Privacy Impact Assessment

An assessment of the privacy impacts associated with the Canadian Paediatric Surveillance Program's collection and use of health-related data for public health surveillance

privpro | Privacy Professionals

Preamble

The importance of public health surveillance to the practice of medicine cannot be overstated. The ongoing and systematic collection, analysis, and interpretation of health-related information is essential to the planning, implementation, and evaluation of medical and public health practices. Surveillance takes data into action. Through surveillance, the burden of disease can be better determined and interventions to prevent the occurrence of a condition can be better assessed. Surveillance also helps inform and shape the development of health policy.

The value of surveillance must of course be balanced against the need to protect the privacy of patients. This is particularly true of patients who suffer from rare paediatric diseases and conditions – conditions so rare, that in exceptional cases the analysis or reporting of a disease (alone or in combination with other information) could theoretically reveal a patient's identity. Although re-identification is highly unlikely in the conduct of surveillance, the Canadian Paediatric Surveillance Program (CPSP) takes privacy extremely seriously.

For that reason, the CPSP has undertaken this Privacy Impact Assessment (PIA) in relation to its surveillance activities. Although the primary purpose of the PIA is to ensure that the Program continues to comply with Canadian privacy laws, it is hoped that the PIA – led by an independent privacy professional – will provide some assurance to practising Canadian paediatricians, paediatric subspecialists, health care providers, and governmental agencies that health-related information shared with the CPSP is being properly managed and protected.

The CPSP provides the means to undertake active paediatric surveillance, and to increase awareness of childhood medical conditions that are high in disability, morbidity, mortality, and economic cost to society, despite their low frequency. Its success depends on the accurate and timely collection of health- related information from Program participants. To this end, the CPSP remains committed to sharing information about its privacy practices, and in showcasing the value of active surveillance to keep participants interested, engaged, and involved in its work.

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Executive Summary

This report examines the privacy impacts associated with the Canadian Paediatric Surveillance Program (CPSP) and its collection and use of health-related information for public health surveillance activities. Its purpose is to assess the Program's data handling practices for compliance with federal and provincial privacy laws, and to ensure that surveillance data is being managed in keeping with best practices.

About the CPSP

The CPSP is a joint project of the Public Health Agency of Canada (PHAC) and the Canadian Paediatric Society (CPS). Established in 1996, the Program contributes to the improvement of the health of children and youth through national public health surveillance into childhood disorders that are high in disability, morbidity, and economic costs to society.

Although the CPSP's work centres on the performance of public health surveillance and the facilitation of paediatric research, its primary goal is to advance clinical practices and policy in relation to important, rare, and emerging childhood conditions and health threats. The Program also plays an important role in the promotion and awareness of uncommon paediatric conditions within the medical community and the Canadian public.

The CPSP is the only active surveillance network that covers both paediatricians and paediatric subspecialists in Canada in partnership with a national specialty society, the CPS. It gathers data from approximately 2700 paediatricians and paediatric subspecialists each month on a number of rare paediatric conditions affecting children and youth in Canada and enables the study of those conditions over time.

Conducting Active Surveillance

The primary duty of the CPSP is to maintain a national population-based surveillance system to monitor low-frequency and high-impact conditions and diseases in children and youth in Canada. Public health surveillance, as defined by the World Health Organization, includes the systematic collection, collation, and analysis of health-related information. It also includes the integration, analysis, and interpretation of that data into surveillance products, such as reports, alerts, or warnings.

Surveillance is an important part of the practice of medicine and an integral component of public health. Not only can surveillance data help determine

the burden of disease and assess interventions to prevent the occurrence of a medical condition, but it also allows for the development of health policies to address the needs of children with these conditions. Active surveillance helps researchers, decision makers, and health professionals to improve public health policy, programming, and clinical practice.

Supporting Studies

In keeping with its mandate, the CPSP facilitates and supports public health surveillance into rare paediatric conditions and uncommon complications of more common conditions. In doing so, it helps advance the medical community's understanding of those conditions, thereby improving treatments, prevention, and health care planning. Since its inception, the CPSP has facilitated studies in a variety of fields such as infectious diseases, congenital and inherited (genetic) diseases, injury prevention and mental health. These studies have led to significant changes in clinical practice and have helped inform public health policy in many ways.

Although the CPSP does not itself undertake research, it conducts national surveillance in support of health studies. Its collection and management of public health surveillance data (through PHAC) is subject to strict conditions. The CPSP Scientific Steering Committee reviews all project proposals and selects only those of highest medical and public health importance. Proposals are evaluated against set criteria and are subject to comprehensive feedback from the Committee, which is composed of representatives from PHAC, CPS, former CPSP investigators, academic clinicians, and community paediatricians.

Creating Awareness

The CPSP's surveillance activities ultimately support the learning needs of paediatricians, paediatric subspecialists, paediatric residents, and other child health professionals, helping them provide the best health care to Canada's children and youth. Surveillance data and the results of CPSP-enabled studies and surveys encourage awareness and education within the medical profession and among the public of uncommon paediatric conditions and help facilitate the study and treatment of those conditions. The CPSP also promotes awareness of rare childhood conditions through its participation in the International Network of Paediatric Surveillance Units (INOPSU). When applicable, findings from CPSP studies and surveys help to inform CPS professional and public education initiatives.

Taking Privacy into Account

The CPSP recognizes that the clinical, scientific, and public health value of surveillance conducted into rare paediatric conditions must be balanced against the need to protect the privacy of patients. The CPSP falls under the responsibility of PHAC's Centre for Surveillance and Applied Research and CPSP officials must comply with the federal *Privacy Act* and its supporting policies and directives in the conduct of surveillance activities. The Program also strives to comply with provincial and territorial data privacy laws, which are substantially similar in their prescriptions for the handling and protection of health-related information.

In keeping with its commitment to privacy, the CPSP has elected to undertake this Privacy Impact Assessment (PIA) in relation to its core surveillance activities. The purpose of the PIA is to ensure that the CPSP's handling of surveillance data is in keeping with the federal and provincial privacy laws relating to health records. It is also intended to help ensure that privacy risks, if any, associated with the Program's surveillance practices are being properly managed or mitigated.

Program Privacy Assessment

Privacy risks arising from the CPSP's surveillance activities are inherently low. The Program collects basic information about reporting paediatricians, subspecialists, and related health care providers but not identifying information about patients. This includes information which may qualify as "personal information" or "personal health information."

While paediatric diseases and conditions tracked by the CPSP could, in exceptional cases, be so rare so as to lead to the identification of a patient in combination with other information, the CPSP has put the following measures in place to mitigate Program privacy risks, including the risk of patient identification:

- Data reporting forms are strictly vetted to ensure that they do not include fields which may contain personal or identifying information about patients.

- Case reports are reviewed by the CPSP to ensure that any identifying information about patients that was inadvertently included is removed before analysis.

- All information collected through the Program is stored and safeguarded in a manner commensurate with its sensitivity.

- The use of surveillance data (including for individual studies) is strictly limited, as prescribed by PHAC, the CPSP, and the Program's multidisciplinary Scientific Steering Committee.

- Case data is never used to make a decision about a patient or a reporting physician.

- Neither study investigators, nor CPSP, have direct contact with individual patients or their families.

- The dissemination of surveillance data is highly restricted and subject to strict privacy and ethical requirements.

- Paediatricians, subspecialists, and related health care providers who report cases to the CPSP have the right to access their case reports, and to make corrections or amendments to the information they provided.

Overall, the PIA found that CPS, in concert with PHAC, is actively managing privacy risks related to the CPSP through a range of legal, administrative, and technological controls. No material modifications to the Program are required by the CPSP to conform with federal and provincial privacy laws.

Conclusion and Summary Recommendations

The CPSP is complying with federal and provincial privacy requirements pertaining to the collection and use of health-related information. The following recommendations, if implemented, would help improve Program delivery and better align the CPSP with best practices in the Canadian health sector:

1. **Identifying Purposes**: the CPSP should consider developing and publishing a more comprehensive privacy notice, on both paper and online reporting forms, to better inform program participants of the way case information will be used, disclosed, and retained.

2. **Data Management:** the CPSP should consider developing a comprehensive data management framework or information policy to support the proper governance of surveillance data, and to establish express rules for the internal use, disclosure, safeguarding, and retention of that data.

3. **Monitoring and Compliance:** the CPSP, in partnership with PHAC, should consider implementing measures to track and monitor compliance with data handling practices imposed on principal investigators through Principal Investigator's Agreements, particularly those pertaining to data retention.

4. **Safeguards**: the CPSP should consider phasing out the use of paper forms for surveillance reporting, bearing in mind that some forms may contain health-related information which could be sensitive in certain contexts. The use of fax systems to transmit completed forms should also be discouraged.

For a full list of Program privacy risks, recommendations, and mitigating measures, see Section 7 of this report.

About this Report

This report was prepared by PRIVPRO | Privacy Professionals, an independent consulting firm specializing in privacy compliance. It examines the privacy impacts associated with the collection, use, disclosure, and retention of health-related information by the CPSP. The purpose of the PIA was to assess the CPSP's data handling practices, and to ensure that surveillance data is being managed in keeping with best practices in the Canadian health sector. The information provided in this PIA is not, and is not intended to, constitute legal advice. Information, content, and materials provided are for information purposes only. The performance of a PIA does not constitute an audit.

Report Structure

The report is structured in keeping with the core PIA requirements set out in the Government of Canada's *Directive on Privacy Impact Assessment*. It complies with federal standards for the performance of PIAs, as set out in the Government of Canada's *Policy on Privacy Protection*, and those of the Office of the Privacy Commissioner of Canada, as set out in *Expectations: A Guide for Submitting Privacy Impact Assessments*. The PIA also includes all mandatory requirements established by Health Canada and PHAC for the performance of PIAs. The PIA, as performed, provides evidence of the CPSP's compliance with legislative and policy requirements for the proper handling of personal information[1].

Project Authority

The PIA was completed under the direction of the CPSP's Senior Manager, Surveillance. Key stakeholders at PHAC and the CPS were consulted where necessary on an issue-by-issue basis. The PIA report was reviewed and approved by PHAC and CPSP's Medical Affairs Director.

Scope Limitations

The PIA included a review of the CPSP's key surveillance practices, including policies, procedures and controls implemented by the CPS to ensure that its collection and use of health-related information complies with the requirements of the federal *Privacy Act*. Its focus was on the assessment of practices pertaining to the collection, analysis, and dissemination of surveillance data. Although the PIA speaks incidentally to the practices of PHAC, study investigators, and other program participants in relation to surveillance activities, it does not include an assessment of third-party practices (including those of paediatricians, paediatric subspecialists, and other health care providers who support and participate in active health surveillance). In addition, while the PIA speaks about data safeguards it is not intended as an information technology security or vulnerability assessment of PHAC or CPSP systems.

[1] "Personal information," as defined in section 3 of the *Privacy Act*, means information about an identifiable individual, recorded in any form.

1. Program Overview

Background

The need for national surveillance of rare paediatric conditions was first conceived by the Royal College of Paediatrics and Child Health (RCPCH) in the United Kingdom (UK) in 1986. Following the failure of paediatricians in the UK to report cases of rare childhood diseases and conditions – including necrotizing fasciitis, Reye's syndrome, Kawasaki disease, and hemolytic/hemorrhagic shock syndromes – and the significant health, social, and economic fallouts of those failures, the RCPCH created the British Paediatric Surveillance Unit (BPSU), arguably the first public health surveillance program dedicated to children and youth in Europe.

In 1995, in recognition of the positive impacts of the BPSU on paediatric care and public health, the CPS and Health Canada's then Laboratory Centre for Disease Control formed a small working group to set up a national paediatric surveillance program in Canada, modeled after the BPSU. In January 1996, after several months of planning and consultation, a joint pilot program for the surveillance of rare paediatric diseases and conditions was established and commenced surveillance activities. The three pilot studies conducted as part of those activities would emerge as the foundation for the establishment of the CPSP and as a framework for paediatric public health surveillance in Canada.[2] Although surveillance of infectious diseases was the main impetus for the establishment of the CPSP, the mandate of the Program has since expanded to examine a wide variety of rare paediatric diseases and conditions in Canada.

The Importance of Public Health Surveillance

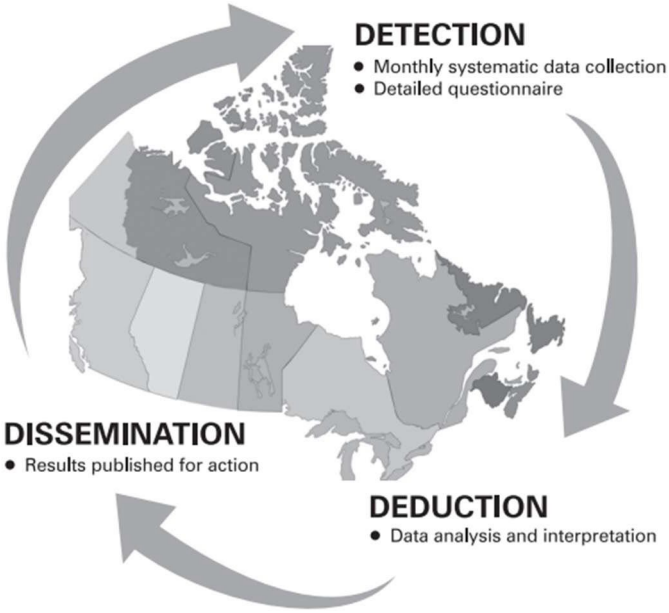
Public health surveillance is best understood as the tracking of a specific health event or health determinant through the continuous collection of high-quality data (detection); the integration, analysis, and interpretation of the data into surveillance products (deduction); and the dissemination of those surveillance products to those who need to know (dissemination).

There is perhaps no more recent or significant event than the COVID-19 pandemic to better demonstrate the importance of having a robust health surveillance data network in place to quickly gain a deeper understanding of emerging public health issues and to support evidence-informed decision-making. Emerging diseases or infections are often rare, at least initially, and can remain undetected for significant periods of time. Difficulties in recognizing these diseases can result in their spread. They can also result in delayed diagnosis, increasing the risk and likelihood of health complications or death to individuals. Such diseases are sometimes very difficult to study. Their low frequency often means that little may be known about their etiology, clinical spectrum, complications, pathological features, diagnosis, treatment, or management.

[2] Acute flaccid paralysis surveillance was one of three pilot studies conducted and, to this day, remains the main source of data assessed annually by Canada's National Certification Committee for Polio Eradication to ensure Canada remains polio-free.

To identify, track, and better understand emerging diseases, it is necessary to collect data from a large and geographically diverse population. This collection of data can only be accomplished through active public health surveillance. Public health surveillance, as defined by the World Health Organization, is the "continuous and systematic collection, consolidation and evaluation of pertinent health data with prompt dissemination of results to those who need to know, particularly those who are in a position to take action." Surveillance helps decision-makers and health professionals improve public health policy, programming, and clinical practice. Canadian communities also benefit from surveillance activities as surveillance data helps communities better understand the needs of diverse children and youth across the country.

Figure 1: Pan-Canadian Health Surveillance (Source: CPSP)



About the Canadian Paediatric Surveillance Program

For nearly 30 years, the CPSP has been instrumental in providing Canada with surveillance data on rare diseases and emerging conditions in children and youth. A joint project of PHAC and the CPS, it is a national program that conducts surveillance into rare paediatric conditions and rare complications of more common conditions. The goal of the Program is to generate new knowledge related to important, rare, and evolving conditions and child health threats to advance Canadian knowledge, clinical practice, and policy. Modeled after the BPSU, the CPSP is the only active surveillance network that covers both paediatricians and paediatric subspecialists in Canada in partnership with a national specialty society.

Program Objectives

The CPSP gathers data from approximately 2700 paediatricians and paediatric subspecialists each month to monitor rare diseases and conditions in Canadian children. The Program's objectives are to:

- Maintain and enhance an active national and collaborative population-based surveillance system to monitor low-frequency and high-impact conditions and diseases in Canadian children and youth

- Involve paediatricians, paediatric subspecialists, and other applicable medical professionals in related disciplines in the surveillance of low-frequency, high-impact childhood conditions that are of public health and medical importance

- Facilitate research into these childhood conditions for the advancement of knowledge and the improvement of treatment, prevention, and health care planning

- Encourage awareness and education within the medical profession and the public of less common paediatric conditions

- Respond rapidly to public health emergencies, where these relate to children and youth in Canada, by adaptation of surveillance activities or initiation of appropriate action/follow up

- Participate in international paediatric surveillance efforts through INOPSU

- Establish and maintain a strong working partnership between the CPS and PHAC to support and collaborate around surveillance into child and youth issues in Canada

Governance and Accountability

The CPSP operates under the joint authority of the CPS and PHAC (specifically, PHAC's Centre for Surveillance and Applied Research, Health Promotion and Chronic Disease Prevention Branch). It is led by a multidisciplinary Scientific Steering Committee, which guides the development of the Program, addresses strategic and operational challenges, and determines the overall direction of the CPSP. The Committee meets twice annually to review the progress of existing studies, and to consider protocols submitted for future inclusion in the CPSP.

The Scientific Steering Committee is composed of representatives from various divisions of PHAC, community paediatricians and subspecialists (e.g., neonatologists, adolescent medicine subspecialists, intensivists) representing the CPS, a representative from the CPS' Immunization Monitoring Program ACTive (IMPACT), and a representative from the Paediatric Chairs of Canada. Also included are liaison representatives from the Canadian College of Medical Geneticists and the Canadian Association of Child Neurology.

The focus of the Scientific Steering Committee is on Program development, and the day-to-day management of the CPSP falls to the Manager of Surveillance and a supporting working group that deals with issues and concerns relating to the overall operation of the Program. The working group

coordinates proposals for new studies and ensures the transfer of knowledge and surveillance results.[3] The Manager, Surveillance and the Program working group are also responsible for establishing Program policies and practices, including those related to privacy.

2. Process Overview

The following section highlights the core activities of the CPSP and the business processes supporting the conduct of public health surveillance by the Program.

Receipt of New Proposals

The surveillance process at CPSP begins with the review and approval of new proposals for multi-year studies or one-time surveys. Investigators from across Canada are encouraged to submit proposals that meet the Program's criteria for inclusion or submission. PHAC and/or investigators (called "principal investigators"[4]) approach the CPSP with new project ideas and present those ideas in the form of a "letter of intent" to the CPSP's Scientific Steering Committee. New proposals must align with national health interests (as established by PHAC, Health Canada, and the CPS) and are evaluated against set Program criteria. Studies must ultimately improve or impact clinical practices or public health policies.

Study/Survey Approval

The Scientific Steering Committee reviews new study proposals on a biannual basis and selects those of highest medical and public health importance. Investigators with successful letters of intent are invited to present full project proposals including a study protocol and detailed questionnaire to the Committee for deliberation.

Not all questions warrant a complete study. In some cases, the CPSP may provide the option for investigators to conduct a one-time survey. These surveys can capture early warning or epidemiological signals, help quantify the prevalence of a problem, identify a specific emerging public health concern, or justify the need for a complete study. As a cost-effective and well-established epidemiological tool, surveys can also help document pre- and post-disease knowledge and collect meaningful medical and public health data in support of public policy and medical management.

Although public health surveillance activities do not require research ethics board (REB) approvals, if a study proposal is accepted for inclusion into the Program, principal investigators must apply for and receive approvals from governing REBs (the Health Canada and PHAC Research Ethics Board and

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[3] Surveillance results are highlighted in peer-reviewed manuscripts in high-impact journals such as *Paediatrics & Child Health*, the only peer-reviewed paediatric journal in Canada, published by Oxford University Press on behalf of the Canadian Paediatric Society. The Program also contributes to and leads presentations nationally and internationally on surveillance.

[4] Although most often they are paediatricians, some principal investigators are not.

often the REB for the principal investigator's institution). This decision was made to ensure CPSP studies meet or exceed the highest standards when it comes to ethics and privacy.

Following REB approvals, investigators sign the "Principal Investigator's Agreement" with the CPSP. It sets out, among other things, the responsibilities of the principal investigator and the study team, along with those of the CPSP. The Principal Investigator's Agreement is accompanied by a formal data sharing agreement, which comprises part of the general Agreement and sets out minimum requirements for data confidentiality and security.

Reporting Methodology

For each study initiated through the CPSP, Program participants (i.e., practising paediatricians, paediatric subspecialists, and other health care providers from across Canada) receive a summary of the protocol, including the case definition and a description of the condition. In addition to providing a uniform basis for reporting, the protocol serves to educate and increase awareness of these rare conditions.

Each month, Program participants receive a form listing conditions under study. Program participants are asked to indicate the number of new cases seen in the reporting period for each listed condition, including indicating when no cases were found. The initial reporting form listing the conditions under active surveillance is generally completed online through a secure web or electronic application form (though the CPSP continues to e-mail or mail monthly reports to requesting participants to ensure their continued satisfaction and the maintenance of a minimum response rate). Reminders are sent to participants who have not replied to a reporting request. Reminders greatly improve initial response rates and the rate of clinical questionnaire submissions.

Participants who have identified a case are sent a detailed clinical questionnaire to complete and return to the CPSP. The CPSP sends an online link to Program participants to complete the clinical questionnaire. Each questionnaire has an assigned case number (year, study acronym, incremental case number). Offline participants receive a copy by mail. The clinical questionnaires are developed by study teams comprising paediatric experts in the condition/disease and must receive Scientific Steering Committee and ethical approval before use.

Once completed, clinical questionnaires are returned to the CPSP by the Program participants either online or a hard copy by mail or fax. All responses are reviewed by CPSP security-cleared staff to ensure that if any personal or other identifying information was inadvertently included by a participant in their response to the questionnaire, it is removed.

Most of the clinical questionnaires are submitted electronically through the Canadian Network for Public Health Intelligence (CNPHI), a secure web-based platform hosted by PHAC. The CPSP securely downloads this data into spreadsheet format, de-identifies it, and saves it in a secure, password-protected folder. This de-identified data is uploaded to a secure file transfer platform (FTP) (Liquidfiles) hosted by PHAC for the study principal investigators and PHAC collaborators to access. Hard copy clinical questionnaires are reviewed by security-cleared CPSP staff, scrubbed of any identifying information, and uploaded to Liquidfiles. The hard copy forms are securely stored by the CPSP in locked cabinets to which only CPSP staff have access. The CPSP retains

scanned copies of the hard copy detailed questionnaires in a secure, password-protected folder, accessible only to security-cleared CPSP staff.

Access to Data

Within the CPSP, only security-cleared staff can access the surveillance data. Otherwise, access to surveillance data from individual studies is restricted by PHAC. Principal investigators who are not PHAC or Health Canada employees must apply for access to the data from clinical questionnaires. Applications for access to data from clinical questionnaires are reviewed and approved by PHAC's Privacy Management Division based on several factors, including the sensitivity of information, the type of information, and the third parties involved in the project. Applications must be accompanied by a preliminary privacy risk assessment that takes into consideration the risk of identifying an individual patient or Program participant, among other things, along with Program and/or study team privacy practices. Access to approved data is provided electronically via PHAC's secure file transfer platform (Liquidfiles).

Data Analysis

The principal investigator and study team are responsible for all data analysis relating to a study. They are also responsible for ensuring that a knowledge translation plan is in place to disseminate the results of the study in a timely and effective manner. If requested by the principal investigator, the CPSP may contact Program participants to clarify information on the clinical questionnaire or seek missing data elements, that are required to confirm or exclude a case.

Surveillance Products and Reporting

Study results are published annually and acted upon to improve the health of children and youth in Canada. Study results, publications, and other communication products never include the specifics of individual case reports, Program participants, or patients, and only present aggregated data. Where there are fewer than five cases of a condition reported or confirmed, the CPSP's policy is that data cannot be published or presented. For data elements with fewer than five cases, data is suppressed, or it is reported saying that there were "fewer than five cases" (or <5).

The CPSP has implemented several knowledge translation tools to ensure timely dissemination of study results, including the following:

- **CPSP website:** The CPSP website includes a copy of all study protocols and detailed questionnaires (current and past), a description of the impacts of study and survey results, a section on how to apply for a CPSP study or survey, as well as the Program's policies and procedures.

- **CPSP Highlights:** CPSP Highlights have been published in *Paediatrics & Child Health*, the official journal of the Canadian Paediatric Society, since 2001. These short but informative highlights

provide educational content and include clinical examples with brief but important learning points.

- **Adverse Drug Reaction (ADR) Tips:** The ADR "Tip of the Month" is an educational tool on ADR topics that is sent to participants monthly. These tips provide new information and examples of ADRs that were reported either through the CPSP ADR study, or in recent warnings/ communications from Health Canada or other relevant medical sources.

- **CPSP Annual Results:** The CPSP produces an annual report to provide updates and final reports for CPSP studies and surveys. Annual Results are distributed to all CPSP participants, the CPS membership, leaders of PHAC, provincial ministers of health, and INOPSU.

- **CPS e-news:** Once a month, the CPSP includes a Program highlight in the CPS electronic newsletter.

- **CPS News:** CPS News is a biannual newsletter that keeps the CPS membership up to date about CPS activities and member accomplishments. Each issue features in interview with a CPSP study investigator providing a snapshot of the condition under study and promoting the importance of reporting these cases to the CPSP.

- **Peer-reviewed manuscripts:** To date, over 70 peer-reviewed articles on CPSP study or survey findings have been published in high-impact peer-reviewed journals.

- **PHAC Blog:** When possible, CPSP content is featured in PHAC's data blogs that provide quick facts, and the latest data on different public health topics.

3. Program Authorities

As stated at the outset of this report, the CPSP is a joint project of PHAC and the CPS. Pursuant to the project's founding agreement, the CPSP is authorized to conduct paediatric health surveillance in support of deepening knowledge of rare diseases and conditions, leading to the protection and prevention of health risks and, in some instances, preventing the spread of infectious diseases in children and youth, consistent with the mandate of PHAC. The agreement expressly allows the CPSP to collect and use health-related information on PHAC's behalf, subject to the provisions of the federal *Privacy Act*. When the CPSP collects health-related data from Program participants, it is doing so on behalf of PHAC, and PHAC retains ownership of all the CPSP's surveillance data.

Federal Statutory Authorities

PHAC is listed in the schedule to the *Privacy Act* and is subject to its provisions for the collection, use, disclosure, and retention of health-related information. Section 4 of the Act requires that federal institutions

have a clear legal authority for the program or activity under which their collection of information is to take place.

Legal authority for government programs or activities can be obtained by way of an Act of Parliament or following the issuance of supporting regulations. Legal authority may also be based in common law or a Crown prerogative, or be obtained through the approval of expenditures proposed in Estimates or an Order in Council. The kind of authority that is required will depend, in part, on the nature of the conduct in question. The more the conduct in question interferes with the rights or freedoms of an individual, the higher the test or threshold will be for the identification of a specific and positive legal authority.

PHAC's authorities for public health surveillance and the establishment of the CPSP rest in the *Public Health Agency of Canada Act*[5] and *Department of Health Act*[6]. Section 3 of the *Public Health Agency of Canada Act* provides for the establishment of PHAC. Its mandate is to assist the federal Minister of Health in exercising and performing his or her duties and functions in relation to public health, as set out in the *Department of Health Act*.

Under subsection 4(1) of the *Department of Health Act*, the Minister is responsible for the promotion and preservation of the health of Canadians. This responsibility includes, but is not limited to:

- the protection of the people of Canada against risks to health and the spreading of diseases (paragraph 4(2)(b)).
- the investigation and research into public health, including the monitoring of diseases (paragraph 4(2)(c)).
- the collection, analysis, interpretation, publication, and distribution of information relating to public health (paragraph 4(2)(h)); and
- the cooperation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health (paragraph 4(2)(i)).

Whereas PHAC was established specifically to assist the Minister in exercising his powers, duties, and functions in relation to public health, and whereas subsection 4(2) of the *Department of Health Act* sets out the particulars of those powers and expressly includes the power to undertake public health monitoring and research, the collection of health-related information by PHAC for surveillance is clearly authorized. Under subsection 31(2) of the *Interpretation Act*, where authority is given to a person to undertake an authorized

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[5] *Public Health Agency of Canada Act*, S.C. 2006, c. 5

[6] *Department of Health Act*, S.C. 1996, c. 8

act, all the powers necessary to enable the person to perform the act are deemed to be given as well. This includes the power and authority to collect health information in relation to an approved project or activity.

Provincial and Territorial Statutes Supporting the Sharing of Health Data

To collect health-related information from Program participants, health custodians must be able to first share that information, and to exercise their discretion to do so knowing that governing provincial and territorial health laws provide for information sharing. Health information sharing practices are determined by jurisdictional health legislation and the provisions of related privacy and access to information regimes.

All provincial and territorial health acts in Canada provide the authority to disclose health-related information for surveillance purposes, though permissions vary from jurisdiction to jurisdiction, both in form and in expression.[7] Most regimes begin with a prohibition on the disclosure of health information, except as expressly set out by statute. In such cases the broad prohibition is narrowed to provide for the disclosure of case information in the following key instances:

a. Where the disclosure is of non-identifying health information (for any purpose)
b. Where the disclosure is made to protect public health and safety
c. Where the disclosure is for the conduct of research subject to an REB review

Disclosures of case information, including diagnostics, treatment and care information are also permitted in many cases to the Government of Canada for its use in health system planning and management, and the development of health policy. For a detailed listing of enabling provincial and territorial provisions for the sharing of health-related information, readers may refer to the provincial and territorial privacy law pages of the Office of the Privacy Commissioner of Canada. Additional information about provincial and territorial information sharing provisions is available through the CPSP.

4. Personal Information

As a matter of both policy and practice, the CPSP does not collect personal or identifiable information about patients. Nominal patient information is requested for each reported case to identify duplicate reports, but that information is strictly limited. The CPSP requires each study to obtain ethical approval by an REB, which carefully considers all data sets to be collected prior to approval. Although REB approvals are not necessary for public health surveillance, the CPSP requests REB approval to meet or exceed the highest provincial privacy standards. The CPSP Scientific Steering Committee also performs a careful review of requested data sets before proceeding to collect case data. The only collection of personal information by the CPSP relates to reporting physicians.

[7] Though distinguished from other provincial health surveillance frameworks, the Quebec *Public Health Act* provides for the ongoing surveillance of the health status of the general population and of health determinants through research approvals. Study teams who wish to collect case information from Quebec participants must appoint a co-investigator at a provincial paediatric tertiary care centre and pursue REB approvals.

Data Collection

Although data sets collected by the CPSP for active surveillance will vary from study to study, the following kinds or categories of information may be collected, used, disclosed, and retained, where relevant:

- General demographic information about the patient (e.g., month and year of birth, gender or sex, partial postal code)
- Relevant medical history (e.g., immunocompromised, pre-existing conditions)
- Condition information (e.g., episode information, health measures, symptoms)
- Treatments, investigations, and procedures conducted (e.g., agents received, duration of treatment)
- Outcomes (e.g., hospitalization, diagnoses)
- Comments or other information (e.g., information relevant or needed for case classification)
- Information about reporting physician (e.g., name, contact information, practice area)

Data Uses

Surveillance data collected by the CPSP is used primarily to deepen Canada's knowledge of rare paediatric conditions. Data collected through the Program supports professional education and critical public education initiatives,[8] informs changes to clinical practice guidelines, and helps to shape public policy.

The Program's surveillance data and study results may also be used to:

- Describe populations that are at risk and obtain important epidemiological data on their circumstances
- Evaluate the success of public health interventions by tracking their effectiveness
- Provide scientific evidence in support of the position taken by health care professionals in establishing and promoting health programs/interventions
- Take the pulse of an issue at the national level, for example related to injury prevention
- Signal emerging public health issues

Data Retention

Clinical questionnaires from Program participants are collected by the CPSP and stripped of all identifiable patient information (inadvertent or otherwise). Notifications of potential cases are assessed against the case definition, and duplicates or cases that don't meet the case definition are excluded. Information about reporting physicians is also removed at this time. The CPSP prepares an Excel spreadsheet of all data sets and

[8] Consider, for example, the historical use of surveillance data to reduce the risks of button battery ingestion and to reduce serious adverse outcomes relating to teething necklaces worn by infants and toddlers.

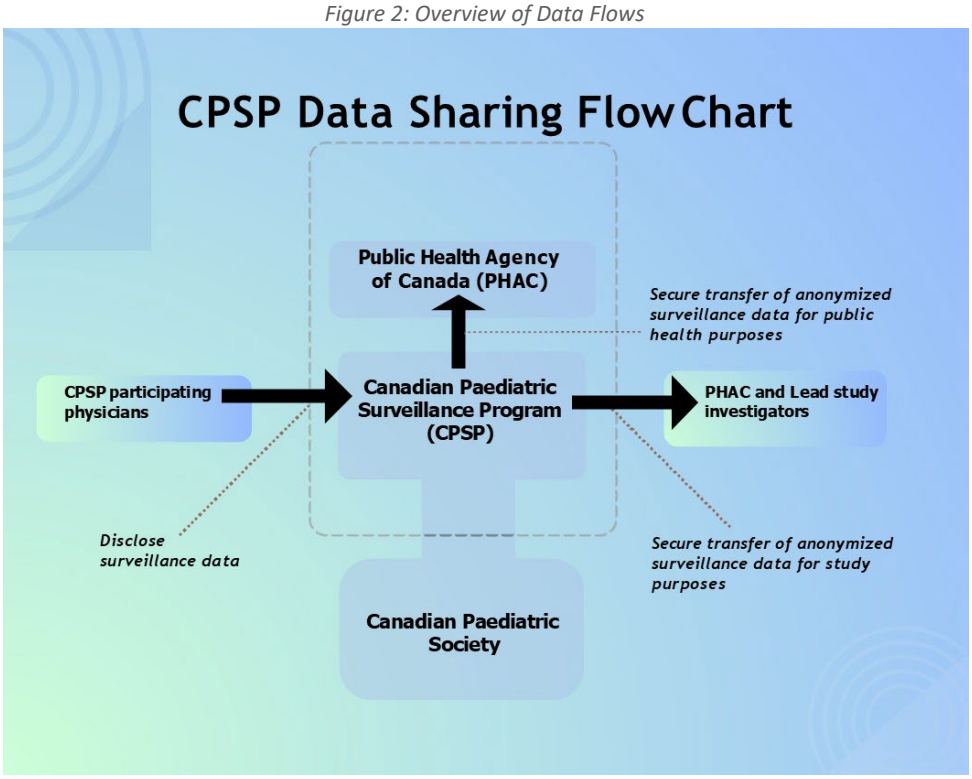
securely uploads that information to PHAC using a secure portal (LiquidFiles, a Privileged Access Security Infrastructure solution hosted by PHAC).

A copy of all clinical questionnaires is retained by the CPSP. Electronic data is stored within its eCPSP application, and strict controls are in place to limit access to surveillance data to authorized personnel. Hard-copy information is stored in locked cabinets. While retention periods for surveillance data vary by project, clinical questionnaires are retained by the CPSP for a minimum of two years (in keeping with federal regulations) and for up to seven years following the completion of a study. Thereafter, clinical questionnaires are securely destroyed by the CPSP, and surveillance data is stored in PHAC's CNPHI platform.[9]

Data Flows and Disclosures

Surveillance data is shared by the CPSP with PHAC for its own use and use by authorized study teams, but only once the data has been scrubbed of personal or identifiable information. This scrubbing includes the removal of personal or identifying information about reporting physicians and other health care providers. Anonymous surveillance data, including clinical questionnaires, are shared with the principal investigators by PHAC, following a formal request for the information and an assessment of the request. Figure 2 below provides a general overview of data flows associated with the CPSP's surveillance activities.

Figure 2: Overview of Data Flows



[9] See PHAC's information policies for more information about the retention of surveillance data in CNPHI.

5. Preliminary Assessment and Categorization of Privacy Risks

The following section is designed to highlight Program features or characteristics which, where attributable to the CPSP's health surveillance activities, may impact the privacy of individuals.

The Treasury Board of Canada Secretariat *Directive on Privacy Impact Assessment* identifies multiple privacy risk markers against which all federal programs must be assessed. Supplementary risk markers have been added to this risk assessment in consideration of provincial and territorial PIA guidelines. These markers are not intended to determine the actual nature of privacy risks relating to the CPSP, but rather potential or preliminary privacy risks based on an evaluation of Program characteristics.

The first step in the risk analysis consists of evaluating each risk area or marker independently. The second step consists of grouping the individual results to determine if a more in-depth analysis is required. The greater the number of risk areas identified as level 4 or 5, the higher the overall program or activity risk and the more likely specific risk areas will need to be addressed as part of the PIA process.

Privacy Risk Markers

The following table show's the assessment of the CPSP's risk in each privacy risk category on a scale from 0 (no risk) to 5 (most risk):

Risk Category	Risk scale	
Type of program or activity		
A program or activity that does not involve a decision about an identifiable individual	1	☒
General program, activity, or service administration	2	☐
A program or activity that does involve a decision about an identifiable individual	3	☐
Compliance or regulatory investigations and enforcement	4	☐
Criminal investigation and enforcement or national security	5	☐
Type of personal information involved and context		
The program or activity does not include the collection, use, or disclosure of identifiers or identifying information	0	☒
Non-sensitive personal information, collected directly from the individual, and authorized for use or disclosure for the program or activity in question	1	☐

Risk Category	Risk scale	
Non-sensitive personal information, collected indirectly from a trusted third party or system, but with the individual's consent, for purposes of the program or activity in question	2	☐
Personal information of minors, legally incompetent individuals, or a representative acting on behalf of another individual	3	☐
Sensitive personal information, including unique identifiers, which may be used for identity fraud	4	☐
Sensitive information, including biometric, DNA, genetic, health, or financial information, which may be identifiable or particularly sensitive in certain contexts	5	☒
Program or activity partners and private sector involvement		
Program partners include other groups within the institution	1	☐
Program partners include federal government institutions	2	☒
Program partners include a combination of federal, provincial, or territorial, and municipal governments	3	☐
Program partners include private sector organizations	4	☐
Program partners include international organizations or foreign governments	5	☐
Duration of the program or activity		
The program involves a one-time activity	1	☐
The program is short or limited in duration (1-2 years)	2	☐
The program is of moderate duration (3-5 years)	3	☐
The program is of a long duration (5-10 years)	4	☐
The program is expected to operate without a pre-determined sunset date	5	☒
Program population		
The program does not use personal information to make decisions about an individual	1	☒

Risk Category	Risk scale	
The program's use of personal information is for internal administrative purposes but only affects certain employees	2	☐
The program's use of personal information is for internal administrative purposes and affects all employees	3	☐
The program's use of personal information is for external administrative purposes but only affects certain individuals	4	☐
The program's use of personal information is for external administrative purposes and affects all individuals	5	☐
Personal information transmission		
Personal information will be used within a closed system (i.e., no connections to the Internet, Intranet, or any other system). The circulation of hard or paper records is limited and/or controlled.	1	☐
The personal information is used in a system that has connections to at least one other system	2	☒
The personal information may be transferred to a portable device or converted into a different medium	3	☐
The personal information is transmitted using wireless technologies	4	☐
The personal information is transmitted through a Cloud service	5	☐
Technology		
The project does not involve any new systems or substantial modifications to existing systems	1	☒
The program or activity requires substantial modifications to legacy information technology systems	2	☐
The program or activity involves the implementation of a new electronic system, application, or platform to collect, process, or store personal information	3	☐
The program or activity involves the use of a new or emerging technology such as artificial intelligence, biometrics, body scanning, facial recognition, or knowledge discovery	4	☐

Risk Category	Risk scale	
The program or activity involves surveillance systems or technologies that can be used to track and monitor individuals or the use of technologies that can circumvent individually established privacy controls or settings	5	☐
Potential impact of a breach on the individual		
Inconvenience or embarrassment	1	☒
Reputational harm	2	☒
Psychological harm	3	☒
Financial harm	4	☐
Physical security	5	☐
Potential impact of a breach on the institution		
The embarrassment of public officials	1	☒
A short-term loss of institutional credibility	2	☒
Financial harm	3	☒
Legal action	4	☒
A lasting decrease in public confidence in the institution, or the need for organizational restructuring or reform	5	☒
Likelihood of breach of information		
Highly unlikely	1	☐
Unlikely	2	☒
Plausible	3	☐
Likely	4	☐
Almost certain	5	☐
Risk of a privacy complaint		
Highly unlikely	1	☐

Risk Category	Risk scale	
Unlikely	2	☒
Plausible	3	☐
Likely	4	☐
Almost certain	5	☐

Program Risk Rating

The following table summarizes the results of the standardized risk assessment above. The overall risk rating is based on a grouping of low, moderate, and high-risk project characteristics. It provides an overall evaluation of risk markers and a preliminary risk rating for the CPSP and its surveillance activities at the time of drafting the PIA.

Identified Risk Categories	Aggregate Risk Rating
Number of project characteristics assessed at level 0 (i.e., characteristics suggesting no project risk)	1
Number of project characteristics assessed at level 1 or 2 (i.e., characteristics suggesting a low project risk)	12
Number of project characteristics assessed at level 3 (i.e., characteristics suggesting a moderate project risk)	2
Number of project characteristics assessed at level 4 or 5 (i.e., characteristics suggesting an elevated project risk)	4
Inherent Risk Rating	**Low**

Privacy risks arising from the CPSP's core activities are inherently low. Although the Program collects case-specific health information, that information is not linked to and does not include patient identifiers or identifying information. Policies, procedures, and internal controls have been adopted to reduce potential privacy impacts, including the risk of identification. These policies, practices, and controls are detailed in Section 6 of this report.

6. Privacy Compliance Analysis

This section provides a comprehensive analysis of CPSP's obligations for the proper handling and protection of health-related information. For ease of review, the analysis has been structured according to the analytical framework used by the Office of the Privacy Commissioner of Canada in its review of PIAs. This includes an analysis of the necessity, effectiveness, proportionality, and intrusiveness of the CPSP's public health surveillance activities.

Following a discussion of the Program's rationale, the analysis turns to an assessment of the CPSP's statutory responsibilities for privacy, as set out in sections 4 through 8 of the federal *Privacy Act*. It includes an assessment of privacy best practices, common to all Canadian provinces and territories, as set in the Canadian Standards Association (CSA) Model Code for the Protection of Personal Information (also referred to as "Fair Information Principles" or the "Ten Principles of Privacy Protection").

Program Rationale

As stated invariably throughout this report, the importance of the CPSP's surveillance activities for public health policy and the practice of paediatric medicine cannot be overstated. The ongoing and systematic collection, analysis, and interpretation of health-related information relating to rare conditions and diseases in children and youth is essential to the planning, implementation, and evaluation of medical and public health practices.

Necessity

Since many rare diseases and conditions begin in childhood, an accurate and rigorous paediatric health surveillance system is not only necessary but essential. The CPSP was founded in 1996 following a recognition that the failure of paediatricians to report cases of rare childhood diseases or conditions could result in significant health, social, and economic fallout. Although a "rare" disease or condition may affect fewer than five in 10,000 individuals, collectively these conditions may affect more than a million Canadian children and youth. The CPSP provides the means to undertake active paediatric health surveillance of childhood diseases and conditions that are high in disability, morbidity, mortality, and economic cost to society, despite their low frequency.

Emerging diseases or infections are often rare, at least initially, and can remain undetected for significant periods of time. Difficulties in recognizing these diseases can result in their spread. They can also result in delayed diagnosis, increasing the risk and likelihood of health complications or death to individuals. Such diseases are sometimes very difficult to study. Their low frequency often means that little may be known about their etiology, clinical spectrum, complications, pathological features, diagnosis, treatment, or management. To identify, track, and better understand emerging diseases, it is necessary to collect data from a large and geographically diverse population through an active public health surveillance system like the CPSP.

Effectiveness

A tremendous body of evidence has been collected over the past several decades that paediatric surveillance can change the life course of some of society's most vulnerable and disadvantaged children. CPSP data has contributed to many significant changes in public health policies and interventions and led to changes in clinical care guidelines.[10] Some of the Program's positive impacts include the following:

- The international comparison of haemorrhagic disease of the newborn of five national paediatric surveillance units illustrated the importance of intramuscular vitamin K prophylaxis
- The severe neonatal hyperbilirubinemia study confirmed many cases in term newborns and contributed to the revised CPS guidelines on the management of neonatal hyperbilirubinemia
- The medium-chain acyl-coenzyme A dehydrogenase deficiency study documented the efficacy of newborn metabolic screening programs in detecting asymptomatic cases and allowing for early preventive measures
- The vitamin D deficiency rickets study confirmed the importance of reinforcing the CPS recommendation that exclusively breast-fed infants and children receive vitamin D supplementation
- Findings from the lap-belt syndrome study contributed to changes in legislation regarding the need for longer use of booster seats for children
- The wheeled baby walker survey contributed to the total ban on their sale, import, and advertisement in Canada

In its first 15 years alone, CPSP participants reported thousands of confirmed cases of rare diseases and conditions in children and youth which resulted in significant positive public health impacts. Since then, CPSP studies have continued to highlight risks and emerging issues in child and youth health, demonstrating the Program's effectiveness and importance.[11] Guidelines revised as a result of Program studies have moreover demonstrated the effectiveness of the Program and its outputs.

Proportionality

The CPSP recognizes that the important clinical and public health benefits of surveillance must be balanced with the need to protect the privacy of patients. To this end, the Program has adopted best in class practices

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10 The CPSP: An active surveillance program protecting and promoting the health of Canadian children and youth *Paediatrics & Child Health*, Volume 21, Issue 5, 06 June 2016, Pages 263–264, Oxford Academic.

11 See, for example, the results of a study on the COVID-19 pandemic and its impacts on new cases of anorexia nervosa in children and youth.

for the handling of the surveillance data it collects from Program participants. As stated in Section 4 of this report, the CPSP does not collect personal or identifiable information about patients. Data reporting forms are strictly vetted to ensure that they do not include fields which may contain personal or identifying information about patients, and case reports received by the CPSP are reviewed and stripped of inadvertent personal or identifying information before analysis. All information collected through the Program is stored and safeguarded, and the use and disclosure of surveillance data is strictly limited. These measures help ensure that privacy impacts associated with the CPSP's surveillance activities are low and far outweighed by Program benefits to Canadian society and children.

Alternatives

There are currently no known viable alternatives to the kind of public health surveillance activities conducted by the CPSP, and indeed, its methodology is consistent with those of leading paediatric surveillance programs worldwide and the surveillance protocols of the World Health Organization (WHO)[12]. As set out in Section 2 of this report, the CPSP's active surveillance methodology involves a monthly call-out to clinically active paediatricians, paediatric subspecialists, and other child health professionals to report cases of conditions under surveillance seen in the past month or make a nil return. Case reports are followed up with a clinical questionnaire requesting case-specific information, absent any identifying information about the patient. Responses returned to the CPSP are reviewed and vetted before being forwarded to PHAC and on to principal investigators for analysis.

Through this process, the CPSP has facilitated studies which have increased Canada's knowledge about a range of childhood diseases, conditions, and disorders, and supported and informed national policy decisions with strong evidence and reliable data. The Program has also increased diagnostic awareness and showed itself able to respond to public health emergencies, such as COVID-19. The Program's emulation in other countries is demonstrative of its merits, effectiveness, and ongoing importance. Although the ubiquitous and open access to information produced by the public on the Internet has sparked an increased interest in developing so-called "digital public health surveillance systems," such systems remain in their infancy, and have been shown to have many inherent practical limitations and potential pitfalls.[13]

Program Design and Compliance

Accountability

It is generally accepted as a privacy best practice for the head of an organization to designate an individual (or individuals) accountable for privacy compliance. The head of the organization or his/her delegate is

[12] See Protocol for the Evaluation of Epidemiological Surveillance Systems, World Health Organization, Emerging and other Communicable Diseases, Surveillance and Control (WHO/EMC/ DIS/97.2).

[13] See Abad et al., Digital public health surveillance: a systematic scoping review, npj Digital Medicine (2021) 4:41.

required to implement policies and practices to give effect to core privacy principles, including establishing procedures to receive and respond to privacy complaints and inquiries.

Responsibility for privacy and the handling of health-related information in relation to surveillance rests with the CPSP's Surveillance Manager. This position is responsible for establishing policies and procedures for the proper handling of surveillance data and for directing study teams on compliance. These policies have been established with the assistance of the CPS and PHAC, bearing in mind the privacy practices of each organization and the CPSP's founding agreement. The Manager, Surveillance is supported by the CPSP's Medical Affairs Director, who helps ensure that study teams and principal investigators leading studies understand and abide by rules limiting the collection, use, and disclosure of health-related information.

The CPSP's Manager, Surveillance, is supported by the CPS and PHAC, who respond to access and privacy requests made in relation to the Program. This includes responding to privacy complaints or inquiries and answering requests for information about the CPSP's privacy policies. Ultimate responsibility for corporate privacy matters relating to the Program rests with the CPSP Medical Affairs Director and the Executive Director of CPS. In promoting good health-related information handling practices, the CPS relies on longstanding practices related to information management (IM), information technology (IT), and security.

Identifying Purposes

Subsection 5(2) of the Privacy Act requires that government institutions inform individuals from whom they intend to collect personal information of the purposes for which that information is to be collected.

The CPSP does not collect identifiable information about patients, and information about Program participants is limited to what is at best described as work contact information. Reporting physicians and health care providers participating in the Program are notified of the way their information and any reported case information is to be used through a variety of corporate communications. This includes information about the Program (as provided at the time of registration), CPSP Annual Reports, the CPS website, patient and family posters, and the CPSP's public facing Privacy Policy.

Recommendation – Identifying Purposes

Although the CPSP's surveillance reporting forms (both the initial form and detailed clinical questionnaire) include a short statement committing to patient and participant confidentiality, the forms do not include a full "Privacy Notice." In keeping with legal requirements to notify individuals of the purpose for which their personal information is to be collected and, bearing in mind the benefits of notification for Program participation, it is recommended that the CPSP develop and draft a Privacy Notice for inclusion in its surveillance reporting forms. The Notice should also be included in online forms and be displayed prior to clinical questions and the request for physician information. Ideally, the Notice should meet the minimum disclosure requirements set out in subsection 4.2.5 of the Government of Canada's *Directive on Privacy Practices* (bearing in mind consideration of form and design).

Consent

As per sections 7 and 8(1) of the Privacy Act, the consent of an individual is required where the use or disclosure of that information is inconsistent with the purposes for which the information was first collected. The consent of an individual is not required for the initial collection of personal information. The Act requires only that the collection of personal information be directly related to an authorized program or activity of the institution (and that it be demonstrably necessary to fulfill that program's purpose).

As a joint project of the CPS and PHAC, the CPSP relies on the authorities of PHAC under the *Public Health Agency of Canada Act* and *Department of Health Act* for its collection of surveillance data. Consent is not a prerequisite for the collection of information in clinical questionnaires. Notwithstanding the above, the CPSP and the CPS encourage physicians to present the Program to patients/families, and to underscore the importance of public health surveillance of rare and/or emerging conditions. Physicians are in turn encouraged to exercise their discretion to disclose non-identifiable information about conditions, absent express objections to the reporting from patients/families, bearing in mind permissions under provincial and territorial health and privacy statutes.

Limiting Collection

Section 4 of the Privacy Act precludes government institutions from collecting the personal information of individuals except where it relates directly to an institution's operating program or activities. Where authorized, subsection 5(1) of the Privacy Act requires that government institutions collect that information, if intended to be used for an administrative purpose, directly from the individual to whom it relates. Exceptions to direct collection are set out under subsection 8(2) of the Act.

The CPSP does not collect identifiable information about patients. CPSP-supported studies only collect and use de-identified case data. Principal investigators have no direct contact with individual patients or participating physicians and study teams are not permitted to match data in a manner which may render a case or patient identifiable in their research. Detailed clinical questionnaires are designed so as to request only that information which is demonstrably necessary for the surveillance study, and only that which is "defendable" as necessary for the research. Requested data are reviewed by the CPSP's Scientific Steering Committee. Those data elements must be comprised of health data reasonably expected to be noted in a medical chart. Where a data element requested is not available, the physician does not contact the patient/family for missing information.

Although there is a risk that, in the completion and processing of detailed clinical questionnaires, the CPSP inadvertently collects personal information – information not requested but volunteered by the participating physician – or that it collects more information than needed for purposes of a study or surveillance generally, that risk is being minimized by the review of all questionnaires by the CPSP prior to analysis and submission to PHAC. As stated earlier, once a detailed questionnaire is returned to the CPSP, it is stripped of all identifying information (if any is provided). All notifications of potential cases are assessed against the case definition, and all duplicates or cases that don't meet the case definition are excluded.

Limiting Use

Section 7 of the Privacy Act states that personal information under the control of a government institution shall not be used for purposes other than that for which it was collected (or for a use consistent with that purpose), except with the individual's consent (or as provided for by law).

The CPSP's use of surveillance data is strictly limited and in keeping with its core mandate for health surveillance and education. The Program does not use clinical or participant information for its own research, or for decisions about or affecting specific individuals. Data collected by the CPSP may be used for the following purposes: to describe populations that are at risk, and to obtain important epidemiological data on their circumstances; to measure or assess the effectiveness and success of public health interventions; to support public health programming and policy choices with scientific evidence; to gauge public, professional, and stakeholder opinions on injury and disease prevention issues; and to highlight and alert public officials of emerging public health issues. Neither PHAC nor study teams using surveillance data are authorized to use that data for secondary purposes[14], or purposes unrelated to those for which the information was first collected.

Limiting Disclosure

Subsection 8(1) of the Privacy Act states that information under the control of a government institution shall not, without the consent of the individual to whom it relates, be disclosed by the institution, except as provided for in subsection 8(2) of the Act.

Clinical information collected by the CPSP through its surveillance program is shared with PHAC only once stripped of any personal or identifying information. This includes information that may inadvertently identify a patient, and information about reporting physicians. Anonymous case information is disclosed to PHAC who, subject to a formal assessment and the provision of written assurances over data confidentiality, may share the information with a requesting study team. PHAC generally relies on paragraph 8(2)(j) (research) or paragraph 8(2)(a) (consistent use) of the *Privacy Act* as the basis for sharing information with investigators. Under Principal Investigator Agreements with the CPSP, study teams may not disclose clinical information to others. Final study results may be published in peer-reviewed journals and may be presented at national and international conferences, but all results must be presented as summary statistics.

Limiting Retention

Subsection 6(1) of the Privacy Act prescribes that personal information used by a government institution for an administrative purpose be retained by the institution for such a period so as to allow the individual to

[14] A "secondary purpose" means a purpose different than that for which the information was first collected, and which could not be reasonably contemplated by the individual providing the information at the time of collection. The CPSP does not use personal information for secondary purposes. Surveillance data may be used in aggregate or in a de-identified format for research and statistics, but those uses are consistent with the purposes for which the data is first collected (and not secondary in nature).

whom it belongs a reasonable opportunity to obtain access to that information. Section 6(3) goes on to say that the ultimate disposal of personal information under the control of an institution should be performed securely, and in accordance with the record disposition authorities of Library and Archives Canada.

Electronic surveillance data is stored in the CPSP's e-reporting and case management system ("eCPSP"). Hard-copy information is stored in locked cabinets. While retention periods for surveillance data vary by project, all clinical questionnaires are retained for a minimum of two years (in keeping with federal regulations) and for up to seven years after study completion. Thereafter, the information is securely destroyed, and surveillance data is only used in aggregate. Strict procedures ensure the secure destruction and disposal of data. At the end of the required storage period, paper records are shredded by certified personnel, and a certificate of destruction is obtained once complete.

Recommendation – Data Management

Although the CPSP benefits from a range of internal policies and practice guidelines in the support of its work, many of which support and inform the proper handling of surveillance data, it does not have a data management framework or stand-alone privacy policy. Currently, the Program relies on (and abides by) the privacy policies of the CPS in the management and processing of surveillance data. Although that policy is not deficient in and of itself, it does not provide guidance or limitations on the processing and handling of information by the CPSP. Given the nature of the CPSP's work and the sensitivity of the information it may collect, it is recommended that the Program develop a more comprehensive data management framework or information policy to support the proper governance of surveillance data. That framework or internal policy should, among other things, establish express rules for the internal use, disclosure, safeguarding, and retention of surveillance data.

Accuracy

Subsection 6(2) of the Privacy Act requires that a government institution take reasonable steps to ensure that personal information that is to be used for administrative purposes remains as accurate, up-to-date, and complete as possible.

To help ensure that health information collected in relation to its surveillance activities is accurate, up-to-date, and as complete as possible – bearing in mind its intended uses – the CPSP collects data directly from Program participants. This includes reporting paediatricians, subspecialists, and other health care providers and their patients.

Each month Program participants receive a prescribed form listing health conditions under study. Program participants are asked to indicate the number of new cases seen in the reporting period for each listed condition, including indicating when no cases were found. Participants who have identified a case are then sent a detailed clinical questionnaire to complete and return to the CPSP. In most cases, the CPSP sends an online link to Program participants to complete the clinical questionnaire. CPSP provides Program participants with the ability to access their reports, and to make corrections or amendments to the reports where needed. Access to reports is provided through the CPSP reporting portal, and only physicians with

appropriate credentials can access that portal. Access is, in all cases, limited to data the Participant has provided, and portal use and logins are monitored.

Safeguards

Personal information created, collected, used, disclosed, and retained by federal institutions must be safeguarded in accordance with government standards for the protection of personal information, mainly the Policy on Government Security. As a rule, information should be safeguarded in a manner commensurate with its sensitivity.

In meeting its obligations for the safeguarding of health-related information, the CPSP relies on core organizational controls for privacy and security. These include physical, technological, and procedural safeguards in place at the CPS to govern, restrict and track access to all Program data. Data is transmitted using secure socket layer (SSL) technology; host servers are protected by firewalls; role-based access controls are in place to limit access to electronic records; and system auditing features are used to track and monitor user actions. All CPSP staff members are security cleared, and mandatory training on privacy and security is provided to all staff at the time of their onboarding (and when there is a change in responsibilities affecting data handling responsibilities).

CPSP data is hosted in Canada by CNPHI infrastructure, which is managed by security cleared CNPHI team members. Security procedures for access to the CPSP reporting system and for the secure transmission and storage of case information are set out in PHAC's general IT security procedures and supplemented in data handling guidelines. All PHAC systems are subject to the institution's Security Assessment and Authorization (SA&A) process, which requires the continuous assessment and testing of key systems, and a formal authority to operate.

Recommendation – Safeguards

Although the CPSP does not collect personal information in surveillance reports, except for physician tombstone information, and though Program participants are asked not to provide identifying information in reporting case-level data, clinical questionnaires can include information that is confidential or sensitive in nature. As such, and whereas the interception or use of that information (alone or in combination with other information) might create a risk to patient privacy, the CPSP should consider phasing out the use of paper forms for surveillance reporting. Although the CPSP receives only a small percentage of reports by regular mail or fax, a risk remains that information sent by mail or fax could be intercepted (unlike electronic submissions, which are encrypted and protected in transit). Should the CPSP elect to continue the use of mail and fax for report transmission, it should consider the risks of doing so and take measures to mitigate the risk of a breach.

Openness

It is generally accepted as a privacy best practice for an organization to make specific information about its policies and practices in relation to the management of personal information readily available to individuals.

Information about the CPSP's information handling practices is available on its external web site. That information includes detailed descriptions of data collection practices and limits on Program uses and disclosures. The CPSP's external website also provides information about its health surveillance activities and studies more generally. This information is supplemented by promotional materials and other corporate communications, many of which include descriptions of the CPSP's policies and practices in relation to the management and protection of personal information.

Note: as described earlier in this report, it has been recommended that the CPSP develop a more detailed Privacy Notice to communicate the purposes for which it collects and uses surveillance information (see recommendation relating to "identifying purpose" above). This notice – included in all reporting forms – coupled with the CPSP's general Privacy Policy and a reference to PHAC's InfoSource publication will help ensure that the CPSP remains open and transparent about its privacy handling practices. In addition to the above, as per the Treasury Board of Canada Secretariat Directive on Privacy Impact Assessment, the CPSP will post a summary or full copy of this PIA and its findings to its external website.

Individual Access

Where an institution collects, uses, discloses, or retains personal information, it must ensure that the individuals to whom the information relates are informed of its existence, use and disclosure. This practice is closely related to an individual's right to access that information under the Privacy Act. Under the Act, an individual must be able to challenge the accuracy and completeness of any personal information used for administrative purposes, and to have his or her information updated or corrected upon demand.

Clinical reports are not used by the CPSP to make decisions about reporting physicians, and clinical information is never used to make decisions about patients. That said, the CPSP provides physicians with the ability to access their reports, and to make corrections or amendments to the reports where needed. While access to reports is provided through the CPSP reporting portal, physicians also have the right to access their personal information through a formal access request, and to have the request processed, subject to the exceptions noted in the *Privacy Act*. Should a formal access request be received, ordinary privacy and access to information procedures will be respected. In such cases, the CPSP may consult with the CPS and/or PHAC prior to issuing a release.

Access requests from patients cannot be honoured or processed, as the CPSP does not collect identifying information about patients, and clinical information provided by Program participants is not available or retrievable by patient name or identifier.

Challenging Compliance

As a best practice for privacy, an individual should be able to address a challenge concerning compliance with core privacy principles with the individual accountable for privacy.

Concerns relating to the collection, use or disclosure of information in relation to the CPSP's surveillance activities, or those particular to the processing of access requests, will be directed to the CPS's Executive Director. Privacy concerns may also be directed to PHAC's Access to Information and Privacy group (should

the concern directly relate to PHAC responsibilities). Failing the resolution of an individual's privacy concerns or issues, individuals may exercise their right to pursue outstanding issues by way of complaint to the Office of the Privacy Commissioner of Canada. Individuals are notified of this process through CPSP's Policy on Privacy and Information Management (published on-line) as well as its Privacy Notice to participants.

Recommendation – Compliance and Monitoring

It is recommended that the CPSP implement measures to track and monitor compliance with data handling practices imposed on principal investigators through Principal Investigator's Agreements, particularly those pertaining to data retention.

7. Summary of Findings and Management Action Plan

The following table summarizes key observations and recommendations emanating from the PIA process. It also includes the CPSP's response and action plan to mitigate risks identified.

Issue	Recommendation	CPSP Response
Identifying Purposes	The CPSP should consider developing and publishing a more comprehensive privacy notice on both paper and online reporting forms to better inform Program participants of the way case information will be used, disclosed, and retained.	**Recommendation accepted** A more comprehensive privacy notice has been developed and will be available on the CPSP website and appear on both paper and electronic clinical questionnaires.
Data Management	The CPSP should consider developing a comprehensive data management framework or information policy to support the proper governance of surveillance data, and to establish express rules for the internal use, disclosure, safeguarding, and retention of that data.	**Recommendation accepted** A privacy and information management policy has been prepared and will be available on the CPSP website.
Safeguards	The CPSP should consider phasing out the use of paper forms for surveillance reporting, bearing in mind that some forms may contain health-related information which could be sensitive in certain contexts. The use of fax systems to transmit completed forms should also be discouraged.	**Recommendation accepted** The oldest CPSP studies are being revamped to move them from paper-based reporting to electronic reporting, with an anticipated completion date of 2026.
Monitoring and Compliance	The CPSP, in partnership with PHAC, should consider implementing measures to track and monitor compliance with data handling practices imposed on principal investigators through Principal Investigator's Agreements, particularly those pertaining to data retention.	**Recommendation accepted** A mechanism to track compliance with data handling practices related to data retention will be developed and implemented, including follow up with principal investigators on a yearly basis until they confirm in writing that study data has been destroyed.

8. PIA Contacts

For more information about the CPSP and the findings of this report, please contact:

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