

Canadian Nosocomial Infection Surveillance Program

Acute Care Point Prevalence Survey: Pilot Validation Study Protocol

Version 1.3, 2024

Contact Information

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Working Group

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BACKGROUND

The Canadian Nosocomial Infection Surveillance Program (CNISP) is a hospital-based surveillance system that collects data on healthcare-associated infections (HAIs), antimicrobial resistant organisms (AROs) and antimicrobial use (AMU). In addition to its routine surveillance activities, CNISP has conducted three point prevalence surveys (PPSs) (2002, 2009 and 2017). CNISP will conduct its next PPS – the CNISP acute care point prevalence survey (CAPPS) – in 2024. These repeated surveys are widely utilized to benchmark HAI, ARO and AMU rates, measure changes in prevalence over time, inform infection prevention and control and antimicrobial stewardship programs, and identify new targets for surveillance. Further, they raise awareness of the burden of HAIs and AROs in Canada.

Multiple countries conduct validation studies in parallel with their primary PPS. During the 2011-2012 European Centre for Disease Prevention and Control (ECDC) PPS, a validation study was piloted in 10 countries and later implemented by five countries in 2012. The results of the pilot study and 2012 validation study identified a low sensitivity of 83% and 72% respectively, in the detection of HAIs, highlighting the importance of validation to interpret primary PPS results (1,2). As a result, during the 2016-2017 ECDC PPS, 28 countries conducted validation studies and results showed a HAI detection sensitivity of 69% and specificity of 99% (3).

Validation of CNISP prevalence survey data was not conducted for the 2002, 2009 or 2017 surveys. In order to add confidence in the interpretation of the primary PPS data, CNISP will conduct a pilot validation study in parallel with a 2024 primary PPS.

OBJECTIVES

The objective of the pilot validation study is to assess the validity of HAI and AMU prevalence estimates collected during the 2024 CNISP acute care point prevalence survey (CAPPS). Conclusions from this pilot study will inform the validation methodology of future point prevalence surveys.

CONDITIONS FOR PARTICIPATION

- All sites who participate in the primary PPS are strongly encouraged to participate in the validation study
- Conduct data collection for the validation study on the same day (preferred) or following the collection of data for the primary PPS, noting that all data are to be submitted to the Public Health Agency of Canada (PHAC) by March 21, 2024
- Blinded data collection (i.e., validation team member(s) cannot look at primary PPS forms)
- Validation study data collectors cannot be part of the primary PPS data collection team
- Records for the same patients present at 8:00 am on the primary PPS day need to be reexamined for the pilot validation study day regardless of HAI status

METHODS

Timing and blinding

It is highly recommended that data are collected on the same day for both the primary PPS and validation study to ensure that data availability is similar for primary and validation study data collectors. However, if not possible, data collection for the validation study may occur after the data collection for the primary PPS.

Data collection is blinded; i.e., the validation study data collectors cannot be part of the primary PPS data collection team, and results are not shared between teams.

Sample size and ward/patient selection

All patients included in the primary PPS are eligible for inclusion in the validation study. Site must reexamine a **minimum of 5% of patient records** from the primary PPS.

Sites may use any of the 3 strategies for ward/patient selection:

- 1. Option 1 (recommended): Select ward(s) with higher expected HAI prevalence, e.g. intensive care units (purposive sampling). Random selection of patients within the selected ward(s) is preferred.
- 2. Option 2: Choice of ward(s) not influenced by expected HAI prevalence. Random selection of patients within the selected ward(s) is preferred.
- 3. Option 3: Random selection of patients from all wards included in the primary PPS.

If the primary PPS is conducted across multiple days, sites should consider coordination of their validation when selecting a sampling strategy.

Data collection and submission

The validation study data collector(s) are not to collect data for the primary PPS, however they should be of similar level of experience in HAI and AMU surveillance to primary PPS data collectors.

Data to be collected are summarized as follows:

- 1. Variables specific to the validation study (including ward-level validation date, sampling method, etc.). Please refer to Appendix 1.
- 2. Selected patient-level variables regarding HAI and AMU from the primary PPS. Please refer to Appendix 2.

Data will be submitted electronically through a secure online web-based platform, LimeSurvey. In LimeSurvey, one validation form is to be submitted per patient. Please note that forms can time out after approximately two hours of inactivity potentially resulting in a loss of data. To prevent these issues, LimeSurvey allows forms to be saved as drafts and accessed at a later time. Further, LimeSurvey is approved by the Public Health Agency of Canada (PHAC) for the collection of CAPPS data, which are considered Protected A and/or B data.

Because LimeSurvey does not allow bulk uploads of patient-level data, hospitals also have the option of submitting data electronically to CNISP at cnisp-pcsin@phac-aspc.gc.ca. If doing so, please contact CNISP

to request an excel template to ensure formatting is compatible with LimeSurvey. In this template, one row of data will be comparable to one LimeSurvey form.

Hospitals participating in CAPPS will have until <u>Thursday, March 21st, 2024</u> to complete the pilot validation study data collection forms **AND** submit the validation data to CNISP via one of the data submission methods described above.

Training of surveyors

Training material for the validation study personnel will be made available by CNISP. Webinars to review the validation study methodology as well as case studies will be coordinated and provided by CNISP.

Data analysis

Epidemiologists at CNISP will clean, validate, and analyse the data. Patients in the validation study will be matched with their corresponding data collected in the primary PPS in order to measure the level of agreement for the selected variables. Primary PPS data will not be corrected based on these validation findings. Site level reports will be produced to improve data quality and build capacity for future data validation studies.

Ethics

This surveillance project is observational and does not involve any alteration in patient care. Surveillance for HAI is a routine component of quality assurance and patient care in Canadian health care institutions and therefore informed consent will not be required. Review Ethics Board (REB) approval was not required by PHAC. However, individual hospitals may seek institutional REB approval according to local hospital policy. A unique identifier linked to patient name will only identify patients at the hospital site and will not be transmitted to PHAC. All data will be strictly confidential.

REFERENCES

- Reilly JS, Price L, Godwin J, Cairns S, Hopkins S, Cookson B, Malcolm W, Hughes G, Lyytikainen O, Coignard B, Hansen S, Suetens C; National Participants in the ECDC pilot validation study. A pilot validation in 10 European Union Member States of a point prevalence survey of healthcare-associated infections and antimicrobial use in acute hospitals in Europe, 2011. Euro Surveill. 2015 Feb 26;20(8):21045. Doi: 10.2807/1560-7917.es2015.20.8.21045. PMID: 25742434.
- European Centre for Disease Prevention and Control (ECDC). Point prevalence survey of healthcare-associated infections and antimicrobial use in European acute care hospitals – ECDC PPS validation protocol version 3.1.2. Stockholm: ECDC; 2019.
- 3. Suetens C, Latour K, Karki T, Ricchizzi E, Kinross P, Moro ML, Jans B, Hopkins S, Hansen S, Lyytikainen O, Reilly J, Deptula A, Zingg W, Plachouras D, Monnet DL, the Healthcare-Associated Infections Prevalence Study Group. Prevalence of healthcare-associated infections, estimated incidence and composite antimicrobial resistance index in acute care hospitals and long-term care facilities: results from two European point prevalence surveys, 2016 to 2017. Euro Surveill. 2018;23(46):pii=1800516. https://doi.org/10.2807/1560-7917.ES.2018.23.46.1800516.

Appendix 1 – Ward data form for validation study

This form must be completed for each ward selected for validation (e.g., if you select patients from three different wards for validation, you will complete this form three times, once per ward).

1.	CHEC number							
2.	War	Ward						
] Medicine			☐ Hematology/Oncology/Bone Marrow Transplant		one Marrow	
		Pediatrics		☐ Surgery including Gynecology☐ Solid Organ Transplant		Surgery including Gynecology		
		Adult Intensive Care Unit (ICL	J)					
		Pediatric ICU				Trauma/Burn		
		Neonatal ICU				Mixed Medical/Surgion	cal	
		☐ Obstetrics				Coronary Care (not ICU)		
		☐ ER (admitted, awaiting inpatient		d)		Step down Unit		
		Other (please specify):						
3.	Ward primary PPS survey date /							
4.		Ward primary PPS data collection start date			/_ _{им}	YYYY		
5.	_	Ward validation data collection start date			DD / MMM / YYYY			
6.	War	Vard sampling strategy:						
		High prevalence ward(s) selected (Option 1)	□ ir	nfluen	ced b	ward(s) not by estimated (Option 2)		All wards (Option 3)
		Other (please specify):						
7.	Patients included in ward validation			☐ All eligible patients in ward ☐ Sample of eligible patients in ward				

Appendix 2 – Patient-level validation data form

 2. 	Patient identifier (validation): Patient identifier (primary PPS):					Patient unique identifier Patient unique identifier
PATIL	ENT L	DEMOGRAPHIC INFORMAT	ION			
3. 4.	Age Sex:		Ente	er age. S Male Female Unknov		y: Years, months or days
5.	Date	e of admission¹:		//	YYYY	_
6.	Plea	se select the ward the pation	ent w	vas on at	8am	on the day of the survey <i>(check only <u>ONE</u>)</i> :
		Medicine				Hematology/Oncology/Bone Marrow Transplant
		Pediatrics				Surgery including Gynecology
		Adult Intensive Care Unit (ICU)			Solid Organ Transplant
		Pediatric ICU				Trauma/Burn
		Neonatal ICU				Mixed Medical/Surgical
		Obstetrics				Coronary Care (not ICU)
		ER (admitted, awaiting inp	atier	nt bed)		Step down Unit
		Other (please specify):				_

¹ The date of admission for an ER patient is the date on which the decision to admit was made rather than the date they were moved to the ward. For example, a patient has been in the ER for more than 48 hours and is admitted on Wednesday, February 29, 2024. They are moved to the ward on Friday, March 1, 2024. The date of admission would be Wednesday, February 29, 2024.

ANTIMICROBIAL USE FOR ALL PATIENTS, REGARDLESS OF HAI STATUS 7. Is this patient currently receiving systemic therapy with any antimicrobial ☐ Yes ☐ No (skip to Q12) agents? **Antimicrobial #1** 8. Antimicrobial generic name (Appendix 9. Route □ Parenteral □ Oral □ Rectal □ Inhalation 10. Indication of use (diagnosis) – what the □ Medical prophylaxis clinician aims to treat □ Surgical prophylaxis □ Central nervous system therapy ☐ Eye therapy ☐ Ear, nose, throat □ Respiratory □ Cardiovascular system ☐ Gastro-intestinal ☐ Skin, soft tissue ☐ Bone and joint ☐ Urinary tract infection $\ \ \Box \ Genito-Urinary/Obstetric/Gynecological$ □ Neonatal ☐ Other (please specify): _____ □ Unknown/not defined 11a. Treatment □ Empiric □ Targeted □ Unknown 11b. If targeted treatment, please indicate ☐ Methicillin-resistant *Staphylococcus aureus* (MRSA) the resistant organism(s) being treated, □ Vancomycin-resistant enterococci (VRE) please check all that apply: □ Carbapenemase producing Enterobacterales (CPE) ☐ Bacteria, producing extended-spectrum beta-lactamases (ESBL) OR resistant to 3rd generation cephalosporins

□ Other (please specify): _____

LTHC	ARE-ASSOCIATED INFECTIONS								
follo trea mo (Re)	owing HAIs OR are they presently be ated with antimicrobial agents for our re of the following HAIs? fer to Appendix 4 for HAI definitions, es, what type? (please check <u>all</u> tha	eing ne or) at app							
	Type of Pneumonia:		Ventilator associated						
			Non Ventilator associated						
	Healthcare-associated Urinary Tra	ct Inf	fection						
	Type of urinary tract infection:		Catheter-Associated Urinary Tract Infection (CAUT						
			Non-Catheter-Associated Urinary Tract Infection (non-CAUTI)						
	Surgical Site Infection								
	SSI type:		☐ Superficial incisional						
			☐ Complex (deep incisional/organ/space)						
	Healthcare-associated Clostridioides difficile infection								
☐ Healthcare-associated bloodstream infection									
	Type:		□ Primary						
			☐ CLABSI						
			☐ Source unknown						
			☐ Other, specify:						
	Healthcare-associated viral respira	atory	infection						
	Healthcare-associated viral gastro	entei	ritis						
	Doe follitree mo (Reg If ye If	following HAIs OR are they presently be treated with antimicrobial agents for or more of the following HAIs? (Refer to Appendix 4 for HAI definitions If yes, what type? (please check all the Healthcare-associated Pneumonia Type of Pneumonia: Healthcare-associated Urinary Tratype of urinary tract infection: Surgical Site Infection SSI type: Healthcare-associated Clostridioid Healthcare-associated bloodstreatype: Healthcare-associated bloodstreatype:	Does the patient have one or more of the following HAIs OR are they presently being treated with antimicrobial agents for one or more of the following HAIs? (Refer to Appendix 4 for HAI definitions) If yes, what type? (please check all that appears of Pneumonia Type of Pneumonia: Healthcare-associated Pneumonia Type of urinary tract infection: Surgical Site Infection SSI type: Healthcare-associated Clostridioides digitation Healthcare-associated bloodstream information Type:						

Appendix 3 – Antimicrobial agents

Amikacin	Cefuroxime	Moxifloxacin
Amoxicillin	Ciprofloxacin	Nitrofuratoin
Amoxicillin/Clavulanate	Clarithromycin	Norfloxacin
Amphotericin B	Clindamycin	Oseltamivir
Ampicillin	Cloxacillin	Other antituberculous medications
Anidulafungin	Colistin	Other antiviral medications
Azithromycin	Daptomycin	Others (specify)
Aztreonam	Doxycycline	Penicillin G
Caspofungin	Ertapenem	Penicillin V
Cefadroxil	Erythromycin	Piperacillin
Cefalexin	Ethambutol	Piperacillin Tazobactam
Cefalotin	Fluconazole	Posaconazole
Cefazolin	Gentamicin	Pyrazinamide
Cefepime	Imipenem	Rifampicin
Cefixime	Isoniazid	Sulfamethoxazole/Trimethoprim
Cefotaxime	Itraconazole	Tetracycline
Cefoxitin	Levofloxacin	Tigecycline
Ceftazidime	Linezolid	Tobramycin
Ceftazidime/Avibactam	Meropenem	Vancomycin
Ceftolazane/Tazobactam	Metronidazole	Voriconazole
Ceftriaxone	Micafungin	

Appendix 4 – Healthcare-associated infection definitions

Pneumonia	
Imaging test evidence	Signs and symptoms
Two or more serial chest	For ANY PATIENT, at least one of the following:
imaging test results with at	• Fever (> 38.0°C or > 100.4°F)
least one of the following:	• Leukopenia (≤ 4000 WBC/ mm³) or leukocytosis (≥ 12,000 WBC/mm³)
	• For adults ≥ 70 years old, altered mental status with no other recognized cause
New and persistent or	
Progressive and persistent	And at least two of the following:
Infiltrate	• New onset of purulent sputum or change in character of sputum , or increased
 Consolidation 	respiratory secretions, or increased suctioning requirements
Cavitation	New onset or worsening cough, or dyspnea, or tachypnea
 Pneumatoceles, in infants ≤1 	Rales or bronchial breath sounds
year old	• Worsening gas exchange (for example: O2 desaturations (for example: PaO2/FiO2
	≤ 240), increased oxygen requirements, or increased ventilator demand)
Note: In patients without	
underlying pulmonary or	
cardiac disease (for example:	ALTERNATE CRITERIA, for infants ≤ 1 year old:
respiratory distress syndrome,	
bronchopulmonary dysplasia,	Worsening gas exchange (for example: O2 desaturations [for example pulse
pulmonary edema, or chronic	oximetry < 94%], increased oxygen requirements, or increased ventilator demand)
obstructive pulmonary	
disease), one definitive	And at least three of the following:
imaging test result is	Temperature instability
acceptable.	• Leukopenia (≤ 4000 WBC/mm³) or leukocytosis (≥ 15,000 WBC/mm³) and left
	shift (≥ 10% band forms)
	• New onset of purulent sputum or change in character of sputum, or increased
	respiratory secretions, or increased suctioning requirements
	• Apnea, tachypnea, nasal flaring with retraction of chest wall, or nasal flaring with
	grunting
	Wheezing, rales, or rhonchi
	• Cough
	Bradycardia (< 100 beats/min) or tachycardia (> 170 beats/min)
	ALTERNATE CRITERIA, for child > 1 year old or ≤ 12 years old, at least three of the
	following:
	• Fever (> 38. 0°C or > 100. 4°F) or hypothermia (< 36. 0°C or < 96.8°F)
	• Leukopenia (≤ 4000 WBC/mm³) or leukocytosis (≥ 15,000 WBC/mm³)
	New onset of purulent sputum or change in character of sputum, or increased
	respiratory secretions, or increased suctioning requirements • New onset or
	worsening cough, or dyspnea, or apnea, or tachypnea
	Rales or bronchial breath sounds
	Worsening gas exchange (for example: O2 desaturations [for example pulse
	oximetry < 94%], increased oxygen requirements, or increased ventilator demand)

Ventilator-associated pneumonia (VAP)

A pneumonia where the patient is on mechanical ventilation for > 2 consecutive calendar days on the date of event, with day of ventilator placement being Day 1,*

AND

the ventilator was in place on the date of event or the day before.

*If the ventilator was in place prior to inpatient admission, the ventilator day count begins with the admission date to the first inpatient location.

If a break in mechanical ventilation occurs for at least one full calendar day, ventilator day count for ventilator association starts anew upon reintubation and/or re-initiation of mechanical ventilation.

	tinfortion (UTI)				
Urinary tract	t infection (UTI)				
	Symptomatic UTI (SUTI)				
	Must meet at least <u>one</u> of the following criteria:				
Catheter-	Patient must meet 1, 2, and 3 below:				
associated					
Urinary Tract	1. Patient had an indwelling urinary catheter that had been in place for more than 2 consecutive				
Infection (CAUTI)	days in an inpatient location on the date of event (with Day 1= day of device placement) AND				
in any age	was either:				
patient	 Present for any portion of the calendar day on the date of event, OR 				
	Removed the day before the date of event				
	2. Patient has at least <u>one</u> of the following signs or symptoms:				
	• fever (>38.0°C)				
	• suprapubic tenderness				
	• costovertebral angle pain or tenderness				
	• urinary urgency^				
	• urinary frequency^				
	• dysuria^				
	3. Patient has a urine culture with no more than two species of organisms identified, at least				
	one of which is a bacterium of ≥105 CFU/ml (See Comments). All elements of the SUTI criterion must occur during the IWP (See IWP Definition Chapter 2 Identifying HAIs in NHSN).				
	^ These symptoms cannot be used when catheter is in place. An IUC in place could cause patient complaints of "frequency" "urgency" or "dysuria".				
	Note: • Fever is a non-specific symptom of infection and cannot be excluded from UTI				
	determination because it is clinically deemed due to another recognized cause.				
Non-Catheter-	Patient must meet 1, 2, and 3 below:				
associated					
Urinary Tract	1. One of the following is true:				
Infection (Non-	• Patient has/had an indwelling urinary catheter, but it has/had not been in place for more than				
CAUTI) in any age	two consecutive days in an inpatient location on the date of event				
patient	OR .				
	• Patient did not have an indwelling urinary catheter in place on the date of event nor the day				
	before the date of event				

- 2. Patient has at least one of the following signs or symptoms:
- fever (>38°C)
- suprapubic tenderness*
- costovertebral angle pain or tenderness*
- urinary frequency ^
- urinary urgency ^
- dysuria ^
- 3. Patient has a urine culture with no more than two species of organisms identified, at least one of which is a bacterium of ≥105 CFU/ml. (See Comments) All elements of the SUTI criterion must occur during the IWP (See IWP Definition Chapter 2 Identifying HAIs in NHSN).
- *With no other recognized cause (see Comments)
- ^These symptoms cannot be used when IUC is in place. An IUC in place could cause patient complaints of "frequency" "urgency" or "dysuria".

Note: • Fever is a non-specific symptom of infection and cannot be excluded from UTI determination because it is clinically deemed due to another recognized cause.

Surgical Site Infection (SSI)

Superficial incisional infection

Must meet the following criteria:

Date of event occurs within 30 days after any operative procedure (where day 1 = the procedure date)

AND

involves only skin and subcutaneous tissue of the incision

AND

patient has at least one of the following:

- a. purulent drainage from the superficial incision.
- b. organism(s) identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue 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. superficial incision that is deliberately opened by a surgeon, physician or physician designee and culture or non-culture based testing of the superficial incision or subcutaneous tissue is not performed

AND

patient has at least <u>one</u> of the following signs or symptoms: localized pain or tenderness; localized swelling; erythema; or heat.

d. diagnosis of a superficial incisional SSI by a physician or physician designee.

Deep incisional SSI

Must meet the following criteria:

The date of event occurs within 30 or 90 days after the operative procedure (where day 1 = the procedure date) according to the list in Table 1.

AND

involves deep soft tissues of the incision (for example, fascial and muscle layers)

AND

patient has at least one of the following:

- a. purulent drainage from the deep incision.
- b. deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, physician or physician designee

AND

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 method is not performed. A culture or non-culture based test from the deep soft tissues of the incision that has a negative finding does not meet this criterion.

AND

patient has at least <u>one</u> of the following signs or symptoms: fever (>38°C); localized pain or tenderness.

c. an abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test.

Organ/Space SSI

Must meet the following criteria

The date of event occurs within 30 or 90 days after the operative procedure (where day 1 = the procedure date) according to the list in Table 1.

AND

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:

- a. purulent drainage from a drain that is placed into the organ/space (for example, closed suction drainage system, open drain, T-tube drain, CT-guided 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 that is detected on gross anatomical or histopathologic exam, or imaging test evidence suggestive of infection.

AND

meets at least <u>one</u> criterion for a specific organ/space infection site listed in Table 2.

Table 1. Surveillance periods for SSI following operative procedures

Operative procedures			
30-day Surveillance			
Abdominal aortic aneurysm repair	Laminectomy		
Limb amputation	Liver transplant		
Appendix surgery	Neck surgery		
Shunt for dialysis	Kidney surgery		
Bile duct, liver or pancreatic surgery	Ovarian surgery		
Carotid endarterectomy	Prostate surgery		
Gallbladder surgery	Rectal surgery		
Colon surgery	Small bowel surgery		
Cesarean section	Spleen surgery		
Gastric surgery THOR Thoracic surgery	Thyroid and/or parathyroid surgery		
Abdominal hysterectomy	Vaginal hysterectomy		
Kidney transplant	Exploratory laparotomy		
90-day Surveillance			
Breast surgery	Open reduction of fracture		
Cardiac surgery	Herniorrhaphy		
Coronary artery bypass graft with both chest and	Hip prosthesis		
donor site incisions	W		
Coronary artery bypass graft with chest incision only	Knee prosthesis		
Craniotomy	Pacemaker surgery		
Spinal fusion	Peripheral vascular bypass surgery		
	Ventricular shunt		
	VEHILICUIAI SHUHL		

Table 2. Specific Sites of Organ/Space SSI

Specific site			
Osteomyelitis	Mediastinitis		
Breast abscess or mastitis	Meningitis or ventriculitis		
Myocarditis or pericarditis	Oral cavity infection (mouth, tongue, gums)		
Disc space infection	Deep pelvic tissue infection or other infection of the male or female reproductive tract		
Ear, mastoid infection	Periprosthetic joint infection		
Endometritis	Spinal abscess/infection		
Endocarditis	Sinusitis		
Gastrointestinal (GI) tract infection	GIT Gastrointestinal (GI) tract		
Intraabdominal infection, not specified elsewhere	Urinary System Infection		
Intracranial infection VASC	Arterial or venous infection		
Joint or bursa infection	Vaginal cuff infection		
Other infection of the lower respiratory tract			

Clostridioides difficile Infection (CDI)

Criterion 1: has diarrhea* or fever, abdominal pain and/or ileus AND a laboratory confirmation of a positive toxin assay or positive polymerase chain reaction (PCR) for *C. difficile* toxin gene(s) (without reasonable evidence of another cause of diarrhea).

OR

Criterion 2: has a diagnosis of pseudomembranes on sigmoidoscopy or colonoscopy (or after colectomy) or histological/pathological diagnosis of CDI.

OR

Criterion 3: is diagnosed with toxic megacolon (in adult patients only).

Exclusions

- Any patients under 1 year of age.
- Any pediatric patients (aged 1 year to less than 18 years) with alternate cause of diarrhea found (i.e. rotavirus, norovirus, enema or medication etc.) are excluded even if C. difficile diagnostic test result is positive.

*Diarrhea is defined as one of the following:

- 6 or more watery/unformed stools in a 36-hour period
- 3 or more watery/ unformed stools in a 24-hour period and this is new or unusual for the patient (in adult patients only)

Source: CNISP 2023 definition

Bloodstream Infection (BSI)

The BSI is NOT related to an infection at another site (not a secondary BSI according to National Healthcare Safety Network (NHSN) definitions – please refer to <u>Chapter 2</u> and <u>Chapter 4-Appendix B</u>) and it meets one of the following criteria:

Criterion 1: Recognized pathogen cultured from at least one blood culture, unrelated to infection at another site (not a secondary BSI according to NHSN definitions).

OR

Criterion 2: At least one of: fever (>38°C core), chills, hypotension; if aged < 1 year: fever (>38°C core), hypothermia (<36°C core), apnea, or bradycardia AND common skin contaminant cultured from ≥ 2 blood cultures drawn on separate occasions, or at different sites, unrelated to infection at another site (not a secondary BSI according to NHSN definitions).

Criterion elements must be met within a seven-day time period which includes three days before and three days after the collection date of the first positive blood culture.

Diphtheroids (Corynebacterium spp. not C. diphtheria), Bacillus spp (not B. anthracis), Propionibacterium spp., coagulase-negative staphylococci, (including S. epidermidis) viridans group streptococci, Aerococcus spp., Micrococcus spp and Rhodococcus spp

Different sites may include peripheral veins, CVCs, or separate lumens of a multiumen catheter. Different times include 2 blood cultures collected on the same or consecutive calendar days via separate venipunctures or catheter entries. The collection date of the first positive blood culture is the date used to identify the date of positive culture. Two positive blood culture bottles filled at the same venipuncture or catheter entry constitute only one positive blood culture.

Source: CNISP 2023 definition

Central line-associated bloodstream infection

A CLABSI must meet one of the following criteria:

Criterion 1: A laboratory-confirmed bloodstream infection (LCBSI) where a central line catheter (CL) or umbilical catheter (UC) was in place for >2 calendar days on the date of the positive blood culture, with day of device placement being Day 1.

OR

Criterion 2: A LCBSI where CL or UC was in place >2 calendar days and then removed on the day or one day before positive blood culture drawn.

CL = venous access device that terminates at or close to the heart or in one of the great vessels. The CDC/NHSN defines great vessels as: aorta, pulmonary artery, inferior and/or superior vena cava, brachiocephalic, internal jugular, subclavian, external iliac, common iliac, femoral veins, and umbilical artery and vein.

CLs include non-tunnelled (standard) CL, coated or not, peripherally inserted CL (PICC), tunnelled devices (e.g. Broviac, Hickman), tunnelled haemodialysis line, intra-cardiac catheters such as intra-atrial & and ventricular lines, dual function lines such as temperature/venous catheters e.g. Cool line catheters, Quattro catheters, introducers etc.), pulmonary artery catheters, umbilical artery and vein catheters and implanted catheters (including ports). Other arterial catheters are NOT included. AV fistulas and or grafts, pacemaker leads and other non-infusion devices (ECMO, IABP and VAD) inserted into central blood vessels or the heart are NOT included

Source: CNISP 2023 definition

VIRAL RESPIRATORY INFECTION (VRI)

Positive viral culture test by PCR (polymerase chain reaction), DFA (direct fluorescent antigen) or EIA (enzyme immunoassay) for a viral respiratory tract pathogen.

AND

At least one of the following signs or symptoms:

fever (> 38 °Celsius) or single temperature >1.1°Celsius over baseline from any site (oral, rectal, tympanic, axillary), rhinitis, nasal congestion, pharyngitis, sneezing, cough, wheeze, stridor, apnea, dyspnea, laboured breathing, increased respiratory secretions, change in characteristics of chronic secretions, decreased air entry on auscultation, rales, rhonchi, decreased oxygen saturation, need for increased Fi02, increased ventilator support, increased suctioning or new abnormality on chest radiograph.

AND

No other evident cause for the abnormality.

COVID-19 case definition

Positive viral culture test by PCR (polymerase chain reaction) for SARS-CoV-2 in the past 14 days (prior to admission or during hospitalization).

Source: CNISP 2023 definition

VIRAL GASTROENTERITIS

Gastroenteritis must meet at least one of the following criteria:

- 1. Patient has an acute onset of diarrhea (liquid stools for > 12 hours) and no likely noninfectious cause (for example, diagnostic tests, therapeutic regimen other than antimicrobial agents, acute exacerbation of a chronic condition, or psychological stress information).
- 2. Patient has at least **two** of the following signs or symptoms: nausea*, vomiting*, abdominal pain*, fever (>38.0°C), or headache*

And at least one of the following:

- a. an enteric pathogen is identified from stool or rectal swab 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).
- b. an enteric pathogen is detected by microscopy on stool
- c. diagnostic single antibody titer (IgM) or 4-fold increase in paired sera (IgG) for organism.
- * With no other recognized cause

Source: NHSN definition Surveillance Definitions (cdc.gov)

Revision history

Date	Revisions				
Feb 8, 2024	 Updated wording for timing of data collection for validation Merged Appendix 1 and 2 to collect sampling methodology information. 				