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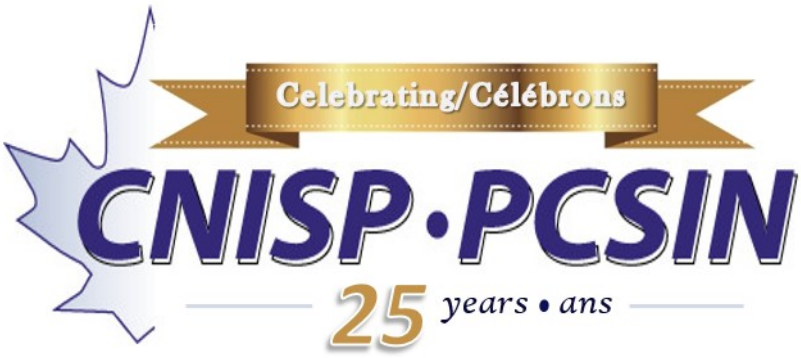

Canadian Nosocomial Infection Surveillance Program

Surveillance of Surgical Sites Infections Following Pediatric Cardiac Surgery

Pediatric Cardiac SSI Surveillance Protocol

Contact Information

Please direct all questions to:

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Working Group

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OBJECTIVES

To establish ongoing surveillance of pediatric surgical site infections (SSIs) associated with cardiac surgery within the CNISP hospital network. Specific objectives of this surveillance are:

1. To determine rates of healthcare-associated cardiac SSIs in children < 18 years of age across Canada
2. To identify risk factors for pediatric cardiac SSIs
3. To provide data for the development of guidelines on prevention and control of pediatric cardiac SSIs

METHODS

Site Eligibility

All hospitals that are part of the CNISP network and perform pediatric open heart cardiac surgeries.

Patient Population

Ongoing, prospective surveillance of SSI in children (< 18 years of age) following open-heart cardiac surgeries.

Inclusion Criteria

- ✓ Surgery performed at your CNISP site
- ✓ Surgeries where patient is on cardiopulmonary bypass

Exclusion Criteria

Surgeries in which the patient died in the operating room or within 24 hours of surgery.

Surveillance Period

Infections that develop within 90 days (3 months) of surgery (or 30 days if classified as superficial SSI) will be included and reported retrospectively based on date of surgery.

Numerators

The primary outcome measure is a healthcare-associated SSI following open-heart surgery with cardiopulmonary bypass among pediatric patients, defined according to the National Health and Safety Network (NHSN) definitions as outlined in the CASE CLASSIFICATION section below and in APPENDIX 1 – CASE CLASSIFICATION ALGORITHM.

Patients less than 18 years of age with post open-heart cardiac surgery SSIs with cardiopulmonary bypass will be identified at each CNISP site through the most comprehensive method to detect procedures and SSI cases. This may include:

- Review of microbiology laboratory results
- Review of patient charts
- Review of physician notes
- Notifications by clinical personnel
- Review of internal patient safety data collection systems

Case Classification

1. Superficial Incisional SSI

Infection occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision and meets at least **ONE** of the following criteria:

Criteria 1: Purulent drainage from the superficial incision.

Criteria 2: Organisms isolated from an aseptically-obtained culture of fluid or tissue from the superficial incision.

Criteria 3: Patient has at least one of the following signs or symptoms: localized pain or tenderness; localized swelling; erythema; or heat AND superficial incision that is deliberately opened by a surgeon, attending physician* or other designee and culture or non-culture based testing of the superficial incision or subcutaneous tissue is not performed.

A culture-negative finding does not meet this criterion

Criteria 4: Diagnosis of superficial incisional SSI by the surgeon or attending physician.

2. Deep Incisional SSI

Infection occurs within 90 days (3 months) after the operative procedure and the infection appears to be related to the operative procedure AND involves deep soft tissues (e.g., facial and muscle layers) of the incision AND the patient has at least **ONE** of the following:

Criteria 1: Purulent drainage from the deep incision but not from the organ/space component of the surgical site.

Criteria 2: Deep incision spontaneously dehisces or is deliberately opened by the surgeon, attending physician*or other designee and is culture-positive or not cultured and the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness.

A culture-negative finding does not meet this criterion

Criteria 3: An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

3. Organ/space SSI

Infection occurs within 90 days (3 months) after the operative procedure and the infection appears to be related to the operative procedure **AND** infection involves any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure **AND** patient has at least **ONE** of the following:

Criteria 1: Purulent drainage from a drain that is placed into the organ/space.

Criteria 2: Organisms isolated from culture of fluid or tissue in the organ/space for purposes of clinical diagnosis or treatment.

Criteria 3: An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

AND meets at least one of the following criterion for a specific organ/space infection site listed in the table below:

Category	Specific Site	Category	Specific Site
BONE	Osteomyelitis	**MED**	Mediastinitis
CARD	Myocarditis or pericarditis	**ENDO**	Endocarditis
IAB	Intraabdominal, not specified elsewhere	**LUNG**	Other infections of the lower respiratory tract
VASC	Arterial or venous infection		

Denominators

Each participating hospital will submit the following denominator data:

a) The number of open-heart surgeries with cardiopulmonary bypass
b) The number of surgeries as above with delayed sternum closures by setting

As per NHSN guidelines, a single trip to the operating room, in which multiple procedures are performed, will be counted as a single contribution to denominator data. Patients can potentially be included in the denominator data more than once during the surveillance period if they have multiple open heart surgeries involving separate trips to the operating room.

Data Submission

Cases

For each case meeting the criteria for a Cardiac SSI, a Pediatric Cardiac SSI Patient Questionnaire should be completed on CNPHI Appendix 2 – Pediatric Cardiac SSI Patient Questionnaire. For instructions on how to find the Pediatric Cardiac SSI Patient Questionnaire on CNPHI's Collaboration Center under Web Data forms see Appendix 4 – Web Data Form Submission CNPHI.

Surgery Performed at another CNISP Site

If the hospital identifying the infection is not the one where the surgery was performed, the hospital is asked to notify the hospital where the surgery was performed. If the hospital that has performed the surgery is a CNISP site, then the SSI should be reported to CNISP if they participate in this surveillance project.

Reporting a second SSI (same surgery)

If a second SSI develops following the same surgery, please complete another patient questionnaire and assign the same unique patient identifier number with a lower case letter (e.g., 07A18001**b**).

Zero Report

For no cases at your site, a zero report must be submitted so that zero counts can be differentiated from missing data. If no cases are submitted and you are missing zero reports for a surveillance year, your hospital data will not be included in rates. Zero case status is collected via the Pediatric Cardiac SSI Denominator and Zero Report Form under Web Data on CNPHI Appendix 3 – Pediatric Cardiac SSI Denominator and Zero Report Form. For instructions on how to find the Pediatric Cardiac SSI Denominator Form on CNPHI's Collaboration Center under Web Data forms see Appendix 4 – Web Data Form Submission CNPHI.

Denominators

The number of open heart procedures performed on all pediatric patient (<18 years) in your facility for the calendar year are collected via the Pediatric Cardiac SSI Denominator Form under Web Data on CNPHI Appendix 3 – Pediatric Cardiac SSI Denominator and Zero Report Form. For instructions on how to find the Pediatric Cardiac SSI Denominator Form on CNPHI's Collaboration Center under Web Data forms see Appendix 4 – Web Data Form Submission CNPHI.

NOTE: *When entering data into CNPHI, please ensure that the case is entered in the correct surveillance year based on the date of procedure and NOT the date the infection was identified (e.g. procedure Dec 20, 2019; infection identified Jan 17, 2020 – this is a 2019 case).*

Numerator (cases)	Patient questionnaires due by Sep 30th	Patient questionnaires due by Dec 31st	Patient questionnaires due by Mar 31st of the following year	Patient questionnaires due by June 30th of following year
Denominators /Zero Report	Due by March 31st of the following year			

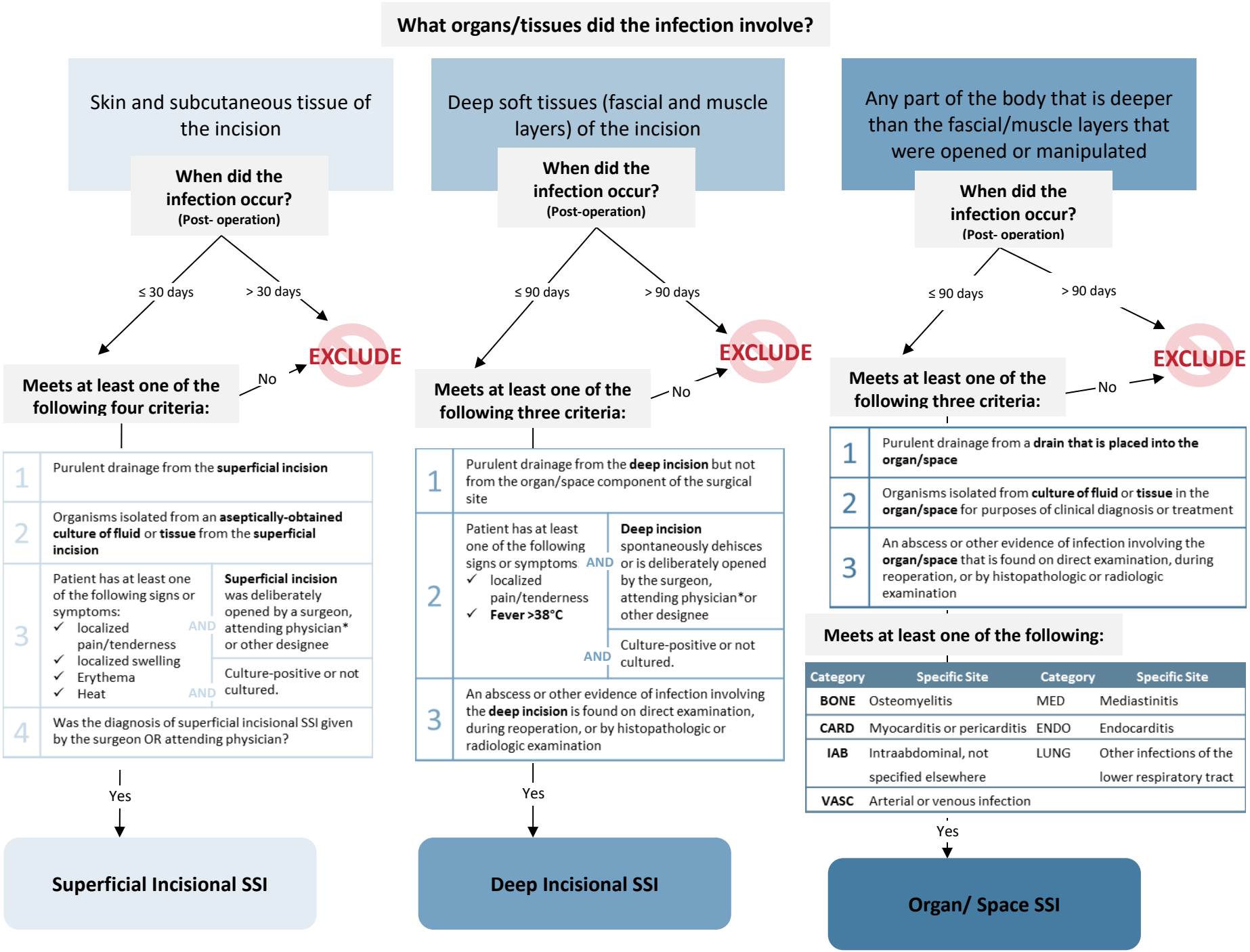
ETHICS

While this surveillance project is observational and does not involve any alteration in patient care, ethics approval may be sought at some hospital sites. Surveillance for healthcare-associated infections is a routine component of quality assurance and patient care in Canadian healthcare institutions and therefore, informed consent is not required. A unique identifier linked to patient name will only identify patients at the local CHEC site and is not transmitted to the Public Health Agency of Canada. All data submitted to the Public Health Agency of Canada is kept strictly confidential.

PRIVACY

There is current demand for public disclosure of hospital-associated infections. Any data released by CNISP will be in summary format and will not identify individual hospitals. Hospital administrators should be made aware that national reporting of aggregate data will occur.

Appendix 1 – Case Classification Algorithm



Appendix 2 – Pediatric Cardiac SSI Patient Questionnaire

1.	CHEC Site: _____	
2.	Unique Patient ID: _____ YY _____ (e.g. 99A19001) *(CHEC site #) (Surveillance year) (case number)*	
3.	Date of birth:	____ /_____ /_____ *DD MMM YYYY*
4.	Sex:	☐ Male ☐ Female
5.	Date SSI identified:	_____ /_____ /_____ *DD MMM YYYY*
6.	Does this patient have or meet the criteria for (please check <u>one</u> the following): (Please see CASE CLASSIFICATION for definitions)	☐ **SUPERFICIAL** incisional SSI ☐ **DEEP** incisional SSI ☐ **ORGAN/SPACE** SSI
7.	Microbiology investigation	☐ Positive culture ☐ Negative culture (go to question 11) ☐ Not cultured (go to question 11)
8.	Site of positive culture:	☐ Incision (e.g. chest) ☐ Other, please specify: _____
9.	Pathogen(s) isolated: (Please check **all** that apply)	☐ *Staphylococcus aureus* MRSA ☐ Yes ☐ No ☐ Coagulase-negative staphylococci ☐ *Enterococcus* species VRE ☐ Yes ☐ No ☐ *Streptococci* species, specify:_____ ☐ *Enterobacter* species ☐ *Klebsiella pneumoniae* ☐ *Escherichia coli* ☐ *Acinetobacter baumannii* ☐ *Klebsiella oxytoca* ☐ *Pseudomonas aeruginosa* ☐ *Candida* species ☐ Other: _____

10. Please indicate the organism(s) susceptibility/resistance for any of the following antimicrobials/anti-fungals listed below: (R for resistant, S for susceptible, I for intermediate)

	Genus species of Organism1: _____	Genus species of Organism 2: _____	Genus species of Organism 3: _____
Amikacin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Amphotericin B	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Ampicillin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Amoxicillin-clavulanic acid	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Caspofungin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Cefazolin (Ancef)	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Cephalexin (Keflex)	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Cefepime	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Cefotaxime	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Ceftriaxone	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Cefuroxime	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Ciprofloxacin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Clindamycin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Cloxacillin / Oxacillin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Ertapenem	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Fluconazole	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Gentamicin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Imipenem	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Levofloxacin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Linezolid	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Meropenem	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Micafungin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Moxifloxacin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Penicillin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Piperacillin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Piperacillin-tazobactam	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Rifampin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Ticarcillin-clavulanic acid	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Trimthoprim-sulfamethoxazole	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Tobramycin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Vancomycin	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Voriconazole	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Other, specify : _____	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S
Other, specify : _____	□ R □ I □ S	□ R □ I □ S	□ R □ I □ S

11.	Date of surgery:	_____ /_____/_____ *DD* *MMM* *YYYY*

12.	Type of surgery: (Please check all that apply)	☐ Repair of congenital defect (please check all that apply): ☐ Ventricular septal defect (VSD) ☐ Atrial septal defect (ASD) ☐ Coarctation of the aorta ☐ Tetralogy of Fallot (TOF) ☐ Transposition of the great vessels ☐ Truncus arteriosus ☐ Tricuspid atresia ☐ Total anomalous pulmonary venous return (TAPVR) correction ☐ Hypoplastic left heart repair ☐ Other, specify: _____ ☐ Heart transplant ☐ Valve replacement ☐ AVR ☐ MVR
13.	Delayed sternum closure	☐ Yes ☐ No (go to question 16)
14.	Location where sternum was closed	☐ ICU ☐ OR ☐ Other: _____
15.	Date when sternum was closed	_____ /_____ /_____ ☐ Not available *DD* *MMM* *YYYY*
16.	Outcome 30 days within onset of infection (Check ONLY one)	☐ Alive in your ICU ☐ Alive in your hospital, out of ICU ☐ Discharged ☐ Deceased (in hospital) ☐ Unknown
17.	If deceased, relation to SSI? (Check ONLY one – as judged by reviewing physician)	☐ Direct cause ☐ Indirect (contributing) ☐ Unrelated ☐ Cannot determine

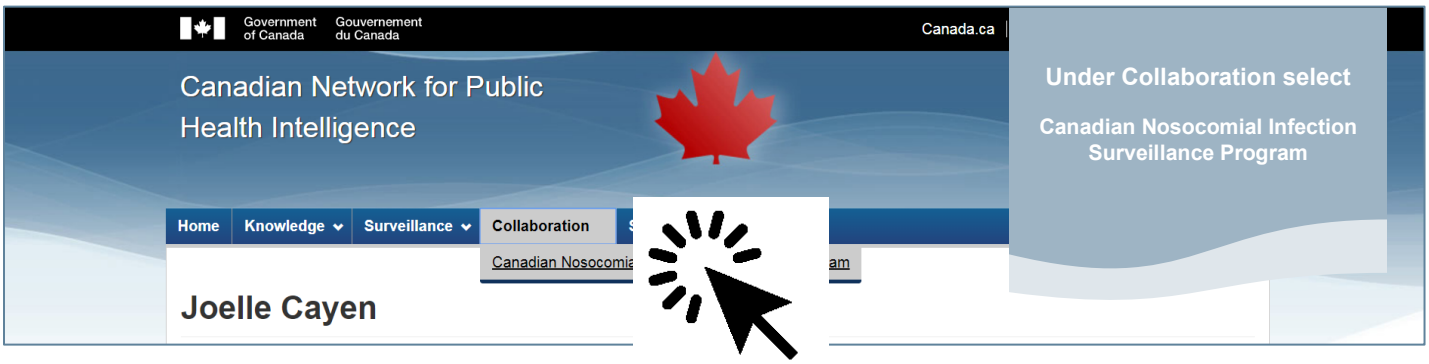
Appendix 3 – Pediatric Cardiac SSI Denominator and Zero Report Form

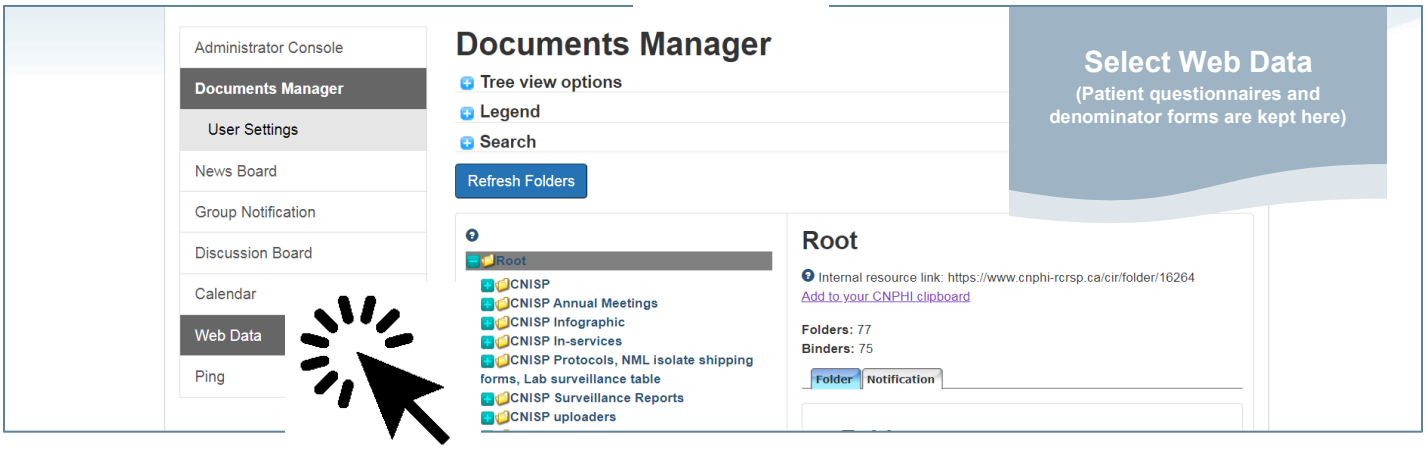
1.	CHEC Site: _____
2.	Surveillance period: (e.g. Jan 1, 2018 to Dec 31, 2018): _____
3.	Please record the number of open heart procedures performed on all pediatric patient (<18 years) in your facility for the calendar year (e.g. January 1, 2018 to December 31, 2018):

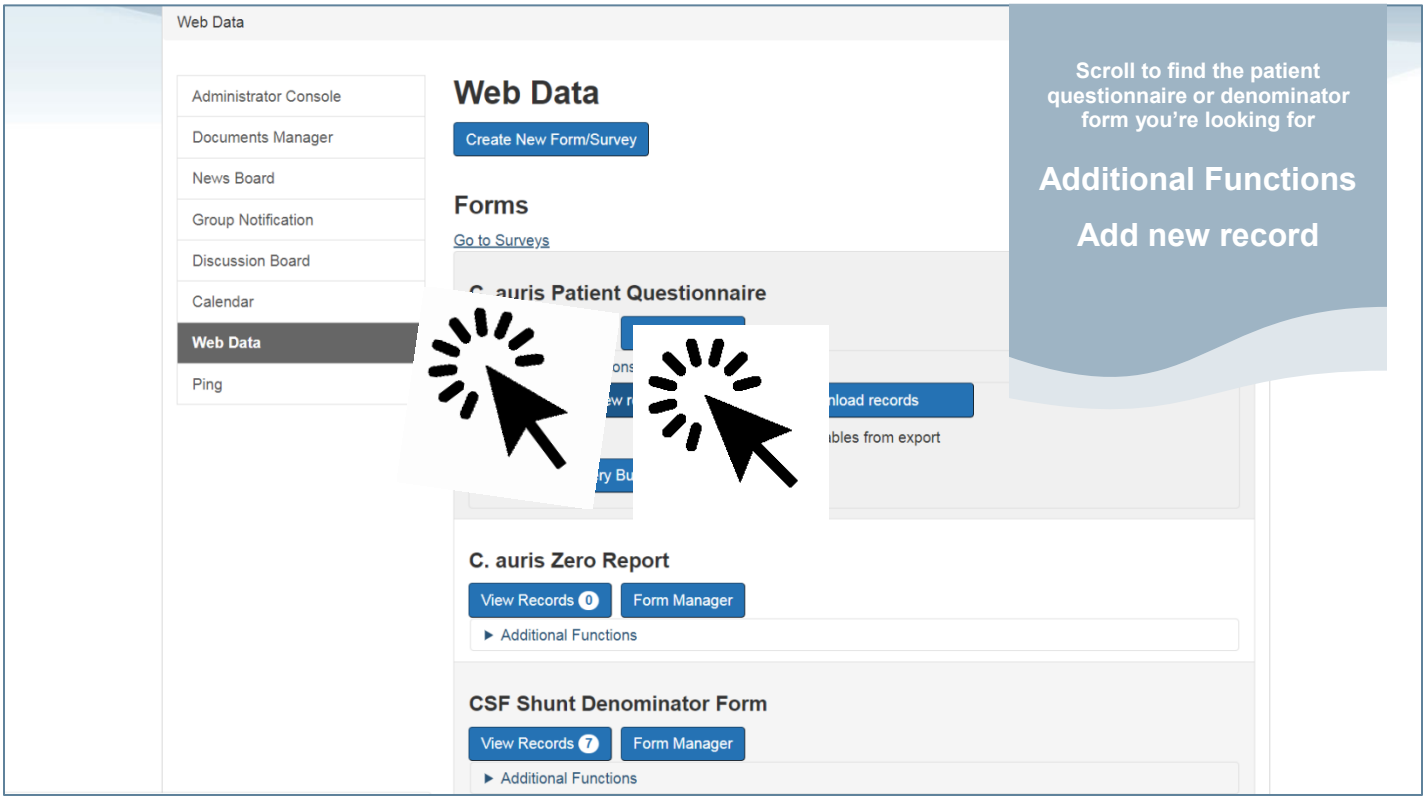
	Sternum closed in OR at the time of initial surgery	**Delayed sternum closure**				**Total**
		ICU	**OR**	**Unknown**	**Total**	
Total						

4.	For the surveillance year specified above, were there zero (0) cases reported for your site? ☐ Yes ☐ No

Appendix 4 – Web Data Form Submission CNPHI







Revision History

Date	Revisions Made
December 2018	Removed surveillance year as protocol will no longer be updated annually
December 2019	○ Updated formatting ○ Updated Case Classification Definitions according to NHSN definitions ○ Updated Data collection and Reporting (now Data Submission) to account for the new form on the Collaboration center of CNPHI under Web Data ○ Also Added Appendix 4 (Instructions on how to access these forms)