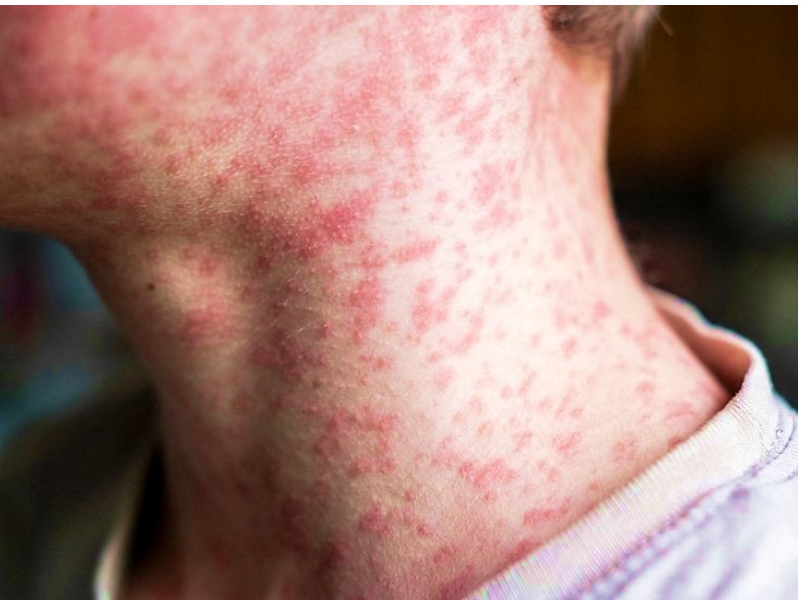
This policy framework outlines the process by which methods for Morbillivirus hominis detection in Canadian wastewater are reviewed, evaluated, and approved for policy implementation.



VALIDATION AND APPROVAL OF MEASLES (Morbillivirus hominis) WASTEWATER MONITORING METHODS

Kirsten Campbell, Ivan Drahun, Alexandra Foley-Eby, Yuxin Hu, Cody Koloski, Kira Mudrey, Amanda Williams

EXECUTIVE SUMMARY

This policy framework outlines a standardized process for the evaluation and approval of measles (Morbillivirus hominis) wastewater testing methods in Canada. It recommends creating a dedicated committee within the Public Health Agency of Canada (PHAC) to evaluate and approve wastewater testing methods to ensure quality management and quality assurance standards are met, with a subcommittee focused on innovative approaches.

Applications submitted will be evaluated based on facility and equipment requirements, sample handling and storage requirements, external and internal quality control and assurance processes, and ethical considerations. This framework also emphasizes the importance of method innovation, data management through an information management system (LIMS), and a public outreach strategy to raise awareness about the inconsistency of current monitoring protocols and engage stakeholders. These recommendations aim to bring forward internationally recognized standards to strengthen public health efforts in Canada.

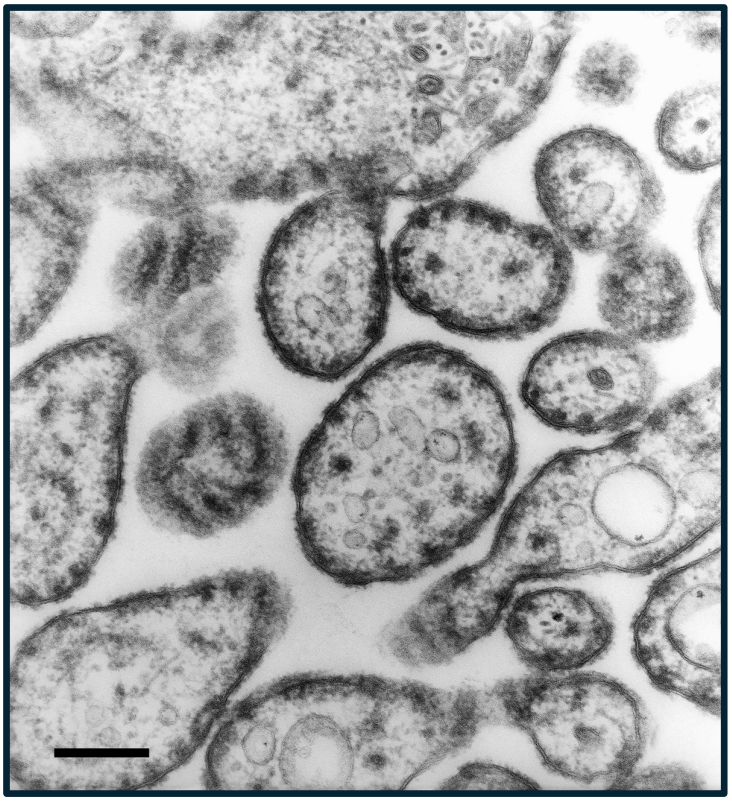


FIG 1. MeV, Measles virus, (Paramyxoviridae). Transmission electron microscopy, ultrathin section. Bar = 100 nm

LAY SUMMARY

This policy framework outlines the approval process for wastewater surveillance of the virus that causes measles in Canada. It recommends that there should be the creation of a committee made up of experts, to evaluate and approve applications for measles testing in wastewater.

A subcommittee should also be created that deals with innovative approaches. The goal is to develop reliable and accurate methods that can be used across the country and recognized internationally. This framework also emphasizes the importance of data transparency and public engagement to help build trust and promote awareness among the public.

INTRODUCTION

Purpose

This policy seeks to standardize the requirements of organizations conducting wastewater pathogen surveillance for Morbillivirus hominis (MeV), the causative agent of measles. The current political climate has led to uncertainty in infectious disease surveillance due to the defunding of key agencies in the United States that have previously served as a standard for research and disease monitoring. Canada stands at a precipice at which it can choose to become a leader in disease surveillance. Globally, Canadian science is well-respected and trusted. By developing a program to effectively standardize MeV surveillance, Canada can bring forward internationally recognized standards to strengthen public health efforts.

Many challenges exist in wastewater-based epidemiology (WBE). Samples are complex, containing traces of many microorganisms and chemicals. Methods must distinguish between these targets (Diamond et al., 2022). There is also a lack of standardization as most WBE is research-oriented and requires a transition to official environmental testing applications. Without a consensus on the requirements for sample processing and testing, the accuracy and effectiveness of wastewater testing come into question.

A suitable method has yet to be established for WBE of measles. Various researchers have tested wastewater in different locations with mixed success. Whether this was due to a lack of MeV in the water or due to a failing of the methodology, it is difficult to ascertain. This further highlights the necessity for standardization because troubleshooting the issues with the assays is very difficult when the processes were vastly different (Chen & Bibby, 2025).

To address the gaps in WBE of MeV, standard protocols must be developed that minimize error and guarantee accurate results. The foci of this policy are:

Quality Management. Ensuring the standard operating procedures (SOPs) follow strict guidelines to maintain the integrity of samples, data collection, and reporting.

Quality Assurance. Evaluation of the accuracy and precision of laboratory assays between different organizations, validated with known standards issued by the governing body.

Innovation. Provision of guidelines for the integration of new technologies for wastewater surveillance of MeV.

Water Surveillance

Wastewater-based surveillance (WSB) can be used for the detection of pathogens at a population level. Infected individuals shed genomic material in their feces, urine, and/or saliva, and this enters wastewater. Water is collected prior to sewage treatment and sent to laboratories for testing (Grassly et al., 2025).

The pathogen must be concentrated from the water; the method for which depends on the properties of the target pathogen. Detection is performed through molecular methods, often done with conventional or quantitative real-time polymerase chain reaction (PCR). This type of testing has been used for monitoring poliovirus, hepatitis A, and most recently SARS-CoV-2 (Grassly et al., 2025).

FIG 2. Wastewater treatment plant.

https://tinyurl.com/kvj5v5wy

INTRODUCTION

The use of WBE has been employed for public health efforts for many years. Multiple European countries have been using WBE to monitor pathogen circulation. The rise of SARS-CoV-2 transmission deemed the system valuable to public health (Benedetti et al., 2024). Canada currently surveys for the presence of SARS-CoV-2, influenza A and B, and respiratory syncytial virus (RSV). Wastewater testing proved particularly useful during the COVID-19 pandemic as a reliable tool to predict trends in infection rates. This was important as data reflected true circulation of the virus, irrespective of people's propensity to be tested and/or display symptoms (Hrudey et al., 2022). The knowledge gained via wastewater testing for COVID-19 should be thoughtfully utilized to prepare for the potential outbreaks of emerging infectious diseases, such as measles.

Measles

Measles is highly contagious, with a basic reproduction number (R_0) of 12-18. This value indicates that in a completely susceptible population, one primary MeV infection would result in 12-18 secondary infections. In comparison, SARS-CoV-2 has an approximate R_0 value of 2.5-5, and influenza has an approximate R_0 value of 1.4-4 (Fine et al., 2023). It is primarily spread through airborne transmission, particularly as suspended aerosols, which can be infectious for several hours.

Symptoms of measles typically begin 8-14 days following exposure. The disease is characterized by fever, cough, rash, and conjunctivitis (i.e., pink-eye). Infection also leads to immunosuppression which significantly increases the patient's risk of secondary infection. This immunosuppression can be prolonged for months to years after infection, increasing overall morbidity and mortality. In 30% of cases, complications arise, such as secondary infection, pneumonia, diarrhea, and vitamin A deficiency.

https://tinyurl.com/mr2xcne7

FIG 3. Measles rash presenting on the back.

Infection can cause severe complications in pregnancy, both for the mother and fetus/newborn.

Prior to the introduction of the measles-containing vaccine (MCV), the United States reported approximately 500,000 annual cases of measles. Of these cases, 48,000 patients were hospitalized, 1000 developed encephalitis, and 400-500 died. In Canada, endemic measles was eliminated following the implementation of mandatory vaccinations. Protection of unvaccinated individuals is achieved when over 95% of the population is vaccinated against MeV. Reports from several Canadian provinces indicate that between 2019 and 2023, vaccination rates for measles, mumps, and rubella declined from 89.5% to 82.5% (Public Health Agency of Canada, 2020). In addition to a reduction in vaccination rates, cases of measles in Canada are rising. Between 1998 and 2024, there was an average of 91 annual cases of measles in Canada. As of April 12, 2025, there have been 915 confirmed and 153 probable cases of measles in Canada. Of these cases, 79% are unvaccinated individuals and 15% are of unknown vaccination status (Public Health Agency of Canada, 2025).

Diseases, particularly those that result in hospitalizations, impose a substantial economic burden. In 2008, communicable diseases accounted for $4.7 billion in direct costs (i.e., hospital, physicians, drugs, etc.) and $3.7 billion in indirect costs (i.e., labour supply effects due to morbidity, caregiving, or premature mortality). The rise of measles in Canada threatens to increase these costs, particularly due to the high communicability and high proportion of hospitalizations and long-term immunosuppression (Public Health Agency of Canada, 2016). Prophylactic measures, such as wastewater testing to predict outbreaks, can help alleviate this economic burden. Early detection of measles in communities can result in a rapid public health response to lower overall infections, thereby reducing morbidity and mortality in communities.

The goal of this policy is to outline the process for approving methods for wastewater testing for the detection of MeV, thereby guiding public health responses and enhancing community awareness. Innovation in testing methods must be encouraged; however, standardizing the approval process will maintain the integrity, legitimacy, and reliability of large-scale testing.

A CANADIAN-LED PARTNERSHIP IN THE APPROVALS PROCESS

Given the urgency of the ongoing multijurisdictional measles outbreak in Canada and the expanding measles outbreaks in the Western world, Canada has taken a leadership role in determining the acceptable methods used to monitor measles activity in wastewater samples. However, Canada is not alone in the process, various national and global organizations have exceptional standards in developing protocols for use by clinicians, researchers and governments across the globe. Acceptable protocols will be determined based on firm recommendations developed in consultation with these organizations. The list below represents the various organizations Canada has worked with in developing the policy framework (See appendix for full list of organizations):

WHO Global Measles & Rubella Laboratory Network (LabNet). Network of laboratories with standardized procedures for measles testing, undergoing annual accreditation at the international (WHO) level. Accreditation includes both internal and external quality assurance processes. WHO also publishes a manual for laboratory-based surveillance of measles, rubella, and congenital rubella syndrome.

The Global Consortium for Wastewater and Environmental Surveillance for Public Health (GLOWACON). A global working group is looking to create an international system for wastewater-based surveillance.

American Public Health Association. Publishes a guide on standard methods for water and wastewater analysis. The 24th edition of this guide is currently in circulation, but *Standard Methods for the Examination of Water and Wastewater* has been in circulation as a reference guide since 1905.

International Organization for Standardization (ISO). Consensus-based, internationally recognized standards across all sectors (health, food and agriculture, energy, transportation, etc.). Known for their quality management standards, which are often applied to laboratory quality management (for example, ISO 15189 for medical laboratories).

International Laboratory Accreditation Cooperation. Publishes a series of guidelines for accreditation bodies and accredited organizations on best practices. Ensures testing laboratories conform to the appropriate ISO standard.

U.S. Centers for Disease Control and Prevention. Coordinates the National Wastewater Surveillance System in the United States. As of March 2023, published guidelines on Wastewater Surveillance Testing Methods for SARS-CoV-2.

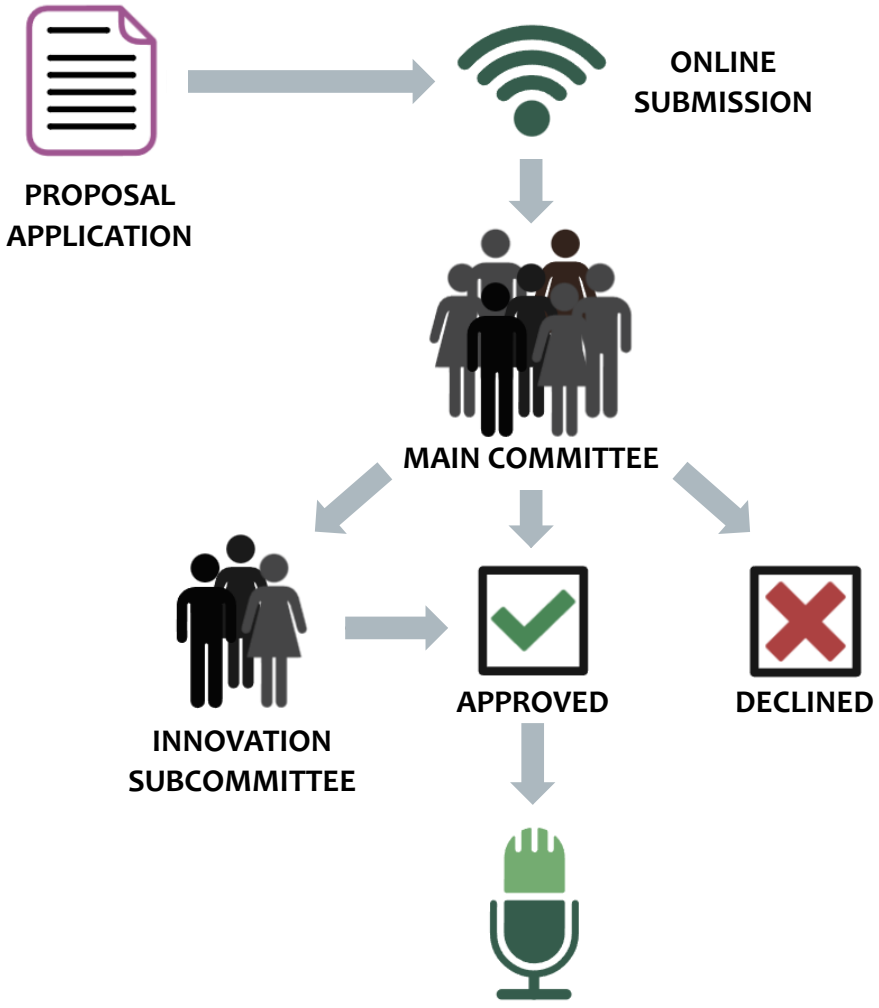
European Centre for Disease Prevention and Control (ECDC). Coordinates surveillance of infectious diseases across the European Union. Published a series of guidelines for the surveillance and monitoring of various diseases.

A CANADIAN-LED PARTNERSHIP IN THE APPROVALS PROCESS

Process of Approving Proposed Methods

A committee of up to 8 experts in various areas, including wastewater surveillance, Measles, and public health, should be established within the Public Health Agency of Canada (PHAC) but independent of the agency to provide guidance and collaborate with relevant organizations on method standardization and the approval process. The committee will develop a set of standards that must be met for the approval of measles wastewater testing. The committee will have consultations with the relevant stakeholders and update its guidance based on objective evidence. An application portal will be established, open to both second-party and third-party stakeholders, for the submission of proposed testing protocols. The time from submission to decision depends on the number of applications received, the complexity of the submission, and the committee's scheduled meetings. A subcommittee will be established to review innovative proposals and facilitate the approval process (See Innovation).

Successful applications must follow the recommendations provided in the subsequent sections. Submissions that fail to pass one or more recommendations will be declined. The committee can provide suggested corrections to any submitted applications and allow a specified period for implementing the requested changes. Upon approval, the relevant stakeholders and testing laboratories will be notified and provided with the material to implement the new methods within their testing facilities.



PROPOSED FRAMEWORK FOR MEASLES WASTEWATER TESTING

[Application to be Submitted]

Any application that is submitted to the committee for review and approval must meet the required recommendations as outlined below. If an innovation is to be used for one or more of the recommendations, please see the section "Innovation" for further details.

1. Facility and Equipment Requirements

1.1 Purpose

It is essential that all facilities being authorized to conduct wastewater testing for MeV meet the standards outlined in this policy to ensure the integrity of the data and protect the health and safety of staff, the public, and the environment. Morbillivirus hominis is a Risk Group 2 Human Pathogen and a Risk Group 1 Animal Pathogen. Therefore, any facility working with this material must be certified at Containment Level 2 (CL2). These facilities adhere to strict operational practices and physical containment requirements designed to minimize the risk of pathogen release.

Molecular amplification of DNA results in high amounts of template DNA which can contaminate workspaces, downstream processes, and subsequent testing. This is known as amplicon-based contamination. Separating the molecular virology stages based on pre-molecular amplification and post-molecular amplification areas is key in preventing this type of contamination which could cause erroneous results in future samples.

1.2 Requirements

1. **Facilities must be CL2 certified and follow all regulations under the Canadian Biosafety Standard Third Edition.** Importantly, the facility and HVAC system must be maintained to a high calibre as well to secure the containment zone.
2. **Facilities must have designated areas for specimen collection and preparation, molecular virology, and office workspace.** Ideally, each stage of the molecular process will be conducted in different rooms. Regulating this is prohibitive to many facilities, however, therefore separate areas/biosafety cabinets for amplification stages is sufficient.
3. **Any associated facility must use equipment that has been appropriately qualified for the assigned work, calibrated, and undergoes regular monitoring and maintenance.**
4. **Equipment must be appropriately documented.** Equipment must be assigned asset numbers that are associated with their serial number, documentation, and records. Procedural documentation must describe how to operate equipment, who is authorized to do so, and when/where the equipment is to be used. Documentation must also contain their record of validation, the outcome of any safety inspections, equipment failures, and servicing events. It is **recommended** that organisations assign a specific user or group to specific equipment to ensure equipment calibration and maintenance is up to date.

2. Sample Selection, Collection, Handling, and Storage

2.1 Goals

Specimen selection, collection, handling, and storage must meet regulatory standards while being able to achieve the goals of the study, which should be to accurately detect the measles virus in wastewater samples. For this to be statistically useful and applicable, decisions must be made about where, when, how, and by whom the study procedures will be conducted.

PROPOSED FRAMEWORK FOR MEASLES WASTEWATER TESTING

2.2 Regulations regarding water treatment facilities in Canada

Any collection of wastewater samples would need to have prior approval from all regulatory bodies. Wastewater treatment in Canada is a joint responsibility between municipal, provincial, and federal governments. While a municipality may operate the wastewater treatment, all overarching regulations for effluent quality come from the Government of Canada (*Wastewater*, 2020).

Wastewater treatment is controlled through multiple regulations including the Wastewater Systems Effluent Regulations under the Fisheries Act (*Wastewater*, 2020). Environment and Climate Change Canada as well as the Public Health Agency of Canada also have roles in regulating wastewater treatment in the country (*Wastewater*, 2020). There are also additional considerations and regulations for wastewater treatment on indigenous reservations and northern areas which involve Aboriginal Affairs and Northern Development Canada (AANDC) (G. of C. I. S. Canada, 2011). As indicated, additional provincial and municipal regulations may apply in addition to overarching federal ones. In the province of Saskatchewan, for instance, wastewater treatment is regulated by Saskatchewan's Waterworks and Sewage Works Regulations. In addition, Saskatchewan has its own Water Security Agency which provides information on the regulations within the province (Water Security Agency, 2018).

Provinces may require their own permits for accessing their wastewater treatment facilities. Additionally, municipalities may have their own regulations that need to be considered, and operators of individual treatment facilities will need to be included in all decisions and scheduling for sample collection (operating hours, staff availability, etc.) This complexity is multiplied by the >4,000 Canadian wastewater treatment facilities as of 2022, according to Statistics Canada (Government of Canada, 2022). Some of these facilities are remote and difficult to access but may be important sentinels for disease spread.

2.3 Who can do sample selection, collection, handling, and transportation.

In prior surveillance of wastewater, samples were collected by employees from one of the regulatory bodies involved in the research. In the Canadian Wastewater Survey (CWS), treatment facility employees were responsible for sample collection (S. C. Government of Canada, 2025). In other surveys employees for Environment and Climate Change Canada have collected samples (Environment and Climate Change Canada, 2024). Testing for SARS-CoV-2 in wastewater was performed by employees of the Public Health Agency of Canada via the National Collaborating Centre for Infectious Diseases (Public Health Agency of Canada, 2022). Transportation has been completed by couriers who are certified to transport biohazardous samples of this type. For private companies interested in wastewater testing, an agreement would need to be reached between all governing bodies and would include some degree of government oversight in addition to meeting all regulations.

3.0 Employee Training and Certification

For certification of employees, all applicable training should be completed including Workplace Hazardous Information System training and any site / task / safety training available through the Public Health Agency website (All Courses | PHAC Training Portal, n.d.). This website also includes tests which should be completed and passed by all individuals prior to participating in study activities.

All certification and experience can be recorded in the form of the Candidate Achievement Record (CAR). The CAR is a form of competency record that assesses key leadership competencies through self-reporting examples of past performance and work-related achievements. This record has the benefit of being scored by assessors at the Personnel Psychology Centre from the Government of Canada (P. S. C. of Canada, 2016). Only individuals with the appropriate competencies, training, and certification should perform tasks. All certificates and records of training should be maintained digitally and in hard copy with the laboratory manual and updated regularly by a designated individual to prepare for internal and external auditing.

PROPOSED FRAMEWORK FOR MEASLES WASTEWATER TESTING

4.0 Standard Operating Procedures

Standard operating procedures (SOPs) and work instructions must both achieve the goals of the study and meet all regulatory requirements. Project approval, laboratory inspections, and audits will ensure that both are met. SOPs must be comprehensive and complete and not suggest any activity that would violate the Canadian Occupational Health and Safety regulations and guidelines. The details pertaining to laboratory inspections in Canada can be found at: https://www.canada.ca/en/employment-socialdevelopment/services/health-safety/reports/laboratory-inspection.html

In addition, all SOPs must be maintained in both digitized and hard copy and available to all members of the research team. These SOPs must also be accessible for auditors and inspectors. An example of a laboratory manual of SOPs can be found at: http://collections.banq.qc.ca/ark:/52327/bs47124

In addition to work instructions, an SOP must include acronym and terminology explanations as well as documents pertaining to the training of employees on specific SOPs. This includes signature pages and lists of updates made to SOPs with indication that the defunct protocol has been removed from the active list, both digitally and in hard copy.

5.0 Audits

For research within the Government of Canada, internal audits are performed by the Office of Audit and Evaluation (OAE) (Office, 2020). According to their website, "OAE reports its audit findings and recommendations directly to the Departmental Audit Committee, chaired by the Deputy Minister. This committee approves or amends the annual audit plan, which is based on a departmental risk assessment, gives formal approval to audit reports, and monitors the implementation of the appropriate corrective action." In addition, the OAE states, "The term "internal audits" refers to audits conducted in respect to the resources, systems, processes, structures, and operational tasks of Health Canada." The objective of OAE is laid out as, "To maintain and enhance the proper management of the public funds administered by Health Canada. This is achieved by providing independent assurance that these areas are supporting the delivery of departmental programs in an economical, efficient, and effective manner." Internal audit reports are published online. The following link includes the cited material here: https://www.canada.ca/en/healthcanada/corporate/transparency/corporate-management-reporting/internal-audits.html

For research done by anyone outside of the Government of Canada, any internal auditing process will need to be detailed and approved as part of the application process.

External audits are conducted by independent external bodies like Health Canada (if Health Canada is not the body doing the testing, as suggested earlier in the description of internal audits). These external audits are completed by independent accreditation bodies (AB) like the SCC and the Description of external auditing with the CFIA can be found at the following link (Agency, 2012). CALA. https://inspection.canada.ca/en/foodsafety-industry/food-chemistry-and-microbiology/laboratory-management/qmof

PROPOSED FRAMEWORK FOR MEASLES WASTEWATER TESTING

6. External and Internal Quality Control and Assurance

6.1 Purpose

To ensure that the measles wastewater testing methods used in Canada are accurate, reliable, and comparable across laboratories and regions, all submissions for method approval must also address both internal and external quality control and external quality assurance components. These elements serve as independent verification tools to validate laboratory performance beyond internal monitoring, reduce bias.

Health Canada plays a central role in overseeing laboratory quality practices, particularly in relation to compliance with ISO 17025, which governs the competence of testing and calibration laboratories. Additionally, the Standards Council of Canada (SCC) provides an accreditation system to ensure laboratories meet international ISO standards. For consistency in analytical procedures, laboratories are also expected to align their methodologies with the Compendium of Analytical Methods (Government of Canada, 2023), particularly when dealing with environmental or public health-related testing.

Internal quality controls are employed to ensure that the tests being conducted are not contaminated and are functioning correctly (Wallace and McCulloch, 2021). Sources of error for laboratory tests can be the operator, instrument, reagents, and calibrations (Wallace and McCulloch, 2021). Internal quality assurance is a process where a laboratory internally monitors and evaluates the accuracy and precision of its own testing procedures, equipment, and results (Wallace and McCulloch, 2021). Internal quality controls and practices are important so that high levels of accuracy and precision are maintained. Typically, 0.5 - 10% of previously tested samples are selected at random intervals for retesting to compare the previous results (Wallace and McCulloch, 2021).

External quality controls are independent materials not supplied by the test kit manufacturer, used alongside internal controls to assess the accuracy, reliability, and reproducibility of laboratory tests.

Unlike internal controls, external controls validate the testing system independently of in-house safeguards and confirm that results are free from contamination, reagent degradation, or procedural errors. Examples could include, a third-party measles RNA control obtained from an accredited supplier (e.g., LGC SeraCare Life Sciences or Microbiologics from the USA, or the National Microbiology Laboratory or Bio-Rad Laboratories from Canada), or a standardized wastewater sample with a verified MeV viral load.

External Quality Assurance, also known as proficiency testing, involves the independent evaluation of laboratory performance by submitting blind samples for testing and comparing the results to pre-established standards. This ensures that laboratories are consistently producing accurate and reproducible results.

EQA programs must conform to ISO/IEC 17043:2023 (*Conformity assessment — General requirements for the competence of proficiency testing providers*). Proficiency testing bodies should be recognized by international accreditation bodies, such as the Standard Council of Canada (SCC). EQA ensures that Canadian labs performing measles detection are comparable in accuracy to other provincial, national, and/or global labs. It is critical for detecting false positives and negatives, quantification errors, and analytical drift over time.

To ensure global comparability and maintain best practices, laboratories should also align their procedures with international standards and guidance. These include protocols established by the International Organization for Standardization (ISO), as well as public health agencies such as the World Health Organization (WHO). In cases where domestic EQA programs for measles wastewater testing are unavailable, laboratories may reference or participate in programs supported by the Centers for Disease Control and Prevention (CDC) in the United States or the European Centre for Disease Prevention and Control (ECDC).

PROPOSED FRAMEWORK FOR MEASLES WASTEWATER TESTING

6.2 Requirements for Internal and External Quality Controls (IQC/EQC)

The **key functions** of quality controls are to:

- Verify that the assays correctly detect Morbillivirus hominis in complex matrices like wastewater.
- Confirm that instrument calibration, reagents, and technicians are producing valid results.
- Uncover systematic or operator-related errors that internal controls may not detect.
- Support cross-laboratory comparability of results.

TABLE 1. Application requirements for internal and external quality controls.

Internal Quality Controls (IQCs)	External Quality Controls (EQC)
SOURCES OF CONTROLS	
Can be obtained from third-party kits or made in-house and falls within ISO standards. In-house controls must have proper documentation and pass accepted standards.	Must be procured from accredited third-party providers compliant with ISO 17025 standards.
If synthetic or inactivated measles virus is used, documentation on the control's characterization and concentration must be included.	
IMPLEMENTATION	
Must be verified, positive samples and negative samples to be **run with each diagnostic test.**	Must be **incorporated periodically** and processed blind when feasible.
EVALUATION CRITERIA	
Acceptable thresholds for detection, quantification, and Ct value ranges must be defined.	
Any deviation must trigger a review, retesting, or investigation.	
BEST PRACTICES RECOMMENDATIONS	
Mandatory adoption and incorporation of IQCs and EQCs as a routine component of quality assurance for all laboratories conducting measles wastewater testing.	
—	Laboratories are strongly encouraged to use EQCs in addition to manufacturer-supplied internal controls to foster innovation and independence (Wallace & McCulloch, 2021).
DOCUMENTATION	
—	SOPs for EQC use must be submitted, including: (1) source and storage conditions; (2) frequency of use; (3) interpretation criteria; (4) actions in case of failure or out-of-range results.

PROPOSED FRAMEWORK FOR MEASLES WASTEWATER TESTING

6.3 Internal and External Quality Assurance (QA)

Requirements:

1. **Participation in an Approved EQA Program:**
   - Applicants must commit to participation in a measles-specific or closely related viral pathogen wastewater QA program (e.g., enteric viruses, SARS-CoV-2 as a model, until measles-specific panels are available).
   - If no measles-specific program exists, applicants must outline steps to develop one in collaboration with federal partners or justify the use of analogous programs.

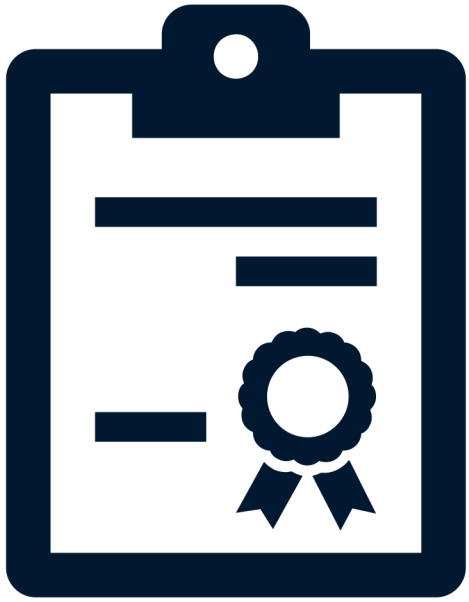
2. **Blind Testing Protocols**
   - All QA samples must be processed by currently employed laboratory staff under routine conditions.
   - Samples must be blinded to ensure the integrity of the evaluation.

3. **Performance Criteria:**
   - Performance metrics such as accuracy, precision, and false detection rates must be documented.
   - Laboratories must describe their procedure for re-testing samples at regular intervals to maintain trust in their results.
   - Clear criteria must be established for measles detection performance, including: (1) sensitivity (i.e., low viral level detection); (2) specificity (no cross-reactivity or false positives); and (3) reproducibility.

4. **Corrective Actions:**
   - In cases of poor performance, labs must: (1) conduct a root cause analysis; (2) implement corrective measures (e.g., retraining, revised SOPs or equipment recalibration); (3) undergo re-evaluation before resuming full-scale testing operations.

5. **Regular Participation:**
   - Laboratories must participate in QA programs at least once annually, with biannual assessments recommended for high-volume labs or those using novel methods.

6. **Transparency and Reporting:**
   - QA results must be reported to the relevant oversight body and incorporated into the laboratory's continuous quality improvement program.
   - Aggregate results and corrective actions should be shared (in a de-identified format) to enhance public trust and policy transparency.



INNOVATION

Submissions are encouraged to foster innovation in their testing methods. Innovative methods should be equal to or improve the current accepted methods. Applications should explicitly state how their application is innovative. Innovations can increase the performance (e.g., specificity, sensitivity) of current methods, reduce the cost, use novel methods, or improve the workflow. Innovations should fall within the acceptable limits of detection and guidelines that are contained in the application guidelines. Innovations should have detailed comparisons with the currently accepted methods and demonstrate the improvements. Below are recommendations in approving and evaluating new methods in MeV testing/surveillance.

Innovation Subcommittee

In parallel with the committee that reviews and evaluates submissions, a subcommittee should be responsible for testing and evaluating new methods that fall outside the approved methods. The committee will work with second- and third-party to foster collaborative studies with PHAC to validate innovative methods. Data will be shared and compared with accepted and approved methods to determine if the innovation is acceptable.
For innovative methods, a tiered system should be implemented that allows the innovation to be accessible to the broader research community while still undergoing rigorous testing and validation.

Established protocols/methods should represent the top tier of acceptable testing and be categorized as ‘approved’ methods. Innovations that have demonstrated high rigour and equal or superior performance to the approved methods can be fast-tracked and designated as having ‘conditional’ approval, as testing and evaluation continue within PHAC and the committees. Methods with conditional approval can be used for the intended application but can be modified or removed at any point until it is categorized as ‘approved’.

DATA SHARING AND MANAGEMENT

General

Internally and between clients, data must be managed through a laboratory information management system (LIMS). These systems are primarily used for tracking samples throughout the testing process. A LIMS tracks a sample through all stages of processing and can separate a sample into processes associated with more than one aliquot. Submitted results from a user are analysed for quality control results and will accept or reject results based on given criteria. The instrument used to collect the data is associated with the results, therefore performance issues can be tracked over time. This system reduces human error and improves efficiency by automating data analysis. By tracking samples and users associated with them, an audit trail is created that increases accountability. In addition, many LIMS are versatile in their utility, allowing reagents, consumables, and equipment to be tracked. This introduces additional quality checks by ensuring no reagents are expired or out of stock and that the maker of reagents is tracked. If a fault is found with a consumable, the LIMS system can mark any samples that were associated with that incident for retesting. Data on a LIMS server is also encrypted with stringent authorized user controls. This will provide data security for clients and ensure that no sensitive information is improperly released. For clients, reports are automatically generated from accepted results. By regulating the use of LIMS for testing results, it standardizes the chain of command, quality control reporting, and client reports between laboratories while also protecting data security.

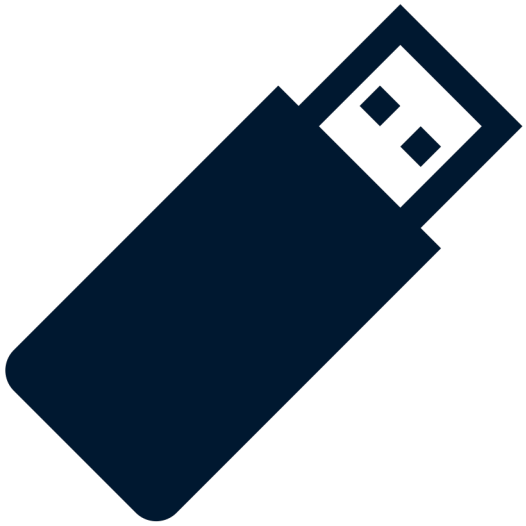
In addition to internal and client reporting, wastewater data must be available to the public to promote transparency and public health efforts. Current systems are in place throughout Canada to publicize wastewater data of SARS-CoV-2, influenza A and B, and respiratory syncytial virus (RSV). These reports share the viral load in RNA copies/mL in different provinces and/or sites over each epidemiological week. Wastewater detection of M. hominis should be reported in a similar manner and be integrated into the existing reporting framework to centralize wastewater surveillance data access.

Ethical Considerations

All research performed as part of an internal government or collaborative study that uses wastewater from Canadians must pass ethics approval by the Research Ethics Board of the Public Health Agency of Canada. The vetting of applications is done according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), available at: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html. (Canada, 2021; Government of Canada, 2023).

Impact and Evaluation

The impact and evaluation of this policy recommendation on the approval process for MeV wastewater analysis will be multifaceted. The first thing to note is that the implementation of this policy will create various approved methods that are effective, cost-saving, reliable, and easily scalable across multiple sites in the country and around the world. It should also lead to the approval of innovative methods that demonstrate Canada's continued leadership on the world stage in testing protocols. The level of detection and decision-making actions of safety measures in the face of future measles outbreaks in communities can also determine the evaluation of the policy.



OUTREACH AND PUBLIC ENGAGEMENT STRATEGY OF POLICY PROCESS

Measles (Morbillivirus hominis) outbreaks in North America are a contentious issue in today's politically charged landscape. Gaining public acceptance for this policy framework is likely to be a significant challenge and will require a series of clear, informative reference materials to effectively communicate technical information to policymakers, scientists, and the public.

The primary objectives of our communications strategy are to raise awareness about the inconsistency of current monitoring protocols, convince policymakers of the importance of standardizing measles virus wastewater monitoring methods, and encourage second- and third-party researchers to engage with the Public Health Agency of Canada as committee members or by submitting protocols for approval. We have devised a two-pronged multimedia strategy to accomplish these goals. The first element consists of an interactive web page with detailed information for researchers and policymakers, while the second element consists of printed materials, including a policy "one-pager" for policymakers and a lay summary for public outreach.

Interactive Webpage

In today's world, many Canadians receive their information online from digital sources. According to the Canadian government, 94% of Canadians use the Internet, and 83% are social media users. To reach the Canadian public effectively, this means digital media is critical for communicating our policy framework.

The cornerstone of this communication strategy is an interactive website designed with scientists and policymakers in mind. Our website will feature sections that explain the need for such a policy and outline the protocol requirements in simple terms. The landing page for the website will be an executive summary that emphasizes the importance of standardizing wastewater monitoring protocols. Links to external resources and the full policy document will be provided for those who may be interested. However, the website is intended to serve as a reference for scientists submitting protocols or participating in the PHAC committee, as well as for policymakers who may require more information than is contained in the printed materials.

The website will also serve as a key tool for implementing our policy. It will include a submissions portal for second- and third-party researchers to upload protocols for review by the PHAC committee, as well as a schedule of committee meetings, profiles of committee members, and contact information. This website will serve as the primary means of communication between researchers and the two committees outlined in this policy: the Method Review Committee and the Innovation Subcommittee. The general public does not need to access the submissions portal, meeting schedule, or contact information for individual committee members. Therefore, the submissions portion of the website will be maintained behind a firewall, requiring users to log in with a recognized government or university email address and password (institutional login). This will help to protect the privacy and intellectual property rights of those submitting protocols for committee review.

Finally, our website will serve as a platform for disseminating knowledge to stakeholders and the public. We will include a wastewater data dashboard for measles virus monitoring to share viral load in RNA copies/mL across provinces and cities, as described in the policy framework. Furthermore, links will be included to the main PHAC Wastewater Monitoring Dashboard, allowing for the integration of measles data with other ongoing surveillance in a centralized location.

After the initial implementation, we will regularly monitor the success of our website through key indicators, including website traffic, page views, and click-through rates for the submissions portal. Content will be refined and adjusted as necessary to meet our goals, approximately every 6 months to 1 year. Additional features that may be added may include a notice board to post approved monitoring protocols or a feedback function for stakeholders to provide feedback on the policy itself, approved protocols, wastewater data, or website features.

OUTREACH AND PUBLIC ENGAGEMENT STRATEGY OF POLICY PROCESS

Policy One-Pager

Our one-page quick reference document will be created in conjunction with the submission portal website, targeting personnel who wish to submit Standard Operating Procedures (SOPs) for proposed methods of monitoring wastewater for M. hominis. It aims to facilitate a smoother and more efficient application process, ultimately contributing to the standardization of MeV surveillance in Canada.

The primary purpose of our one-page summary is to serve as an immediate, accessible, and highly practical guide for prospective SOP submitters, communicating the critical details an SOP must adhere to, thereby ensuring alignment with the Public Health Agency of Canada's (PHAC) standards for quality assurance. Our one-pager will distill the most critical information from the policy proposal, offering a quick yet thorough overview of the submission process and requirements. Our one-pager will include clear instructions to personnel on where and how to submit protocols, directing them to the secure online application portal on the interactive webpage. It will provide a QR code to the website and other relevant resources, allowing submitters to delve deeper into specific requirements as needed. This ensures that while the one-pager provides a rapid overview of submission requirements, it also empowers submitters with immediate access to all the detailed information necessary for a successful and compliant application.

The content will be formatted in the same style as the policy proposal and the submission website. The information will be presented in an easy-to-read and uncluttered format, with ample whitespace to minimize eye fatigue and maintain clarity and conciseness. Bold headings and subheadings will be used to provide an efficient reading experience.

The one-pager will feature the following elements:

- **Title:** A bold and easy-to-read heading that immediately distinguishes the purpose of the document to the reader.
- **PHAC Committee Description:** As the proposed committee will be a new entity, it may require an introduction for those unfamiliar with it and provide clarity on the submission process.
- **Key Requirements for SOP Submission:** A list detailing the criteria that every submission must meet. This includes facility and equipment standards, sample management protocols, employee training and certification, as well as robust internal and external quality control and assurance measures. It will also touch upon data management expectations.
- **Next Steps / How to Submit:** This section will include a QR code that directly links to the official submission portal website.
- **Footer Information:** Essential details, such as author names, publication date, and other relevant information.

The content ensures that our one-pager provides sufficient information to inform and motivate, while simultaneously directing users to the online resources for the full policy framework and the submission process. Its portable format and the inclusion of a QR code make it an ideal tool for workshops, conferences, and direct mailings, acting as a tangible bridge to the digital submission platform.

Executive and Lay Summaries

The executive and lay summaries are included in our communications strategy as a means of making this policy framework more accessible for non-specialist audiences. We understand that busy politicians will not have time to review the full policy and all its details. Therefore, we felt it necessary to include a concise summary of the policy, highlighting the key points of the method approval framework and the rationale behind its development. This executive summary can be distributed to policymakers to generate interest in our policy brief and attract attention from regulators. The executive summary is located at the beginning of this policy brief, and its content is also integrated into the more comprehensive policy "one-pager" described above.

The lay summary is also included at the beginning of this policy brief. This policy framework for the validation and approval of measles wastewater monitoring methods is highly technical and written for a specialist audience. However, measles virus outbreaks worldwide are currently attracting significant public attention, which could draw public attention to our framework for wastewater-based surveillance. The lay summary provides a concise explanation of the framework in plain language for interested members of the public. It will also serve as the basis for some of the public-facing content on our website.

CONCLUSIONS

This policy recommendation provides a clear explanation that outlines the process by which measles wastewater surveillance methods can be approved for use in Canada. It sets strong standards that must be met for approval with a focus on being accurate and precise in the testing methods and with transparency in how the data is reported. It establishes a committee within PHAC that is responsible for evaluating/approving methods which can then be scaled for use in Canada. To foster innovation and provide a competitive landscape on the world-stage a subcommittee will work in collaboration with new, innovative methods contained within applications for the expeditious testing and approval for use. Canada also seeks to be the world leader in MeV testing, that is why the policy also recommends close consultation with international testing bodies and the approval of methods that can be used worldwide.

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