Canadian Perinatal HIV Surveillance Program

Data entry instructions

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1 Inclusion and exclusion criteria

This surveillance program is designed to prospectively capture information on all infants born to HIV infected mothers in Canada, as well as all HIV infected children receiving care in Canadian centres.

Inclusion criteria:

- All live-born infants born in Canada to mothers known to be living with HIV that are followed at the participating sites.

- All children living with HIV, regardless of country of birth, who acquired HIV through perinatal transmission and are receiving care at the participating sites.

- All children living with HIV who acquired HIV through means other than perinatal transmission, or where perinatal transmission is not certain, and are receiving pediatric care at the participating sites. This new group will be included as of 2020, and will be limited to children born since 2000, who acquired HIV prior to the age of 18

- HIV-uninfected siblings of children in the database are included only if they were born in Canada at a time after the mother acquired HIV infection.

Exclusion criteria:

- HIV-uninfected older siblings of children in the database who were born outside Canada.

- HIV uninfected older siblings of children in the database who were born in Canada, but prior to mother's HIV acquisition.

2 System requirements

It is recommended that you use the latest web browser software available for the best experience. The following are the recommended applications for Oracle Application Express.

Mozilla Firefox 35
Microsoft Internet Explorer 9
Google Chrome 40
Apple Safari 7

3 Log in to the database

- Go to **https://cphsp.hivnet.ubc.ca**

- Click on "Database Screen"

- Enter username and password

Log In

Username

Password

Log In

4 Welcome page

- Once logged in, the welcome page will show up.

Function	Please click on
Update contact information	
Change your password	
Log out	→ (top right with your username)
Go to record listing page to enter/review data	 (at the top or bottom of page) See section 5 for details

5 Record listing page

Function	Buttons to click
Review or edit data for existing record	✏️ (under one of the five data pages)
Add a new record	1) Click **➕ Add Patient** 2) Enter patient ID and click "Create" *Add Patient* dialog — Centre ID: BCCH, Patient ID: ___, **Create** 3) The record listing page is now filtered to show the newly added record. Click ✏️ under one of the five data pages to begin. See section 6 for instructions regarding each data page.
Sort listing by patient ID or birth year	**Patient ID** or **DOB Year** → ⬆️ or ⬇️ Ascending descending

Function	Buttons to click
Find a particular patient	**Patient ID** → (Filter... / BCCH-0001 / BCCH-0002) select from list *or* click on "Filter" → enter ID → select from list
Filter listing by child infection status	**Child Infected?** → (- / No / Unknown / Yes) Click on one of the values; "–" for status being blank
Filter listing by child birth year	**DOB Year** → (Filter... / 1987 / 1988 / 1989) select from list *or* click on "Filter" → enter year → "Enter"
Remove filter created above	[Go] [Actions ∨] ▼ ☑ ▼ Patient ID = 'BCCH-9999' ✕ (Click x)
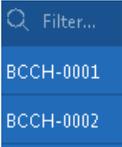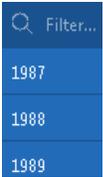
6 Data entry

6.1 General infomation

- To record the data into the database, you must click [Save] before leaving a data page. A green confirmation box will display. Click [×] to close the confirmation box.

- When you are at the bottom of the page, click [^] at the very bottom to quickly move back to the top.

- To navigate between data pages within a patient, please use the [Previous] and [Next] buttons. Do not use the "Back" or "Forward" button in the internet broswer. Please save the data before leaving a data page.
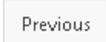
- A warning box will appear when you navigate away from a data page without saving. Selecting "Leave page" will discard all the changes.
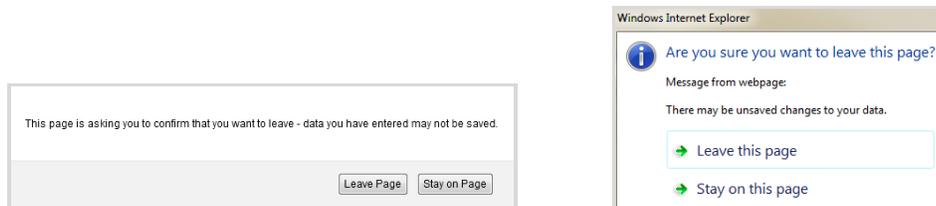
- After finish entering data for a particular patient, click [View/Add Patients] at the top to go back to the record listing page.

- There are restrictions as to what can be entered in some fields (e.g., numeric only) and logical checks on the data are automatically performed for some of the fields. If data are entered incorrectly, an error message will be displayed at the top and the data will NOT be saved. Please go back to the fields indicated and correct the data.
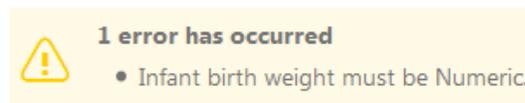
- Additional information regarding some fields can be found by clicking on (?) .

- Please be as comprehensive as possible when filling out these forms. If a piece of information is missing, however, select "unknown" from the drop-down list or leave the field blank if it is a text field.

Please refer to section 5 on how to create a new record for data entry

6.2 Child page

Country of birth	Select from the drop-down list. For quicker access, type the first letter of the country repeatedly until you are at the desired selection. For country not listed, please select "Other" and provide the country in the comment box. You can also select "Other-Caribbean" or "Other-Africa" if you only know the region, but not the exact country.
Siblings	Does the child have siblings <u>in this surveillance database</u>? If the child has siblings who do not meet the entry criteria, the answer should be "No".
Diagnostic HIV test	To enter a new test, click [Add Row] and enter data into the blank row. To delete a test, select the box ☐ beside the test, click [Delete]
Comments	If there are additional comments, please provide them in the comment field
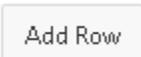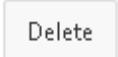
6.3 Mother & delivery page

Mother's ID	<u>If this child already has sibling(s) in the database, please type over with their mother's previous ID (as per the first sibling entered).</u>
Viral load closest to delivery	Viral load closest to delivery (copies/mL) [▼] [ ] Select from the list in the first box **or** Type in the number of copies/ml in the second box
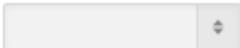
6.4 Perinatal antiretrovirals page

Drugs	If the drug is not in the drop-down list, please select "Other" and write the drug name in the comment field.

6.5 Child's infection/ immune status page

Congenital anomalies/ Other major events	If yes, please provide details.
Child infected	<u>For child with indeterminate HIV status, select "Unknown".</u> <u>Please update the HIV status once it is known.</u> <u>Not infected</u>: 2 separate negative PCR results at or after age 1 month and with no positive virologic test results. For children older than 18 months, one negative antibody test is sufficient. <u>Infected</u>: 2 separate HIV-PCR that are reactive (either 2 diagnostic HIV PCR or one diagnostic HIV PCR and one detectable viral load) OR one positive serology result at age>18 months.
Genotype	Genotype [♦] [ ] Select from the list in the first box **or** Enter the genotype in the second box
Comments	Additional information on infection and cause of death appreciated here.
Clinical/Immun status Antiretroviral Therapy and Viral Suppression	To create a new row, click [Add Row] and enter data into the blank row. There is a button that opens a document with the CDC guidelines. Also see section 7 for the same CDC guidelines. For VL, select from the list in the first box or type in the number of copies/ml in the second box

6.6 Transfer page

Transfers	These data are required to keep track of individuals that move between pediatric centres, are transferred to adult clinics, or leave the country. If you know the patient's ID from the old location, please enter it here.

7 Appendix – CDC classification

TABLE 1. Pediatric human immunodeficiency virus (HIV) classification*

Immunologic categories	Clinical categories			
	N: No signs/ symptoms	A: Mild signs/ symptoms	B:† Moderate signs/ symptoms	C:† Severe signs/ symptoms
1: No evidence of suppression	N1	A1	B1	C1
2: Evidence of moderate suppression	N2	A2	B2	C2
3: Severe suppression	N3	A3	B3	C3

*Children whose HIV infection status is not confirmed are classified by using the above grid with a letter E (for perinatally exposed) placed before the appropriate classification code (e.g., EN2).
†Both Category C and lymphoid interstitial pneumonitis in Category B are reportable to state and local health departments as acquired immunodeficiency syndrome.

See page 12 and 13 for more details.

TABLE 2. Immunologic categories based on age-specific CD4+ T-lymphocyte counts and percent of total lymphocytes

Immunologic category	Age of child					
	<12 mos		1–5 yrs		6–12 yrs	
	µL	(%)	µL	(%)	µL	(%)
1: No evidence of suppression	≥1,500	(≥25)	≥1,000	(≥25)	≥500	(≥25)
2: Evidence of moderate suppression	750– 1,499	(15–24)	500– 999	(15–24)	200– 499	(15–24)
3: Severe suppression	<750	(<15)	<500	(<15)	<200	(<15)

BOX 1. Diagnosis of human immunodeficiency virus (HIV) infection in children*

DIAGNOSIS: HIV INFECTED

a) A child <18 months of age who is known to be HIV seropositive or born to an HIV-infected mother **and:**

  - has positive results on two separate determinations (excluding cord blood) from one or more of the following HIV detection tests:
    — HIV culture,
    — HIV polymerase chain reaction,
    — HIV antigen (p24),

<div align="center">or</div>

  - meets criteria for acquired immunodeficiency syndrome (AIDS) diagnosis based on the 1987 AIDS surveillance case definition (*10*).

b) A child ≥18 months of age born to an HIV-infected mother or any child infected by blood, blood products, or other known modes of transmission (e.g., sexual contact) who:

  - is HIV-antibody positive by repeatedly reactive enzyme immunoassay (EIA) and confirmatory test (e.g., Western blot or immunofluorescence assay [IFA]);

<div align="center">or</div>

  - meets any of the criteria in a) above.

DIAGNOSIS: PERINATALLY EXPOSED (PREFIX E)

A child who does not meet the criteria above who:

  - is HIV seropositive by EIA and confirmatory test (e.g., Western blot or IFA) and is <18 months of age at the time of test;

<div align="center">or</div>

  - has unknown antibody status, but was born to a mother known to be infected with HIV.

DIAGNOSIS: SEROREVERTER (SR)

A child who is born to an HIV-infected mother and who:

  - has been documented as HIV-antibody negative (i.e., two or more negative EIA tests performed at 6–18 months of age or one negative EIA test after 18 months of age);

<div align="center">and</div>

  - has had no other laboratory evidence of infection (has not had two positive viral detection tests, if performed);

<div align="center">and</div>

  - has not had an AIDS-defining condition.

*This definition of HIV infection replaces the definition published in the 1987 AIDS surveillance case definition (*10*).

BOX 2. Clinical categories for children with human immunodeficiency virus (HIV) infection

CATEGORY N: NOT SYMPTOMATIC

Children who have no signs or symptoms considered to be the result of HIV infection or who have only one of the conditions listed in Category A.

CATEGORY A: MILDLY SYMPTOMATIC

Children with two or more of the conditions listed below but none of the conditions listed in Categories B and C.

- Lymphadenopathy (≥0.5 cm at more than two sites; bilateral = one site)
- Hepatomegaly
- Splenomegaly
- Dermatitis
- Parotitis
- Recurrent or persistent upper respiratory infection, sinusitis, or otitis media

CATEGORY B: MODERATELY SYMPTOMATIC

Children who have symptomatic conditions other than those listed for Category A or C that are attributed to HIV infection. Examples of conditions in clinical Category B include but are not limited to:

- Anemia (<8 gm/dL), neutropenia (<1,000/mm^3), or thrombocytopenia (<100,000/mm^3) persisting ≥30 days
- Bacterial meningitis, pneumonia, or sepsis (single episode)
- Candidiasis, oropharyngeal (thrush), persisting (>2 months) in children >6 months of age
- Cardiomyopathy
- Cytomegalovirus infection, with onset before 1 month of age
- Diarrhea, recurrent or chronic
- Hepatitis
- Herpes simplex virus (HSV) stomatitis, recurrent (more than two episodes within 1 year)
- HSV bronchitis, pneumonitis, or esophagitis with onset before 1 month of age
- Herpes zoster (shingles) involving at least two distinct episodes or more than one dermatome
- Leiomyosarcoma
- Lymphoid interstitial pneumonia (LIP) or pulmonary lymphoid hyperplasia complex
- Nephropathy
- Nocardiosis
- Persistent fever (lasting >1 month)
- Toxoplasmosis, onset before 1 month of age
- Varicella, disseminated (complicated chickenpox)

CATEGORY C: SEVERELY SYMPTOMATIC

Children who have any condition listed in the 1987 surveillance case definition for acquired immunodeficiency syndrome (*10*), with the exception of LIP (Box 3).

BOX 3. Conditions included in clinical Category C for children infected with human immunodeficiency virus (HIV)

CATEGORY C: SEVERELY SYMPTOMATIC*

- Serious bacterial infections, multiple or recurrent (i.e., any combination of at least two culture-confirmed infections within a 2-year period), of the following types: septicemia, pneumonia, meningitis, bone or joint infection, or abscess of an internal organ or body cavity (excluding otitis media, superficial skin or mucosal abscesses, and indwelling catheter-related infections)
- Candidiasis, esophageal or pulmonary (bronchi, trachea, lungs)
- Coccidioidomycosis, disseminated (at site other than or in addition to lungs or cervical or hilar lymph nodes)
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis or isosporiasis with diarrhea persisting >1 month
- Cytomegalovirus disease with onset of symptoms at age >1 month (at a site other than liver, spleen, or lymph nodes)
- Encephalopathy (at least one of the following progressive findings present for at least 2 months in the absence of a concurrent illness other than HIV infection that could explain the findings): a) failure to attain or loss of developmental milestones or loss of intellectual ability, verified by standard developmental scale or neuropsychological tests; b) impaired brain growth or acquired microcephaly demonstrated by head circumference measurements or brain atrophy demonstrated by computerized tomography or magnetic resonance imaging (serial imaging is required for children <2 years of age); c) acquired symmetric motor deficit manifested by two or more of the following: paresis, pathologic reflexes, ataxia, or gait disturbance
- Herpes simplex virus infection causing a mucocutaneous ulcer that persists for >1 month; or bronchitis, pneumonitis, or esophagitis for any duration affecting a child >1 month of age
- Histoplasmosis, disseminated (at a site other than or in addition to lungs or cervical or hilar lymph nodes)
- Kaposi's sarcoma
- Lymphoma, primary, in brain
- Lymphoma, small, noncleaved cell (Burkitt's), or immunoblastic or large cell lymphoma of B-cell or unknown immunologic phenotype
- *Mycobacterium tuberculosis*, disseminated or extrapulmonary
- *Mycobacterium*, other species or unidentified species, disseminated (at a site other than or in addition to lungs, skin, or cervical or hilar lymph nodes)
- *Mycobacterium avium* complex or *Mycobacterium kansasii*, disseminated (at site other than or in addition to lungs, skin, or cervical or hilar lymph nodes)
- *Pneumocystis carinii* pneumonia
- Progressive multifocal leukoencephalopathy
- Salmonella (nontyphoid) septicemia, recurrent
- Toxoplasmosis of the brain with onset at >1 month of age
- Wasting syndrome in the absence of a concurrent illness other than HIV infection that could explain the following findings: a) persistent weight loss >10% of baseline OR b) downward crossing of at least two of the following percentile lines on the weight-for-age chart (e.g., 95th, 75th, 50th, 25th, 5th) in a child ≥1 year of age OR c) <5th percentile on weight-for-height chart on two consecutive measurements, ≥30 days apart PLUS a) chronic diarrhea (i.e., at least two loose stools per day for ≥30 days) OR b) documented fever (for ≥30 days, intermittent or constant)

*See the 1987 AIDS surveillance case definition (*10*) for diagnosis criteria.