



Canadian Nosocomial Infection Surveillance Program

Surveillance of Surgical Sites Infections Following Pediatric Cardiac Surgery

Pediatric Cardiac SSI Surveillance Protocol

2025

Contact Information Please direct all questions to:

> Public Health Agency of Canada CNISP Surveillance E-mail: <u>cnisp-pcsin@phac-aspc.gc.ca</u>

Working Group

Megan Clarke, Jeannette Comeau, Meghan Engbretson, Danielle Munroe, Kevin Katz, Joanne Langley, Bonita Lee (Chair), Diane Lee* (epi Lead), Marie-Astrid Lefebvre, Cassandra Lybeck*, Marie-Ève Benoit, Robyn Mitchell*, Caroline Quach, Jessica Sollereder

* Public Health Agency of Canada (PHAC)

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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.
- Surgeries for extracorporeal membrane oxygenation (ECMO) and insertion of ventricular assisted device and cardiac transplant

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

<u>CASE</u> Classification section below and in <u>APPENDIX 1 – CASE CLASSIFICATION ALGORITHM</u>.

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
- $\circ \quad \text{Review of patient charts} \\$
- Review of physician notes
- Notifications by clinical personnel
- \circ Review of internal patient safety data collection systems

Case Classification

1. Superficial Incisional SSI

Infection occurs within 30 days after the operative procedure (where day 1= the procedure date) and involves only skin and subcutaneous tissue of the incision and meets at least **ONE** of the following criteria:

Criterion 1: Purulent drainage from the superficial incision.

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

Criterion 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.

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

The following do not qualify as criteria for meeting the **<u>NHSN</u>** definition of superficial incisional SSI:

- Diagnosis/treatment of cellulitis (redness/warmth/swelling), by itself, does not meet superficial incisional SSI criterion 4.
- A stitch abscess alone (minimal inflammation and discharge confined to the points of suture penetration).

2. Deep Incisional SSI

Infection occurs within 90 days (3 months) after the operative procedure (where day 1 = the procedure date) and the infection appears to be related to the operative procedure AND involves deep soft tissues (e.g., fascial and muscle layers) of the incision AND the patient has at least **ONE** of the following:

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

Criterion 2: Deep incision spontaneously dehisces or is deliberately opened by the surgeon, attending physician*or other designee **AND** is culture-positive, 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 **AND** the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness.

Criterion 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 (where day 1 = the procedure date) 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:

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

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

Criterion 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
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 more than 24 hours apart.

Note: As noted in the exclusion criteria above, surgeries for ECMO and insertion of ventricular assisted device and cardiac transplant are not included in surveillance, i.e., **not** to be included in the denominator.

Data Submission

Cases

For each case meeting the criteria for a Cardiac SSI, a Pediatric Cardiac SSI Patient Questionnaire should be completed on CNPHI <u>APPENDIX 2 – PEDIATRIC CARDIAC SSI PATIENT QUESTIONNAIRE</u>. For instructions on how to find the Pediatric Cardiac SSI Patient Questionnaire on CNPHI's Collaboration Center under Web Data forms see <u>APPENDIX 4 – WEB DATA FORM</u> <u>SUBMISSION CNPHI</u>.

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 <u>APPENDIX 4 – WEB DATA FORM</u> <u>SUBMISSION CNPHI</u>.

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 <u>APPENDIX 3 – PEDIATRIC CARDIAC</u> <u>SSI DENOMINATOR AND</u> 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 <u>APPENDIX 4 – WEB DATA FORM SUBMISSION CNPHI</u>.

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).

Date of Surgery in CNISP Peds Cardiac SSI Data Submission Timeline					
quarters	Jan 1 st - Mar 31 st	Apr 1 st - Jun 30 th	Jul 1 st - Sep 30 th	Oct 1 st - Dec 31 st	
Numerator (cases)	Patient questionnaires due by Sep 30 th	Patient questionnaires due by Dec 31 st	Patient questionnaires due by Mar 31 st of the following year	Patient questionnaires due by June 30 th of following year	
Denominators /Zero Report		Due by March 31 st	of the following year		

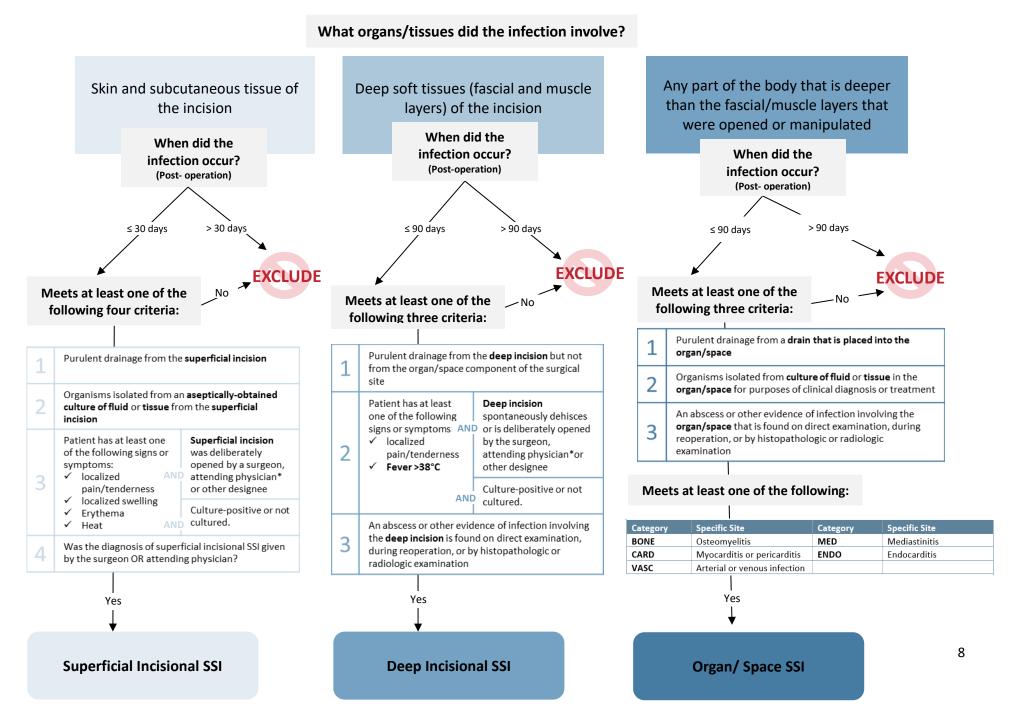
ETHICS

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



Арр	endix 2 – Pediatric Cardiac SSI	Patient Questionnaire			
1.	CHEC Site :				
2.	2. Unique Patient ID : YY (e.g. 99A19001) (CHEC site #) (Surveillance year) (case number)				
3.	Date of birth:	<u></u> / /			
4.	Sex:	Male Female			
5.	Date SSI identified:	///			
6.	Does this patient have or meet the criteria for (please check <u>one</u> the following):	 SUPERFICIAL incisional SSI DEEP incisional SSI 			
	(Please see	ORGAN/SPACE SSI			
	CASE Classification for definitions)				
7.	If classified as a superficial incisional SSI, which of the following criteria did the patient meet? (<i>Please select all that apply</i>)	 Criterion 1: Purulent drainage from the superficial incision. Criterion 2: Organisms isolated from an aseptically- obtained culture of fluid or tissue from the superficial incision. Criterion 3: Patient has at least one of the following signs or cumptomer legalized pair or tenderness legalized qualing. 			
		 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. Criterion 4: Diagnosis of superficial incisional SSI by the analysis of superficial incisional statements. 			
		surgeon or attending physician.			
8.	Microbiology investigation	□ Positive culture			
		 Negative culture (go to question 11) Not cultured (go to question 11) 			
9.	Site of positive culture:	□ Incision (e.g. chest)			
		Other, please specify:			
10.	Pathogen(s) isolated:	Staphylococcus aureus			
	(Please check all that apply)	MRSA 🗆 Yes 🗆 No			

			ative stanhylococci				
	 Coagulase-negative staphylococci <i>Enterococcus</i> species 						
	VRE 🗆 Yes 🗆 No						
		🗆 Streptococci sp	pecies, specify:				
		Enterobacter s	pecies				
		🗆 Klebsiella 10ne	🗆 Klebsiella 10neumonia				
		🗆 Escherichia col	i				
		□ Acinetobacter	baumannii				
		🗆 Klebsiella oxyt	оса				
		□ Pseudomonas					
		🗆 Candida specie	-				
	Please indicate the organism(s) susceptibil	ity/resistance for any of th	e following antimicrobials/a	nti-fungals listed			
11.	below: (R for resistant, S for susceptible, I for inte	rmodiata)					
	(R for resistant, S for susceptible, I for inte	Genus species of	Genus species of	Genus species of			
		Organism1:	Organism 2:	Organism 3:			
	Amikacin						
	Amphotericin B						
	Ampicillin						
	Amoxicillin-clavulanic acid						
	Caspofungin						
	Cefazolin (Ancef)						
	Cephalexin (Keflex)						
	Cefepime						
	Cefotaxime						
	Ceftriaxone						
	Cefuroxime						
	Ciprofloxacin						
	Clindamycin						
	Cloxacillin / Oxacillin						
	Ertapenem						
	Fluconazole						
	Gentamicin						
	Imipenem						
	Levofloxacin						
	Linezolid						
	Meropenem						

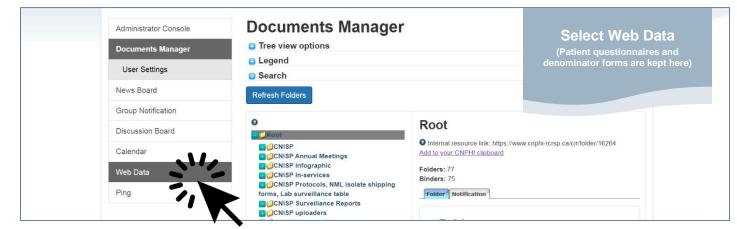
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Piperacillin DR DI DS							
Piperaciliin-tazobactam							
Rifampin Image: Rifampin and the second							
Tearcillin-clavulanic acid							
Trimthoprim-sulfamethoxazole R I S R I OS I I I OS I I I OS I							
Tobramycin IN				I 🗆 S			
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12. Date of surgery:		Other, specify :					
Date of surgery:							
Date of surgery:	12.						
DD MMM YYYY 13. Type of surgery: (Please check all that apply) Repair of congenital defect (VSD) Ventricular septal defect (VSD) A trial septal defect (ASD) Coarctation of the aorta Tetralogy of Fallot (TOF) Transposition of the great vessels Trucus arteriosus Tricuspid atresia Total anomalous pulmonary venous return (TAPVR) correction Hypoplastic left heart repair Other, specify: Heart transplant Valve replacement AVR MVR 14. Delayed sternum closure Yes Isocation where sternum was closed ICU OR Other: OR Other: Isota when sternum was closed ICU OR Other: Incurrent incurent i		Date of surgery:		/	/		
(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 Delayed sternum closure Yes No (go to question 16) Location where sternum was closed ICU OR Other: Not available Mot available					<u>1</u> <u>YYYY</u>		
(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 Delayed sternum closure Yes No (go to question 16) Location where sternum was closed ICU OR Other: Not available Mot available							
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 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 14. Delayed sternum closure Yes No (go to question 16) 15. Location where sternum was closed ICU OR Other: Not available 		(Please check all that apply)		🗆 Ventrio	cular septal defect (VSD)		
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 AVR MVR Delayed sternum closure Yes No (go to question 16) Location where sternum was closed ICU OR Other: Date when sternum was closed / Not available 				🗆 Valve repla	cement		
Id. Delayed sternum closure □ Yes □ No (go to question 16) □ ICU 15. Location where sternum was closed □ ICU □ OR □ Other: 16. Date when sternum was closed / □ Not available							
14. Delayed sternum closure □ Yes □ No (go to question 16) □ ICU 15. Location where sternum was closed □ ICU □ OR □ Other: 16. Date when sternum was closed / □ Not available							
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15. Location where sternum was closed □ ICU □ OR □ OR □ Other: 16. Date when sternum was closed / □ Not available	1.4.						
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16. Date when sternum was closed / Dot available				□ OR			
				Other:			
	16.	Date when sternum was closed		/	/ 🗆 Not	available	
				DD MMM			

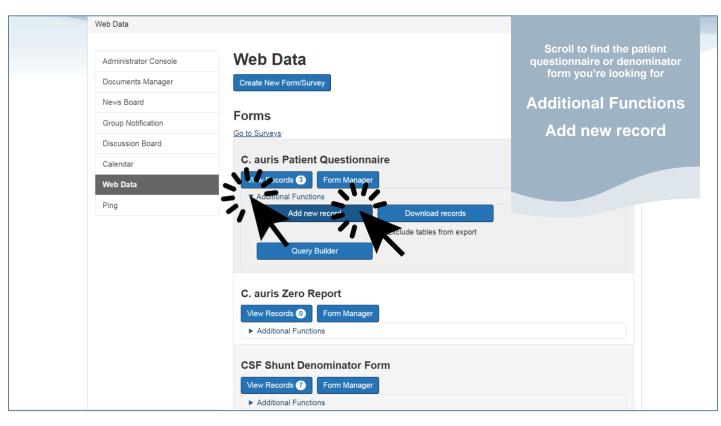
17.	Outcome 30 days within onset of infection	□ Alive in your ICU
(Check ONLY one)		Alive in your hospital, out of ICU
		Discharged
		Deceased (in hospital)
		🗆 Unknown
18.	If deceased, relation to SSI?	Direct cause
	(Check ONLY one – as judged by reviewing	Indirect (contributing)
	physician)	Unrelated
		Cannot determine

Appendix 3 – Pediatric Cardiac SSI Denominator and Zero Report Form						
CHEC Site :						
Surveill	lance 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):					8 years) in your	
	Sternum closed in OR at the time of initial	D	elayed	sternum closi	ure	Total
	surgery	ICU	OR	Unknown	Total	
al la l						
For the surveillance year specified above, were there zero (0) cases reported for your site? □ Yes □ No						
	Surveil Please facility	Surveillance period: (e.g. Jan 1, 2018 to Dec 31, 2018 Please record the number of open heart procedures facility for the calendar year (e.g. January 1, 2018 to Sternum closed in OR at the time of initial surgery For the surveillance year specified above, were there	Surveillance period: (e.g. Jan 1, 2018 to Dec 31, 2018): Please record the number of open heart procedures perform facility for the calendar year (e.g. January 1, 2018 to December Sternum closed in OR at the time of initial surgery ICU For the surveillance year specified above, were there zero (0	Surveillance period: (e.g. Jan 1, 2018 to Dec 31, 2018): Please record the number of open heart procedures performed on a facility for the calendar year (e.g. January 1, 2018 to December 31, 2 Sternum closed in OR at the time of initial surgery ICU OR For the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were there zero (0) cases of the surveillance year specified above, were the year specified above, were the year specified above, we have year specified above, we have year year year year year year year yea	Surveillance period: (e.g. Jan 1, 2018 to Dec 31, 2018): Please record the number of open heart procedures performed on all pediatric particular for the calendar year (e.g. January 1, 2018 to December 31, 2018): Sternum closed in OR at the time of initial surgery ICU OR Unknown For the surveillance year specified above, were there zero (0) cases reported for y	Surveillance period: (e.g. Jan 1, 2018 to Dec 31, 2018): Please record the number of open heart procedures performed on all pediatric patient (<14 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 ICU OR Unknown Total For the surveillance year specified above, were there zero (0) cases reported for your site?

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)
December 2020	 Added "where day 1= the procedure date" followed by "define 30 days after the operative procedure" in the Case Classification section. Removed "A culture-negative finding does not meet this criterion" from the superficial infection case classification as per NHSN definition. Organ space criterion 2 updated: Deep incision spontaneously dehisces or is deliberately opened by the surgeon, attending physician*or other designee and is culture-positive, 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 and the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain or tenderness. A new question added: During this admission or in the 14 days prior to this admission, did this patient test COVID-19 positive for the first time?
January 2022	 Updated the working group list
December 2022	 Updated the working group list COVID-19 question removed: During this admission or in the 14 days prior to this admission, did this patient test COVID-19 positive for the first time?
November 2023	 Updated working group list Added exclusion criteria for superficial SSI according to NHSN Question added: "If classified as a superficial incisional SSI, which of the following criteria did the patient meet? (<i>Please select all that apply</i>)" Removed "intraabdominal, not specified elsewhere" and "other infections of the lower respiratory tract" from the list of organ/space infection sites
November 2024	 Updated working group list Added clarification to exclusion criteria: "Surgeries for extracorporeal membrane oxygenation (ECMO) and insertion of ventricular assisted device and cardiac transplant"