

Surgical Site Infections following Cardiac Implantable Electronic Devices (CIED) Protocol

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Introduction

Surgical site infections (SSIs) following cardiac implantable electronic device (CIED) surgery is associated with substantial patient morbidity, increased mortality, and increased health system costs (Greenspon et al, 2008). CIEDs include pacemakers, implantable cardioverter defibrillators (ICD), and cardiac resynchronization therapy (CRT) devices which consist of a generator (placed subcutaneously or submuscularly) and leads (placed transvenously). Accordingly, CIED infections can include local infections such as pocket infections (involving only the generator) but can also include more severe systemic infections including bloodstream infections and infective endocarditis associated with the leads (Joy et al, 2017).

The ability to track SSIs is essential for monitoring quality of patient care. Unfortunately, there is no provincial or national strategy for comprehensive monitoring and reporting of CIED infection. Reasons for this include the personnel time and costs associated with traditional infection surveillance methods.

An alternate approach uses administrative data (or data collected through electronic health records) to identify CIED infections. This approach is less expensive and can be automated. This administrative surveillance approach was requested by the surgical and IPC partners involved in these areas within Alberta, but will be augmented by an additional investigation into cases by members of the IPC program on a quarterly or annual basis. This protocol outlines the methods for using administrative data to prospectively collect CIED follow up data to monitor trends for infection surveillance and the annual process for validating these cases.

In conjunction with the CIED surveillance protocol, there are four supporting documents to assist in the interpretation and practical use of this protocol:

- General Surveillance Definitions ([Appendix A](#))
- Protocol – specific Definitions ([Appendix B](#))
- Casefinding process ([Appendix C](#))
- SSI User Guide (Alberta Health Services, 2018).

Goal

To decrease rates of SSIs following CIED procedures in Alberta Health Services (AHS) and Covenant Health facilities.

Objectives

1. To determine hospital and provincial SSI rates for CIED procedures performed in Alberta.
2. To assess the quality of administrative data for monitoring SSI rates following CIED procedures.
3. To provide usable data leading to interventions aimed at reducing the rate of SSIs for patients undergoing CIED procedures.
4. To investigate increases in SSI rates.
5. To establish annual SSI incidence rates for trend analysis over time and to compare with internal and external benchmarks.

Methodology

Patient population

All adult patients at AHS/Covenant Health acute care facilities where CIED procedures are performed.

Protocol implementation date

April 1, 2023

Case definition

Administrative data

Surveillance for CIED SSIs will be performed for all included procedures until 90 days after the date of the surgical procedure using administrative databases (DAD for inpatient and NACRS for outpatient). These health encounters will be flagged as meeting criteria for complex (deep or organ/space) CIED SSI if the following ICD-10-CA administrative codes are identified in ANY diagnosis position (primary or secondary). Superficial incisional SSI will not be tracked using administrative data.

Description	ICD-10-CA Codes
ICD-10-CA codes for CIED Infection (any of)	T82.7x T85.7 I33.0 I33.9 I38.x I39.8 L03.30 L03.39 L03.8 L03.9

The algorithm for identifying CIED infection via administrative data was validated for complex CIED SSIs. (Rennert-May et al, 2022). The clinical rationale for focusing on Deep and Organ/Space SSIs is that these SSIs have a longer duration of antibiotics for treatment, surgical intervention for source control of infection, and lengthy hospital stays while patients await CIED reimplantation.

Annual review by ICPs

On an annual basis, cases identified through this administrative linkage will be sent back to ICPs to confirm that the infection met the NHSN definition of a deep or organ/space infection (see [Appendix B](#) for SSI definition), according to the Centre for Disease Control/National Healthcare Safety Network (CDC, 2025) . Once confirmed, the ICP is responsible for entering the case into the provincial surveillance platform.

Inclusion criteria

- Surgeries involving CIED implantation: (1) pacemaker, (2) implantable cardioverter defibrillator, (3) cardiac resynchronization therapy
- Deep incisional or organ/space SSI
- Revisions (i.e. generator replacement or CIED replacement).

Exclusion criteria

- Procedures in patients under 18 years of age.

- Procedures in which the patient died within 24 hours.
- Reoperations via same incision within 3 days are excluded from the denominator; however, the initial procedure is still followed for the development of an SSI.

Case detection while in an AHS/Covenant Health facility can involve review of any of the following:

- Discharge Abstract Database (DAD) for inpatient surgeries
- National Ambulatory Care Reporting System (NACRS) for outpatient surgeries performed within an AHS/Covenant Health facility

ICP Review and use of NHSN definitions to determine if true cases

Attributing SSI to a NHSN procedure when several are performed on different dates: If a patient has several NHSN operative procedures performed on different dates prior to an infection, attribute the SSI to the operative procedure that was performed most closely in time prior to the infection date, unless there is evidence that the infection was associated with a different operation (Centers for Disease Control and Prevention (CDC, 2024). For example,

Example #1: A patient has an initial pacemaker implantation followed by a lead repositioning a month later. Any CIED infections subsequent to the lead repositioning would be attributed to the lead repositioning surgery.

Data collection and data entry

CIED SSIs via administrative data

- To identify complex SSIs (deep and organ/space SSIs), patients will be followed for 90 days using administrative databases (DAD for inpatient and NACRS for outpatient). These health encounters will be flagged as meeting criteria for complex CIED SSI according to specific ICD-10-CA administrative codes are identified in ANY diagnosis position (primary or secondary).
- Denominator data will also be obtained through DAD/NACRS (see Denominator section of protocol).

CIED SSIs annual validation by infection control professionals

- On an annual basis, cases identified using the administrative process will be sent to ICPs for review and confirmation that the NHSN deep or organ/space SSI definition was met. ICPs will have six weeks to review cases and enter them into the Provincial Surveillance platform.
- Should case identification via administrative data prompt further IPC case review, a positive culture is not required for diagnosis of CIED infection as up to 25% of cases may be culture negative (Viola et al, 2017).

Minimum case information

Basic demographic, facility and possible microbiological data will be collected for cases and entered into the Provincial Surveillance Platform as part of the annual review, including:

- Name
- Date of birth
- Gender
- Alberta Personal Healthcare Number (PHN) or Unique Lifetime Identifier (ULI)
- Connect Care Medical Record Number (MRN)
- Admission date to reporting facility (i.e. date of admission for CIED SSI, if applicable)
- Culture date, laboratory name, accession number and cultured site (if applicable)

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- Date of surgery and facility where implant performed
- Type of surgery (pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy, generator replacement)
- Infection type (Deep incisional or Organ/space).

Denominator data

Denominators (i.e., number of index CIED surgeries) will be derived from DAD and NACRS patients who have an eligible procedural code, limited to the following Alberta Health Services Facilities that perform CIED surgeries:

- Foothills Medical Center, Calgary Zone
- Chinook Regional Hospital, South Zone
- Red Deer Regional Hospital, Central Zone
- Mazankowski Alberta Heart Institute, Edmonton Zone
- Royal Alexandra Hospital / CK Hui Heart Institute, Edmonton Zone
- Grey Nuns Hospital, Edmonton Zone

The overall denominator will be the number of unique encounters in DAD or NACRS with any one of the following CCI codes. We will also collect denominator by device type (i.e., pacemaker, ICD, and CRT) in order to calculate SSI rates by CIED type. These procedural codes are as follows:

	CCI Codes	Description
Pacemaker	1HZ53GRNK	Implantation of dual chamber rate responsive pm
	1HZ53GRNL	Implantation of fixed rate pm
	1HZ53GRNM	Implantation of single chamber rate responsive PM
	1HZ53LANK	Open approach to dual chamber rate responsive PM
	1HZ53LANL	Open approach to fixed rate PM
	1HZ53LANM	Open approach to single chamber rate responsive pm
	1HZ53QANK	Open subxiphoid approach to dual chamber rate responsive pm
	1HZ53QANL	Open subxiphoid approach to fixed rate pm
	1HZ53QANM	Open subxiphoid approach to single chamber rate responsive Pm
ICD	1HZ53HAFS	Implantation of internal device, heart NEC percutaneous approach (to tunnel subcutaneously) cardioverter/defibrillator [AICD]
	1HZ53HNFS	Percutaneous approach to cardioverter/defibrillator
	1HZ53GRFS	Implantation of cardioverter-defibrillator
	1HZ53LAFS	Open approach to cardioverter/defibrillator
	1HZ53SYFS	Combined open and percutaneous approach to cardioverter/defibrillator
CRT	1HZ53SYFU	Combined open and percutaneous approach to CRT defibrillator
	1HZ53GRFR	Implantation of CRT pacemaker
	1HZ53GRFU	Implantation of CRT defibrillator
	1HZ53LAFU	Implantation of CRT defibrillator
	1HZ53LAFR	Open approach to CRT pm
	1HZ53SYFR	Combined open and percutaneous approach to CRT pm

Of clinical interest are the infection rates associated with a subset of CIED surgeries where the battery of the CIED is replaced (i.e. generator replacement) or the CIED is replaced. These will be considered revisions and identified based on the following administrative definition: any of the following removal codes:

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Removal Codes	1HZ55GP ^{^^}	Removal of device, heart NEC, percutaneous transluminal approach
	1HZ55LAFR	Removal of device, heart NEC, cardiac resynchronization therapy pacemaker [CRT, CRT-P, Biventricular pacemaker], open approach (e.g. sternotomy)
	1HZ55LAFS	Removal of device, heart NEC, cardioverter/defibrillator [AICD], open approach (e.g. sternotomy)
	1HZ55LAFU	Removal of device, heart NEC, cardiac resynchronization therapy defibrillator [CRT-D, BiV-ICD], open approach (e.g. sternotomy)
	1HZ55LANK	Removal of device, heart NEC, dual chamber rate responsive pacemaker, open approach (e.g. sternotomy)
	1HZ55LANL	Removal of device, heart NEC, fixed rate pacemaker, open approach (e.g. sternotomy)
	1HZ55LANM	Removal of device, heart NEC, single chamber rate responsive pacemaker, open approach (e.g. sternotomy)
	1HZ55QA ^{^^}	Removal of device, heart NEC, open subxiphoid approach
	1YY54LAFS	Management of internal device, skin of surgically constructed sites, of cardioverter or defibrillation device using open (subcutaneous) approach
	1YY54LANM	Management of internal device, skin of surgically constructed sites, of cardiac pacemaker battery/generator using open (subcutaneous) approach
	1YY55LAFS	Removal of internal device, skin of surgically constructed sites, of cardioverter or defibrillation device using open (subcutaneous) approach
	1YY55LANM	Removal of internal device, skin of surgically constructed sites, of cardiac pacemaker battery/generator using open (subcutaneous) approach

Note: It is possible that a generator may be removed and not replaced; however, this may be challenging to identify in the administrative dataset – If identified, they will be excluded from the denominator.

Rate calculation

Rates	Calculations
Pacemaker Infection Rate (per 100 procedures)	<u>Number of infections among Pacemaker Cases</u> X 100 procedures Number of Pacemakers
ICD Infection Rate (per 100 procedures)	<u>Number of infections among ICD Cases</u> X 100 procedures Number of ICDs
CRT Infection Rate (per 100 procedures)	<u>Number of infections among CRT Cases</u> X 100 procedures Number of CRTs
Revision Infection Rate (per 100 procedures)	<u>Number of infections among Revision cases</u> X 100 procedures Number of Generator Replacement Surgeries
TOTAL Infection Rate (per 100 procedures)	<u>Number of infections</u> X 100 procedures Number of CIEDs (pacemaker + ICD + CRT+ revisions)

Note: Only complex SSI (deep incisional and organ/space) will be reported.

Comparator rates

Internal rates are used as comparators. The internal rates are the historical rates for the province or facility from the previous fiscal year.

Reporting

Communication and dissemination of surveillance reports is an integral part of surveillance to inform IPC practice within AHS and Covenant Health facilities and provide support for interventions that improve the quality of patient care delivered. Responsibility for compiling, reporting, and disseminating data and reports is

shared between provincial IPC Surveillance and Standards and the provincial IPC program. IPC Surveillance and Standards will generate annual reports once internal case validation of the administrative data is complete.

The reports contain information on the facility and provincial level and are presented to the provincial IPC Surveillance, Evaluation, Quality Improvement and Research committee for approval. Operational reports are created by local ICPs or their designate and may or may not consist of reconciled and validated data, as they are often created with real-time, as is, data.

Data quality

The purpose of evaluating the quality of data is to ensure that SSI-related events are being monitored efficiently and effectively. The evaluation should involve the assessment of the program (i.e., the protocol and reporting) and system (i.e., electronic data collection tool) attributes, including relevance, simplicity, flexibility, data quality, acceptability, consistency, representativeness, timeliness and stability. Additionally, with the increasing use of technology, informatics concerns for surveillance systems need to be addressed. These include evaluating hardware and software, using a standard user interface, applying standard data formatting and coding, performing quality checks and adhering to confidentiality and security standards.

A standardized approach is used to reconcile and validate the data provincially. The first component of data reconciliation and validation of data in the provincial surveillance platform ensures that demographic data is valid and reliable. The second component entails ensuring that the SSI-related events are entered in a manner that is consistent with the protocol definitions.

A pilot project (Rennert-May, 2022) was performed to validate the use of administrative data for identifying complex surgical site infections. In brief, a cohort of adult patients who underwent de novo CIED implantation (including pacemaker (PM), ICD, or CRT) or generator replacement between January 1, 2013 and December 31, 2019 were reviewed retrospectively for the development of a CIED infection within one year of surgery through a manual chart review. CIED infections were adjudicated using the Centers for Disease Control and Prevention/National Healthcare Safety Network (NHSN) standardized definitions for complex SSIs (i.e., deep or organ space). These “gold standard” CIED infections were then used to validate infections identified through administrative coding data from the International Classification of Diseases-10th revision in Canada (ICD-10-CA) and Canadian Classification of Health Intervention (CCI) administrative codes (<https://www.cihi.ca/en/cci-coding-structure>). This project determined that all of the pre-selected algorithms performed well at identifying CIED infections. The algorithm selected had an area under the receiver operating characteristic curve of 94.6%, a sensitivity of 90.6% and specificity of 98.6%.

Following this administrative identification of potential cases, each case will be reviewed by the IPC program. Final designation of cases is a collaborative effort between the facility-based ICPs and the epidemiologists/analysts of the IPC Surveillance and Standards team

Data quality working group

The IPC Surveillance Data Quality Working Group reports to the IPC Surveillance, Evaluation, Quality Improvement and Research committee and is responsible to develop, review and update indicator protocols to include the precise methodology for data collection to ensure consistency. Decisions from the Data Quality Working Group on specific protocol questions are communicated to provincial ICPs through the Data Quality Forum and will be included in the protocol User Guide. These decisions will be considered to be supplemental to the protocol and will be incorporated into the protocol when revised.

Protocol revision history

Date	Details
March 2025	Surveillance approach approved at SEQIR
December 2025	Protocol approved at SEQIR

References

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Appendix A: General surveillance definitions

Terms	Definitions
Encounter types	<p>Type of AHS/Covenant Health healthcare location or facility where the patient is located at the time of identification. The following encounter types are referred to in acute care surveillance protocols (Government of Alberta, 2008; Government of Alberta, 2024).</p> <ul style="list-style-type: none"> • Inpatient acute care: Refers to a General Hospital: According to the Hospitals Act, a general hospital is defined as a “hospital providing diagnostic services and facilities for medical or surgical treatment in the acute phase for adults and children and obstetrical care” (Government of Alberta, 2024). General hospitals have several functional centres. Each functional centre is associated with inpatient, outpatient, or diagnostic and therapeutic services. • Inpatient mental health/rehab: A designated mental health facility providing diagnosis and treatment for mental illness and addiction in the acute phase for adults and children. Inpatient services refer to a person admitted to and assigned a bed in a facility by order of a physician for provision of diagnostic and/or treatment services. They would have a patient/group room in which inpatient services are provided within the patient’s room or within a common group room within the designated mental health facility. AHS facility examples include Glenrose Rehabilitation Hospital, Centennial Centre for Mental Health and Brain Injury.
Infection prevention and control baseline	A comparator rate created for each acute care facility in the IPC Surveillance on-line dashboards and reporting modules, to guide efforts to reduce healthcare-associated infections. The IPC baseline is based on reported monthly rates for the previous fiscal year. The calculation excludes the monthly rates higher than 1 Standard Deviation above the 12-month average but includes all rates where the site had optimal performance. This calculation method biases the IPC baseline rate towards zero, to focus on the best patient safety outcomes.
Continuing Care Home (CCH) Type A (formerly Long Term Care)	This environment provides onsite RN and/or registered psychiatric nurse (RPN) care, assessment and/or treatment 24-hours a day. Licensed practical nurses (LPNs) may also be onsite in addition to onsite personal care and support provided by health care aides (HCAs). CCH Type A may also have a secure space. Some sites may have specialized programs and services available for residents with complex clinical or complex functional care requirements (e.g., rehabilitation) (Alberta Health Services, 2025). To identify if a facility has CCH Type A beds refer to this website: https://www.albertahealthservices.ca/cc/page15328.aspx where you can search by Name and identify what type of beds the facility has.
Patient admission (aka inpatient admission)	A person admitted to and assigned a bed in a hospital by the order of a physician, for the provision of diagnostic or treatment services or both. Includes any time in the emergency department if assigned a bed in hospital, regardless of whether the patient was transferred to an inpatient unit and patients who are directly admitted to an inpatient unit. This is the denominator used for non-hospital-acquired rates (see Rate Calculation Section) (Government of Alberta, 2024).
Patient days (aka inpatient days)	As defined by AHS, this is used to create the denominator for hospital-acquired or hospital-identified cases. The total is equal to midnight census with patients admitted and discharged on the same day counted as a one day stay. It includes patients out on a pass. Day of admission is counted but the day of separation (discharge, death or transfer out of hospital) is not counted. Patient-days are included for inpatient encounters where discharge date is not recorded in the data source. Inpatient totals exclude the time patients are waiting in the emergency department for an inpatient bed (time

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Terms	Definitions
	from decision to admit to discharge from emergency department).
Emergency department inpatient days (EDIP)	As defined by AHS, denominators for provincial surveillance modules include these figures in the total patient-days. Includes the number of acute care inpatient patient-days utilized in the emergency department during the reporting period. The figures reflect the time from emergency department discharge (i.e. decision to admit) to emergency department departure for patients admitted to an acute care hospital. It is calculated as [(emergency department departure date and time – emergency department discharge date and time) ÷ 60 ÷ 24]. Figures exclude cases where the emergency department discharge date and time or emergency department departure date and time were not provided, or the value has a negative number.

Appendix B: Protocol - specific definitions

Terms	Definitions
Deep infection	<p>As per NHSN (CDC, 2025), Date of event occurs within 90 days following the NHSN operative procedure (where day 1 = the procedure date) AND involves deep soft tissues of the incision AND patient has at least <u>one</u> of the following:</p> <ul style="list-style-type: none"> a. purulent drainage from the deep incision. b. a deep incision that is deliberately opened, re-accessed, or aspirated by a surgeon, physician or physician designee or spontaneously dehisces <p style="text-align: center;">AND</p> <p>organism(s) identified from the deep soft tissues of the incision by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing [ASC/AST]) or culture or non-culture based microbiologic testing is not performed. A culture or non-culture based test from the deep soft tissue incision that has a negative finding does not meet this criterion.</p> <p style="text-align: center;">AND</p> <p>Patient has at least <u>one</u> of the following signs or symptoms: fever, (>38°C); localized pain or tenderness</p> <ul style="list-style-type: none"> c. an abscess or other evidence of infection involving the deep incision detected on gross anatomical exam, histopathologic exam, or imaging test.
Organ / Space infection	<p>As per NHSN (CDC, 2025), date of event occurs within 90 days following the NHSN operative procedure (where day 1 = the procedure date)</p> <p style="text-align: center;">AND</p> <p>involves the organ/space tissues (deeper than the fascia/muscle)</p> <p style="text-align: center;">AND</p> <p>patient has at least <u>one</u> of the following:</p> <ul style="list-style-type: none"> a. purulent drainage from a drain placed into the organ/space (for example, closed suction drainage system, open drain, T-tube drain, CTguided drainage) b. organism(s) identified from fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing [ASC/AST]) c. an abscess or other evidence of infection involving the organ/space detected on: <ul style="list-style-type: none"> • gross anatomical exam or • histopathologic exam or • imaging test evidence definitive or equivocal for infection <p style="text-align: center;">AND</p> <p>meets at least one criterion for a specific organ/space infection site listed in Table 3 (CARD, ENDO, see chapter 17).</p>

Appendix C: Surveillance team casefinding process

Diagnosis and procedure codes for 90 days following the patients CIED procedures are used to identify potential surgical site infection cases. This case-finding process repeats annually. Medical charts of patients with potential surgical site infections were reviewed by an ICP at the acute care facility where the patient was identified with a diagnosis or procedure code.

Activity	Steps	Timelines for Quarter 3 procedures
Surveillance data range	Twelve months of patient procedures reviewed in this cycle, including procedures in timeframe under review.	April 2024 – March 2025
Data request to Analytics	Analytics query – use numerator and denominator to identify patients with a CIED surgery who may have had a complex infection during a subsequent hospitalization.	July 2025
Results to infection control professionals	Send patients with suspicious readmissions to infection control professionals at CRH, FMC, RDRH, GNCH, RAH and UAH, cc Senior Consultants and Directors;	(5 months following end of surveillance quarter) August 2025
Casefinding back from infection control professionals	Responses received indicating investigation and response for all patients.	(4 weeks after receiving cases for review) September 2025
Data entry into the provincial surveillance platform	Infection control professionals to enter confirmed SSI cases into the provincial surveillance platform. For SSI cases identified by infection control professionals at a facility that did not perform the original CIED procedure, the infection control professional identifying the SSI must contact the procedure facility infection control professional prior to entering the case	September 2025
Surveillance SSI report date	Update SSI rates based on new numerator information.	(7 months following end of surveillance year) October 2025