



Newfoundland and Labrador Provincial Perinatal Program

**Provincial Perinatal Surveillance Program
Management, Access and Release Policies**

Adopted 2005

Background

The Provincial Perinatal Surveillance Program (PPSP) is included within the mandate of the Newfoundland and Labrador Provincial Perinatal Program (PPP). The PPP is funded through an operational grant provided by the Department of Health and Community Services, and is supported by the corporate services of Eastern Health. The PPP operates under the direction of the Provincial Perinatal Advisory Committee, which has representation from all provincial health regions, various related health professions and the Department of Health and Community Services.

The Perinatal Program is a multifaceted and integrated program that; offers developmental follow-up of high risk infants; implements education programs for perinatal health care providers; promotes standardized provincial perinatal clinical competencies; and provides perinatal surveillance and epidemiology services for the province. This blend of program and service promotes shared expertise and evidenced-based practice.

The terms of reference of the program are:

- Organization and implementation of the Perinatal Follow-Up Clinic for high-risk infants.
- Development of guidelines for perinatal care, including obstetrical and neonatal care.
- Provision of education services and resources to centres providing perinatal care.
- Review and implementation of relevant nationally developed programs, related to perinatal health.
- Prevention and health promotion advocacy in improving perinatal outcomes.
- Facilitation and support of research and quality assurance initiatives, in perinatology and developmental outcomes.
- Development and implementation of a Provincial Perinatal Database System.

By the collection, maintenance, analysis and dissemination of data, the PPSP is essential in the evaluation of obstetrical care in the province and in making recommendations for best practice. The monitoring of indicators, such as maternal lifestyle behaviours, provides surveillance that can positively influence health outcomes by providing information on trends and patterns of risk and protective factors that help to explain morbidity and mortality. This surveillance can help determine effective interventions, improve the identification of women at risk, educate health care providers and determine appropriate allocation of resources.

The Canadian Institute for Health Information (CIHI) maintains the Discharge Abstract Database (DAD) and requires all Canadian acute care institutions to collect data on each hospitalization, including demographic information, length of stay, most responsible diagnosis, co-morbid diagnoses and procedures. All diagnoses are coded using the International Classification of Diseases 10 (ICD 10). The perinatal database contains the DAD information plus the addition of a maximum of 102 perinatal variables (80 maternal and 22 neonatal) from every personal health record, and is designed to be

compatible with the Canadian Perinatal Database Committee's minimum requirements, so as to facilitate provincial comparisons.

An important source of the PPSP information, in addition to the personal health record, is the provincial prenatal record. Documentation of this prenatal record is by medical practitioners, midwives, regional nurses and nurse practitioners. A copy of this prenatal record is kept with every individual health record in institutions providing obstetrical care, thereby enabling retrieval of data from both the personal health record and prenatal record for the PPSP.

Introduction

The Provincial Perinatal Program is developing a population-based perinatal database. The confidentiality of personal information and the security and integrity of all data contained in the Provincial Perinatal database is ensured by; the PPSP Data Management, Access and Release Policies; Newfoundland and Labrador's Hospital Act; the Human Investigations Committee of Memorial University; and the Access to Information and Protection of Privacy Act (ATIPP). As identified by ATIPP, specific provisions of personal information are:

1. Collected with consent and for a reasonable purpose
2. Used and disclosed for the limited purpose for which it was collected
3. Accurate
4. Accessible for inspection and correction
5. Stored securely

Personal Information is....

- name, address or telephone number
- race, national or ethnic origin, colour, religious or political beliefs or associations
- age, sex, sexual orientation, marital status or family status
- identifying number, symbol or other particular assigned to an individual
- fingerprints, blood type or inheritable characteristics
- health care status or history, including a physical or mental disability
- educational, financial, criminal or employment status or history
- personal views or opinions
- opinions of others about the individual

(Newfoundland and Labrador's Access to Information and Protection of Privacy Act 2002).

According to the Newfoundland and Labrador's Hospital Act, hospital records are the property of that facility. The PP database acts, then, as a data repository. The PPP utilizes data contained in this database for clinical review and evaluation purposes in accordance with its provincial and regional role.

The Newfoundland and Labrador Provincial Perinatal Program has developed these Surveillance Program Management, Access and Release Policies, in order to ensure and safeguard the proper protocol for data sharing, data access requests and reporting by all contributors to the PP database.

Data Management

1. The PPP recognizes that every health care facility is responsible and accountable for documentation of data related to obstetrical clinical events, in the form of health records and information provided to the facility and the PP database by an individual practitioner or group of practitioners (e.g. prenatal records). As standard practice, checks are undertaken by each facility: Canadian Institute for Health Information (CIHI) on a quarterly basis; the Newfoundland and Labrador Centre for Health Information (NLCHI) annually, or following error detection; and the Provincial Perinatal Program (PPP) annually, or following error detection, to ensure accuracy and reliability of data.
2. A copy of the database for each facility may reside at or be accessed from that facility. Use of this database is governed by principles and policies established by the facility/region and the Newfoundland and Labrador's Hospital Act.
3. An individual, identified by the region, acts as a representative (**data steward**) for the hospital and/or all the organizations in one of the four Regional Integrated Health Authorities (RIHA). This identifies a spokesperson for the Health Authority when permission or consultation by the PPP is required.
4. In general, requests for information
 - a. specific to a health facility or facilities in a Health Authority will be directed to that particular Health Authority. **Upon request from the Health Authority, the PPP will assist facilities with both data release and/or analysis.**
 - b. general to the province will be reviewed by the PPP.
5. As per the Hospital's Act, PPP will only release aggregate data that does not identify any individual (i.e., woman or infant), physician, member of a hospital staff, or person employed by the hospital authority. **Additionally, the PPP will not release data in which groupings of fewer than five individuals appear** (As recommended by Statistics Canada).
6. Data that could potentially identify an individual, health care provider, or person employed by the hospital authority, will not be released by the PPP to any group or individual unless approval from the Data Access Committee* has been obtained.
 - a. Requests should indicate the purpose for which the data will be used and the name of the individual(s) requesting data.
 - b. If the Committee responsible for giving data release approval expresses any concern, data will not be released.

* The Data Access Committee is comprised of PPP staff and research and perinatal experts, abiding by the PPSP Management, Access and Release Policies.

- c. Modifications to data requests may then be necessary to obtain approval.
7. All research projects, with potential for publication and presentation, may be accommodated provided the project has been approved by a recognized research and ethics review committee (such as the Human Investigations Committee of Memorial University).
8. Transfer of data will be secure, in accordance with the policies of the Regional Integrated Health Authorities, to prevent unauthorized access.
9. Data in the PPSP will be retained indefinitely, with appropriate backup as secured by Eastern Health and the PPP.

Storage and Security

Participating Hospitals

Each Integrated Health Authority is the owner of the data and is responsible for authorizing the release of data to the PPSP and others. Each hospital is responsible to its Health Authority for implementing procedures, developed either by the Health Authority or the hospital to ensure safekeeping of the data. This includes the use of software that provides the ability to secure accesses by password implementation.

The Provincial Perinatal Database

The perinatal data elements are stored in the 3M Health Record Management System. The Newfoundland and Labrador Provincial Perinatal Program recognizes that each hospital facility has safeguards in place to protect the perinatal data elements, such as policies and procedures based on the Canadian Standards Association (CSA) Privacy Code outlined by Schedule 1 of the Federal Personal Information Protection and Electronic Documents Act, staff confidentiality agreements, layers of passwords, firewalls and other state-of-the-art technology based on industry standards, and extensive back-up systems to prevent loss of data.

Data extracted from this system to the Perinatal Database are stored on a password-protected computer, in a series of excel files which are also password-protected. Analysis is conducted using Excel Pivot Tables and/or the Statistical Package for Social Sciences (SPSS) software program.

Access to the complete perinatal database is only provided to designate staff of the Newfoundland and Labrador Provincial Perinatal Program.

The Perinatal Program office has restricted access in the evenings, nights and weekends. Offices are locked and all computers are password protected.

Process for Submission and Approval of Requests from the Provincial Perinatal Surveillance Program

Background Information

Any health care provider or individual interested in perinatal health may request data from the PPSP. Requests are addressed in the order in which they are received, unless there are extenuating circumstances. The information provided from the surveillance database may vary from raw data for researchers to aggregate summaries for decision makers.

There is a cost associated with the data retrieval. An estimate of the retrieval fee can be obtained from the PPP for budget planning purposes. Requesters should be prepared to describe the variables required, the type of data file needed and pertinent details of the project (e.g. data linkage needs) so that an accurate estimate can be provided.

Those receiving a grant for their projects are asked to build in a retrieval fee to their budget submission.

In some situations, the cost for data retrievals requested by groups or individuals from Newfoundland and Labrador may be waived.

All groups from outside of Newfoundland and Labrador will be billed a retrieval fee based on cost recovery.

Submission Process

1. All requests must be in writing and describe in sufficient detail the purpose of the request and the intended use for the information (please refer to the attached Data Request Form). Identification of the specific variables required will improve the turn-around time for the data requested. If requesters are unfamiliar with the PPSP, consultation with a staff member from PPP is recommended prior to submitting a request.
2. Requesters are asked to specify whether they are requesting data tables or a data file to manipulate. Data tables will be returned to the requester by e-mail or Canada Post unless otherwise specified. Individuals requesting data files are required to return a form outlining the length of time they will need the data set and indicating their agreement to abide by the PPSP Management, Access and Release Principles (please refer to the attached Data Use Agreement).
3. Users of the data must acknowledge the Provincial Perinatal Surveillance Program of the Newfoundland and Labrador Provincial Perinatal program in

all publications or presentations. A copy of any manuscript using data from the PPSP should be forwarded to the Provincial Perinatal Program once it is accepted for publication. Notification of acceptance for poster or oral presentation should be forwarded to the PPP with details about the title, date and expected audience. N.B. Any publications or presentations using individual level data, facility-specific data, or analyses that report cells containing fewer than five observations must be reviewed by PPP prior to submission. Additional review may be required.

4. Data requests can be denied by the PPP.
5. Breach of the PPSP Management, Access and Release Principles or of any data sharing agreement specific to a particular project will result in denial of future requests from that individual or group.

Approval Process

To determine the Program's ability to respond to data requests, either the database consultant or program director will first review the requests. Requests are categorized according to the presence or absence of identifiers or potential identifiers (listed below) and determined whether approval by the Data Access Committee* and/or recognized ethics review committee is required.

There are four categories of data request. Regulations for access and release are specific for each category.

Category 1 – Non-identifiable/aggregate data

- Data without identifiers or potential identifiers.

Category 2 – Partially identifiable data

- Data that may potentially identify a care provider or person employed by the hospital authority.

Category 3 – Identifiable or potentially identifiable data

- Data containing personal identifiers or potential personal identifiers.
- Data that can potentially be linked to other databases.

Category 4 – Facility/care provider specific data for that facility/care provider

- Data requested from hospital representatives and physicians, for data pertaining to their facility or practice; required for audit purposes.

* The Data Access Committee is comprised of PPP staff and research and perinatal experts, abiding by the PPSP Management, Access and Release Policies.

Approval Process for Category 1 (Non-identifiable/aggregate data):

- Includes all data that does not contain or allow for the identification of a specific person or care provider.
- Non-identifiable aggregate data is for multipurpose use and may be released to a Health Authority designate, researchers, educators, students and general requestors by the Provincial Perinatal Program.
- Data can be released to identify the level of the Health Authority or region.
- Respect for anonymity of the patient is of cardinal importance.
- Data is used for routine reports; comparative evaluation and benchmarking, both regionally and provincially.
- Requests are reviewed through the PPP; the purpose of the review is to ensure that the requester's question is fully understood and appropriate.
- The PPP maintains the right to refuse data requests.

Approval Process for Category 2 (Partially identifiable data):

- Data that involve potential identifiers of healthcare provider(s) or person (s), for example a single obstetrician, employed by the hospital authority.
- Requests in Category 2 are
 - 1) Reviewed through the PPP; the purpose of the review is to ensure that the requester's question is understood fully and the retrieval proposed is appropriate.
 - 2) Reviewed through the Data Access Committee; the release of potential identifiers will be negotiated with the requester and restrictions on the use of the data set may be imposed or data access denied.
 - 3) Requires consultation and/or approval with/from the appropriate Health Authority Data Steward(s)**. Data stewards have the right to refuse permission if it is deemed not to be in the best interests of the individual or health care provider.
 - 4) For projects in this category, collaboration with PPP or the appropriate data steward is recommended.

Approval Process for Category 3 (Identifiable or potentially identifiable data):

- Includes all data containing personal identifiers or potential identifiers (such as, infant birth date and time, postal code, etc) that is requested, and data that involve a database linkage (can potentially be linked to other databases).
- Requesters are advised to review the PPSP Management, Access and Release Policies to ensure that proposals are consistent with these principles.

** The Data Steward is a designated representative of the Health Authority owning the data source, who is consulted by PPP when necessary

- A meeting with a PPP representative is recommended to clarify any questions.
- Requests that require identifiers or potential identifiers **will be subject to a stringent review process that includes approval from** the PPP Data Access Committee.
- Researchers should be aware of the following caveats:
 1. All research projects must be reviewed by a recognized Ethics Board, such as the Human Investigations Committee (HIC) of Memorial University for Faculty of Medicine and School of Nursing submissions, or the Interdisciplinary Committee on Ethics in Human Research (ICEHR) for all other academic units.
 2. The Research Proposal Approval Committee (RPAC) must review any projects that will use data pertaining to patients of the Health Care Corporation of St. John's.
 3. If researchers intend to contact patients or physicians from facilities outside the Health Care Corporation of St. John's, or need to access health records in these facilities, approval from the Research Board for each facility/region is required.
- In the event linked health data is required, principles as developed by the Newfoundland and Labrador Center for Health Information will be incorporated.
- The NL Provincial Perinatal Program will formally document terms, conditions and the procedure for the release of personal information for research purposes.

Approval Process for Category 4 (Facility/care provider specific data for that facility/care provider):

- Includes all data specific to own facility and practice, **and** is released only to those hospital representatives or physicians.
- Requests are reviewed through the PPP; the purpose of the review is to ensure that the requester's question is fully understood and appropriate

Contact Information:

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Nova Scotia Reproductive Care Program
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Newfoundland and Labrador Provincial Perinatal Program

Data Request Form

Date Submitted: _____ **Date Required:** _____

Name(s): _____

Organization(s): _____

Contact Information: _____

Mailing Address: _____

Research Ethics Board Approval (e.g., HIC, ICEHR, SWGCERC) ___ Yes ___ No ___ N/A

Preferred Data Format: ___ Paper ___ Electronic File

Specify Month(s)/Year(s) Required: _____

Preferred Electronic File Format: ___ MS Access ___ MS Excel ___ MS Word

___ Text (Tab delimited) ___ CSV (Comma delimited) ___ SPSS ___ dBase IV

Specify Variables Needed:

Project Title:

Purpose of the request/Objective of the study:

Use of this information (please indicate all that applies and provide details about journals targeted, and the expected audience for presentations or any other forms of information dissemination):

Link to another data file Publication Grant application
 Poster presentation Oral presentation Information pamphlets

Contact Information:

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Date Received: _____
Category of Request: _____
Missing Attachments/Information: _____
Approval Date: _____
Contact Date: _____



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Data Use Agreement

The enclosed data set in electronic format/hard copy from the Provincial Perinatal Database is provided to

_____ for the project entitled:

_____.

Please read and initial each box to indicate your agreement with the statement.

- I certify that I have carefully read the Newfoundland and Labrador Provincial Perinatal Database Management, Access and Release Principles (attached), and will abide by these principles.
- I plan to work with this data file until _____ . After this date the data set will be returned to the PPP unless alternate arrangements for file erasure and destruction are made with the PPP.
- I will not distribute data to individuals outside the group identified in this proposal.
- I will use the data set only for the project identified above. Use of the data set for another project requires submission and approval of that project.

_____ (Signature)	_____ (Position)	_____ (Date)
_____ (Witness)	_____ (Position)	_____ (Date)