LABORATORY RESPONSE CHECKLIST FOR INFECTIOUS DISEASE OUTBREAKS

Preparedness and response considerations for emerging threats

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CPHLN– Canadian Public Health Laboratory Network

EOC – Emergency Operations Centre

ERAP – Emergency Response Assistance Plan

GHSAG– Global Health Security Action Group

ID – Infectious Disease

IHR – International Health Regulations

IM – Information Management

IT – Information Technology

LDT – Laboratory Developed Test

LIMS – Laboratory Information Management System

LLTO – Laboratory Liaison Technical Officer

MERS-CoV – Middle East Respiratory Syndrome Coronavirus

MLISA – Multi-lateral Information Sharing Agreement

NML – National Microbiology Laboratory

PHAC – Public Health Agency of Canada

P/T – Provincial/Territorial

REB – Research Ethics Board

SME – Subject Matter Expert

SOP – Standard Operating Procedure

TDG – Transportation of Dangerous Goods

TRF – Test Requisition Form

WGS – Whole Genome Sequencing

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ABSTRACT

The purpose of the Laboratory Response Checklist for Infectious Disease Outbreaks (the Checklist) is to provide public health laboratories and laboratory networks operating at multiple jurisdictional levels with a useful, adaptable tool to rapidly identify important outbreak response considerations, particularly when investigating a previously unknown infectious disease threat. To achieve this goal, the Checklist was developed by the National Microbiology Laboratory (NML) of Canada in collaboration with provincial/ territorial, national and international laboratory experts including the Canadian Public Health Laboratory Network (CPHLN), and the Global Health Security Action Group (GHSAG) Laboratory Network. Incorporating lessons learned through NML participation in extended national and international outbreak responses (e.g. Ebola virus epidemic, West Africa (2014-2016), Zika virus epidemic (2015-2016)), the Checklist identifies five laboratory response themes, each of which encompasses multiple considerations that are critical to a coordinated, strategic outbreak response. To optimize laboratory response coordination, a comprehensive review of all Checklist considerations is recommended at the outset of a response, with engagement of appropriate laboratory expertise to inform operational planning. Given the extensive interdependencies noted between laboratory response themes, this implementation approach provides the best opportunity to identify and mitigate risks with the potential to impact public health action during all phases of a coordinated laboratory response.

LABORATORY RESPONSE CHECKLIST FOR INFECTIOUS DISEASE OUTBREAKS

INTRODUCTION

Infectious disease (ID) outbreak response poses a number of unique challenges and considerations for laboratories, particularly when investigating a previously unknown infectious disease[1]. Response requirements may include the rapid development and validation of novel pathogen-specific testing methods to support diagnosis; collaborative, iterative case definition development to reflect evolving scientific evidence as the outbreak progresses; strategic engagement of key public health partners to develop and optimize both response capacity and coordination; and establishment and communication of information sharing processes and procedures to support timely public health laboratory investigation, surveillance, messaging and action. Rapidly evolving public health genomics and other 'omics' approaches present additional challenges, and provide important opportunities to further enhance ID response capacity[2, 3]. Given the complex, outbreak-specific nature of laboratory response considerations, timely and effective coordination can prove challenging in the absence of a strategic, structured approach.

The Laboratory Response Checklist for Infectious Disease Outbreaks (the Checklist) is intended as a useful tool to rapidly highlight key outbreak response considerations for public health laboratory partners and networks operating at subnational, national and international levels, to support public health action.

LABORATORY RESPONSE THEMES

To inform planning and decision-making, the Checklist identifies five central themes, each of which encompasses multiple considerations that are critical to a coordinated, strategic laboratory outbreak response. Laboratory response themes are as follows:

- Laboratory Investigation
- Laboratory Response Capacity and Training
- Laboratory Surveillance and Data Management
- Interjurisdictional Engagement and Communication
- Research and Ethics

Importantly, significant interdependencies exist between public health laboratory functions (e.g. diagnostic and reference testing, surveillance, outbreak detection and response, research), such that considerations identified within a given laboratory response theme may have far-reaching implications across multiple ID response activities within the broader public health context (Appendix I).

CHECKLIST DEVELOPMENT AND IMPLEMENTATION

Development of the Checklist was guided by the need for a systematic approach to enable rapid identification of outbreak response requirements by laboratory partners operating at various jurisdictional levels. To encompass considerations associated with larger scale, protracted laboratory responses, Checklist content was significantly informed by lessons learned through involvement of the NML in extended national and international outbreak responses (e.g.: Ebola virus epidemic in West Africa (2014-2016), Zika virus epidemic (2015-2016)).[4, 5, 6, 7]

For ease of use and implementation, the Checklist was designed to incorporate the following attributes: [8]

- **Adaptability** – Response considerations are described at a very high level and in general terms, allowing Checklist content to be easily modified by users to reflect jurisdiction-specific laboratory processes and terminology. Additional Checklist customization can be achieved by adding organization-specific appendices; a sample 'NML Response Toolkit' (Appendix II) including NML key contacts and references is provided as a model adaptable by other laboratory partners.

- **Ease of Use** – Response considerations are grouped into five 'Laboratory Response Themes' for ease of reference and focused review. Appendix III provides a Checklist 'Review Table' template that can be replicated and adapted electronically using preferred spreadsheet or database applications, then used to quickly select, sort and monitor the status of actions required following review (Appendix III, IV).

- **Scalability –** Content can be readily expanded or edited to reflect the scope of pathogen-specific outbreak response activities relevant to organization or jurisdiction-specific roles (Appendix IV).

- **Acceptability –** To verify content acceptability and validity, the Checklist was collaboratively reviewed by federal and provincial/territorial (P/T) laboratory experts (NML, Canadian Public Health Laboratory Network (CPHLN)), and by the Global Health Security Action Group (GHSAG) Laboratory Network. A scenario-based, tabletop review exercise engaging NML Emergency Operations Centre (EOC) personnel and interjurisdictional laboratory liaison staff was also conducted to further refine content, and to identify how to best operationalize the Checklist to enhance NML response protocols.

CHECKLIST USE

To optimize usefulness of the Checklist, a strategic review of all Checklist considerations is recommended at the outset of an ID outbreak response, with engagement of appropriate laboratory expertise to identify gaps and priorities, and inform operational planning. Given the extensive interdependencies noted between the five response themes, this approach provides the best opportunity to identify and mitigate risks with the potential to impact public health action during all phases of a laboratory response.

1. LABORATORY INVESTIGATION

1.1. Specimen Collection and Transportation: To support timely, coordinated laboratory investigation, identify and document specimen collection and transportation needs in advance, including:

- ☐ 1.1.1 Appropriate specimen types, volumes and amounts; to be reassessed as required
- ☐ 1.1.2 Appropriate specimen container(s) for transportation as per Risk Group classification
- ☐ 1.1.3 Detailed specimen container packaging and labeling instructions
- ☐ 1.1.4 Cold chain management requirements, i.e. temperature and timelines for shipping/arrival
- ☐ 1.1.5 Transportation of Dangerous Goods (TDG) documentation requirements
- ☐ 1.1.6 Preferred courier service recommendations in alignment with pathogen risk classification
- ☐ 1.1.7 Biosafety and infection control guidelines, requirements and protocols for specimen handling and processing applicable to both clinical and laboratory settings, including:
  - ☐ 1.1.7.1. Personal protective equipment, containment and decontamination
  - ☐ 1.1.7.2. Specimen retention, storage and disposal
- ☐ 1.1.8. Additional documentation requirements and considerations within existing legislative and regulatory frameworks, including:
  - ☐ 1.1.8.1. Import and export permits
  - ☐ 1.1.8.2 Material transfer agreements between client and laboratory entities (e.g. to support distribution of control reagents, validation panels)
  - ☐ 1.1.8.3. Alignment of specimen collection requirements with existing data sharing agreements
  - ☐ 1.1.8.4. Laboratory guideline, licensing and certification requirements relevant to the investigation of a new/emerging infectious agent (e.g. FDA, HC, HPTA, HPTR requirements)
  - ☐ 1.1.8.5. Emergency response assistance plans and protocols for transport (e.g. ERAP for Risk Group 4 pathogens, and engagement of Regional Response Coordinators)
- ☐ 1.1.9. Drafting of a specimen flow chart to guide collection and transport requirements

1.2. Laboratory Testing: To support laboratory investigation efforts; review, develop, document and communicate evidence-based ID testing recommendations and protocols in collaboration with public health partners, with consideration of:

☐ 1.2.1. Diagnostic algorithm(s) to be used for laboratory confirmation of case investigations, to inform and/or align with the current ID case definition (which may be outbreak-specific)

☐ 1.2.2. Triaging protocols for high volume testing, using available knowledge of exposure history (e.g. close contact, travel history) and other key risk factors (e.g. pregnancy, hospitalization)

☐ 1.2.3. Test Requisition Form (TRF) data field requirements, in alignment with the ID case definition to support timely and effective case management and public health response

☐ 1.2.4. Specimen acceptance and rejection criteria

☐ 1.2.5. Specimen retention and storage protocols (for diagnostic, surveillance and research purposes)

☐ 1.2.6. Quality control and standardization of laboratory testing methods and reporting processes within the context of a quality management system, including:

- ☐ 1.2.6.1. Validation, verification and comparison of diagnostic laboratory test performance specifications; including sensitivity, specificity, accuracy and precision
- ☐ 1.2.6.2. Implementation and use of Standard Operating Procedures (SOPs)
- ☐ 1.2.6.3. Monitoring and assessment of laboratory test turn-around times (upon specimen receipt)

☐ 1.2.7. Test result reporting requirements, including:

- ☐ 1.2.7.1. Use of standardized test result communication processes, report forms, and terminology
- ☐ 1.2.7.2. Possible need to report 'preliminary' results prior to issuance of a final report
- ☐ 1.2.7.3. Ability to support result reporting for submitted specimens vs. case investigations

☐ 1.2.8. Alignment and standardization of test methods and interpretation criteria across decentralized testing sites/jurisdictions to support accurate, consistent case reporting and surveillance efforts

☐ 1.2.9. Review and updating of testing-related processes and protocols to support evolving outbreak response requirements in keeping with current scientific evidence

☐ **REVIEW COMPLETE - LABORATORY INVESTIGATION**

2. LABORATORY RESPONSE CAPACITY AND TRAINING

2.1. Laboratory Response Capability: To address laboratory response challenges specific to the ID threat, collaboratively assess the following with public health laboratory partners on an ongoing basis:

☐ 2.1.1. Laboratory capabilities for front-line screening and confirmatory testing methods at all jurisdictional levels (i.e. regional, provincial/territorial (P/T), state, national and international)

☐ 2.1.2. Availability of validated diagnostic testing methods (e.g. serological, molecular, subtyping, genomic, proteomic), including commercially available kits and lab-developed tests (LDTs)

☐ 2.1.3 Performance characteristics of currently used diagnostic test methods, including sensitivity, specificity, turn-around times, and throughput using current platforms

☐ 2.1.4. Requirement to develop and validate LDTs where external capacity does not exist, or is not reliably accessible during an outbreak

☐ 2.1.5. Decentralized diagnostic testing capabilities and potential for technology transfer to improve national laboratory response capacity, dependent upon magnitude and duration of response

☐ 2.1.6. Ongoing availability of critical equipment and reagents via established suppliers

☐ 2.1.7. Ability to acquire specimens from the international community to support the development of diagnostic tools to detect novel pathogens emerging in international settings (e.g. MERS-CoV)

2.2 Surge Capacity and Training: To support flexible, scalable and timely laboratory response to ID threats, dynamically assess requirements related to the following surge capacity considerations:

☐ 2.2.1. ID-related scientific expertise and technical response capacity amongst current staff

☐ 2.2.2. Availability of laboratory space, biocontainment facilities, equipment and consumables

☐ 2.2.3. Identification of 'surge capacity' positions that can be mobilized and/or cross-trained to mitigate workload issues

☐ 2.2.4. Cross-training needs and priorities (e.g. personnel testing proficiencies, data entry/management)

☐ 2.2.5. Standardized approaches for training and documentation of personnel proficiencies (e.g. testing methods; data collection, analysis and interpretation)

☐ 2.2.6. Engagement of Emergency Operations Centre (EOC) support to enhance response capacity

☐ 2.2.7. Identification of funding constraints, and opportunities to access emergency funding mechanisms

☐ 2.2.8. alternative approaches to work-shift scheduling to increase available person-hours during heightened response periods

☐ 2.2.9. Mobile laboratory capacity to support ID outbreak field response

☐ 2.2.10. Laboratory test throughput assessment, including the identification of any bottlenecks

☐ 2.2.11. Available technologies with the potential to facilitate surge capacity development, including:

- ☐ 2.2.11.1. Alternate testing platforms to increase testing throughput
- ☐ 2.2.11.2. Training videos, e.g. to demonstrate specimen collection requirements
- ☐ 2.2.11.3. Web-based information exchange tools and platforms

☐ 2.2.12. Risk mitigation planning to address operational vulnerabilities observed during all phases of the laboratory response effort

☐ 2.2.13. Participation in preparedness assessment exercises (including joint simulations) with interjurisdictional, interdisciplinary public health partners involved in coordinated ID response (e.g. epidemiologists, physicians, field investigators); typically during inter-outbreak periods

☐ **REVIEW COMPLETE - LABORATORY RESPONSE CAPACITY AND TRAINING**

3. LABORATORY SURVEILLANCE AND DATA MANAGEMENT

3.1. Laboratory-based Surveillance and Data Management: To support timely and integrated laboratory-based ID surveillance activities, key considerations are as follows:

☐ 3.1.1. Assess the current surveillance status of the ID at all jurisdictional levels including the existence of, or requirement for:

- ☐ 3.1.1.1. An established case definition to support case investigation and confirmation using laboratory and epidemiological criteria within the current outbreak context
- ☐ 3.1.1.2. Alignment of case confirmation criteria between reporting jurisdictions to ensure national consistency of case counts, reporting, surveillance and response efforts
- ☐ 3.1.1.3. Reporting/notification processes for suspected and/or confirmed cases at each jurisdictional level (subnational, national, international (e.g. IHR reporting obligations))
- ☐ 3.1.1.4. Surveillance systems/platforms capable of supporting timely ID detection, reporting and outbreak monitoring within the context of the current response
- ☐ 3.1.1.5. Information management and information technology (IM/IT) operational support for data transfer pipelines and bioinformatics tools needed to acquire and analyze genomic (e.g. whole genome sequencing (WGS)) and other 'omics' data.

☐ 3.1.2. Identify laboratory-based surveillance considerations related to ID case/outbreak detection, confirmation, characterization, monitoring and reporting, including:

- ☐ 3.1.2.1. Current knowledge of ID epidemiology to inform laboratory testing and triage recommendations
- ☐ 3.1.2.2. Monitoring and classification of laboratory investigations in alignment with established case definition criteria (e.g. suspect case under investigation, laboratory-confirmed, not a case/discarded)
- ☐ 3.1.2.3. Key laboratory and epidemiological data elements necessary to inform laboratory investigation processes, including triaging of specimens, diagnostic algorithm selection, result interpretation, data linkage, and case classification and confirmation efforts (e.g. unique case identifiers, test history, symptom onset date, travel history, etc.)
- ☐ 3.1.2.4. Data linkage and integration requirements to support timely surveillance and response, e.g.:

- linkage of specimens and associated test result(s) with the case under investigation
- linkage of laboratory and epidemiological case data held by separate public health jurisdictions
- linkage of confirmed cases with a given outbreak, or outbreak source

☐ 3.1.2.5. Laboratory-confirmed case review, verification, monitoring and reporting processes

☐ 3.1.2.6. Molecular epidemiology/public health genomics approaches to support ID surveillance, outbreak characterization and source attribution

☐ 3.1.2.7. Feasibility of using web-based tools and public health informatics platforms to support timely linkage of case investigation data from disparate public health sources

☐ 3.1.2.8. Design and development of surveillance reports to support ongoing laboratory-based monitoring, assessment and reporting of ID outbreak information, e.g.:

- Monitoring the status of laboratory investigation processes (real-time)
- Laboratory-confirmed case counts (e.g. cumulative totals, new cases/unit time)
- Final classification of all laboratory investigations (e.g. % positive, % confirmed)
- Distribution of laboratory-confirmed cases using available data (e.g. by age, sex, geography, exposure history, etc.)
- Molecular epidemiology of the outbreak (e.g. case linkage, source attribution)
- Estimation of lab-based indicators to monitor and assess surveillance performance (e.g. timeliness, laboratory-based ID investigation rates, data quality and completeness)

☐ 3.1.2.9. Legislative context and agreements relevant to interjurisdictional sharing of information and data to support ID laboratory investigation activities (e.g. MLISA, IHR)

☐ 3.1.3. Align laboratory test requisition form (TRF) data fields with the ID case definition to support effective surveillance and response, with consideration of the following key data field types:

☐ 3.1.3.1. **Submitting laboratory/client contact information** to support result reporting and other communication to inform clinical decision-making

☐ 3.1.3.2. **Unique identifiers** to enable non-nominal, interjurisdictional linkage of laboratory result(s) with the case under investigation to support accurate case classification, reporting, clinical decision-making, surveillance and response

☐ 3.1.3.3. **Geolocator information** for the case under investigation, as jurisdictionally relevant (e.g. city, reporting health region, province/territory/state, country, postal code, forward sortation area (i.e. three-digit postal code))

- ☐ 3.1.3.4. **Clinical, epidemiological and laboratory fields** needed to support triaging of high priority specimens (e.g. travel history, pregnancy status), appropriate test algorithm selection and result interpretation, as well as case confirmation and reporting
- ☐ 3.1.3.5. **Date fields** needed to support diagnostic algorithm selection, test result interpretation, and to estimate laboratory-based surveillance indicators (i.e. symptom onset, specimen collection, specimen receipt, test result and case reporting dates)

☐ 3.1.4. Assess laboratory information management system (LIMS) data flow requirements, and implement LIMS processes to support ID investigation, surveillance and response, including:

- ☐ 3.1.4.1. Standardized approaches to the documentation and monitoring of test requisition, specimen tracking, data entry/review, data linkage and result reporting processes
- ☐ 3.1.4.2. Terminology standardization, and definition of data flow and retention/life cycle
- ☐ 3.1.4.3. 'Chain of custody' documentation requirements for high-profile laboratory investigation and result reporting (e.g. microbial forensics)
- ☐ 3.1.4.4. Development of customized queries to support ongoing surveillance and response
- ☐ 3.1.4.5. Summary report generation to facilitate monitoring, assessment and reporting of laboratory-based ID surveillance and outbreak response efforts
- ☐ 3.1.4.6. Use of web-based tools and platforms to support test requisition and reporting, as well as timely interjurisdictional linkage of case investigation data

☐ 3.1.5. Dynamically assess and address operational vulnerabilities impacting overall response and reporting efforts, including:

- ☐ 3.1.5.1. External communication and interjurisdictional reporting challenges
- ☐ 3.1.5.2. Interjurisdictional differences in laboratory testing algorithms and result interpretation
- ☐ 3.1.5.3. Changes to interjurisdictional confirmed case definitions that may impact surveillance
- ☐ 3.1.5.4. Data linkage issues impacting accuracy and timeliness of case counting and reporting

☐ **REVIEW COMPLETE – LABORATORY RESPONSE CAPACITY AND TRAINING**

4. INTERJURISDICTIONAL ENGAGEMENT AND COMMUNICATION

4.1. Interjurisdictional Engagement and Communication: To support coordinated public health stakeholder engagement and consistent messaging of laboratory information, develop a strategic communication strategy incorporating the following considerations:

☐ 4.1.1. Accessibility of current ID laboratory response information to the public and to public health professionals through the timely availability of:

- ☐ 4.1.1.1. Web-based content and social media tools
- ☐ 4.1.1.2. 24-hour emergency contact information to access laboratory support services
- ☐ 4.1.1.3. A 'Guide to Laboratory Services', including specimen and test requisition requirements
- ☐ 4.1.1.4. Laboratory testing recommendations and guidance documents to support decision-making by clinical and public health partners
- ☐ 4.1.1.5. Alerting and notification processes to simultaneously disseminate time-sensitive information to interjurisdictional public health decision-makers

☐ 4.1.2. Engagement of external laboratory partners, public health networks and interjurisdictional working groups involved in the coordination of ID public health response, including:

- ☐ 4.1.2.1. Physician networks and committees responsible for clinical guideline development
- ☐ 4.1.2.2. Public health laboratory and epidemiology partners, and interjurisdictional networks responsible for developing consensus case definitions, and coordinating public health surveillance and intervention activities
- ☐ 4.1.2.3. Biosafety networks and partners involved in the development of biosafety guidelines

☐ 4.1.3. Strengthened mechanisms for collaboration and information sharing with public health partners and networks to enable::

- ☐ 4.1.3.1. Evidence-based development of laboratory and clinical recommendations and guidelines, and public health surveillance and intervention strategies
- ☐ 4.1.3.2. Consistent public health messaging of specimen collection and testing guidelines and recommendations for identified at-risk groups
- ☐ 4.1.3.3. Alignment of ID case definitions used at multiple jurisdictional levels, including international case definitions where feasible

- ☐ 4.1.3.4. Consensus regarding laboratory-confirmed case inclusion and exclusion criteria
- ☐ 4.1.3.5. Accurate and consistent case classification, counting and reporting in fulfillment of P/T, state, national and international surveillance requirements
- ☐ 4.1.3.6. Updating of publicly available web-based content to support coordinated laboratory response efforts and evidence-based public health decision-making

☐ 4.1.4. Review and revision of external communication and reporting processes to address:

- ☐ 4.1.4.1. Challenges impacting the timeliness of external reporting of ID cases and test results to inform clinical decision-making and public health action
- ☐ 4.1.4.2. Inconsistencies and interjurisdictional differences in testing algorithms, result interpretation, case confirmation and surveillance processes
- ☐ 4.1.4.3. Required changes to test reporting algorithms and information sharing methods
- ☐ 4.1.4.4. Data sharing and linkage issues impacting timeliness of confirmed case reporting

☐ 4.1.5. Event-specific internal communication and reporting structures and mechanisms needed to support coherent, effective information sharing and public health messaging, including:

- ☐ 4.1.5.1. Identification of a lead subject matter expert (SME) responsible for scientific oversight of ID-specific laboratory response efforts (e.g. field deployment activities, participation in research and surveillance studies)
- ☐ 4.1.5.2. A 'single-window' point of contact responsible for coordinating the receipt and distribution of event-specific information within the organization (e.g. EOC support)
- ☐ 4.1.5.3. Appropriate routing mechanisms for external requests received within the organization (e.g. public health stakeholder requests for information, outbreak support, media-related communications, etc.)

☐ **REVIEW COMPLETE – INTERJURISDICTIONAL ENGAGEMENT AND COMMUNICATION**

5. RESEARCH AND ETHICS

5.1. Research Requirements and Ethical Considerations: To advance scientific research in support of public health action, consider the following laboratory-related issues in collaboration with public health partners:

☐ 5.1.1. ID-specific applied and basic research requirements and priorities, e.g.:

- ☐ 5.1.1.1. Pathogen identification and characterization studies (phenotypic, genomic, proteomic)
- ☐ 5.1.1.2. Diagnostic and confirmatory reference test method development
- ☐ 5.1.1.3. Transmission studies, development of risk models
- ☐ 5.1.1.4. Field studies, vector competency studies
- ☐ 5.1.1.5. Vaccine and other medical countermeasure development and assessment
- ☐ 5.1.1.6. Applied biosafety research with a focus on timely knowledge translation
- ☐ 5.1.1.7. Public health surveillance studies requiring research ethics approval

☐ 5.1.2. Clear differentiation between applied public health research projects that will require research ethics approval, and routine laboratory-based pathogen investigation, characterization and surveillance activities that are integral to timely public health response

☐ 5.1.3. Prioritization of research-associated testing activities within the context of available laboratory capacity and resources to support broader public health response

☐ 5.1.4. Ethical, safety and environmental requirements relevant to investigation of the ID agent using the proposed methods and study design(s)

☐ 5.1.5. Patient consent requirements having the potential to impact laboratory testing for public health research purposes

☐ 5.1.6. Available mechanisms to address consent-related concerns (e.g. development/updating of patient consent and test requisition forms)

☐ 5.1.7. Procurement requirements and availability of relevant animal models and vectors

☐ 5.1.8. Research Ethics Board (REB) approval requirements (human and animal), including coordination of multiple REB approval processes to support interjurisdictional collaboration

☐ 5.1.9. Authorship and intellectual property considerations associated with interjurisdictional collaboration and publication

☐ 5.1.10. Requirements for timely analysis and publication of research findings to inform public health decision-making

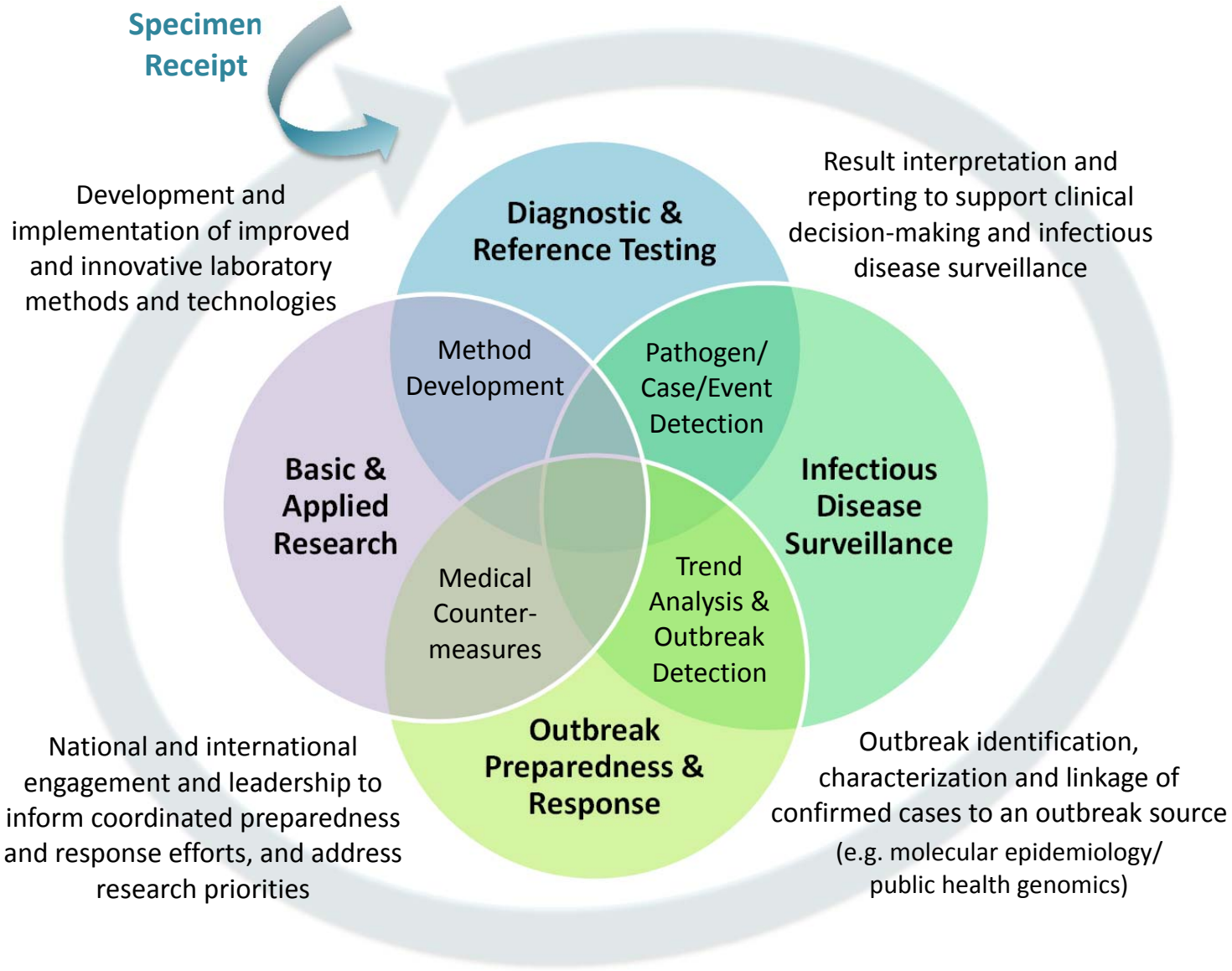
☐ 5.1.11. Ongoing review and re-assessment of ID research priorities (applied and basic) within the context of current scientific evidence and evolving ID response requirements

☐ 5.1.12. Identification of strategic partnerships and funding opportunities to advance research objectives

☐ 5.1.13. Maintenance of REB approval status for ongoing research projects

☐ **REVIEW COMPLETE – RESEARCH AND ETHICS**

APPENDIX I: INTERDEPENDENCIES OF PUBLIC HEALTH LABORATORY FUNCTIONS



INTERDEPENDENCIES OF PUBLIC HEALTH LABORATORY RESPONSE FUNCTIONS

T. EisBrenner, C. Jorowski. 2017.

APPENDIX II: RESPONSE TOOLKIT – NATIONAL MICROBIOLOGY LABORATORY

INTERJURISDICTIONAL PUBLIC HEALTH PARTNERS

International Partners

World Health Organization (WHO)
http://www.who.int/en/

☐ International Health Regulations (WHO)
http://www.who.int/topics/international_health_regulations/en/

Pan-American Health Organization (PAHO)
http://www.paho.org/hq/

☐ International Health Regulations – Region of the Americas
http://www.paho.org/hq/index.php?option=com_content&view=category&layout=blog&id=2258&Itemid=3901&lang=en

World Organisation for Animal Health (OIE)
http://www.oie.int/

Centers for Disease Control and Prevention (CDC), US
http://www.cdc.gov/

Food and Drug Administration (FDA), US
https://www.fda.gov/

National Partners

Canadian Blood Services (CBS)
https://blood.ca/en

Canadian Food Inspection Agency (CFIA)
http://www.inspection.gc.ca/eng/1297964599443/1297965645317

Global Affairs Canada
http://www.international.gc.ca/international/index.aspx?lang=eng

Health Canada (HC)
http://www.hc-sc.gc.ca/index-eng.php

National Research Council Canada (NRC)
http://www.nrc-cnrc.gc.ca/eng/index.html

Public Health Agency of Canada (PHAC)
http://www.phac-aspc.gc.ca/index-eng.php

☐ Centre for Communicable Diseases and Infection Control (CCDIC), PHAC

☐ Centre for Emergency Preparedness and Response (CEPR), PHAC
http://www.phac-aspc.gc.ca/cepr-cmiu/index-eng.php

☐ Centre for Foodborne, Environmental and Zoonotic Infectious Diseases (CFEZID), PHAC

☐ Centre for Immunization and Respiratory Infectious Diseases (CIRID), PHAC

☐ National Microbiology Laboratory (NML), PHAC
https://www.nml-lnm.gc.ca/index-eng.htm

Royal Canadian Mounted Police (RCMP)

☐ Chemical, Biological, Radiological, Nuclear Explosives (CBRNE) Response Team
http://www.rcmp-grc.gc.ca/fsis-ssji/fis-sij/cbrne-eng.htm

Interjurisdictional Networks and Expert Committees

Association of Public Health Laboratories (APHL), US
https://www.aphl.org/Pages/default.aspx

Biosafety Level 4 Zoonotic Laboratory Network (BSL4ZNet), CFIA – *national/international representation*
http://www.oie.int/eng/BIOTHREAT2017/posters/14_CEMMA-poster.pdf

Canadian Laboratory Response Network, PHAC/NML

Committee to Advise on Tropical Medicine and Travel (CATMAT), PHAC
http://www.phac-aspc.gc.ca/tmp-pmv/catmat-ccmtmv/references-eng.php#jmp-lan1

Global Health Security Action Group (GHSAG), WHO, European Commission, and G7+Mexico Health Ministers – GSHAG Laboratory Network
http://www.ghsi.ca/english/contact.asp

Global Public Health Intelligence Network (GPHIN), WHO
http://www.who.int/csr/alertresponse/epidemicintelligence/en/

Pan-Canadian Public Health Network (PHN), PHAC – *includes PHN steering committees*, task groups***
http://www.phn-rsp.ca/index-eng.php

☐ Canadian Public Health Laboratory Network** (CPHLN), PHAC/NML
https://www.nml-lnm.gc.ca/cphln-rlspc/index-eng.htm

☐ Communicable Infectious Disease Steering Committee* (CIDSC)

LABORATORY RESPONSE – RESOURCES, REFERENCES

Biosafety, Biosecurity and Emergency Response

Biosafety Directives, Advisories and Notifications
http://www.phac-aspc.gc.ca/lab-bio/res/advi-avis/index-eng.php

Human Pathogens and Toxins Act (HPTA)
http://laws-lois.justice.gc.ca/eng/acts/H-5.67/index.html

Human Pathogens and Toxins Regulations (HPTR)
http://lois-laws.justice.gc.ca/eng/regulations/SOR-2015-44/index.html

Laboratory Biosafety and Biosecurity, PHAC
http://www.phac-aspc.gc.ca/lab-bio/index-eng.php

Emergency Response Assistance Plan (ERAP), Government of Canada
https://www.tc.gc.ca/eng/tdg/erap-menu-72.htm

National Emergency Strategic Stockpile (NESS), PHAC
http://www.phac-aspc.gc.ca/ep-mu/ness-eng.php

Canadian Biosafety Standard (CBS), 2nd Edition, 2015
http://canadianbiosafetystandards.collaboration.gc.ca/cbs-ncb/index-eng.php

Canadian Biosafety Handbook (CBH), 2nd Edition, December 1st, 2015
http://canadianbiosafetystandards.collaboration.gc.ca/cbh-gcb/index-eng.php

WHO Laboratory Biosafety Manual
http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

Health Research Investment

Canadian Institutes of Health Research (CIHR)
http://www.cihr-irsc.gc.ca/e/193.html

Canadian Safety and Security Program (CSSP), Defence Research and Development Canada (DRDC)
http://www.drdc-rddc.gc.ca/en/dynamic-article.page?doc=canadian-safety-and-security-program/hzvlql9b

Information Sharing Agreements

Multi-Lateral Information Sharing Agreement (MLISA)
http://www.phn-rsp.ca/pubs/mlisa-eng.pdf

Government of Canada (GoC)

GoC Operations Centre
http://www.publicsafety.gc.ca/cnt/mrgnc-mngmnt/rspndng-mrgnc-vnts/gvrnmnt-prtns-cntr-en.aspx

Public Safety Canada Contact Information
General enquiries
Contact: 613-944-4875 or 1-800-830-3118
Fax: 613-954-5186

Media relations
Contact: 613-991-0657
E-mail: media@ps-sp.gc.cahttp://www.publicsafety.gc.ca/cnt/nws/md-cntctcs-en.aspx

National Health Portfolio Response

Health Portfolio Operations Centre (HPOC) – 24/7 Contact Information
Phone: 1-800-545-7661
http://healthycanadians.gc.ca/diseases-conditions-maladies-affections/disease-maladie/ebola/professionals-professionnels/index-eng.php

PHAC Medical Officer On-Call
Phone: 1-613-952-7940 *(after hours)*

National Laboratory Response

NML Guide to Services
https://www.cnphi-rcrsp.ca/gts/main

NML Emergency Operations Centre – 24/7 Contact Information
Phone: 1-866-262-8433
Email: OCNML.Director@phac-aspc.gc.ca

National Reference Centre for Parasitology (NML External Reference Laboratory)
https://www.mcgill.ca/tropmed/services/national-reference-centre-parasitology

Canadian Network for Public Health Intelligence (CNPHI)
https://www.cnphi-rcrsp.ca

National Notifiable Disease (NND) Surveillance

Case Definitions for Communicable Diseases under National Surveillance, PHAC, *CCDR* 2009
http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/09vol35/35s2/index-eng.php

Infectious Diseases – National Surveillance and Infection Control Information, PHAC
http://www.phac-aspc.gc.ca/id-mi/index-eng.php

Diseases and Conditions – National List, Links for Public Health Professionals
http://healthycanadians.gc.ca/diseases-conditions-maladies-affections/index-eng.php

Research Ethics Approval

HC/PHAC Research Ethics Board (REB)
http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/index-eng.php

HC/PHAC REB Secretariat Contact Information
http://www.hc-sc.gc.ca/contact/ahc-asc/ocs-besc/reb-cer-eng.php

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2014
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

APPENDIX III: LABORATORY RESPONSE CHECKLIST FOR INFECTIOUS DISEASE OUTBREAKS – REVIEW TABLE

ACTION REQUIRED	ACTION STATUS	PRIORITY	CHECKLIST ITEM
			1. LABORATORY INVESTIGATION
			1.1. Specimen Collection and Transportation: To support timely, coordinated laboratory investigation, identify and document specimen collection and transportation needs in advance, including:
			1.1.1 Appropriate specimen types, volumes and amounts; to be reassessed as required
			1.1.2 Appropriate specimen container(s) for transportation as per Risk Group classification
			1.1.3 Detailed specimen container packaging and labeling instructions
			1.1.4 Cold chain management requirements, i.e. temperature and timelines for shipping/arrival
			1.1.5 Transportation of Dangerous Goods (TDG) documentation requirements
			1.1.6 Preferred courier service recommendations in alignment with pathogen risk classification
			1.1.7 Biosafety and infection control guidelines, requirements and protocols for specimen handling and infection control processing applicable to both clinical and laboratory settings, including:
			1.1.7.1. Personal protective equipment, containment and decontamination
			1.1.7.2. Specimen retention, storage and disposal
			1.1.8. Additional documentation requirements and considerations within existing legislative and regulatory frameworks, including:
			1.1.8.1. Import and export permits
			1.1.8.2 Material transfer agreements between client and laboratory entities (e.g. to support distribution of control reagents, validation panels)

			1.1.8.3. Alignment of specimen collection requirements with existing data sharing agreements
			1.1.8.4. Laboratory guideline, licensing and certification requirements relevant to the investigation of a new/emerging infectious agent (e.g. FDA, HC, HPTA, HPTR requirements)
			1.1.8.5. Emergency response assistance plans and protocols for transport (e.g. ERAP for Risk Group 4 pathogens, and engagement of Regional Response Coordinators)
			1.1.9. Drafting of a specimen flow chart to guide collection and transport requirements
			1.2. Laboratory Testing: To support laboratory investigation efforts; review, develop, document and communicate evidence-based ID testing recommendations and protocols in collaboration with public health partners, with consideration of:
			1.2.1. Diagnostic algorithm(s) to be used for laboratory confirmation of case investigations, to inform and/or align with the current ID case definition (which may be outbreak-specific)
			1.2.2. Triaging protocols for high volume testing, using available knowledge of exposure history (e.g. close contact, travel history) and other key risk factors (e.g. pregnancy, hospitalization)
			1.2.3. Test Requisition Form (TRF) data field requirements, in alignment with the ID case definition to support timely and effective case management and public health response
			1.2.4. Specimen acceptance and rejection criteria
			1.2.5. Specimen retention and storage protocols (for diagnostic, surveillance and research purposes)
			1.2.6. Quality control and standardization of laboratory testing methods and reporting processes within the context of a quality management system, including:
			1.2.6.1. Validation, verification and comparison of diagnostic laboratory test performance specifications; including sensitivity, specificity, accuracy and precision
			1.2.6.2. Implementation and use of Standard Operating Procedures (SOPs)
			1.2.6.3. Monitoring and assessment of laboratory test turn-around times (upon specimen receipt)
			1.2.7. Test result reporting requirements, including:

			1.2.7.1. Use of standardized test result communication processes, report forms, and terminology
			1.2.7.2. Possible need to report 'preliminary' results prior to issuance of a final report
			1.2.7.3. Ability to support result reporting for submitted specimens vs. case investigations
			1.2.8. Alignment and standardization of test methods and interpretation criteria across decentralized testing sites/jurisdictions to support accurate, consistent case reporting and surveillance efforts
			1.2.9. Review and updating of testing-related processes and protocols to support evolving outbreak response requirements in keeping with current scientific evidence
			2. LABORATORY RESPONSE CAPACITY AND TRAINING
			2.1. Laboratory Response Capability: To address laboratory response challenges specific to the ID threat, collaboratively assess the following with public health laboratory partners on an ongoing basis:
			2.1.1. Laboratory capabilities for front-line screening and confirmatory testing methods at all jurisdictional levels (i.e. regional, provincial/territorial (P/T), state, national and international)
			2.1.2. Availability of validated diagnostic testing methods (e.g. serological, molecular, subtyping, genomic, proteomic), including commercially available kits and lab-developed tests (LDTs)
			2.1.3 Performance characteristics of currently used diagnostic test methods, including sensitivity, specificity, turn-around times, and throughput using current platforms
			2.1.4. Requirement to develop and validate LDTs where external capacity does not exist, or is not reliably accessible during an outbreak
			2.1.5. Decentralized diagnostic testing capabilities and potential for technology transfer to improve national laboratory response capacity, dependent upon magnitude and duration of response
			2.1.6. Ongoing availability of critical equipment and reagents via established suppliers
			2.1.7. Ability to acquire specimens from the international community to support the development of diagnostic tools to detect novel pathogens emerging in international settings (e.g. MERS-CoV)
			2.2 Surge Capacity and Training: To support flexible, scalable and timely laboratory response to ID threats, dynamically assess requirements related to the following surge capacity considerations:

			2.2.1. ID-related scientific expertise and technical response capacity amongst current staff
			2.2.2. Availability of laboratory space, biocontainment facilities, equipment and consumables
			2.2.3. Identification of 'surge capacity' positions that can be mobilized and/or cross-trained to mitigate workload issues
			2.2.4. Cross-training needs and priorities (e.g. personnel testing proficiencies, data entry/management)
			2.2.5. Standardized approaches for training and documentation of personnel proficiencies (e.g. testing methods; data collection, analysis and interpretation)
			2.2.6. Engagement of Emergency Operations Centre (EOC) support to enhance response capacity
			2.2.7. Identification of funding constraints, and opportunities to access emergency funding mechanisms
			2.2.8. Alternative approaches to work-shift scheduling to increase available person-hours during heightened response periods
			2.2.9. Mobile laboratory capacity to support ID outbreak field response
			2.2.10. Laboratory test throughput assessment, including the identification of any bottlenecks
			2.2.11. Available technologies with the potential to facilitate surge capacity development, including:
			2.2.11.1. Alternate testing platforms to increase testing throughput
			2.2.11.2. Training videos, e.g. to demonstrate specimen collection requirements
			2.2.11.3. Web-based information exchange tools and platforms
			2.2.12. Risk mitigation planning to address operational vulnerabilities observed during all phases of the laboratory response effort
			2.2.13. Participation in preparedness assessment exercises (including joint simulations) with interjurisdictional, interdisciplinary public health partners involved in coordinated ID response (e.g. epidemiologists, physicians, field investigators); typically during inter-outbreak periods

			3. LABORATORY SURVEILLANCE AND DATA MANAGEMENT
			3.1. Laboratory-based Surveillance and Data Management: To support timely and integrated laboratory-based ID surveillance activities, key considerations are as follows:
			3.1.1. Assess the current surveillance status of the ID at all jurisdictional levels including the existence of, or requirement for:
			3.1.1.1. An established case definition to support case investigation and confirmation using laboratory and epidemiological criteria within the current outbreak context
			3.1.1.2. Alignment of case confirmation criteria between reporting jurisdictions to ensure national consistency of case counts, reporting, surveillance and response efforts
			3.1.1.3. Reporting/notification processes for suspected and/or confirmed cases at each jurisdictional level (subnational, national, international (e.g. IHR reporting obligations))
			3.1.1.4. Surveillance systems/platforms capable of supporting timely ID detection, reporting and outbreak monitoring within the context of the current response
			3.1.1.5. Information management and information technology (IM/IT) operational support for data transfer pipelines and bioinformatics tools needed to acquire and analyze genomic (e.g. whole genome sequencing (WGS)) and other 'omics' data.
			3.1.2. Identify laboratory-based surveillance considerations related to ID case/outbreak detection, confirmation, characterization, monitoring and reporting, including:
			3.1.2.1. Current knowledge of ID epidemiology to inform laboratory testing and triage recommendations
			3.1.2.2. Monitoring and classification of laboratory investigations in alignment with established case definition criteria (e.g. suspect case under investigation, laboratory-confirmed, not a case/discarded)
			3.1.2.3. Key laboratory and epidemiological data elements necessary to inform laboratory investigation processes, including triaging of specimens, diagnostic algorithm selection, result interpretation, data linkage, and case classification and confirmation efforts (e.g. unique case identifiers, test history, symptom onset date, travel history, etc.)

			3.1.2.4. Data linkage and integration requirements to support timely surveillance and response, e.g.:
			▪ linkage of specimens and associated test result(s) with the case under investigation
			▪ linkage of laboratory and epidemiological case data held by separate public health jurisdictions
			▪ linkage of confirmed cases with a given outbreak, or outbreak source
			3.1.2.5. Laboratory-confirmed case review, verification, monitoring and reporting processes
			3.1.2.6. Molecular epidemiology/public health genomics approaches to support ID surveillance, outbreak characterization and source attribution
			3.1.2.7. Feasibility of using web-based tools and public health informatics platforms to support timely linkage of case investigation data from disparate public health sources
			3.1.2.8. Design and development of surveillance reports to support ongoing laboratory-based monitoring, assessment and reporting of ID outbreak information, e.g.:
			▪ Monitoring the status of laboratory investigation processes (real-time)
			▪ Laboratory-confirmed case counts (e.g. cumulative totals, new cases/unit time)
			▪ Final classification of all laboratory investigations (e.g. % positive, % confirmed)
			▪ Distribution of laboratory-confirmed cases using available data (e.g. by age, sex, geography, exposure history, etc.)
			▪ Molecular epidemiology of the outbreak (e.g. case linkage, source attribution)
			▪ Estimation of lab-based indicators to monitor and assess surveillance performance (e.g. timeliness, laboratory-based ID investigation rates, data quality and completeness)
			3.1.2.9. Legislative context and agreements relevant to interjurisdictional sharing of information and data to support ID laboratory investigation activities (e.g. MLISA, IHR)
			3.1.3. Align laboratory test requisition form (TRF) data fields with the ID case definition to support effective surveillance and response, with consideration of the following key data field types:

			3.1.3.1. **Submitting laboratory/client contact information** to support result reporting and other communication to inform clinical decision-making
			3.1.3.2. **Unique identifiers** to enable non-nominal, interjurisdictional linkage of laboratory result(s) with the case under investigation to support accurate case classification, reporting, clinical decision-making, surveillance and response
			3.1.3.3. **Geolocator information** for the case under investigation, as jurisdictionally relevant (e.g. city, reporting health region, province/territory/state, country, postal code, forward sortation area (i.e. three-digit postal code))
			3.1.3.4. **Clinical, epidemiological and laboratory fields** needed to support triaging of high priority specimens (e.g. travel history, pregnancy status), appropriate test algorithm selection and result interpretation, as well as case confirmation and reporting
			3.1.3.5. **Date fields** needed to support diagnostic algorithm selection, test result interpretation, and to estimate laboratory-based surveillance indicators (i.e. symptom onset, specimen collection, specimen receipt, test result and case reporting dates)
			3.1.4. Assess laboratory information management system (LIMS) data flow requirements, and implement LIMS processes to support ID investigation, surveillance and response, including:
			3.1.4.1. Standardized approaches to the documentation and monitoring of test requisition, specimen tracking, data entry/review, data linkage and result reporting processes
			3.1.4.2. Terminology standardization, and definition of data flow and retention/life cycle
			3.1.4.3. 'Chain of custody' documentation requirements for high-profile laboratory investigation and result reporting
			3.1.4.4. Development of customized queries to support ongoing surveillance and response
			3.1.4.5. Summary report generation to facilitate monitoring, assessment and reporting of laboratory-based ID surveillance and outbreak response efforts
			3.1.4.6. Use of web-based tools and platforms to support test requisition and reporting, as well as timely interjurisdictional linkage of case investigation data

			3.1.5. Dynamically assess and address operational vulnerabilities impacting overall response and reporting efforts, including:
			3.1.5.1. External communication and interjurisdictional reporting challenges
			3.1.5.2. Interjurisdictional differences in laboratory testing algorithms and result interpretation
			3.1.5.3. Changes to interjurisdictional confirmed case definitions that may impact surveillance
			3.1.5.4. Data linkage issues impacting accuracy and timeliness of case counting and reporting
			4. INTERJURISDICTIONAL ENGAGEMENT AND COMMUNICATION
			4.1. Interjurisdictional Engagement and Communication: To support coordinated public health stakeholder engagement and consistent messaging of laboratory information, develop a strategic communication strategy incorporating the following considerations:
			4.1.1. Accessibility of current ID laboratory response information to the public and to public health professionals through the timely availability of:
			4.1.1.1. Web-based content and social media tools
			4.1.1.2. 24-hour emergency contact information to access laboratory support services
			4.1.1.3. A 'Guide to Laboratory Services', including specimen and test requisition requirements
			4.1.1.4. Laboratory testing recommendations and guidance documents to support decision-making by clinical and public health partners
			4.1.1.5. Alerting and notification processes to simultaneously disseminate time-sensitive information to interjurisdictional public health decision-makers
			4.1.2. Engagement of external laboratory partners, public health networks and interjurisdictional working groups involved in the coordination of ID public health response, including:
			4.1.2.1. Physician networks and committees responsible for clinical guideline development

			4.1.2.2. Public health laboratory and epidemiology partners, and interjurisdictional networks responsible for developing consensus case definitions and coordinating public health surveillance and intervention activities
			4.1.2.3. Biosafety networks and partners involved in the development of biosafety guidelines
			4.1.3. Strengthened mechanisms for collaboration and information sharing with public health partners and networks to enable:
			4.1.3.1. Evidence-based development of laboratory and clinical recommendations and guidelines, and public health surveillance and intervention strategies
			4.1.3.2. Consistent public health messaging of specimen collection and testing guidelines and recommendations for identified at-risk groups
			4.1.3.3. Alignment of ID case definitions used at multiple jurisdictional levels, including international case definitions where feasible
			4.1.3.4. Consensus regarding laboratory-confirmed case inclusion and exclusion criteria
			4.1.3.5. Accurate and consistent case classification, counting and reporting in fulfillment of P/T, state, national and international surveillance requirements
			4.1.3.6. Updating of publicly available web-based content to support coordinated laboratory response efforts and evidence-based public health decision-making
			4.1.4. Review and revision of external communication and reporting processes to address:
			4.1.4.1. Challenges impacting the timeliness of external reporting of ID cases and test results to inform clinical decision-making and public health action
			4.1.4.2. Inconsistencies and interjurisdictional differences in testing algorithms, result interpretation, case confirmation and surveillance processes
			4.1.4.3. Required changes to test reporting algorithms and information sharing methods
			4.1.4.4. Data sharing and linkage issues impacting timeliness of confirmed case reporting
			4.1.5. Event-specific internal communication and reporting structures and mechanisms needed to support consistent, effective information sharing and public health messaging, including:

			4.1.5.1. Identification of a lead subject matter expert (SME) responsible for scientific oversight of ID-specific laboratory response efforts (e.g. field deployment activities, participation in research and surveillance studies)
			4.1.5.2. A 'single-window' point of contact responsible for coordinating the receipt and distribution of event-specific information within the organization (e.g. EOC support)
			4.1.5.3. Appropriate routing mechanisms for external requests received within the organization (e.g. public health stakeholder requests for information, outbreak support, media-related communications, etc.)
			5. RESEARCH AND ETHICS
			5.1. Research Requirements and Ethical Considerations: To advance scientific research in support of public health action, consider the following laboratory-related issues in collaboration with public health partners:
			5.1.1. ID-specific applied and basic research requirements and priorities, e.g.:
			5.1.1.1. Pathogen identification and characterization studies (phenotypic, genomic, proteomic)
			5.1.1.2. Diagnostic and confirmatory reference test method development
			5.1.1.3. Transmission studies, development of risk models
			5.1.1.4. Field studies, vector competency studies
			5.1.1.5. Vaccine and other medical countermeasure development and assessment
			5.1.1.6. Applied biosafety research with a focus on timely knowledge translation
			5.1.1.7. Public health surveillance studies requiring research ethics approval
			5.1.2. Clear differentiation between applied public health research projects that will require research ethics approval, and routine laboratory-based pathogen investigation, characterization and surveillance activities that are integral to timely public health response
			5.1.3. Prioritization of research-associated testing activities within the context of available laboratory capacity and resources to support broader public health response

			5.1.4. Ethical, safety and environmental requirements relevant to investigation of the ID agent using the proposed methods and study design(s)
			5.1.5. Patient consent requirements having the potential to impact laboratory testing for public health research purposes
			5.1.6. Available mechanisms to address consent-related concerns (e.g. development/updating of patient consent and test requisition forms)
			5.1.7. Procurement requirements and availability of relevant animal models and vectors
			5.1.8. Research Ethics Board (REB) approval requirements (human and animal), including coordination of multiple REB approval processes to support interjurisdictional collaboration
			5.1.9. Authorship and intellectual property considerations associated with interjurisdictional collaboration and publication
			5.1.10. Requirements for timely analysis and publication of research findings to inform public health decision-making
			5.1.11. Ongoing review and re-assessment of ID research priorities (applied and basic) within the context of current scientific evidence and evolving ID response requirements
			5.1.12. Identification of strategic partnerships and funding opportunities to advance research objectives
			5.1.13. Maintenance of REB approval status for ongoing research projects

APPENDIX IV: CHECKLIST IMPLEMENTATION SUGGESTIONS – REVIEW TABLE

CHECKLIST USE

Implementation of an electronic version* of the Checklist Table can facilitate collaborative, real-time review, identification and prioritization of Checklist Items to support follow-up action. The following content includes basic suggestions to guide user customization and adaptation of the reference version of the Checklist Table to meet organization and jurisdiction-specific requirements and preferences.

**Note: As the Checklist Table was created using Microsoft Excel 2010, software-specific functions described below may not operate similarly using other spreadsheet software, but will likely be compatible with later versions of Excel.*

CHECKLIST ITEM CLASSIFICATION

Using the three 'classification' columns provided to the left of the Checklist Item column, reviewers can indicate for each item during the review process:

1. If there is '**Action Required'*** – this can be indicated by simply placing an '**x**' in the corresponding cell; cells are left blank if action is not required to support current response efforts.

2. The '**Action Status'** – this can be indicated for actionable items as preferred, e.g. by using simple, user-defined status designations such as **Pending (P)**, **Ongoing (O)**, **Deferred (D)**, or **Complete (C)**.

3. '**Priority**' – ranks items for which action is required according to user-defined priority levels, e.g.: **Urgent (U)**, **High (H)**, **Medium (M)**, **Low (L)**, and **Not Applicable (NA)**.

***Note**: When an item requiring action is marked '**x**' (e.g. '1.1.7.2. Specimen retention, storage and disposal'), it is important to also mark all hierarchical items within the Table Section with an '**x**' (i.e. items 1, 1.1, and 1.1.7). This ensures that the full context of the action item of interest is returned when the table is sorted/filtered using spreadsheet software (e.g. Excel).

CHECKLIST TABLE CUSTOMIZATION

Users can customize the Checklist Table to expand its functionality, or edit its content in a number of potential ways:

1. **Addition of new Checklist Items** (rows) to capture additional, organization or jurisdiction-specific requirements that are not reflected in the published reference version.

   - To insert a new row (Excel): In the left hand margin, click on the row above which the new row is to be inserted. On the 'Home' tab, click 'Insert' to add a row to the Table.

2. **Removal of Checklist Items** that are not relevant within the user's organization or jurisdiction, e.g.: 'Item 5.1.1.5. Vaccine and other medical countermeasure development and assessment'.

- To remove a row (Excel): In the left hand margin, click on the row to be deleted. On the 'Home' tab, click 'Delete' to remove the selected row.

3. **Addition of new Checklist Table data fields*** (columns) to capture additional information relevant to Checklist Item review and follow-up action. Additional data fields that may be useful include, e.g.:

   - **'Comments'** – captures detailed information regarding the specific actions needed to address relevant Checklist Items

   - **'Assigned'** – captures the individual/laboratory program responsible for follow-up action within an organization

   - **'Completion Date'** – records the date of completion for actionable Checklist Items

   - To add a new Table column (Excel), click on the column to the right of the intended location of the new column. On the 'Home' tab, click 'Insert' to add the column to the Table.

***Note**: The reference version of the Checklist Table has been formatted to allow the full Table width to be legibly printed in 'landscape' orientation on 8.5"x11" paper (Excel); if the Table is further customized by adding additional columns, reconfiguration of the current print settings may be required to ensure that all Table data are easily viewed.

ITEM PRIORITIZATION

Once all Checklist Items have been reviewed and classified, the Checklist Table can be easily 'sorted' using spreadsheet software to display only the specific items of interest, e.g.: only items for which there is 'Action Required'.

In Excel, the user can 'sort' the Checklist Table according to user-defined item classification as follows:

1. Click on the 'downward arrow' button displayed at the bottom right of any column header, e.g.: 'Action Required', 'Action Status', 'Priority'.

2. Within the 'Sort' pop-up menu, place a 'check' in each box that corresponds with a classification category to be displayed; multiple categories (within a column) can be selected and displayed simultaneously, e.g.:

   - Under the header 'Action Required' with the following 'sort' options: □ (Select All) □ x □ (Blanks); checking 'x' returns all items marked as 'Action Required'

   - Under the header 'Priority' with the following 'sort' options: □ (Select All) □ U □ H □ M □ L □ NA □ (Blanks); checking 'U' and 'H' returns only 'Urgent' and 'High' priority action items

   - Note: Checking the 'Select All' box will remove the 'sort' filter from the selected column, returning all data in the Table.

Once sorted/filtered, the condensed Checklist Table displays only the items of interest, allowing more focused planning discussion, prioritization and tasking of all action items to support response efforts. It is recommended that users experiment with various table views to optimize its functionality to suit response-specific needs.

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1. Hitchcock P, Chamberlain A, Van Wagoner M, Inglesby TV, O'Toole T. Challenges to global surveillance and response to infectious disease outbreaks of international importance. Biosecur Bioterror. 2007; 5(3): 206-227.

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