropriate health lens.
- Capable of leading, coordinating, training, and performing services in a surge capacity situation.
- Capable of carrying out clinical and environmental testing for surveillance and outbreak management.
- Capable of responding to special requests for unique testing and follow-up.
- Capable of biosafety and biohazard containment, including bioterrorism response.
- Capable of long-term biological sample storage and biosecurity of dangerous pathogens.
- Able to respond to change quickly, e.g., to react to new emerging pathogens or bio-terrorism agents.
- Largely microbiology focused with competence in the areas of infection control and biosafety.

Samples (both environmental and clinical) may flow through a provincial clinical network and then, as needed, into the provincial/federal public health network. The provincial public health laboratory is the central node in this network, answering questions of public health or reference importance and linking the provincial public health reference laboratory with the national laboratory public health network. Questions arising in the areas of clinical or environmental public health often start with medical health officers, public health nurses, environmental health officers, or other public health workers.

Molecular testing is the future of modern diagnostic epidemiology services, requiring unique training and quality standards. Its function has never been more important than in today's "global village". Diseases are able to spread more widely and at greater speed than ever before. The phenomenon of emerging diseases such as Severe Acute Respiratory Syndrome (SARS), West Nile virus, antibiotic resistant organisms, and avian influenza are well recognized, as are re-emerging diseases such as cholera, dengue fever, and drug-resistant tuberculosis. Public health laboratories, because of their need to respond quickly to new pathogens, and by virtue of their scientific leadership and reference functions, are also leaders in molecular microbiology.

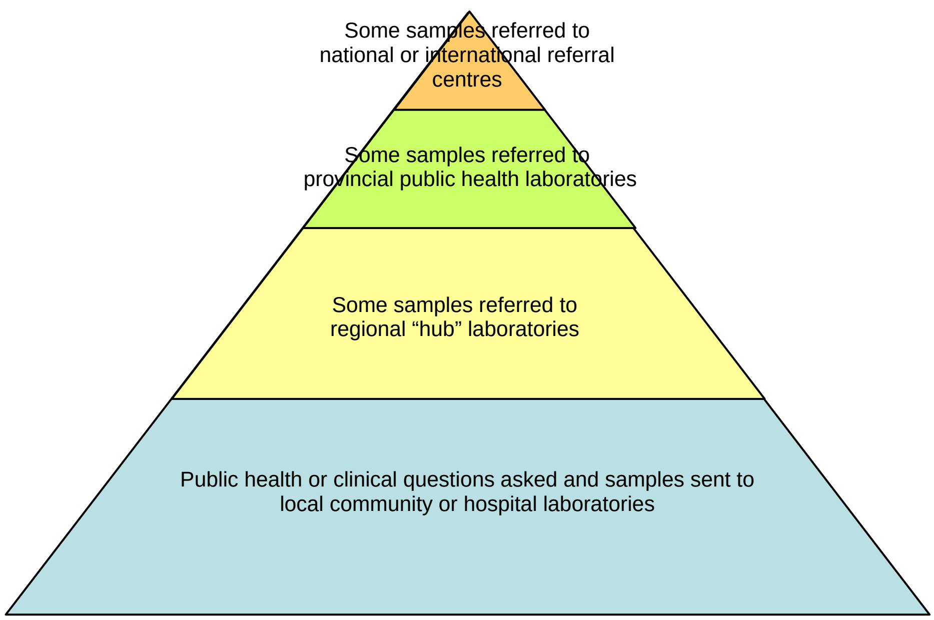
The unique functions of public health laboratories were first identified in the mid-1970s, being regarded as an essential public health function by the World Health Organization (Skeels, 1999). Since that time, both Naylor and Kirby in their post-SARS reports to the Canadian government strongly recommended strengthening existing public health laboratory capacity to enable rapid and effective responses to infectious disease outbreaks (Kirby, 2003; Naylor, 2003).

2.5 Laboratory networks

Communicable disease surveillance, prevention, and control functions are fundamental to public health laboratories worldwide (Health Assessment and Disease Surveillance, 2006; Yuan & Vogel, 2006). Inherent in a public health laboratory's ability to effectively perform surveillance is the need for it to lead in the provincial laboratory network. Thus networks provide data standardization and the sharing of information with other laboratories. Provincial public health laboratories act as the focal centres within their networks for surveillance and reference work and also serve as provincial nodes in national and international public health laboratory networks. They help to shape the nature of networked services using a population lens and they assist in making sure that services necessary to public health are provided effectively, with information available to track trends, plan policies, and evaluate outcomes.

In general, laboratories function through a hierarchy of sample flow for testing that depends on requests from case management staff or public health workers (Figure 1). In order for public health to obtain optimal laboratory surveillance information, closely linked and efficient laboratory networks are important.

Figure 1: Hierarchy of Sample Flow in the Provincial Network



The Ministry of Health and laboratory leaders in BC have renewed their commitment to quality improvement through a more efficient and effective laboratory network via the creation of the Provincial Laboratory Coordinating Office (PLCO) whose mandate is coordination and leadership in province-wide laboratory improvement. In order to develop an efficient provincial network, the PLCO led a workshop in June 2006 at which provincial, national, and international experts focused on laboratory testing for the different levels of complexity seen in Figure 1. One proposed outcome from this recent workshop was a "hub-and-spoke" model wherein the BC public health laboratories have programs based on defined core functions (VPDD, 2006)

A strong network requires well-defined roles and responsibilities for all these laboratories, with some redundancy to allow for response to emergencies. These roles and responsibilities are evidence- based as much as possible, and are updated when new knowledge becomes available. Leadership is needed to create a dynamic network because practices are constantly evolving. Following the SARS disaster in Ontario, Naylor's report underscored the risk associated with a fragmented weak public health system and public health laboratory system (Naylor, 2003). The Bayne Report also noted fragmentation to be an issue for the BC laboratory network (Bayne, 2003).

In summary, the role of public health laboratories in the BC network includes:

- Partnering within a network in a recommended "hub-and-spoke" or other relational model.
- Investing in qualified medical, scientific, and technical staff.
- Maintaining a critical mass of laboratory expertise and technology to support the highly specialized public health and tertiary laboratory services not amenable to population-based funding formulas.
- Supporting the roles of community/private sectors for public health with particular leadership for Quality Management Systems (QMS), test standards, and information sharing.

2.6 Change drivers

Drivers of change impacting laboratories world-wide are science, technology, emerging/re-emerging pathogens, human resources, and rising health care costs (Binder et al, 1999; MMWR, 1999; Bayne 2003; APHL 2005b). The greatest defense against emerging pathogens, bioterrorism, and pandemic disease is to ensure that laboratory experts at all levels in a network are in lock-step with related science; that they are well trained and well equipped; and that the provincial public health laboratory working within its pan-Canadian partners, is capable of recognizing unusual isolates and characterizing them quickly and accurately (Barker et al., 2006). Non-communicable diseases require this same network as they consume tremendous resources and require quality assurance processes to ensure good value for expenditures.

3.0 METHODS

Literature search

For the base document, the Ovid® system was used to search for journal articles in Medline and EBSCO, using the key words *core function*, *public health*, *laboratory,* and *surveillance.* For grey literature, relevant documents were located through a Google™ Scholar search resulting in links to provincial, national, and international laboratories. Experts at facilities such as the BC Centre for Disease Control (BCCDC), the Canadian Public Health Laboratory Network (CPHLN), the NML, and the Association of Public Health Laboratories (APHL) were contacted for advice as to other pertinent material. The report was augmented using reference documents that describe best practices for public health laboratories, including the APHL white paper (APHL, 2000); *Core Functions and Capabilities of State Public Health Laboratories* (MMWR, 2002); and *Core Functions of Canadian Public Health Laboratories* (CPHLN, 2004). Additional material was contributed by a number of experts in specific areas.

4.0 QUALITY MANAGEMENT SYSTEMS AS BEST PRACTICES

Laboratory practice based on a QMS is considered to be "Best Practice" for all types of laboratories, including public health laboratories. Structured planning, continuous review and analysis, and ongoing process improvements, are important parts of the renewal needed in any QMS. Thorough implementation and ongoing use of the "Deming Cycle" (Plan→Do→Check→Act) means that Best Practices for any type of laboratory (as well as more efficient use of scarce resources) will evolve. Public health laboratories should not only implement Best Practices through use of a QMS, they should also serve as provincial resources to lead, support, and train laboratory network staff province-wide to meet high quality standards.

The International Organization for Standardization (ISO), and its Canadian affiliates, the Standards Council of Canada and the Canadian Standards Association (CSA), have been leaders in QMS, including systems for laboratories. The ISO has promulgated standards for laboratories as Standard ISO 15189. The first version of the standards was released in 2003 and was then taken up in Canada as CAN/CSA Z15189-03 *Medical Laboratories-Particular requirements for quality and competence.* ISO 15189 is a standard with multiple applications. However, its primary application is to improve the structure and function of medical laboratories. Laboratory accrediting bodies find ISO 15189 valuable. It is being used in several Canadian provinces for provincial accreditation of diagnostic facilities, by the Canadian Council on Health Services Accreditation (CCHSA) in a new laboratory accreditation initiative, and in a number of countries around the world. (See www.csa.ca and www.sccsc.ca for more on ISO 15189.)

Accreditation has been defined as *"a program in which trained external peer reviewers evaluate a health care organization's compliance with pre-established performance standards"* (Shaw, 2004). Increasingly, accreditation is rising to an international standard. The shared exercise involved in meeting accreditation standards is common to all medical laboratories and is separate from leadership roles in quality. Official recognition in the form of accreditation can be an important step for a laboratory because it demonstrates in a clear, objective, and independent fashion the competence of a laboratory and its personnel. A medical laboratory must have a QMS in place to ensure that it functions effectively and efficiently and the QMS must address both typical management concerns and special technical aspects. The standards are as relevant in a full-service medical laboratory as they are in a laboratory providing specialty public health core functions. The key elements of ISO 15189 are noted below in Tables 1 and 2.

Table 1: ISO 15189 Management Requirements

Organization and management
Quality management system
Document control
Evaluation and selection of referral laboratories
External services and supplies review
Advisory services
Resolution of complaints
Identification and control of non-conformity
Corrective action
Preventative action
Continual improvement
Quality and technical records
Internal audits
Management review

Table 2: ISO 15189 Technical Requirements

Personnel
Environmental conditions
Laboratory equipment
Pre-examination procedures
Examination procedures
Quality assurance
Post-examination procedures
Reporting results

According to Canadian Standards Association materials (CSA, 2004), a well-developed QMS clarifies that the quality of a laboratory's operations is intimately tied to the efforts of its quality partners. In a performance-based improvement model for public health, this refers to many other core programs. For example, other evidence reviews performed for the BC Ministry of Health make reference to the importance of both laboratories and specifically the public health laboratory (Health Assessment and Disease Surveillance, 2006).

5.0 CORE FUNCTIONS OF PUBLIC HEALTH LABORATORIES AS BEST PRACTICES

While a QMS is an overarching Best Practice for all medical laboratories, recent expert-opinion-derived core functions of public health laboratories are considered to be Best Practices for the unique roles of public health laboratories. System-wide failures in public health laboratories in the United States led to the assembling of an expert panel through the Association of Public Health Laboratories (APHL). From this, a white paper was published reporting on the core functions and capabilities of state public health laboratories (APHL, 2000). Roles and values were emphasized and core functions were defined.

The core functions developed by the APHL are experience-based rather than being purely evidence-based. They serve a vital role in defining the place of public health laboratories in the health system. The APHL published a white paper in 2000, defining the core functions of public health laboratories and giving examples of responsibilities under each core function. These core functions are tied to 10 essential services of public health that were defined in the late 1980s (MMWR, 2002). The core functions cut across and are critical to many public health programs and strategies.

The APHL White Paper material has been adopted internationally. In Canada, the Public Health Agency's CPHLN embraced the core functions as the minimum required to maintain services, competency, and capabilities for public health programs. Core functions are not primarily testing functions but are program based. The 10 public health laboratory core functions are set out as:

1. Communicable disease surveillance, prevention, and control
2. Outbreak and emergency response to communicable diseases
3. Environmental health and food safety
4. Reference testing, specialized screening, and diagnostic testing
5. Biosafety, biocontainment, and biohazard response
6. Integrated data management
7. Policy development and evaluation
8. Laboratory improvement and regulation (quality assurance)
9. Training and education of health care and public health workers
10. Public health related research and development.

Performance standards for public health laboratories are currently under development and, by 2007, the APHL intends to develop and field test an instrument for determining how well public health laboratories are meeting these standards (Personal communication, Dr. Stanley Inhorn, Chair, Laboratory Systems and Standards Committee, APHL).

1. Communicable disease surveillance, prevention, and control

Surveillance is defined as "the ongoing, systematic use of routinely collected health data to guide public health action in a timely fashion" (Breslow, 2002). An evidence review of communicable diseases states, *"Surveillance underpins all communicable disease efforts and is a public health strategy which has application across all programs"* (Yuan & Vogel, 2006). The stages of surveillance include collection, analysis, and interpretation as well as timely communication of findings (Chambers et al., 2006). Among the many potential sources of surveillance reports, the four most common are laboratories, physicians, infection control practitioners, and specialty units, with laboratories providing the largest amount of diagnostic surveillance data (Halperin, 1992).

All types of microbiology laboratories have an important role in identifying communicable diseases. Public health laboratories and their networks play a pivotal role in surveillance, using molecular as well as traditional technologies to enable the detection of disease in a single individual, groups of individuals, or the environment (Hutwagner et al., 1997; Peterson, 2002; Yuan & Vogel, 2006). The role of the public health laboratory is also one of province-wide leadership in quality assurance, test standardization, core data set developments, and specialty/confirmatory reference testing as new infectious agents and technologies emerge. Public health laboratories must help ensure that there is an overall effective network capacity and that relevant information is shared in a timely manner.

The CPHLN states that the minimal surveillance activities a public health laboratory should be able to perform are (CPHLN, 2004):

- Providing enhanced laboratory surveillance using state-of-the-art information technology
- Determining the immune status of patients or communities to communicable diseases
- Testing for environmental contaminants, e.g., in food and water
- Studying antibiotic resistance.

To respond promptly to any new or changing microbial threat, a laboratory network must function smoothly. First detection might be in a front-line health authority microbiology laboratory with notification and referral of the isolate to the public health laboratory. In other cases, the public health reference laboratory might be the first-responder, e.g., new emerging pathogens such as SARS or avian influenza. For optimal and accurate surveillance, networking with well-defined roles and responsibilities is important.

Surveillance needs are developing and dynamic. Advances in public health medical microbiology platforms are also developing exponentially with new molecular laboratory testing tools providing more rapid and accurate information. The speed with which test results can now be conducted directly impacts outbreak detection, response and management. This "laboratory" epidemiology is often more powerful and accurate than classic epidemiologic (interview) tools. With increasingly sophisticated methods for testing (e.g., point-of-care diagnostic tests, molecular microbiology tests), the speed at which information is generated today is unprecedented. Paper-based surveillance systems are obsolete (Pfaller & Herwaldt, 1997; Bean & Martin, 2001). For example, the use of public health laboratory methods such as pulsed field gel electrophoresis (PFGE) has allowed public health to identify outbreaks that were not otherwise detected (Bender et al., 1997; Mahon et al., 1997; Swaminathan et al., 2006).

Surveillance related to health care acquired infections (HCAI) is an increasingly important issue for facility-based public health. This is partly due to the decreased number of acute care bed days available to patients before they return to the community or extended care/assisted living facilities. In the United States, HCAIs are estimated to impact more than 2 million people and cost over $4 billion health care dollars annually (Haley et al., 1985a; Haley et al., 1985b; Martone et al., 1992). However, infection rates could be reduced by approximately 32% if best practices were adhered to (MMWR, 1992).

Surveillance of trends in HCAI is also now based on laboratory molecular tools (McDonald et al., 2005). For example, public health laboratories currently submit characterized samples of provincial *Salmonella* isolates and related isolate information to the national microbiology laboratory where further tests are carried out. These data are consolidated into a national surveillance program, the Canadian Integrated Program for Antimicrobial Resistance Surveillance (CIPARS) that links antibiotic resistance trends to agricultural, environmental, and clinical areas (Conly, 2002).

2. Outbreak and emergency response

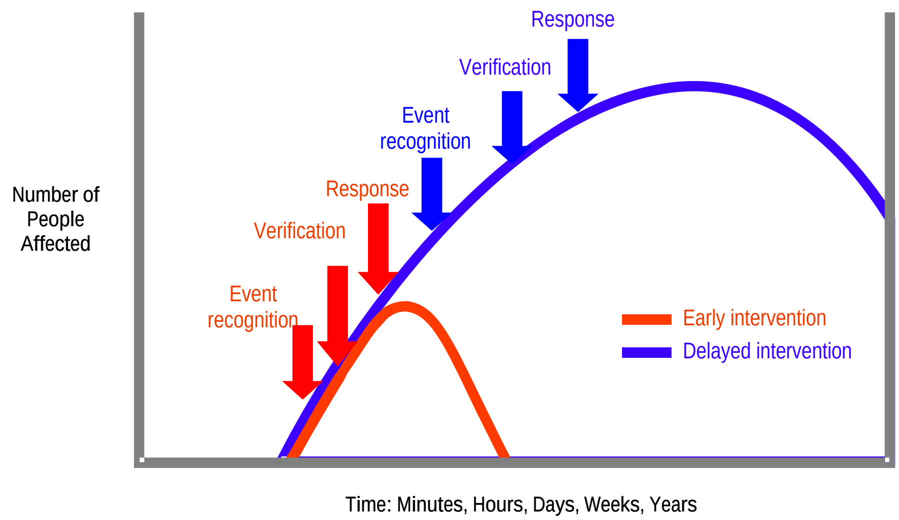
A public health laboratory should be able to lead and provide laboratory support and expertise for response/investigation of all microbiological agent outbreaks or clusters of communicable diseases. Accordingly, laboratories must support their epidemiology and public health counterparts in obtaining comprehensive information about communicable disease trends as well as supporting the investigation of outbreaks and clusters of communicable disease, including HCAIs. A public health laboratory must also have the ability to support provincial and national disaster preparedness and response; should lead in the performing, coordinating, and developing of province-wide capacity to respond quickly and accurately to new agents of disease; and should lead in coordinating large volumes of testing associated with public health emergencies (CPHLN, 2004).

Fewer infections save lives and health care dollars, and laboratories provide much of the needed data. Effective event recognition, verification, and response capacities lead to narrower epidemic curves and result in fewer people being affected by an agent or event. This important concept in epidemiological control is displayed in Figure 2. The challenge is to narrow an epidemic curve in a timely manner at both the population and individual levels. Public health laboratories lead in event recognition, verification, and early response. Their intrinsic capacity is also crucial to effect a coordinated response. The better the response, the faster the intervention.

Responses to outbreak and emergency situations require that public health laboratories (CPHLN, 2004):

- Provide laboratory, medical, scientific, and infection control support in the detection and investigation of outbreaks due to microbiological agents regardless of the source of exposure, e.g., bio-terrorism, natural disasters, and epidemics.
- Provide laboratory support and expertise as part of provincial and national disaster preparedness plans for environmental and health emergencies.
- Act as provincial centres to provide infection control and laboratory microbiological support for the prevention, outbreak investigation, and control of HCAIs and microbial antibiotic resistance trends.
- Assist in the coordination and development of capacity to respond quickly to the need for the testing of the large volumes associated with public health emergencies.

Figure 2: Event recognition, verification, and response



3. Environmental health and food safety

The burden of water-borne diseases is not known (Craun et al., 2006). With respect to the safety of drinking water, monitoring and surveillance for public health purposes is based on a network of public and private laboratories, often in a provincially legislated framework. Although over 30 waterborne outbreaks have been documented in BC over the past two decades (PHO, 2000), there are few studies documenting the impact of endemic waterborne diseases. New approaches to public health environmental surveillance and monitoring are needed related to water-borne disease surveillance including seroepidemiology and molecular typing of pathogens (Calderon & Craun, 2006; Casemore, 2006; Nichols et al., 2006).

What role can public health laboratories play? They should provide leadership in public health audits for monitoring, surveillance support for designated systems (such as small systems), development of new tools to investigate waterborne outbreaks of disease including specific pathogen detection and molecular epidemiology testing, and drinking water quality assurance (CPHLN, 2004).

With respect to food safety, the burden of food-borne illness is also not well defined (Flint et al., 2005) but food is capable of transmitting more than 200 known diseases (APHL, 2005a). Larry Copeland, Director of Food Protection Services with the BCCDC, has produced a core program evidence report for food safety in BC. Using a number of information sources and projections, the report estimates the annual number of cases of food-borne illness in BC to fall between 208,980 and 652,248 (between one in nineteen and one in six residents) and to cost between $206m million and $644 million annually (Copeland, 2006).

Copeland (2006) also presents data for Canada stating that between 1978 and 1982 there were an estimated 2.2 million cases for food-borne illness annually. To provide a context, in the United States, the Centers for Disease Control and Prevention (CDC) estimates that there are approximately 76 million cases of food-borne illnesses annually, accounting for 325,000 hospitalizations and 5,000 deaths (MMWR, 2004). Similar estimates in England and Wales put the numbers at over 2.3 million cases, 21,138 hospitalizations, and 718 deaths (Mead, 1999; Adak, 2005).

Public health laboratories act as the provincial reference laboratories for all types of food-borne illnesses, as well as providing some food safety monitoring. They work with health authorities and national experts to investigate, identify, and manage clusters of disease following food-borne spread to reduce cases of disease. For example, bacteria in contaminated food that may cause fatal or non-fatal illnesses can be identified in public health laboratories through use of DNA fingerprinting technologies such as PFGE (McLaughlin et al., 2005). The capacity requirement is increasing with the globalization of food supplies.

PulseNet™ is a CDC-led network for food-borne disease laboratory surveillance that electronically links all public health laboratories throughout North America and in some cases Australia and Europe, for timely reporting to public to prevent further illness (Gerner-Smidt et al. 2006). Canadian public health laboratories are partners in this international laboratory surveillance and response network. Assessing both societal costs and benefits, Elbasha et al (2000) estimated that preventing five cases per year would recover all costs of this public laboratory surveillance system.

This core function states that minimally a public health laboratory should be able to (CPHLN, 2004):

- Lead in environmental health monitoring, including all levels of testing, to provide excellent networked surveillance for public health.
- Provide expertise and capacity in laboratory environmental health in order to support public health workers with the capacity to identify water or food-borne contamination, clusters or outbreaks of food-borne or water-borne disease or risk of same in a timely manner.
- Provide laboratory experts to support enhanced water quality assurance and other environmental quality assurance programs for the provincial network.
- Provide training and education for public health workers in laboratory aspects of environmental health.
- Assist and lead in public health environmental research and development.

4. Reference testing, specialized screening, and diagnostic testing

In North America, public health laboratories serve an essential function as reference laboratories in all provinces and states. These laboratories act as reference centres where isolates can be sent when they are difficult to identify or when specific investigations are required (Ou et al., 1992). Expertise is also concentrated in provincial public health laboratory nodes for new pathogen recognition. At these laboratories, unique platforms or technologies such as whole genome sequencing technology are used to uncover characteristics of new pathogens, e.g., SARS, avian influenza, and *Cryptococcus*. They are key partners with national and other centres of excellence e.g., the NML in Winnipeg and the BC Cancer Agency Genome Science Centre.

Laboratory diagnostics are important for public health outcomes but the link may not always be obvious. In the absence of a unique clinical syndrome or diagnostic tool, an illness or outbreak may remain undetected and its health impact unmeasured. For example, recent spread of a previously uncommon and hyper-virulent strain of *Clostridium difficile* in Quebec (producing serious illness and death) was only identified through new molecular laboratory tools (McDonald et al., 2005). SARS is another such example. Until this new viral agent was identified, optimal public health interventions were severely hampered. This scenario was identical for Hepatitis C where the infectious agent was not known prior to the development of a specific laboratory test.

Recently, molecular tools to fingerprint microorganisms have been used to provide information on the causal agent, the source of the agent, and the relatedness of organisms/strains (Ou et al., 1992; Esteban et al., 1996; McIntyre et al., 2002; Riley, 2004; Harrington & Bishai, 2004). However, although molecular tools help identify the etiology of most outbreaks, the causes of many are as yet unknown.

Based on APHL core functions, the CPHLN recommends that a provincial public health laboratory provide specialized tests for emerging or re-emerging pathogens, for pathogens of low-incidence or for high-risk diseases (CPHLN, 2004). This includes, but is not limited to:

- Testing requested by public and private health care providers in the investigation and control of rare communicable or environmental diseases, e.g., unusual/emerging/re-emerging pathogens, SARS.
- Testing influenza specimens as directed by national and international surveillance efforts to identify viral strains and control influenza as well as other new respiratory viruses.
- Testing specimens from suspect cases of tuberculosis to identify *M tuberculosis* infections and determine effective antibiotic treatment.
- Perform tests to meet specific program needs for public health workers and agencies (e.g., confirmation of isolates detected in food or water from private laboratories in health authorities).

Specific to the role of a public health laboratory in reference testing, specialized screening, and diagnostic testing, the CPHLN (2004) also identified the following minimal requirements based on defined core functions. Public health laboratories must be able to:

- Provide services and support programs with national and inter-jurisdictional links.
- Test for unusual, rare, or high risk pathogens e.g., emerging/re-emerging pathogens, tuberculosis.
- Provide nucleic acid amplification and sequencing as well as other advanced molecular microbiology testing and molecular epidemiology services.
- Confirm atypical laboratory test results and verify results of laboratory testing for other microbiology laboratories within their network, particularly involving infections of public health importance.

Thus, public health laboratories provide reference diagnostic testing to “provincial” hub laboratories (health authority designated central feeder microbiology laboratories) that may not have the capability to fully identify disease agents of public health importance.

5. Biosafety, biocontainment, and biohazard response

A public health laboratory must be capable of performing the following minimal activities in support of epidemics/outbreaks (CPHLN, 2004):

- Laboratory support for provincial and national disaster preparedness planning for environmental or health emergencies.
- Infection control and laboratory support for the investigation of outbreaks, including support of facility-based clusters.
- Specimen examination and analysis in the identification of disease outbreaks.
- Rapid response to emerging pathogens through development of new testing.
- Laboratory support for testing of Containment Level 3 (CL-3) organisms such as tuberculosis.
- Leadership in the testing, coordinating, and developing of capacity to quickly and accurately process a large volume of tests for public health emergencies or bioterrorism events.

Bioterrorism and pandemic events are signaled by the emergence of an organism that affects an unusually diverse group of people, causing uncommon symptoms and often associated with significant risk of death. Emergency preparedness involves preplanning to manage all aspects of such an event. Specific concerns relating to bioterrorism or “germ warfare” have been characterized: *“Unlike other potential weapons of mass destruction (nuclear and chemical weapons), replicating agents pose a unique challenge because terrorists might have the capability to ‘reload’ and perpetrate repeated attacks that could potentially overwhelm defensive or security measures and our public health infrastructure and capabilities”* (Jaax, 2005).

The anthrax incident in the United States in 2001 clearly illustrated the overwhelming burden placed on the public health system following the intentional release of an infectious agent in a susceptible population (Sewell, 2003; Cockerill & Smith, 2004). As a result of that threat, the Laboratory Response Network (LRN) in the United States performed more than 1 million anthrax tests. The LRN subsequently tested, in one 18 month period, over 25,000 "unknown' samples and suspicious powders in support of law enforcement and public health agencies (APHL, 2005a; APHL, 2005b).

A public health laboratory must be capable of examining specimens and analyzing unknown risk groups or CL-3 Risk Groups (bio-terrorism agents) and must be able to lead a provincial network in the co-ordination and development of capacity to quickly and accurately handle a large volume of tests for public health emergencies (APHL, 2000; Cockerill & Smith 2004; CPHL, 2004; APHL, 2005a).

The continued, real threat of bioterrorism requires that a public health laboratory have the ability to serve as a resource for biohazard containment, and biosafety through:

- Testing to support public and private emergency workers as well as other health care providers in the investigation and control of unusual communicable or environmental diseases.
- Maintaining high quality biosafety programming and training for laboratory staff in the public health laboratory, as in other laboratories in the provincial network.
- Providing leadership and training opportunities in biosafety at all levels.
- Acting as a link with other national and international biosafety programs.
- Working with other jurisdictions to ensure an integrated response to Risk Group 4 organisms (e.g., a medical microbiologist 24/7 on-call service, emergency assistance plans, etc.).

Chemical and/or nuclear bio-terrorism must also be acknowledged. Across North America, the ability of public health laboratories to test chemical weapons agents and environmental samples containing unknown chemical agents is limited (Schoenfeld, 2002) and minimum requirements have not yet been established.

6. Integrated communicable disease data management

Ideally, all microbiology laboratories would be able to electronically communicate with public health officials to enhance detection of trends and to intervene to prevent the further spread of disease (Bean & Martin, 2001; Yuan & Vogel, 2006; Health Assessment and Disease Surveillance, 2006). Linking all microbiology laboratories, including public health laboratories, in a quality network would be a key goal in a public health continuous improvement model. Public health laboratory experts work with other public health colleagues to generate hypotheses and to help with interpretation.

This core function states that the minimal capacity for data management at provincial public health and reference laboratories is to first and foremost provide timely and accurate information to provincial public health workers to *"participate as a key link in Canadian and, where appropriate, international database systems to collect, monitor, and analyze laboratory data and serve as the primary data link for the surveillance of diseases of national and global concern"* (CPHLN, 2004).

Implicit in optimizing this core function of public health laboratories is the ability to evaluate and implement new data management technologies and analytical methodologies. Public health laboratories should conduct applied studies into the new analytical methods and services necessary to meet changing public health surveillance (CPHLN, 2004). Peterson et al. (2002) describe emerging techniques known as virtual surveillance and pattern identification, and data mining. Other new approaches have been reported as well (Yuan & Vogel, 2006).

A provincial public health laboratory must have an integrated data management system that, at a minimum, enables it to (CPHLN, 2004):

- Collect laboratory data, both "positive/reactive" and "negative/non-reactive" essential for public health analysis and decision-making.
- Ensure the maintenance and communication of laboratory data using standardized formats.
- Provide primary data necessary to inform and carry out policy and planning.
- Participate in nation-wide disease reporting networks, with centralized facilities for receipt, storage, retrieval, and analysis of data.

Ideally, to support the core functions, collaborations should be built with researchers and government agencies with high priority being placed on this post-examination phase of the common laboratory cycle that links community and hospital laboratories to the public health laboratory. An important challenge will be evolution of patient-centric electronic records for individuals who lack a unique identifier or for individuals where stigma and discrimination might prevent testing if there was a risk that sensitive information would be disclosed contrary to legislation, e.g. HIV. Public health laboratories thus play an important role in tracking illnesses in vulnerable populations.

The challenges of data security, data access, data safety through back-up systems, and data transfer, as well as issues of privacy and confidentiality, make data management challenging. Health Canada has a public health laboratory system that connects directly to a public health surveillance system (the Laboratory Data Management System); however, it has not been implemented widely at this point.

Long-term integrated data management solutions are required to connect laboratory, clinical, and epidemiological datasets into a seamless, real-time surveillance system. Suggested elements to allow the optimizing of such solutions are:

- A secure, scalable environment with the technical infrastructure and expertise to perform linkages between/among relevant datasets.
- Efficient and secure ways for appropriate personnel to access datasets.
- Annotated datasets (contents characterized in standardized formats), updated in near real time.
- Privacy and confidentiality safeguards.
- The capacity for end-to-end system design, planning, and implementation.
- Resources and sustainability.
- The availability and level of specificity of data (core function: reference testing).
- The need for continuous system support.
- Measurement of the impact on personnel, funding, and workload (i.e., resources).
- The ability to gather high-quality data through standard testing, definitions, etc. (core function: quality).
- Implementation of data sharing agreements including the agreed upon minimum data elements.

Public health laboratories should be leaders by virtue of this core function in such initiatives as one described in a recent announcement from Canada Health Infoway and the BC Government titled "New Surveillance System Will Protect Canadian's Health". The announcement states, "*SARS has taught us that it is time to invest in a new generation of surveillance systems to track infectious diseases…Canada Health Infoway and BC will develop a pan-Canadian Public Health Surveillance System to help carry out faster, more coordinated responses to potential epidemics*". (CHI, 2006)

7. Policy development and evaluation

Through interpretation, validation and analysis of population-based test results, public health laboratories assist by providing information for policy development, planning, and public health response. A Canadian public health laboratory should have the ability to serve as a resource to (CPHLN, 2004):

- Provide medical and scientific leadership in assisting in the development of public health policy and in the integration of public health laboratory science into public health practice.
- Participate in the development of standards for health related laboratories, including environmental, clinical, and research standards.
- Actively participate in evaluation of relevant public health programs.

8. Laboratory improvement and regulation (quality assurance)

The importance of a QMS for laboratories, including public health laboratories, has been noted (Section 4.0). Leadership in laboratory improvement and regulation are fundamental to other core functions such as surveillance, environmental health, data management, and policy development. Poor quality laboratory data can produce poor public health outcomes. A public health laboratory must therefore (CPHLN, 2004):

- Maintain accreditation through the provincial system, College of American Pathologists, and/or ISO.
- Support development of quality assurance programming for clinical and environmental laboratories province-wide by training, consulting, and monitoring through external quality assessment (proficiency testing). In other words, be a leader in laboratory QMS.
- Develop and manage program delivery to ensure the quality (reliability and timeliness) of laboratory data used for communicable disease environmental monitoring.
- Provide testing in support of provincial and federal environmental regulations.

It has been recommended that 15% of an overall laboratory staff time should be used to address ongoing quality assurance issues (Eaton et al., 2005).

9. Training and education of health care and public health workers

A public health laboratory is a unique learning/teaching environment and should have the ability to serve as an academic centre in areas related to public health, including (CPHLN, 2004):

- Provision of training to improve the scientific and technical skills of public health laboratory and other microbiology laboratory staff in a network, including laboratory biosafety and discipline/method cross-training to enable province-wide, outbreak surge response requirements.
- Participation in training of technologists, and undergraduate and postgraduate medical and non-medical trainees.
- Assistance with training and education of public health workers and infection control personnel.

Like other health care organizations, public health laboratories face a scarcity in skilled professionals including microbiologists and highly-trained technologists. An aging population of technologists has resulted in a need to develop a focused human resources plan to address this requirement, as the number of graduates from technical institutions is far below the demands of both private and public laboratories. Recruitment in this environment requires the ability to compete in a larger market by offering excellent working conditions, competitive remuneration, educational and research opportunities, and opportunities for personal growth.

10. Public-health-related research and development

The sustainability of public health in an environment of ever-changing societal behaviours and evolving microbes requires public health laboratories to evaluate and implement new technologies and analytical methodologies (Barker et al., 2006). Public health laboratories must identify the need for new laboratory methodologies for the dynamics of communicable disease detection and prevention. Given their other core functions, a research and development program is vital.

Each provincial public health laboratory must (CPHLN, 2004):

- Be able to continually identify, evaluate, and implement new laboratory methodologies impacting on all programs in public health and population health for communicable disease detection and prevention, including development of and evaluation of new tests.
- Have the ability to explore evolving fields such as molecular epidemiology, immuno-epidemiology, genomics, and proteomics.
- Carry out effective research with appropriate partners to improve laboratory tests for communicable disease surveillance and response.
- Conduct studies to support public health program evaluation, policy development, and regulatory change, e.g., guidelines for testing drinking water or reporting of communicable diseases.

6.0 LABORATORY FAILURES: IMPACTS AND COSTS

Public health laboratory Best Practices are based on consensus-driven standards including quality management systems (QMS) and expert opinion. Other evidence, although indirect, to support key core functions of public health laboratories is found in reports on failures. When community or hospital laboratories fail to perform to accepted standards, individual patient care can suffer. When public health laboratories and their networks fail, health at a population level can suffer. The impact of such failures is illustrated below, using examples within the core function framework for public health laboratories. Some examples are also used to highlight successes.

1. Core function failures*:* communicable disease surveillance, prevention, and control

- Severe Acute Respiratory Syndrome (SARS)

  In March 2003, a severe respiratory disease (subsequently identified as SARS) emerged in Canada as patients infected with the SARS-associated coronavirus (SARS-CoV) arrived in both Vancouver and Toronto. The outcomes of the importation of these cases have been reviewed in Skowronski et al. (2006). In Toronto, the disease spread to 247 people, resulted in 43 deaths, and cost Ontario over $2 billion. In Vancouver, three cases and one asymptomatic individual were affected, with one health care worker acquiring the disease. The provincial public health reference laboratory (BCCDC Laboratory Services) was involved in the internationally recognized, rapid sequence determination of the virus, developing and implementing two reverse transcriptase polymerase chain reaction (RT-PCR) assays. The BCCDC public health and reference laboratory utilized its CL-3 facility to culture SARS-CoV and develop a virus neutralization test which has become the definitive gold standard for diagnosing SARS-CoV infection. Using this technology, it was shown that there were no additional cases of SARS-CoV infection, even amongst the close contacts of the cases. (See Appendix B for a description of the BCCDC model.)

  In contrast, the diagnostic ability in Toronto was not as well developed. The provincial laboratory in Ontario, although staffed by a few experts who remained after years of downsizing, was unable to carry out its core function of testing and surveillance. All Ontario samples were forwarded to Winnipeg's National Microbiology Laboratory for testing, with subsequent delays and other challenges.

  The benefits of BCCDC's SARS-CoV testing were also realized with an outbreak of respiratory infection at the Kinsmen Park Lodge in Surrey, BC, in 2004. Despite initial erroneous reports of SARS, the BCCDC public health laboratory demonstrated that the illness was due to a coronavirus other than SARS, thereby averting a major crisis. BCCDC's success with respect to successful surveillance for SARS was due, at least in part, to its infrastructure of CL-3 facilities and sufficient expert personnel in the form of medical, scientific, and technical staff. These are resources that had been downgraded in the Ontario public health laboratory system.

- <u>Blood-borne hepatitis C</u>
  Hepatitis C provides another example of the impact of a core laboratory function failure. Before Chiron Corporation cloned and sequenced the Hepatitis C virus by molecular means in 1989, there was only a limited capacity to detect non-A, non-B virus transmission in blood product recipients. The characterization of hepatitis C virus led to the rapid development and implementation of diagnostic tests that were applied to the screening of blood products. This has virtually eliminated blood product transmission of hepatitis C in developed counties, enabled worldwide epidemiological studies on the burden of illness, and allowed its causal role in hepatocellular carcinoma to be recognized. In addition, characterization of the virus has allowed increasingly effective anti-viral treatments to be developed, meaning that hepatitis C is becoming a virologically curable infection.

  Our evolving knowledge about the impact of hepatitis C virus infection serves to illustrate the dark side of poor event recognition, verification, and response capacity. Whereas the United States blood system implemented surrogate marker laboratory testing for the non-A, non-B hepatitis virus in 1986, these surrogate markers (which might have prevented approximately 50% of transfusion-related hepatitis C virus infections in Canada) were not implemented by the Canadian Red Cross. This resulted in preventable blood product transmission of hepatitis C virus between 1986 and 1990, and major blood claimant compensation (Commission, 1997).

2. Core function failures/successes: outbreak emergency response to communicable diseases

- <u>Legionnaires' disease outbreaks</u>
  In 1976, a large point-source outbreak of pneumonia caused by a previously unknown agent with rapid transmission and high mortality, killed 34 of 221 persons affected at a convention of Legionnaires (war veterans) in Philadelphia, Pennsylvania. This outbreak involved a disease subsequently called Legionnaires' disease. This is an example of the failure of the laboratory system, unfamiliar with a new emerging pathogen, to be able to identify the cause of an outbreak (*Legionella pneumophila)*. Once a laboratory test was developed, appropriate public health and clinical interventions were possible (Fraser et al., 1977). More recently in Canada, at least 20 people died and a $600 million class action lawsuit was filed on behalf of residents at a Toronto nursing home as a result of an outbreak of Legionnaires' disease. Initial testing of outbreak specimens by public health laboratories was falsely negative, which consequently delayed appropriate treatment and public health interventions.

- <u>Hemolytic uremic syndrome (HUS) outbreaks</u>
  In 1981 an outbreak of HUS in Ontario was epidemiologically linked with the consumption of apple juice (Steele et al., 1982). The public health system was unable to undertake a meaningful investigation of this outbreak, largely due to the lack of a laboratory infrastructure. The outbreak, however, did lead to local interest in this condition and within 2 years the role of a Shiga-like verocytotoxin in the etiology of HUS was discovered at Toronto's Hospital for Sick Children (Karmali et al., 1983). This microbial verocytotoxin subsequently caused severe disease in the Walkerton water-borne outbreak.
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Shiga-Toxin *E. coli* in salami early interventions
In 1999, the BCCDC public health reference laboratory used molecular fingerprinting to detect Shiga-toxin *E. coli* in contaminated dry fermented salami. This laboratory-based early intervention saved lives and an estimated $3.5 million in health care costs (Personal communication, Dr. Murray Fyfe, Medical Health Officer, Vancouver Island Health Authority, Victoria, BC). The 2000 William H. Foege Award (Division of International Health Epidemiology Program Office, CDC, Atlanta) was presented to a BCCDC team including Laboratory Services leaders for outstanding public health intervention in their response to this outbreak (BCCDC, 2000; BCCDC, 2001).

3. Core function failures and successes: environmental health and food safety

- Walkerton outbreak
  In May 2000, in the Ontario town of Walkerton, *E. coli* O157:H7 contaminated the town's drinking water system. An estimated 2,300 cases of illness resulted, including kidney failure due to HUS. Seven people died and many, including many children, are now enduring life-long health impacts. While Justice Dennis O-Connor's reports made several recommendations, the issues related to laboratories were noteworthy, e.g., provincial government budget reductions led to the 1999 discontinuation of government testing through the public health laboratory network and also failed to support monitoring of laboratory practices through public health audits or laboratory accreditation/inspection (O'Connor, 2002a; O'Connor, 2002b).

- Food-borne diseases molecular network: improvements
  In the United States, the CDC estimates that there are approximately 76 million cases of food-borne illness every year, accounting for 325,000 hospitalizations and 5,000 deaths (Mead, 1999). In Canada it has been estimated that approximately 2.2 million cases of food-borne disease occur annually at a cost of Can$1.3 billion (1985 estimate) (Todd, 1989). In the US, as a result of this burden of illness, a laboratory-based molecular epidemiology network, PulseNet (a CDC laboratory-based program), was established with certified labs carrying out molecular fingerprinting of food-borne microbes. Early identification and thus early intervention has saved both lives and health care dollars. (More information on PulseNet is available at www.cdc.gov/pulsenet/.)

4. Core function failures/successes: specialized screening, and reference and diagnostic testing

- Lyme disease failure
  The trend to high-volume automation in laboratory practice has been significant. Arising primarily from the private sector in the United States, benefits include better efficiency and turn-around times (Skeels, 1995). However, a laboratory reference network that functions well (as described above) is needed before safe use of screening tests may be used. One example of the impact of a failure of this core function in BC occurred in July 2003 when a patient died as a result of being incorrectly diagnosed and treated for Lyme disease. Since 1995, the public health laboratory has provided a clinically validated two-tier (confirmation or reference level testing following screening test) blood test to diagnose Lyme disease as recommended by Health Canada (Consensus conference on Lyme Disease, 1991) and the CDC (MMWR, 1995). Use of the laboratory reference network by clinicians may have prevented this unfortunate incident.

Mycoplasma pneumonia outbreak success

In December 2005, a health authority public health worker contacted the public health medical microbiologist about a community outbreak of pneumonia that had not been diagnosed by local community or hospital laboratories. Many cases of disease had been reported by community physicians but no agent was identified using traditional methods. The provincial public health laboratory used a newly developed molecular test to confirm the unusual cause of these cases – *Mycoplasma pneumonia* – allowing community responses to kick in (Sebastian, 2006).

5. Core function failure: biosafety, biocontainment, and biohazard response

Bioterrorism events

The anthrax threat in the United States in 2001 clearly illustrated the overwhelming burden placed on the public health system (Sewell, 2003; Cockerill & Smith, 2004). As a result of those events, the LRN in the United States was created and performed more than 1 million anthrax tests. The ability of a public health laboratory to respond effectively relies on highly-trained staff, collaboration within partnership networks, and access to well-maintained and operated certified CL-3 laboratories. The cost of not responding effectively and efficiently is high, both for public health and economic systems.

6. Core function failures: integrated communicable disease data management

- Paper versus electronic reporting

  When comparison of automated laboratory reporting to paper-based reporting was carried out in one study, delay was reduced from 10 days to 1 day (Ward, 2005).

- Failure of integrating information: SARS

  According to Naylor et al. (2003) reporting on shortcomings in the management of the SARS outbreak in 2003, *"the collective activity in epidemic investigation during the SARS outbreak in Toronto was embarrassingly meagre…no shared database was established; jurisdictions squabbled over data flow; and clinicians and public health physicians were unable to collaborate effectively on investigation and researc*h". The SARS failure cost Ontario over $2 billion.

7. Core function failure: policy development and evaluation

- SARS and infection control

  Infection control, closely connected to laboratory functions (including public health functions), is key to the provision of care within all types facilities across the continuum of health care. With the arrival of SARS in March 2003, it became clear that there was no consensus on personal protective equipment (PPE) for laboratories or health care workers. Senior BC Ministry of Health personnel urgently convened a task group of public health experts, acute care laboratory personnel, public health laboratory personnel, and other health care workers. Interdisciplinary fragmentation was evident. In 2005, the Ministry addressed this fragmentation by creating the Provincial Infection Control Network (PICNet). This interdisciplinary collaborative, co-chaired by the public health laboratory director and the microbiologist leading the largest acute care and regional infection control program in BC, is now being recognized across Canada (see: www.picnetbc.ca/). PICNet is a networked community that works together to communicate standards, share information, and support each other during significant events.

8. Core function failure/success: laboratory improvement and regulation (quality assurance)

- HIV point-of-care testing
  The failure of a commercial HIV point-of-care test was highlighted in a letter in the Canadian Medical Association Journal. This short report, based on studies done by public health laboratory and clinical workers, had significant consequences on point-of-care testing across Canada. The public health laboratory was the first to detect the fact that further production of this commercial assay was defective, although it had worked well during trial evaluations. The evaluation led to a nation-wide recall of the assay and re-testing of thousands of patients (Rekart et al., 2002).

- Influenza A/H2N2 virus major deficiency (a failure in quality):
  The following example, although not a failure of a public health laboratory, illustrates a related failure – that of an internationally recognized laboratory external quality assessment proficiency testing program. At a Vancouver hospital, in 2005, a patient who had received a bone marrow transplant was diagnosed as having an influenza A/H2N2 virus. Because the H2N2 influenza virus has not been circulating since 1968, it is considered a candidate pandemic strain. On follow up, it was found that the patient specimen was most likely contaminated in the hospital laboratory by an adjacent proficiency testing specimen. The proficiency testing sample, to the consternation of all, did contain the H2N2 pandemic strain. This event was resolved only after a substantial investigation and reflected two important issues of quality management: the first was the inappropriate, worldwide distribution of a potential pandemic strain of influenza by a laboratory proficiency accrediting body and the second was the existence of inadequate procedures and the absence of quality control that allowed the event to occur.

- Walkerton outbreak quality assurance failure
  It has been noted that laboratory quality assurance measures in the area of environmental testing (drinking water monitoring for public health purposes) were deficient in Ontario, contributing to the outcomes of the Walkerton tragedy. Public health laboratories, as leaders in laboratory QMS, must act as provincial reference nodes for environmental and clinical services.

9. Core function failures: training and education of health care and public health workers

- Subspecialization of technologists
  As diagnostic testing becomes increasingly complex, technologists must become increasingly sub-specialized. This fact, combined with fiscal pressures decreasing the numbers of technical staff in many laboratories, has resulted in situations where specific tests can only be performed to a high level of competence by only one or two people. Should these individuals become incapacitated, these tests cannot be performed. For example, death or serious clinical complications due to malaria have been documented where technologists have not been able to stay current with best practices. In the event of an overwhelming pandemic situation, a public health laboratory would be unable to re-allocate adequate numbers of technologists to specific testing due to inadequate training or experience.

- SARS
  Naylor's investigation of the SARS crisis commented on training issues: *"Newly-qualified persons rarely have the additional skills essential (e.g., epidemiology and management training) for public health work. PhD-trained microbiologists are critically important in staffing reference laboratories and research centres. The Committee did not have a detailed inventory of training opportunities and output of research scientists who have the capacity to play a role in cutting-edge laboratory activities that will lead to better diagnostic and therapeutic capacity for emerging infectious diseases. However, we are concerned that these highly-skilled personnel are not being trained, recruited, and retained in sufficient numbers"* (Naylor et al., 2003).

- Recruitment of public health laboratory leaders

  An APHL survey recently documented challenges in the recruitment of public health laboratory leader (Schoenfeld et al., 2002). The impact of this important international situation is starting to be seen in Canada as posted positions go unfilled for years. For example, the Ontario Public Health Laboratory has been unable to fill four of the five medical microbiology positions posted in 2005.

10. Core function failures: public health related research and development

- Failure in SARS

  Naylor's report on public health renewal provides relevant commentary: *"There are probably more examples of public health research labs not having the capacity to respond in a timely fashion due to lack of resources (funding, staff, expertise etc.) or not being able to respond at all because the public health lab does not carry out research. Research is usually such a long term venture that more often than not, its impact is not immediate. However it is during outbreak investigations that failures in a core function such as public health-related research are demonstrated clearly. This may be due to a lack of research capacity causing the public health laboratory to be unable to carry out or participate in the outbreak investigation as was experienced in Ontario during the SARS outbreak"* (Naylor et al., 2003).

  In his 2004 report examining response to the SARS crisis, the Honourable Justice Archie Campbell also noted the lack of medical/scientific leadership and surge capacity in Ontario's public health system. In particular, Justice Campbell stated, *"These scientists were engaged in the diagnosis and surveillance of new and emerging infections as well as research and development. Within the government, there seemed to be a complete lack of understanding of the importance of the work done by scientists at the provincial laboratory."* Campbell also cited the 2003 report of Naylor et al.: *"Significant involvement in fundamental curiosity-driven research is a public health laboratory function that has withered. Most public health research laboratories view basic research as someone else's job".* The Ontario Ministry of Health and Long Term Care had laid off all PhD-level scientists in 2001. As a benchmark, the New York State Public Health Laboratory has 150 PhD-level scientists (Campbell, 2004).

  More comments from Naylor et al. (2003) apply: *"Outbreak investigations are a type of fast-paced epidemiologic research, undertaken to determine the cause of the outbreak and what remedial actions are required. Public health agencies and governments have often regarded research capacity as academic, irrelevant, and discretionary rather than the core public health function that it is. A related challenge is the profoundly multidisciplinary nature of effective research targeting an outbreak or epidemic. All must be engaged for the response to be optimally effective. A shortfall in one dimension cannot be covered by strength in another".*

7.0 CONCLUSIONS

As leaders within their jurisdictions, public health laboratories are important components of the public health system. They are responsible for unique links and leadership roles in the well established microbiology laboratory networks in the provinces, acting as nodes linking to the federal public health microbiology laboratory. The cost of their failure is significant, both provincially and for all of Canada.

Based on general laboratory requirements, this report presents the evidence for Best Practices in public health laboratories, with a focus on the growing need to meet QMS and accreditation standards. As new public health challenges arise in the province, the effectiveness of response of the public health system will depend in part on the ability of BC's public health laboratory network to work to Best Practice standards.

Originally resulting from system-wide failures in the public health laboratories in the United States, an expert group in that country produced core functions to guide correction of the infrastructure collapse and these core functions have been accepted across Canada. Beyond research-based evidence for the importance of meeting and sustaining core functions, support also comes from consensus-based core functions specific to public health laboratories. Examples of successes and failures in public health provide indirect evidence.

The authors feel that Best Practices in public health laboratories and their networks will be achieved in BC by:

- Strengthening the public health laboratory network through enhanced partnerships with other types of microbiology laboratories within the jurisdiction through building on current networking.
- Strengthening specific provincial public health laboratory core functions and specific nodes/functions in the national public health system.
- Enhancing efficiencies and effectiveness through clearly defined roles and responsibilities regarding service/program core functions within laboratory networks.
- Supporting the need for leadership in fundamental areas, particularly in information management and QMS development.

The next step is to arrange a consultation process to review the material presented in this report. A working group will be established consisting of representatives from BC's six health authorities, public health personnel who use and interact with laboratories, stakeholders familiar with the public health laboratory world, and other relevant experts in the field, including representation from the Ministry of Health.

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APPENDIX A: MEDICAL LABORATORY TESTING PRINCIPLES

All medical laboratories carry out testing in three areas: pre-examination, examination, post-examination. They also provide value-added activities such as teaching and research. Although similar in general performance standards, these differ for laboratories depending on their role, populations served, and clinical links, e.g., family practitioners, specialists, medical health officers.

The common principles important to optimal public health laboratory practice are:

(a) Similar pre-examination principles
All medical laboratories work in continuous quality improvement cycles with their stakeholders to carry out pre-examination "Best Practices". This includes keeping current written technical operating procedures (collection protocols), providing acceptable turn-around-times, ensuring sample integrity in a transparent system, communicating about test menus, maintaining sample collection and transport procedures, and receiving/triaging/accessioning. A shared role for a provincial public health laboratory network is to work with other laboratories to use optimal standards for sample transport, particularly in the face of public health emergencies, e.g., bioterrorism events and pandemics.

(b) Similar examination principles
All medical laboratories conduct testing services. However, the test menu, test system, and sample types (volume, collection protocol, and transportability) vary by type of laboratory, along with the level of expertise required to lead and maintain these services. Analytic/examination areas also have common quality indicators that reflect "Best Practice". Standardization of some laboratory testing, e.g., nomenclature and platforms that relate to public health issues such as communicable disease, is important to optimal public health surveillance.

(c) *Similar post-examination principles*
All medical laboratories work in related disciplines such as information management and information technology to develop the infrastructure for reporting test results rapidly. Integrated data management is a core public health laboratory function that depends on networking through laboratory information systems.

(d) Similarities in value-added services
All laboratory leaders are expected to provide "value-add". This includes consultations, teaching, program evaluation, and research (where there is an academic affiliation), as well as leadership and communication within their jurisdictions.

APPENDIX B: THE BCCDC MODEL

The BCCDC provincial public health reference laboratory (BCCDC Division of Laboratory Services), now part of Provincial Health Services Authority (PHSA) Laboratories, is embedded in the BCCDC, an integrated public health facility. It actively networks with medical microbiology laboratories in BC's five geographic health authorities. Direct linkages with BCCDC Laboratory Services are also provided to health authorities through contractual arrangements, legislated requirements, and professional collaborations.

Like other Canadian provincial public health laboratories and their provincial networks, BCCDC Laboratory Services provides services and support to frontline health care workers and laboratories across the province. BCCDC Laboratory Services is the largest centre of medical microbiology in BC, providing expertise for the detection, identification, and characterization of micro-organisms of importance in communicable and infectious diseases, as well as expertise in environmental safety, bioterrorism response, and many other centralized public health functions. BCCDC Laboratory Services is the main reference microbiology laboratory for BC, enabling the establishment and maintenance of high-level expertise to provide early rapid response to new and emerging threats.

The BCCDC Laboratory Services team is made up of more than 120 highly skilled laboratory experts including medical microbiologists, clinical microbiologists, and senior scientists; the latter are faculty at the University of BC. A number of experienced and senior technologists, many with advanced science degrees, use state-of-the-art technology to support public health programs by performing outbreak investigation, population-based screening, and diagnostic testing. Tests related to communicable diseases include all microbiology disciplines (bacteriology, mycology, parasitology, serology, and virology) employing both traditional and molecular testing.

Experts at BCCDC Laboratory Services lead many specialized public health programs including:

- Molecular laboratory epidemiology (fingerprinting microbes for outbreak detection and management as well as epidemiological trending).
- Molecular tools for surveillance and response to emerging and re-emerging pathogens.
- Biosafety and biocontainment [three state-of-the-art CL-3 facilities and programs, including bacteriology, tuberculosis (biosafety requirement), and virology (avian influenza, SARS)].
- Environmental testing for food and water for outbreak and cluster investigation as well as surveillance and quality monitoring.
- QMS leadership in both the clinical and environmental areas.