Sentinel Event Reporting Guidance

Compliance Manual

version 1.2

2012

surgery on wrong body part

event category	full term	short term	specifications	standard
surgical	surgery or other invasive procedure	surgery on wrong body part	Defined as any surgery or other invasive procedure	NQF
	performed on the wrong site		performed on a body part or site that is not	1A
			consistent with the correctly documented informed	
			consent for that patient.	
			Surgery or other invasive procedure includes, but is	
			not limited to, endoscopies, lens implants, lesion	
			removal, injection into joints.	
			Excludes emergent situations that occur in the course of surgery or other invasive procedure	
			and/or whose exigency precludes obtaining	
			informed consent.	

implementation guidance

Wrong site surgery or invasive procedure, corrected during the procedure, is still a wrong site procedure if the surgery/procedure had begun, based on the definition in glossary.

This event is intended to capture instances of:

- surgery or other invasive procedure on the right body part but on the wrong location/site on the body; example.ge, left/right (appendages and/or organs), wrong digit, level (spine), stent placed in wrong iliac artery, steroid injection into wrong knee, biopsy of wrong mole, burr hole on wrong side of skull;
- delivery of fluoroscopy or radiotherapy to the wrong region of the body;
- use of incorrectly placed vascular catheters;
- use of incorrectly placed tubes (for example, feeding tubes placed in the lung or ventilation tubes passed into the esophagus);

SENTINEL EVENT REPORTING GUIDANCE SURGICAL

This event is not intended to capture:

• changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery or procedure outweighs the benefit of patient consultation or unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

examples

actual sentinel event: A hand surgeon performs trigger finger surgery on the wrong finger. Before applying the dressing, the surgeon realizes the mistake. He then performs the procedure on the correct finger.

surgery on wrong patient

event category	full term	short term	specifications	standard
surgical	surgery or other invasive procedure	surgery on wrong patient	Defined as any surgery or invasive procedure on a	NQF
	performed on the wrong patient		patient that is not consistent with the correctly	1B
			documented informed consent for that patient.	
			Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints.	

implementation guidance

This event is intended to capture:

• surgical procedures (whether or not completed) initiated on one patient intended for a different patient.

examples

risk thereof sentinel event: A 42 year-old male is admitted for pneumonia. The patient is not planning to have any surgical procedure. The patient's roommate is scheduled to have an elective cyst removal. A nurse confuses the bed numbers and takes the patient with the pneumonia to the operating room. The patient is prepped and placed under general anesthesia. Following the administration of anesthesia, the mistake is identified. There has been no skin perforation, yet there was a risk of surgery on the wrong patient.

wrong surgical procedure

event category	full term	short term	specifications	standard
surgical	wrong surgical or other invasive procedure performed on a patient	wrong surgical procedure	Defined as any surgical or other invasive procedure procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient. Surgery or other invasive procedure includes, but is not limited to, endoscopies, lens implants, lesion removal, injection into joints. Excludes emergent situations that occur in the course of surgery or other invasive procedures and/or whose exigency precludes obtaining informed consent.	NQF 1C

implementation guidance

This event is intended to capture:

• Any surgical procedure performed incorrectly.

This event is not intended to capture:

• changes in plan upon surgical entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery/procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).

This event is not intended to capture; changes in plan upon entry into the patient with discovery of pathology in close proximity to the intended place where risk of a second surgery/procedure outweighs benefit of patient consultation, or unusual physical configuration (for example adhesions, spine level/extra vertebrae).

examples

retained foreign object

event category	full term	short term	specifications	standard
surgical	unintended retention of a foreign	retained foreign object	Excludes a) objects present prior to surgery or other	NQF
	object in a patient after surgery or		invasive procedure that are intentionally left in	1D
	other invasive procedure		place; b) objects intentionally implanted as part of a	
	Carret invasive processing		planned intervention; and c) objects not present	
			prior to surgery/procedure that are intentionally	
			left in when the risk of removal exceeds the risk of	
			retention (such as microneedles, broken screws).	

implementation guidance

This event is intended to capture:

- occurrences of unintended retention of objects at any point after the surgery/procedure ends regardless of setting (post anesthesia recovery unit, surgical suite, emergency department, patient bedside) and regardless of whether the object is to be removed after discovery.
- unintentionally retained objects (including such things as wound material, sponges, catheter tips, trocars, guide wires) in all applicable settings.

examples

risk thereof sentinel event: A 29 year-old female presents in active labor. The patient is taken to labor and delivery. During labor, the baby is found to be in fetal distress and a leg is identified at the cervical os. The mother is taken to the operating room emergently. A C-section is performed and a healthy baby is delivered. During the initial count, a missing lap is identified. The cavity is examined, and the count is repeated, but the missing lap remains. Radiologic evaluation does not reveal the lap either. The incision is closed. While the patient is transferred to the recovery room, an end of a lap is noted in the vaginal canal and is successfully removed.

intra- or post-operative death

event category	full term	short term	specifications	standard
surgical	intraoperative or immediately postoperative/postprocedure death in an ASA Class I patient	intra- or post-operative death	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.	NQF 1E
	ASA 1: No organic pathology or patients in whom the pathological process is localized and does not cause any systemic disturbance or abnormality		Immediately post-operative means within 24 hours after surgery or other invasive procedure was completed or after administration of anesthesia (if surgery/procedure was not completed).	
	(Unexpected death in other ASA Class patients would be captured in OTHER category)			

implementation guidance

This event is intended to capture:

• ASA Class I patient death associated with the administration of anesthesia whether or not the planned surgical procedure was carried out.

examples	

contaminated drug, device, or biologic

event category	full term	short term	specifications	standard
product or device	patient death or serious injury	contaminated drug, device,	Includes contaminants in drugs, devices, or	NQF
	associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting	or biologic	biologics regardless of the source of contamination and/or product. Includes threat of disease that changes patient's risk status for life requiring medical monitoring not needed before the event	2A

implementation guidance

This event is intended to capture:

• contaminations that can be seen the naked eye or with use of detection mechanisms in general use. These contaminations are to be reported at such time as they become known to the provider or healthcare organization. Contaminants may be physical, chemical, or biological in nature. Not all contaminations can be seen with the naked eye (e.g., acid testing, mass spectrometry, and tests that signal changes in pH or glucose levels). Contamination that is inferred and changes risk status for life (e.g., consider a syringe or needle contaminated once it has been used to administer medication to a patient by injection or via connection to a patient's intravenous infusion bag or administration set).

This event is intended to capture:

- administration of contaminated vaccine or medication (e.g., intramuscular antibiotic);
- serious infection from contaminated drug or device used in surgery or an invasive procedure (e.g., a scalpel);
- occurrences related to use of improperly cleaned or maintained device.

examples

Hepatitis C is an example of a disease that change's a patient's risk status for life, requiring on-going treatment.

SENTINEL EVENT REPORTING GUIDANCE PRODUCT OR DEVICE

device failure

event category	full term	short term	specifications	standard
product or device	patient death or serious injury	device failure	Includes, but is not limited to, catheters, drains and	NQF
	associated with the use or function of		other specialized tubes, infusion pumps, ventilators,	2B
	a device in patient care, in which the		and procedural and monitoring equipment.	
	device is used or functions other than			
	as intended			

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This event is intended to capture:

• occurrences whether or not the use is intended or described by the device manufacturers' literature

examples	

SENTINEL EVENT REPORTING GUIDANCE PRODUCT OR DEVICE

air embolism

event category	full term	short term	specifications	standard
product or device	patient death or serious injury	air embolism	Excludes death or serious injury associated with	NQF
	associated with intravascular air embolism that occurs while being cared for in a healthcare setting		neurosurgical procedures known to present a high risk of intravascular air embolism.	2C

implementation guidance

This event in intended to capture:

- high-risk procedures, other than neurosurgical procedures, that include, but are not limited to, procedures involving the head and neck, vaginal delivery and cesarean section, spinal instrumentation procedures, and liver transplantation;
- low-risk procedures, including those related to lines placed for infusion of fluids in vascular space.

examples

risk thereof sentinel event: Air embolism includes procedures that have a small but known risk—again confirming the fact that risk does not imply expected outcome.

discharge to wrong person

event category	full term	short term	specifications	standard
patient protection	discharge or release of a	discharge to wrong person		NQF
	patient/resident of any age, who is unable to make decisions, to other than an authorized person			3A

implementation guidance

The terms "authorized" and "decision-making capacity" are defined in the glossary. Release to "other than an authorized person" includes removing the patient/resident without specific notification and approval by staff, even when the person is otherwise authorized.

Examples of individuals who do not have decision-making capacity include: newborns, minors, adults with Alzheimer's.

Individual healthcare organizations or other relevant jurisdictional authorities may have specific requirements for assessing decisionmaking capacity

examples

risk thereof sentinel event: Mrs. M delivers a healthy baby boy. In preparation for discharge home, Mrs. M signs all documents and is ready to go. At the time of departure, Mrs. G's baby is delivered to Mrs. M. Upon arrival of the baby, Mrs. M states that the baby is not hers. Nursing is notified, the error is acknowledged, and the correct baby goes home with Mrs. M. In this situation, multiple corrective measures failed to recognize the wrong baby.

elopement

event category	full term	short term	specifications	standard
patient protection	patient death or serious injury	elopement	Includes events that occur after the individual	NQF
	associated with patient elopement		presents him/herself for care in a healthcare	3B
	(disappearance)		setting.	
			Excludes events involving competent adults with decision-making capacity who leave against medical advice or voluntarily leave without being seen.	

implementation guidance

The term "elopement" and "competent" adult should be interpreted in accordance with prevailing legal standards in applicable jurisdictions.

This event is not intended to capture:

• death or serious injury that occurs (after the patient is located) due to circumstances unrelated to the elopement.

examples	

suicide

event category	full term	short term	specifications	standard
patient protection	patient suicide, attempted suicide, or	suicide	Includes events that result from patient actions	NQF
	self-harm that results in serious		after they present themselves for care in a	3C
	injury, while being cared for in a		healthcare setting.	
	healthcare setting		Excludes deaths resulting from self-inflicted injuries that were the reason for admission/presentation to the healthcare facility.	

implementation guidance

This event is not intended to capture patient suicide or attempted suicide when the patient is not physically present in the "healthcare setting" as defined in the glossary.

examples	

medication error

event category	full term	short term	specifications	standard
care management	patient death or serious injury	medication error	Excludes reasonable differences in clinical judgment	NQF
	associated with a medication error		on drug selection and dose.	4A
	(e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)		Includes, but is not limited to, death or serious injury associated with: a) over- or under-dosing; b) administration of a medication to which a patient has a known allergy or serious contraindictation, c) drug-drug interactions for which there is known potential for death or serious disability, and improper use of single-dose/single-use and multidose medication vials and containers leading to death or serious injury as a result of dose adjustment problems.	
			adjustment prodicins.	

implementation guidance

This event is intended to capture:

- the most serious medication errors including occurrences in which a patient receives a medication for which there is a contraindication, or a patient known to have serious allergies to specific medications/agents, receives those medications/agents, resulting in serious injury or death. These events may occur as a result of failure to collect information about contraindications or allergies, failure to review such information available in information systems, failure of the organization to ensure availability of such information and prominently display such information within information systems, or other system failures that are determined through investigation to be the cause of the adverse event;
- occurrences in which a patient dies or suffers serious injury as a result of failure to administer a prescribed medication;
- occurrences in which a patient is administered an over- or under-dose of a medication including insulin, heparin, and any other high alert medication including but not limited to medications listed on the Institute for Safe Medication Practices "High Alert Medication List";
- occurrences in which a patient dies or suffers serious injury as a result of the wrong administration technique.

This event is not intended to capture:

• patient death or serious injury associated with allergies that could not reasonably have been known or discerned in advance of the event. These unexpected deaths would be captured in "other" category.

examples

actual sentinel event: A terminally ill cancer patient receives a 10-fold overdose of morphine and dies within 24 hours. The patient was lucid prior to the overdose; after the overdose, the patient is comatose and never recovers consciousness before dying. Despite the patient's terminal condition this is a medication error event if the patient was resuscitated and lived, this would still be a sentinel event.

transfusion error

event category	full term	short term	specifications	standard
care management	patient death or serious injury	transfusion error		NQF
	associated with unsafe			4B
	administration of blood products			

implementation guidance

Unsafe administration includes, but is not limited to, hemolytic reactions and administering: a) blood or blood products to the wrong patient; b) the wrong type; or c) blood or blood products that have been improperly stored or handled.

This event is not intended to capture:

- patient death or serious injury associated with organ rejection other than those attributable to a hyperacute hemolytic reaction
- patient death or injury when cause is not detectable by ABO/HLA matching.
- These deaths would be categorized in 'other' category.

examples	

maternal labor or delivery

event category	full term	short term	specifications	standard
care management	maternal death or serious injury	maternal labor or delivery		NQF
	associated with labor or delivery in a			4C
	pregnancy while being cared for in a			
	healthcare setting			

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This event is not intended to create a new obligation. The organization's obligation, under this event, is to report only maternal death or serious injury associated with labor or delivery in a pregnancy when made aware of the maternal death or serious injury either by readmittance or by the patient's family.

examples	

neonate labor or delivery

event category	full term	short term	specifications	standard
care management	death or serious injury of neonate	neonate labor or delivery	Includes, for the office-based surgery, birthing	NQF
	associated with labor or delivery in a		center or "home" setting, unplanned admission to	4D
	pregnancy		an inpatient setting within 24 hours of delivery	

implementation guidance	
examples	

fall

event category	full term	short term	specifications	standard
care management	patient death or serious injury	fall	Includes but is not limited to fractures, head	NQF
	associated with a fall while being		injuries, and intracranial hemorrhage	4E
	cared for in a healthcare setting			

implementation guidance

Of note, an assessment that identifies patients at "risk" of fall, findings of risk accompanied by organizationally defined measures to be taken when risk is identified could be useful in both prevention and event analysis.

This category is not intended to include slips and trips.

examples

risk thereof sentinel event: A 44 year-old morbidly obese male is admitted for a knee replacement. At the time of diagnosis, patient is assessed as a high risk for a fall and appropriate measures are recommended. The measures include 2-person assist, call light, close proximity to nursing, and room signage. During hospitalization, the patient uses the call light to alert nursing that he needs to use the restroom. Only 1 nurse responds and assists the patient to the restroom. The nurse then leaves the patient on the toilet to get the second nurse to assist. The patient falls from the toilet and strikes his hip and leg. Two nurses then return to the room and assist the patient back to bed. The patient complains of sore hip and X-rays are done, but no fracture is identified. This is a process failure and falls into the risk thereof category and thus needs to be reported. A fall does not need to result in permanent loss of function or death as a direct result of injuries sustained by the fall to qualify as a sentinel event.

actual sentinel event: A patient is admitted with a diagnosis of lithium intoxication. The patient falls while in the hospital resulting in a fracture of the right humerus. Post X-ray, the patient is placed in a sling, and no other intervention is required. Hospital reasons that this is not a sentinel event because the injury sustained as a result of the fall did not lead to major permanent loss of function or death. The sentinel event definition contains no such criterion by which an event must result in permanent loss or death to qualify as a sentinel event. Permanent loss of function or death are not required outcomes for an event to be considered a sentinel event.

pressure ulcer

event category	full term	short term	specifications	standard
care management	any stage 3, stage 4, and unstageable	pressure ulcer	Excludes progression from Stage 2 to Stage 3 if	NQF
	pressure ulcers acquired after admission/presentation to a healthcare setting		Stage 2 was recognized upon admission and excludes pressure ulcers that develop in areas where deep tissue injury is documented as present on admission/presentation.	4F

implementation guidance	

examples

actual sentinel event: A 68 year-old male with history of acute and chronic respiratory failure and diagnosis of lung cancer presents. Skin assessment on admission is clear. Nursing notes revealed redness on hospital day 14. On hospital day 23, patient found to have stage 4 pressure ulcer. Despite patient's diagnosis and co-morbidities, a pressure ulcer is not expected.

wrong sperm or egg

implementation guidance

event category	full term	short term	specifications	standard
care management	artificial insemination with the wrong	wrong sperm or egg		NQF
	donor sperm or wrong egg			4G

Th	The organization's obligation is to report the event when it is made aware of the occurrence.		
ех	xamples		

lost specimen

event category	full term	short term	specifications	standard
care management	patient death or serious injury	lost specimen	Includes events where specimens are misidentified,	NQF
	resulting from the irretrievable loss		where another procedure cannot be done to	4H
	of an irreplaceable biological		produce a specimen	
	specimen			
			Includes progression of an undiagnosed disease or	
			threat of disease that changes the patient's risk	
			status for life, requiring monitoring not needed	
			before the event	

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This event is not intended to capture:

• procedures where the specimen was properly handled, but the specimen proved to be nondiagnostic.

examples	

electric shock

event category	full term	short term	specifications	standard
environment	patient or staff death or serious	electric shock	Excludes events involving patients during planned	NQF
	injury associated with an electric shock in the course of a patient care process in a healthcare setting		treatments such as electric countershock/elective cardioversion.	5A

implementation guidance

This event is intended to capture:

- patient death or injury associated with unintended electric shock during the course of care or treatment;
- staff death or injury associated with unintended electric shock while carrying out duties directly associated with a patient care process, including preparing for care delivery.

This event is not intended to capture:

- patient death or injury associated with emergency defibrillation in ventricular fibrillation or with electroconvulzine therapies;
- injury to staff who are not involved in patient care.

amples	

wrong or contaminated gas

event category	full term	short term	specifications	standard
environment	any incident in which systems	wrong or contaminated gas		NQF
	designated for oxygen or other gas to			5B
	be delivered to a patient contains no			
	gas, the wrong gas, or are			
	contaminated by toxic substances			

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This event is intended to capture:

events in which the line is attached to a reservoir distant from the patient care unit or in a tank near the patient such as E-cylinders, anesthesia machines.

xamples	

SENTINEL EVENT REPORTING GUIDANCE ENVIRONMENTAL

burn

event category	full term	short term	specifications	standard
environment	patient or staff death or serious	burn		NQF
	injury associated with a burn incurred			5C
	from any source in the course of a			
	patient care process in a healthcare			
	setting			

implementation guidance

This event is intended to capture burns that result from:

- operating room flash fires, including second-degree burn in these cases;
- hot water;
- sunburn in the patient with decreased ability to sense pain;
- smoking in the patient care environment.

examples	

SENTINEL EVENT REPORTING GUIDANCE ENVIRONMENTAL

restraint

event category	full term	short term	specifications	standard
environment	patient death or serious injury	restraint		NQF
	associated with the use of physical			5D
	restraints or bedrails while being			
	cared for in a healthcare setting			

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This event is intended to capture:

• instances where physical restraints are implicated in the death, e.g., lead to strangulation/entrapment, etc.

examples	

introduction of metallic object into MRI area

event category	full term	short term	specifications	standard
radiologic	death or serious injury of a patient or	introduction of metallic	Includes events related to material inside the	NQF
	staff associated with the introduction	object into MRI area	patient's body or projectiles outside the patient's	6A
	of a metallic object into the MRI area		body.	

implementation guidance

This event is intended to capture:

- retained foreign objects
- external projectiles
- pacemakers

amples	

impersonation of healthcare provider

event category	full term	short term	specifications	standard
criminal	any instance of care ordered by or	impersonation of healthcare		NQF
	provided by someone impersonating	provider		7A
	a physician, nurse, pharmacist, or			
	other licensed healthcare provider			

implementation guidance

This event is intended to capture:

- those without licensure to provide the care given;
- those with licensure who represent themselves and act beyond the scope of their licensure.

It is not intended to capture individuals who are practicing within the scope of their license on whom patients or others mistakenly bestow titles beyond that scope when such is not encouraged by the provider

examples	

SENTINEL EVENT REPORTING GUIDANCE POTENTIAL CRIMINAL

abduction

event category	full term	short term	specifications	standard
criminal	abduction of a patient/resident of	abduction		NQF
	any age			7B

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This event is intended to capture:

• removal of a patient/resident, who does not have decisionmaking capacity, without specific notification and approval by staff even when the person is otherwise authorized to be away from the setting.

Examples of individuals who do not have decisionmaking capacity include: newborns, minors, adults with Alzheimer's.

examples	

SENTINEL EVENT REPORTING GUIDANCE POTENTIAL CRIMINAL

sexual assault

event category	full term	short term	specifications	standard
criminal	sexual abuse/assault on a patient or	sexual assault		NQF
	staff member within or on the			7C
	grounds of a healthcare setting			

implementation guidance
Language and definitions may vary based on state statute; however, the principle and intent remain regardless of language required based on jurisdiction.

examples	

SENTINEL EVENT REPORTING GUIDANCE POTENTIAL CRIMINAL

physical assault

event category	full term	short term	specifications	standard
criminal	death or serious injury of a patient or	physical assault		NQF
	staff member resulting from a			7D
	physical assault (i.e., battery) that			
	occurs within or on the grounds of a			
	healthcare setting			

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Language and definitions may vary based on state statute (e.g., many states have existing statutes that use the terms "first degree assault" or "second degree assault" or "battery").

amples	

CLABSI

event category	full term	short term	specifications	standard
healthcare-	primary bloodstream infection that is	CLABSI		AHRQ
associated	central line-associated			
infection				NHSN

implementation guidance

A simplified tool based on NHSN guidance and a CLABSI checklist are included on the next few pages.

examples

actual sentinel event: A catheter tip isolate is *S aureus*. The blood culture isolate is coagulase-negative *staphylococci* (CNS). The hospital reasons that when CNS is found in a blood culture, it is usually a skin contaminant and the specimen is probably just contaminated and, therefore, unreliable. The case could not rule out infection from another source causing the blood-stream infection. Despite this reasoning, if a common commensal is isolated, it should not be automatically assumed that it does not meet the criteria for a CLABSI. NHSN criteria must be reviewed to help make the appropriate determination.

actual sentinel event: One of two cultures test positive. The hospital reasons that the positive test is probably just due to contamination since only one of two cultures test positive; therefore, the CLABSI is not proven. Despite this reasoning, it should not be assumed that just because only one of two cultures test positive that the NHSN criteria for a CLABSI are not met. NHSN criteria must be reviewed to help make the appropriate determination.



Central Line-Associated Bloodstream Infection (CLABSI) Event

Introduction: An estimated 248,000 bloodstream infections occur in U.S. hospitals each year¹, and a large proportion of these are associated with the presence of a central vascular catheter. For the purposes of NHSN, such infections are termed central line-associated bloodstream infections (CLABSI). Bloodstream infections are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality.

CLABSI can be prevented through proper management of the central line. These techniques are addressed in the CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HIPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011.*²

Settings: Surveillance will occur in any inpatient location where denominator data can be collected, which may include critical/intensive care units (ICU), specialty care areas (SCA), neonatal units including neonatal intensive care units (NICUs), stepdown units, wards, and long term care units. A complete listing of inpatient locations can be found in Chapter 15.

NOTE: Surveillance for CLABSIs after the patient is discharged from the facility is not required, however, if discovered, these infections should be reported to NHSN. No additional central line days are reported.

Requirements: Surveillance for CLABSI in at least one inpatient location in the healthcare institution for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106).

Definitions: As for all infections reported to NHSN, infections associated with complications or extensions of infections already present on admission, unless a change in pathogen or symptoms strongly suggests the acquisition of a new infection, are not considered healthcare associated. Therefore, infections that become apparent within the first few days of admission must be carefully reviewed to determine whether they should be considered healthcare associated.

<u>Primary bloodstream infections (BSI)</u> are laboratory-confirmed bloodstream infections (LCBI) that are not secondary to an HAI meeting CDC/NHSN criteria at another body site (see criteria in <u>Chapter 17</u> or a community-associated infection.) Report BSIs that are <u>central line associated</u> (i.e., a central line or umbilical catheter was in place at the time of, or within 48 hours before, onset of the event).

NOTE: There is no minimum period of time that the central line must be in place in order for the BSI to be considered central line associated.



<u>Location of attribution</u>: The inpatient location where the patient was assigned on the date of the BSI event, which is further defined as the date when the first clinical evidence appeared or the date the specimen used to meet the BSI criteria was collected, whichever came first.

EXAMPLE: Patient who had no clinical signs or symptoms of sepsis upon arrival to the Emergency Department, has a central line inserted there before being admitted to the MICU has a central line inserted in the Emergency Department and then is admitted to the MICU. Within 24 hours of admission to the MICU, patient meets criteria for BSI. This is reported to NHSN as a CLABSI for the MICU, because the Emergency Department is not an inpatient location and no denominator data are collected there.

TRANSFER RULE EXCEPTION: If a CLABSI develops within 48 hours of transfer from one inpatient location to another in the same facility, or a new facility, the infection is attributed to the transferring location. This is called the <u>Transfer Rule</u> and examples are shown below:

- Patient with a central line in place in the SICU is transferred to the surgical ward. Thirty six (36) hours later, the patient meets the criteria for BSI. This is reported to NHSN as a CLABSI for the SICU.
- Patient is transferred to the medical ward from the MSICU after having the central line removed. Within 24 hours, patient meets criteria for a BSI. This is reported to NHSN as a CLABSI for the MSICU.
- Patient with a central line in place is transferred from the medical ward to the coronary care ICU (CCU). After 4 days in the CCU, the patient meets the criteria for a BSI. This is reported to NHSN as a CLABSI for the CCU.
- Patient on the urology ward of Hospital A had the central line removed and is discharged home a few hours later. The IP from Hospital B calls the next day to report that this patient has been admitted to Hospital B with a BSI. This CLABSI should be reported to NHSN for, and by, Hospital A and attributed to the urology ward. No additional catheter days are reported.

Central line: An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring. The following are considered great vessels for the purpose of reporting central-line BSI and counting central-line days in the NHSN system: Aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, common iliac veins, femoral veins, and in neonates, the umbilical artery/vein.

NOTES:

- 1. Neither the insertion site nor the type of device may be used to determine if a line qualifies as a central line. The device must terminate in one of these vessels or in or near the heart to qualify as a central line.
- 2. An introducer is considered an intravascular catheter, and depending on the location of its tip, may be a central line.



- 3. Pacemaker wires and other nonlumened devices inserted into central blood vessels or the heart are <u>not</u> considered central lines, because fluids are not infused, pushed, nor withdrawn through such devices.
- 4. The following devices are <u>not</u> considered central lines: extracorporeal membrane oxygenation (ECMO), femoral arterial catheters and Intraaortic balloon pump (IABP) devices. If you have a question about whether a device qualifies as a central line, please email us at NHSN@cdc.gov.

<u>Infusion</u>: The introduction of a solution through a blood vessel via a catheter lumen. This may include continuous infusions such as nutritional fluids or medications, or it may include intermittent infusions such as flushes or IV antimicrobial administration, or blood, in the case of transfusion or hemodialysis.

<u>Umbilical catheter</u>: A central vascular device inserted through the umbilical artery or vein in a neonate.

Temporary central line: A non-tunneled catheter.

Permanent central line: Includes

- o Tunneled catheters, including certain dialysis catheters
- o Implanted catheters (including ports)

<u>Laboratory-confirmed bloodstream infection (LCBI)</u>: Must meet one of the following criteria:

<u>Criterion 1</u>: Patient has a recognized pathogen cultured from one or more blood cultures

and

organism cultured from blood is <u>not</u> related to an infection at another site. (See Notes 1 and 2 below.)

<u>Criterion 2</u>: Patient has at least <u>one</u> of the following signs or symptoms: fever (>38°C), chills, or hypotension

and

signs and symptoms and positive laboratory results are <u>not</u> related to an infection at another site

and

common commensal (i.e., diphtheroids [Corynebacterium spp. not C. diphtheriae], Bacillus spp. [not B. anthracis], Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or more blood cultures drawn on separate occasions.

<u>Criterion 3</u>: Patient \leq 1 year of age has at least <u>one</u> of the following signs or symptoms: fever (>38°C core) hypothermia (<36°C core), apnea, or bradycardia and



signs and symptoms and positive laboratory results are <u>not</u> related to an infection at another site

and

common skin commensal (i.e., diphtheroids [Corynebacterium spp. not C. diphtheriae], Bacillus spp. [not B.anthracis], Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or more blood cultures drawn on separate occasions. (See Notes 3, 4 and 5 below.)

NOTES:

- 1. In criterion 1, the phrase "one or more blood cultures" means that at least one bottle from a blood draw is reported by the laboratory as having grown organisms (i.e., is a positive blood culture).
- 2. In criterion 1, the term "recognized pathogen" does <u>not</u> include organisms considered common commensals (see criteria 2 and 3 for a list of common commensals). A few of the recognized pathogens are *S. aureus*, *Enterococcus* spp., *E. coli*, *Pseudomonas* spp., *Klebsiella* spp., *Candida* spp., etc.
- 3. In criteria 2 and 3, the phrase "two or more blood cultures drawn on separate occasions" means 1) that blood from at least two blood draws were collected within two days of each other (e.g., blood draws on Monday and Tuesday or Monday and Wednesday would be acceptable for blood cultures drawn on separate occasions, but blood draws on Monday and Thursday would be too far apart in time to meet this criterion), and 2) that at least one bottle from each blood draw is reported by the laboratory as having grown the same common commensal (i.e., is a positive blood culture). (See Note 4 for determining sameness of organisms.)
 - a. For example, an adult patient has blood drawn at 8 a.m. and again at 8:15 a.m. of the same day. Blood from each blood draw is inoculated into two bottles and incubated (four bottles total). If one bottle from each blood draw set is positive for coagulase-negative staphylococci, this part of the criterion is met.
 - b. For example, a neonate has blood drawn for culture on Tuesday and again on Saturday and both grow the same common commensal. Because the time between these blood cultures exceeds the two-day period for blood draws stipulated in criteria 2 and 3, this part of the criteria is not met.
 - c. A blood culture may consist of a single bottle for a pediatric blood draw due to volume constraints. Therefore, to meet this part of the criterion, each bottle from two or more draws would have to be culture-positive for the same commensal.
- 4. If the common commensal is identified to the species level from one culture, and a companion culture is identified with only a descriptive name (e.g., to the genus level), then it is assumed that the organisms are the same. The organism identified to the species level should be reported as the infecting pathogen along with its antibiogram if available (see Table 1 below).



Table 1. Examples of how to report speciated and unspeciated common commensals			
Culture Report	Companion Culture Report	Report as	
S. epidermidis	Coagulase- negative staphylococci	S. epidermidis	
Bacillus spp. (not anthracis)	B. cereus	B. cereus	
S. salivarius	Strep viridans	S. salivarius	

- 5. Only genus and species identification should be utilized to determine the sameness of organisms. No additional comparative methods should be used (e.g., morphology or antibiograms) because laboratory testing capabilities and protocols may vary between facilities. This will reduce reporting variability, solely due to laboratory practice, between facilities reporting LCBIs meeting criterion 2. Report the organism to the genus/species level only once, and if antibiogram data are available, report the results from the most resistant panel.
- 6. LCBI criteria 1 and 2 may be used for patients of any age, including patients \leq 1 year of age.
- 7. Specimen Collection Considerations:

 Ideally, blood specimens for culture should be obtained from two to four blood draws from separate venipuncture sites (e.g., right and left antecubital veins), not through a vascular catheter. These blood draws should be performed simultaneously or over a short period of time (i.e., within a few hours). If your facility does not currently obtain specimens using this technique, you must still report BSIs using the criteria and notes above, but you should work with appropriate personnel to facilitate better specimen collection practices for blood cultures.

REPORTING INSTRUCTIONS:

- Report organisms cultured from blood as BSI LCBI when no other site of infection is evident.
- When there is a positive blood culture and clinical signs or symptoms of localized infection at a vascular access site, but no other infection can be found, the infection is considered a primary BSI.
- Purulent phlebitis confirmed with a positive semiquantitative culture of a catheter tip, but with either negative or no blood culture is considered a CVS-VASC, not a BSI nor an SST-SKIN or ST infection.
- Occasionally a patient with both peripheral and central IV lines develops a primary bloodstream infection (LCBI) that can clearly be attributed to the peripheral line (e.g., pus at the insertion site and matching pathogen from pus and blood). In this situation, enter "Central Line = No" in the NHSN application. You should, however, include the patient's central line days in the summary denominator count.



Numerator Data: The *Primary Bloodstream Infection (BSI)* form (CDC 57.108) is used to collect and report each CLABSI that is identified during the month selected for surveillance. The *Instructions for Completion of Primary Bloodstream Infection Form* (Tables of Instructions, Tables 2 and 2a.) contains brief instructions for collection and entry of each data element on the form. The Primary BSI form includes patient demographic information and whether a central line was present, and, if so, the type of central line the patient had as appropriate to the location; these data will be used to calculate line-specific infection rates. Additional data include the specific criteria met for identifying the primary BSI, whether the patient died, the organisms isolated from blood cultures, and the organisms' antimicrobial susceptibilities.

Denominator Data: Device days and patient days are used for denominators (see Chapter 16, Key Terms). Device-day denominator data that are collected differ according to the location of the patients being monitored; however, they should be collected at the same time each day. When denominator data are available from electronic databases, these sources may be used as long as the counts are not substantially different (+/- 5%) from manually-collected counts.

For ICUs and locations other than specialty care areas (SCAs) and NICUs, the number of patients with one or more central lines of any type is collected daily, at the same time each day, during the month and recorded on the *Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or Specialty Care Area (SCA))* (CDC 57.118). Only the totals for the month are entered into NHSN. When denominator data are available from electronic sources (e.g., central line days from electronic charting), these sources may be used as long as the counts are not substantially different (+/- 5%) from manually-collected counts.

For specialty care areas, the number of patients with one or more central lines is dichotomized into those with permanent central lines and those with temporary central lines on the *Denominators for Specialty Care Area* (CDC 57.117) form. Each is collected daily, at the same time each day. Only the total for the month are entered into NHSN. This distinction in lines is made because permanent lines are commonly used in patients frequenting these areas and may have lower rates of associated infection than central lines inserted for temporary use. If a patient has both a temporary and a permanent central line, count the day only as a temporary line day. The *Instructions for Completion of Denominators for Intensive Care Unit (ICU)/Other Locations Form* (Tables of Instructions, Table 6) and *Instructions for Completion of Denominators for Specialty Care Areas (SCA) Form* (Tables of Instructions, Table 7) contain brief instructions for collection and entry of each data element on the forms.

In NICUs, again because of differing infection risks, the number of patients with central lines and those with umbilical catheters is collected daily, at the same time each day, during the month. If a patient has both an umbilical catheter and a central line, count the day only as an umbilical catheter day. On the *Denominators for Neonatal Intensive Care*



Unit (NICU) (CDC 57.116) form, patients are further stratified by birthweight in five categories since risk of BSI also varies by birthweight.

NOTE: The weight of the infant at the time of BSI is not used and should not be reported. For example, if a neonate weighs 1006 grams at birth but remains in the NICU for two months and has a body weight of 1650 grams when it develops a CLABSI, record the birthweight of 1006 grams on the BSI form. The *Instructions for Completion of Denominators for Neonatal Intensive Care Unit (NICU)* form (Tables of Instructions, Table 8) contains brief instructions for collection and entry of each data element on the forms.

Data Analyses: The SIR is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using CLABSI rates from a standard population during a baseline time period as reported in the NHSN Report.

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥ 1 .

While the CLABSI SIR can be calculated for single locations, the measure also allows you to summarize your data across multiple locations, adjusting for differences in the incidence of infection among the location types. For example, you will be able to obtain one CLABSI SIR adjusting for all locations reported. Similarly, you can obtain one CLABSI SIR for all specialty care areas in your facility.

The <u>CLABSI rate</u> per 1000 central line days is calculated by dividing the number of CLABSI by the number of central line days and multiplying the result by 1000. The <u>Central Line Utilization Ratio</u> is calculated by dividing the number of central line days by the number of patient days. These calculations will be performed separately for different types of ICUs, specialty care areas, and other locations in the institution. Separate rates and ratios will also be calculated for different types of catheters in specialty care areas and NICUs, and for birthweight categories in NICUs.

¹Klevens RM, Edward JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160-166.

² O'Grady NP, Alexander M, Burns LA,, Dellinger EP, Garland J, Heard SO, Maki DG, et al. Guidelines for the prevention of intravascular catheter-related infections, 2011. Clinical Infectious Diseases 2011; 52 (a):1087-99.



³ Clinical and Laboratory Standards Institute (CLSI). *Principles and Procedures for Blood Cultures; Approved Guideline*. CLSI document M47-A (ISBN 1-56238-641-7). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania, USA, 2007.

⁴ Baron EJ, Weinstein MP, Dunne Jr WM, Yagupsky P, Welch DF, and Wilson DM. Blood Cultures IV. ASM Press: Washington, DC; 2005.

CLABSI Criteria 1 & 2 - Used for Patients of any Age Facility: _____ Date: ____ Patient #_____ Medical Record #____ Admission Date: Discharge Date: **Blood Cultures** (list here) Non-blood cultures (list here) Reviewer Initials: _____ Notes: Date: ___Source: ____Organism: _____ Date: _____#____ Date: Source: Organism: Date: Organism: # Date: _____ Source: ____ Organism: _____ Date: Organism: # Date: Source: Organism: Date: __ Organism: _____#___ Date: Source: Organism: Date: _____ Organism: _____#____ Date: Source: Organism: Date: Organism: # Date: Source: Organism: Central line (CL) in place or within 48 hours of CL discontinuation when blood cultures drawn (mark yes & to Criteria 1 or 2) No – Does not **Notes:** Dates & site notes if needed: meet NHSN Criteria 1 Criteria 2 Patient has a recognized pathogen cultured from one or more blood Common commensal cultured from two or more blood cultures No – Does not Yes 🗆 **cultures** (circle pathogen in blood culture section & check yes) drawn on separate occasions (circle commensals in blood culture section & meet NHSN Yes 🗀 check yes) Organism cultured from blood is <u>not</u> related to an infection at another No – Does not Organism cultured from blood is not related to an infection at another site (check if not related) meet NHSN site (check if not related) Yes (not related) - Meets Criteria Patient has at least one of the following signs or symptoms (circle all that apply): (check if yes) Fever (>38 C or 100.4 F) Admit Temp: **CIRCLE CONCLUSION** Chills Signs or symptoms not related to an infection at Hypotension Admit Blood Pressure: YES Date: _____ Symptom: _____ another site (check if not related) Date: Symptom: NO Date: ____ Symptom: _____ **INDETERMINATE** Yes (not related) -No – Does not Meets Criteria 2 meet NHSN

Central Line- Associated Bloodstream Infection (CLABSI) Event Check List Criteria

Instructions for use

Use this check list to determine if an infection meets the NHSN CLABSI criteria.

Blood cultures: Fill in relevant blood cultures in blood culture section, if you need to ensure there are 2 different blood cultures then include the unique identifying number for the blood culture next to #

Non-blood cultures: Fill in the relevant cultures to help you determine if a secondary infection exists.

Then go down the flow sheet using Criteria 1 if you find a recognized pathogen and Criteria 2 if you find common commensals cultured from 2 or more blood cultures. As instructed in the flow sheet, circle the relevant cultures used to assist in make the CLABSI determination, for example, you would circle the recognized pathogen in the blood cultures box that was used to come up with a determination of a CLABSI. If none, do not circle.

You must understand the terms defined in bold below to complete the criteria checklist. You will find the terms in bold letters in the checklist.

Central line defined: An intravascular catheter (used for infusion, withdrawal of blood, or hemodynamic monitoring) that terminates at or close to the heart or in one of the great vessels which includes the: aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, common iliac veins, femoral veins, and in neonates, the umbilical artery/vein.

The Central line (CL) must be in place or within 48 hours of CL discontinuation when blood cultures drawn are drawn.

Common Commensals include but are not limited to (for a more extensive list, please refer to common commensal list):

- Diphtheroids (Corynebacterium spp. not C. diphtheria
- Bacillus spp. not B. anthracis, Propionibacterium spp.
- Coagulase-negative staphylococci including S. epidermidis
- Viridans group streptococci, Aerococcus spp., Mircrococcus spp., S. salivarius

Recognized pathogens (Do Not include common commensals) include but are not limited to:

- S. aureus
- Enterococcus spp.
- E. coli
- Pseudomonas spp.
- Klebsiella spp.
- Candida spp.

One or more blood cultures means at least one bottle from each blood draw (each draw/culture requires 2 bottles) is reported by the laboratory to have grown organisms. It is a positive blood culture. For example, two blood cultures would require 4 bottles and for both blood cultures to be positive, one bottle from each set would have to grown organisms.

Two or more blood cultures drawn on separate occasions means:

- 1. Blood from at least 2 blood draws were collected within two days of each other
- 2. At least one bottle from each blood draw is reported by the laboratory as having grown the same common commensal. It is considered a positive blood culture.

Pediatric blood draw consideration

Blood culture may consist of a single bottle for a pediatric blood draw. Therefore to meet criteria, each bottle from two or more draws would have to be culture-positive for the same commensal.

Infection at another site:

In Criteria's 1 or 2 in order to make the determination of a CLABSI you must ensure that the organism cultured from the blood is not related to an infection at another site. Look at non-blood culture results to see if the organism cultured in the blood is the same as an organism cultured from a different source. In addition, refer to NHSN manual, Chapter 17 to see if the signs or symptoms a patient is having meet the NHSN criteria for an infection. If so, the organism cultured from the blood would be related to an infection at another site and would not meet NHSN criteria for a CLABSI.

Other Considerations:

Patient has a peripheral IV and central line (CL) in place at the same time:

Primary BSI attributed to peripheral line and not the central line if pus at the peripheral line insertion site matches the blood pathogen.

Cather tip cultures

Purulent phlebitis confirmed with a positive semiquantitative culture of a catheter tip, but with either negative or no blood culture is considered a cardiovascular system-venous arterial system related infection, not a BSI or CLABSI.

Localized infection at Central Line site:

A positive blood culture and localized infection at the central line site and no other infection would be considered a primary BSI.

For further details refer to the Device-associated CLABSI module

VAP

event category	full term	short term	specifications	standard
healthcare-	pneumonia that is ventilator-	VAP		AHRQ
associated	associated			
infection				NHSN

implementation guidance		
NHSN guidance included on the next few pages.		
examples		



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Ventilator-Associated Pneumonia (VAP) Event

Introduction: In 2002, an estimated 250,000 healthcare-associated pneumonias developed in U.S. hospitals and 36,000 of these were associated with deaths. Patients with mechanically-assisted ventilation have a high risk of developing healthcare-associated pneumonia. From 2006-2007, within NHSN facilities almost 5,400 VAPs were reported and incidence for various types of hospital units ranged from 2.1-11.0 per 1,000 ventilator days. ¹

Prevention and control of healthcare-associated pneumonia is discussed in the CDC/HICPAC document, *Guidelines for Prevention of Healthcare-Associated Pneumonia*, 2003². The Guideline strongly recommends that surveillance be conducted for bacterial pneumonia in ICU patients who are mechanically ventilated to facilitate identification of trends and for interhospital comparisons.

Settings: Surveillance will occur in any inpatient location where denominator data can be collected, which may include critical/intensive care units (ICU), specialty care areas (SCA), neonatal units, including neonatal intensive care units (NICUs), stepdown units, wards, and long term care units. A complete listing of inpatient locations can be found in Chapter 15.

NOTE: It is not required to monitor for VAPs after the patient is discharged from the facility, however, if discovered, a VAP should be reported to NHSN. No additional ventilator days are reported.

Requirements: Surveillance for VAP in at least one inpatient location in the healthcare institution for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106).

Definitions: As for all infections reported to NHSN, infections associated with complications or extensions of infections already present on admission, unless a change in pathogen or symptoms strongly suggests the acquisition of a new infection area not considered healthcare associated. Therefore, infections that become apparent within the first few days of admission must be carefully reviewed to determine whether they should be considered healthcare associated.

Pneumonia (PNEU) is identified by using a combination of radiologic, clinical and laboratory criteria. The following pages outline the various assessment criteria that may be used for meeting the surveillance definition of healthcare-associated pneumonia (Tables 2-5 and Figures 1 and 2). Report PNEUs that are <u>ventilator-associated</u> (i.e., patient was intubated and ventilated at the time of, or within 48 hours before, the <u>onset of the event</u>).

NOTE: There is no minimum period of time that the ventilator must be in place in order for the PNEU to be considered ventilator associated.

<u>Location of attribution</u>: The inpatient location where the patient was assigned on the date of the PNEU event, which is further defined as the date when the first clinical evidence appeared or the date the specimen used to meet the PNEU criterion was collected, whichever came first. EXAMPLE: Patient is intubated and ventilated in the Operating Room and then is admitted to the MICU. Within 24 hours of admission to the MICU, patient meets criteria for PNEU. This is

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reported to NHSN as a VAP for the MICU, because the Operating Room is not an inpatient location and no denominator data are collected there.

TRANSFER RULE EXCEPTION: If a VAP develops within 48 hours of transfer from one inpatient location to another in the same facility or a new facility,, the infection is attributed to the transferring location. This is called the <u>Transfer Rule</u> and examples are shown below:

- Patient on a ventilator in the SICU is transferred to the surgical ward. Thirty six (36) hours later, the patient meets the criteria for PNEU. This is reported to NHSN as a VAP for the SICU.
- Patient is transferred to the medical ward from the MSICU after having ventilator removed.
 Within 24 hours, the patient meets criteria for a PNEU. This is reported to NHSN as a VAP for the MSICU.
- Patient on a ventilator is transferred from the medical ward to the coronary care ICU (CCU).
 After 4 days in the CCU, the patient meets the criteria for a PNEU. This is reported to NHSN as a VAP for the CCU.
- Patient on the Respiratory ICU (RICU) of Hospital A had the endotracheal tube and ventilator removed and is discharged home a few hours later. The ICP from Hospital B calls the next day to report that this patient has been admitted to Hospital B with a PNEU. This VAP should be reported to NHSN for, and by, Hospital A and attributed to the RICU. No additional ventilator days are reported.

<u>Ventilator</u>: A device to assist or control respiration continuously, inclusive of the weaning period, through a tracheostomy or by endotracheal intubation.

NOTE: Lung expansion devices such as intermittent positive-pressure breathing (IPPB); nasal positive end-expiratory pressure (PEEP); and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP).

General Comments Applicable to All Pneumonia Specific Site Criteria:

- 1. Physician's diagnosis of pneumonia alone is <u>not</u> an acceptable criterion for healthcare-associated pneumonia.
- 2. Although specific criteria are included for infants and children, pediatric patients may meet any of the other pneumonia specific site criteria.
- 3. Ventilator-associated pneumonia (i.e., pneumonia in persons who had a device to assist or control respiration continuously through a tracheostomy or by endotracheal intubation within the 48-hour period before the onset of infection, inclusive of the weaning period) should be so designated when reporting data.
- 4. When assessing a patient for presence of pneumonia, it is important to distinguish between changes in clinical status due to other conditions such as myocardial infarction, pulmonary embolism, respiratory distress syndrome, atelectasis, malignancy, chronic obstructive pulmonary disease, hyaline membrane disease, bronchopulmonary dysplasia, etc. Also, care must be taken when assessing intubated patients to distinguish between tracheal colonization, upper respiratory tract infections (e.g., tracheobronchitis), and early onset pneumonia. Finally, it should be recognized that it may be difficult to determine healthcare-associated pneumonia in the elderly, infants, and immunocompromised patients since such conditions



- may mask typical signs or symptoms associated with pneumonia. Alternate specific criteria for the elderly, infants and immunocompromised patients have been included in this definition of healthcare-associated pneumonia.
- 5. Healthcare-associated pneumonia can be characterized by its onset: early or late. Early onset pneumonia occurs during the first four days of hospitalization and is often caused by *Moraxella catarrhalis, H. influenzae*, and *S. pneumoniae*. Causative agents of late onset pneumonia are frequently gram negative bacilli or *S. aureus*, including methicillin-resistant *S. aureus*. Viruses (e.g., Influenza A and B or Respiratory Syncytial Virus) can cause early and late onset healthcare-associated pneumonia, whereas yeasts, fungi, legionellae, and *Pneumocystis carinii* are usually pathogens of late onset pneumonia.
- 6. Pneumonia due to gross aspiration (for example, in the setting of intubation in the emergency room or operating room) is considered healthcare-associated if it meets any specific criteria and was not clearly present or incubating at the time of admission to the hospital.
- 7. Multiple episodes of healthcare-associated pneumonia may occur in critically ill patients with lengthy hospital stays. When determining whether to report multiple episodes of healthcare-associated pneumonia in a single patient, look for evidence of resolution of the initial infection. The addition of or change in pathogen alone is not indicative of a new episode of pneumonia. The combination of new signs and symptoms and radiographic evidence or other diagnostic testing is required.
- 8. Positive Gram stain for bacteria and positive KOH (potassium hydroxide) mount for elastin fibers and/or fungal hyphae from appropriately collected sputum specimens are important clues that point toward the etiology of the infection. However, sputum samples are frequently contaminated with airway colonizers and therefore must be interpreted cautiously. In particular, *Candida* is commonly seen on stain, but infrequently causes healthcare-associated pneumonia.

Table 1: Abbreviations used in PNEU laboratory criteria

j	
BAL – bronchoalveolar lavage	LRT – lower respiratory tract
EIA – enzyme immunoassay	PCR – polymerase chain reaction
FAMA – fluorescent-antibody staining of	PMN – polymorphonuclear leukocyte
membrane antigen	
IFA – immunofluorescent antibody	RIA – radioimmunoassay

REPORTING INSTRUCTIONS:

- There is a hierarchy of specific categories within the major site pneumonia. Even if a patient meets criteria for more than one specific site, report only one:
 - o If a patient meets criteria for both PNU1 and PNU2, report PNU2
 - o If a patient meets criteria for both PNU2 and PNU3, report PNU3
 - o If a patient meets criteria for both PNU1 and PNU3, report PNU3
- Report concurrent lower respiratory tract infection (e.g., abscess or empyema) and pneumonia with the same organism(s) as pneumonia
- Lung abscess or empyema without pneumonia are classified as LUNG
- Bronchitis, tracheitis, tracheobronchitis, or bronchiolitis <u>without</u> pneumonia are classified as BRON.

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Radiology	Signs/Symptoms/Laboratory
Two or more serial chest radiographs with at least one of the following 1,2: New or progressive and persistent infiltrate Consolidation	FOR ANY PATIENT, at least <u>one</u> of the following: -Fever (>38°C or >100.4°F) with no other recognized cause -Leukopenia (<4000 WBC/mm³) or leukocytosis (≥12,000 WBC/mm³) -For adults ≥70 years old, altered mental status with no other recognized cause and at least two of the following:
Cavitation Pneumatoceles, in infants ≤ 1 year old	-New onset of purulent sputum ³ , or change in character of sputum ⁴ , or increased respiratory secretions, or increased suctioning requirements -New onset or worsening cough, or dyspnea, or tachypnea ⁵ -Rales ⁶ or bronchial breath sounds -Worsening gas exchange (e.g. O ₂ desaturations (e.g., PaO ₂ /FiO ₂ ≤ 240) ⁷ , increased oxygen requirements, or increased ventilator demand)
NOTE: In patients without underlying pulmonary or cardiac disease (e.g. respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), one definitive chest radiograph is acceptable.	ALTERNATE CRITERIA, for infants ≤1 year old: Worsening gas exchange (e.g., O₂ desaturations [e.g. pulse oximetry < 94%], increased oxygen requirements, or increased ventilator demand) and at least three of the following: -Temperature instability with no other recognized cause -Leukopenia (<4000 WBC/mm³) or leukocytosis (≥15,000 WBC/mm³) and left shift (≥10% band forms) -New onset of purulent sputum³ or change in character of sputum⁴, or increased respiratory secretions or increased suctioning requirements -Apnea, tachypnea⁵, nasal flaring with retraction of chest wall or grunting -Wheezing, rales⁶, 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 (>38.4°C or >101.1°F) or hypothermia (<36.5°C or <97.7°F) with no other recognized cause -Leukopenia (<4000 WBC/mm³) or leukocytosis (≥15,000 WBC/mm³) -New onset of purulent sputum³, or change in character of sputum⁴, or increased respiratory secretions, or increased suctioning requirements -New onset or worsening cough, or dyspnea, apnea, or tachypnea⁵Rales⁶ or bronchial breath soundsWorsening gas exchange (e.g. O₂ desaturations [e.g. pulse oximetry < 94%], increased oxygen requirements, or increased ventilator demand)

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Table 3: Specific Site Algorithms for Pneumonia with Common Bacterial or Filamentous Fungal Pathogens and Specific Laboratory Findings (PNU2)

Radiology	Signs/Symptoms	Laboratory
Two or more serial chest radiographs with at least one of the following 1,2:	At least <u>one</u> of the following: Fever (>38°C or >100.4°F) with no other recognized cause	At least <u>one</u> of the following: Positive growth in blood culture ⁸ not related to another source of infection
New or progressive and persistent infiltrate Consolidation Cavitation Pneumatoceles, in infants ≤ 1 year old NOTE: In patients without underlying pulmonary or cardiac disease (e.g. respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), one definitive chest radiograph is acceptable.¹	Leukopenia (<4000 WBC/mm³) or leukocytosis (≥12,000 WBC/mm³) For adults ≥70 years old, altered mental status with no other recognized cause and at least one of the following: New onset of purulent sputum³, or change in character of sputum⁴, or increased respiratory secretions, or increased suctioning requirements New onset or worsening cough, or dyspnea or tachypnea⁵ Rales⁶ or bronchial breath sounds Worsening gas exchange (e.g. O₂ desaturations [e.g., PaO₂/FiO₂ ≤ 240]³, increased oxygen requirements, or increased ventilator demand)	Positive growth in culture of pleural fluid Positive quantitative culture ⁹ from minimally contaminated LRT specimen (e.g., BAL or protected specimen brushing) ≥5% BAL-obtained cells contain intracellular bacteria on direct microscopic exam (e.g., Gram stain) Histopathologic exam shows at least one of the following evidences of pneumonia: Abscess formation or foci of consolidation with intense PMN accumulation in bronchioles and alveoli Positive quantitative culture ⁹ of lung parenchyma Evidence of lung parenchyma invasion by fungal hyphae or pseudohyphae



Table 4: Specific Site Algorithms for Viral, Legionella, and other Bacterial Pneumonias with Definitive Laboratory Findings (PNU2)

Radiology	Signs/Symptoms	Laboratory
Two or more serial chest radiographs with at least one of the following 1.2: New or progressive and persistent infiltrate Consolidation Cavitation	At least <u>one</u> of the following: Fever (>38°C or >100.4°F) with no other recognized cause Leukopenia (<4000 WBC/mm³) or leukocytosis (≥12,000 WBC/mm³) For adults ≥70 years old, altered mental status with no other	At least <u>one</u> of the following 10-12: Positive culture of virus or <i>Chlamydia</i> from respiratory secretions Positive detection of viral antigen or antibody from respiratory secretions (e.g., EIA, FAMA, shell vial assay, PCR) Fourfold rise in paired sera (IgG) for pathogen (e.g., influenza viruses, <i>Chlamydia</i>)
Pneumatoceles, in infants ≤ 1 year old NOTE: In patients without underlying pulmonary or cardiac disease (e.g. respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), one definitive chest radiograph is acceptable.	and at least one of the following: New onset of purulent sputum³, or change in character of sputum⁴, or increased respiratory secretions, or increased suctioning requirements New onset or worsening cough or dyspnea, or tachypnea⁵ Rales⁶ or bronchial breath sounds Worsening gas exchange (e.g. O₂ desaturations [e.g., PaO₂/FiO₂ ≤ 240]⁴, increased oxygen requirements, or increased ventilator demand)	Positive PCR for Chlamydia or Mycoplasma Positive micro-IF test for Chlamydia Positive culture or visualization by micro-IF of Legionella spp, from respiratory secretions or tissue. Detection of Legionella pneumophila serogroup 1 antigens in urine by RIA or EIA Fourfold rise in L. pneumophila serogroup 1 antibody titer to ≥1:128 in paired acute and convalescent sera by indirect IFA.



Table 5: Specific Site Algorithm for Pneumonia in Immunocompromised Patients (PNU3)

Radiology	Signs/Symptoms	Laboratory
Two or more serial chest radiographs with at least one of the following 1.2:	Patient who is immunocompromised ¹³ has at least one of the following:	At least <u>one</u> of the following: Matching positive blood and sputum cultures with <i>Candida</i> spp. ^{14, 15}
New or progressive and persistent infiltrate Consolidation	Fever (>38°C or >100.4°F) with no other recognized cause	Evidence of fungi or <i>Pneumocystis carinii</i> from minimally contaminated LRT specimen (e.g., BAL or protected specimen brushing) from one of the following:
Cavitation Pneumatoceles, in	For adults ≥70 years old, altered mental status with no other recognized cause	- Direct microscopic exam - Positive culture of fungi
infants ≤ 1 year old	New onset of purulent sputum ³ , or change in character of sputum ⁴ , or increased respiratory secretions, or increased suctioning requirements	Any of the following from LABORATORY CRITERIA DEFINED UNDER PNU2
NOTE: In patients without underlying pulmonary or cardiac disease (e.g. respiratory	New onset or worsening cough, or dyspnea, or tachypnea ⁵ Rales ⁶ or bronchial breath sounds	FNOZ
distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), one definitive chest radiograph is	Worsening gas exchange (e.g. O₂ desaturations [e.g., PaO₂/FiO₂ ≤ 240] ⁷ , increased oxygen requirements, or increased ventilator demand)	
acceptable.	Hemoptysis	
	Pleuritic chest pain	

Footnotes to Algorithms:

- 1. Occasionally, in nonventilated patients, the diagnosis of healthcare-associated pneumonia may be quite clear on the basis of symptoms, signs, and a single definitive chest radiograph. However, in patients with pulmonary or cardiac disease (for example, interstitial lung disease or congestive heart failure), the diagnosis of pneumonia may be particularly difficult. Other non-infectious conditions (for example, pulmonary edema from decompensated congestive heart failure) may simulate the presentation of pneumonia. In these more difficult cases, serial chest radiographs must be examined to help separate infectious from non-infectious pulmonary processes. To help confirm difficult cases, it may be useful to review radiographs on the day of diagnosis, 3 days prior to the diagnosis and on days 2 and 7 after the diagnosis. Pneumonia may have rapid onset and progression, but does not resolve quickly. Radiographic changes of pneumonia persist for several weeks. As a result, rapid radiographic resolution suggests that the patient does <u>not</u> have pneumonia, but rather a non-infectious process such as atelectasis or congestive heart failure.
- 2. Note that there are many ways of describing the radiographic appearance of pneumonia. Examples include, but are not limited to, "air-space disease", "focal opacification", "patchy areas of increased density". Although perhaps not specifically delineated as pneumonia by the radiologist, in the appropriate clinical setting these alternative descriptive wordings should be seriously considered as potentially positive findings.

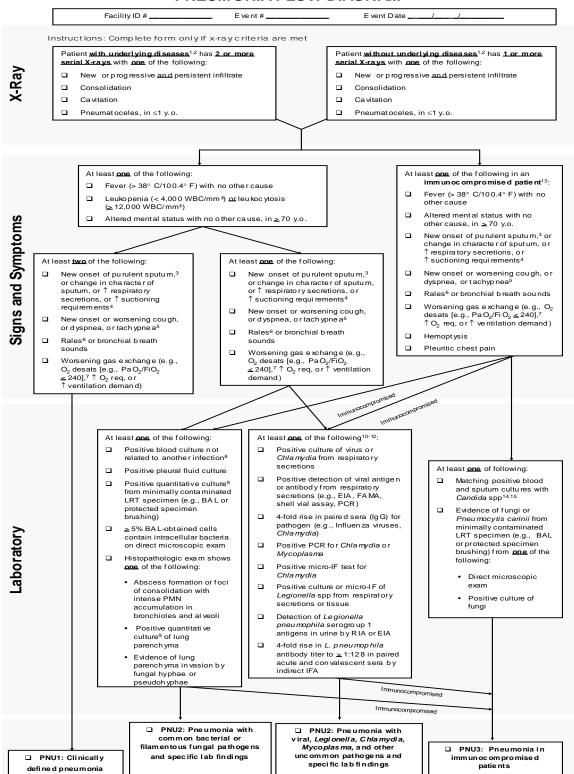


- 3. Purulent sputum is defined as secretions from the lungs, bronchi, or trachea that contain \geq 25 neutrophils and \leq 10 squamous epithelial cells per low power field (x100). If your laboratory reports these data qualitatively (e.g., "many WBCs" or "few squames"), be sure their descriptors match this definition of purulent sputum. This laboratory confirmation is required since written clinical descriptions of purulence are highly variable.
- 4. A single notation of either purulent sputum or change in character of the sputum, is not meaningful; repeated notations over a 24 hour period would be more indicative of the onset of an infectious process. Change in character of sputum refers to the color, consistency, odor and quantity.
- 5. In adults, tachypnea is defined as respiration rate >25 breaths per minute. Tachypnea is defined as >75 breaths per minute in premature infants born at <37 weeks gestation and until the 40th week; >60 breaths per minute in patients <2 months old; >50 breaths per minute in patients 2-12 months old; and >30 breaths per minute in children >1 year old.
- 6. Rales may be described as "crackles".
- 7. This measure of arterial oxygenation is defined as the ratio of the arterial tension (PaO_2) to the inspiratory fraction of oxygen (FiO_2) .
- 8. Care must be taken to determine the etiology of pneumonia in a patient with positive blood cultures and radiographic evidence of pneumonia, especially if the patient has invasive devices in place such as intravascular lines or an indwelling urinary catheter. In general, in an immunocompetent patient, blood cultures positive for coagulase negative staphylococci, common skin contaminants, and yeasts will not be the etiologic agent of the pneumonia.
- 9. Refer to Threshold values for cultured specimens (Table 6). An endotracheal aspirate is not a minimally contaminated specimen. Therefore, an endotracheal aspirate does not meet the laboratory criteria.
- 10. Once laboratory-confirmed cases of pneumonia due to respiratory syncytial virus (RSV), adenovirus, or influenza virus have been identified in a hospital, clinician's presumptive diagnosis of these pathogens in subsequent cases with similar clinical signs and symptoms is an acceptable criterion for presence of healthcare-associated infection.
- 11. Scant or watery sputum is commonly seen in adults with pneumonia due to viruses and *Mycoplasma* although sometimes the sputum may be mucopurulent. In infants, pneumonia due to RSV or influenza yields copious sputum. Patients, except premature infants, with viral or mycoplasmal pneumonia may exhibit few signs or symptoms, even when significant infiltrates are present on radiographic exam.
- 12. Few bacteria may be seen on stains of respiratory secretions from patients with pneumonia due to *Legionella* spp, mycoplasma, or viruses.
- 13. Immunocompromised patients include those with neutropenia (absolute neutrophil count <500/mm³), leukemia, lymphoma, HIV with CD4 count <200, or splenectomy; those who are early post-transplant, are on cytotoxic chemotherapy, or are on high dose steroids (e.g., >40mg of prednisone or its equivalent (>160mg hydrocortisone, >32mg methylprednisolone, >6mg dexamethasone, >200mg cortisone) daily for >2weeks).
- 14. Blood and sputum specimens must be collected within 48 hours of each other.
- 15. Semiquantitative or nonquantitative cultures of sputum obtained by deep cough, induction, aspiration, or lavage are acceptable. If quantitative culture results are available, refer to algorithms that include such specific laboratory findings



Figure 1: Pneumonia Flow Diagram

PNEUMONIA FLOW DIAGRAM

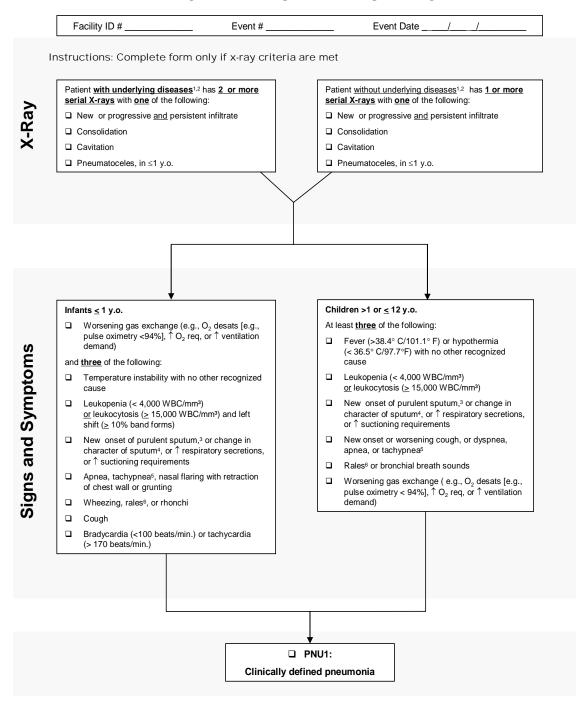


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Figure 2: Pneumonia Flow Diagram, Alternative Criteria for Infants and Children

PNEUMONIA FLOW DIAGRAM ALTERNATE CRITERIA FOR INFANTS AND CHILDREN



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Table 6: Threshold values for cultured specimens used in the diagnosis of pneumonia

Specimen collection/technique	<u>Values</u>
	4
Lung parenchyma*	$\geq 10^4$ cfu/g tissue
Bronchoscopically (B) obtained specimens	
Bronchoalveolar lavage (B-BAL)	$\geq 10^4 \text{cfu/ml}$
Protected BAL (B-PBAL)	$\geq 10^4 \mathrm{cfu/ml}$
Protected specimen brushing (B-PSB)	$\geq 10^3 \text{ cfu/ml}$
Nonbronchoscopically (NB) obtained	
(blind)	
specimens	
NB-BAL	$>10^4$ cfu/ml
NB-PSB	$\geq 10^3 \text{cfu/ml}$

cfu = colony forming units g = gram

ml = milliliter

COMMENT:

* Open-lung biopsy specimens and immediate post-mortem specimens obtained by transthoracic or transbronchial biopsy

Numerator Data: The *Pneumonia (PNEU)* from (CDC 57.111) is used to collect and report each VAP that is identified during the month selected for surveillance. The *Instructions for Completion of Pneumonia Form* (Tables of Instructions, Tables 4 and 2a) includes brief instructions for collection and entry of each data element on the form. The pneumonia form includes patient demographic information and information on whether or not mechanically assisted ventilation was present. Additional data include the specific criteria met for identifying pneumonia, whether the patient developed a secondary bloodstream infection, whether the patient died, and the organisms isolated from cultures and their antimicrobial susceptibilities.

Denominator data: Device days and patient days are used for denominators (see <u>Chapter 16</u> Key Terms). Ventilator days, which are the number of patients managed with a ventilatory device, are collected daily, at the same time each day, according to the chosen location using the appropriate form (CDC 57.116, 57.117, and 57.118). These daily counts are summed and only the total for the month is entered into NHSN. Ventilator and patient days are collected for each of the locations monitored. When denominator data are available from electronic sources (e.g., ventilator days from respiratory therapy),



these sources may be used as long as the counts are not substantially different (+/-5%) from manually collected counts.

Data Analyses: The SIR is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using PNEU rates from a standard population during a baseline time period as reported in the NHSN Report.

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥ 1 .

While the PNEU SIR can be calculated for single locations, the measure also allows you to summarize your data by multiple locations, adjusting for differences in the incidence of infection among the location types. For example, you will be able to obtain one PNEU SIR adjusting for all locations reported. Similarly, you can obtain one PNEU SIR for all specialty care areas in your facility.

The VAP rate per 1000 ventilator days is calculated by dividing the number of VAPs by the number of ventilator days and multiplying the result by 1000. The Ventilator Utilization Ratio is calculated by dividing the number of ventilator days by the number of patient days. These calculations will be performed separately for the different types of ICUs, SCAs, and other locations in the institution, as well as by each birthweight category in NICUs.

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¹Klevens RM, Edward JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160-166.

²Centers for Disease Control and Prevention. Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2004;53(No. RR-3).

SSI

event category	full term	short term	specifications	standard
healthcare-	surgical site infection	SSI	Results in serious physical injury ,death or higher	AHRQ
associated			level of care including but not limited to prolonged	
infection			hospital stay, IV antibiotics	NHSN

implementation guidance

There will be surgical site infections that are reported to NHSN but are NOT sentinel events.

NHSN guidance included on the next few pages.

examples

not a sentinel event: A 41 year-old male presents to hospital to have an ankle fusion. The fusion is done successfully. At day 2 prior to discharge, the wound is noted to be red, painful, and warm to the touch. There is neither purulence nor fluctuation. The patient is treated with post-operative Keflex and discharged. Patient follow up with the surgeon reveals a well-healed wound. This would meet the definition of a superficial, incisional SSI but not a sentinel event.



Surgical Site Infection (SSI) Event

Introduction: In 2002, in the United States, an estimated 14 million NHSN operative procedures were performed (CDC unpublished data). SSIs were the second most common healthcare-associated infection, accounting for 17% of all HAIs among hospitalized patients¹. A similar rate was obtained from NHSN hospitals reporting data in 2006-2008 (15,862 SSI following 830,748 operative procedures) (CDC, unpublished data) with an overall rate of nearly 2%.

While advances have been made in infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis, SSIs remain a substantial cause of morbidity and mortality among hospitalized patients. In one study, among nearly 100,000 HAIs reported in one year, deaths were associated with SSIs in more than 8,000 cases.²

Surveillance of SSI with feedback of appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk.^{3,4,5,6,7} A successful surveillance program includes the use of epidemiologically-sound infection definitions and effective surveillance methods, stratification of SSI rates according to risk factors associated with SSI development, and data feedback.^{4,5} Recommendations are outlined in the CDC's *Guideline for Prevention of Surgical Site Infection*, 1999.⁷

Settings: Surveillance will occur with surgical patients in any inpatient/outpatient setting where the selected NHSN operative procedure(s) are performed.

Requirements: Select at least one NHSN operative procedure category (Table 1) and indicate this on the *Patient Safety Monthly Reporting Plan* (CDC 57.106). Collect numerator and denominator data on all selected procedure categories for at least one month.

The *International Classification of Diseases*, 9th Revision Clinical Modifications (ICD-9-CM) codes, which are defined by the ICD-9 Coordination and Maintenance Committee of the National Center for Health Statistics and the Centers for Medicare and Medicaid Services (CMS), are developed as a tool for classification of morbidity data. The preciseness of the data, as well as their wide use, allows their use in grouping surgery types for the purpose of determining SSI rates. ICD-9-CM codes are updated annually in October and NHSN operative procedure categories are subsequently updated and changes shared with NHSN users. Table 1: NHSN Operative Procedure Category Mappings to ICD-9-CM Codes, below, outlines operative procedures and their grouping into NHSN operative procedure categories according to ICD-9-CM codes. A brief description of the types of operations contained in the NHSN operative procedure categories is also provided.



Table 1. NHSN Operative Procedure Category Mappings to ICD-9-CM Codes

Legacy	Operative		
Code	Procedure	Description	ICD-9-CM Codes
AAA	Abdominal aortic aneurysm repair	Resection of abdominal aorta with anastomosis or replacement	38.34, 38.44, 38.64
AMP	Limb amputation	Total or partial amputation or disarticulation of the upper or lower limbs, including digits	84.00-84.19, 84.91
APPY	Appendix surgery	Operation of appendix (not incidental to another procedure)	47.01, 47.09, 47.2, 47.91, 47.92, 47.99
AVSD	Shunt for dialysis	Arteriovenostomy for renal dialysis	39.27, 39.42
BILI	Bile duct, liver or pancreatic surgery	Excision of bile ducts or operative procedures on the biliary tract, liver or pancreas (does not include operations only on gallbladder)	50.0, 50.12, 50.14, 50.21-50.23, 50.25, 50.26, 50.29, 50.3, 50.4, 50.61, 50.69, 51.31-51.37, 51.39, 51.41-51.43, 51.49, 51.51, 51.59, 51.61-51.63, 51.69, 51.71, 51.72, 51.79, 51.81-51.83, 51.89, 51.91- 51.95, 51.99, 52.09, 52.12, 52.22, 52.3, 52.4, 52.51-52.53, 52.59- 52.6, 52.7, 52.92, 52.95, 52.96, 52.99
BRST	Breast surgery	Excision of lesion or tissue of breast including radical, modified, or quadrant resection, lumpectomy, incisional biopsy, or mammoplasty.	85.12, 85.20-85.23, 85.31-85.36, 85.41-85.48, 85.50, 85.53-85.55, 85.6, 85.70-85.76, 85.79, 85.93- 85.96
CARD	Cardiac surgery	Procedures on the valves or septum of heart; does not include coronary artery bypass graft, surgery on vessels, heart transplantation, or pacemaker implantation	35.00-35.04, 35.10-35.14, 35.20- 35.28, 35.31-35.35, 35.39, 35.42, 35.50, 35.51, 35.53, 35.54, 35.60- 35.63, 35.70-35.73, 35.81-35.84, 35.91-35.95, 35.98-35.99, 37.10- 37.12, 37.31-37.33, 37.35-37.37, 37.41, 37.49, 37.60*
CEA	Carotid endarterectomy	Endarterectomy on vessels of head and neck (includes carotid artery and jugular vein)	38.12



Legacy	Operative		
Code	Procedure	Description	ICD-9-CM Codes
CBGB	Coronary artery bypass graft with both chest and donor site incisions	Chest procedure to perform direct revascularization of the heart; includes obtaining suitable vein from donor site for grafting.	36.10-36.14, 36.19
CBGC	Coronary artery bypass graft with chest incision only	Chest procedure to perform direct vascularization of the heart using, for example the internal mammary (thoracic) artery	36.15-36.17, 36.2
CHOL	Gallbladder surgery	Cholecystectomy and cholecystotomy	51.03, 51.04, 51.13, 51.21-51.24
COLO	Colon surgery	Incision, resection, or anastomosis of the large intestine; includes large-to- small and small-to-large bowel anastomosis; does not include rectal operations	17.31-17.36, 17.39, 45.03, 45.26, 45.41, 45.49, 45.52, 45.71-45.76, 45.79, 45.81-45.83, 45.92-45.95, 46.03, 46.04, 46.10, 46.11, 46.13, 46.14, 46.43, 46.52, 46.75, 46.76, 46.94
CRAN	Craniotomy	Excision repair, or exploration of the brain or meninges; does not include taps or punctures	01.12, 01.14, 01.20-01.25, 01.28, 01.29, 01.31, 01.32, 01.39, 01.41, 01.42, 01.51-01.53, 01.59, 02.11-02.14, 02.91-02.93, 07.51-07.54, 07.59, 07.61-07.65, 07.68, 07.69, 07.71, 07.72, 07.79, 38.01, 38.11, 38.31, 38.41, 38.51, 38.61, 38.81, 39.28
CSEC	Cesarean section	Obstetrical delivery by Cesarean section	74.0, 74.1, 74.2, 74.4, 74.91, 74.99
FUSN	Spinal fusion	Immobilization of spinal column	81.00-81.08
FX	Open reduction of fracture	Open reduction of fracture or dislocation of long bones with or without internal or external fixation; does not include placement of joint prosthesis	79.21, 79.22, 79.25, 79.26, 79.31, 79.32, 79.35, 79.36, 79.51, 79.52, 79.55, 79.56
GAST	Gastric surgery	Incision or excision of stomach; includes subtotal or total gastrectomy; does not include vagotomy and fundoplication	43.0, 43.42, 43.49, 43.5, 43.6, 43.7, 43.81, 43.89, 43.91, 43.99, 44.15, 44.21, 44.29, 44.31, 44.38- 44.42, 44.49, 44.5, 44.61-44.65, 44.68-44.69, 44.95-44.98



Legacy	Operative		
Code	Procedure	Description	ICD-9-CM Codes
HER	Herniorrhaphy	Repair of inguinal, femoral, umbilical, or anterior abdominal wall hernia; does not include repair of diaphragmatic or hiatal hernia or hernias at other body sites.	17.11-17.13, 17.21-17.24, 53.00- 53.05, 53.10-53.17, 53.21, 53.29, 53.31, 53.39, 53.41-53.43, 53.49, 53.51, 53.59, 53.61-53.63, 53.69
HPRO	Hip prosthesis	Arthroplasty of hip	00.70-00.73, 00.85-00.87, 81.51- 81.53
HTP	Heart transplant	Transplantation of heart	37.51-37.55
HYST	Abdominal hysterectomy	Abdominal approach with uterine removal	68.31, 68.39, 68.41, 68.49, 68.61, 68.69
KPRO	Knee prosthesis	Arthroplasty of knee	00.80-00.84, 81.54, 81.55
KTP	Kidney transplant	Transplantation of kidney	55.61, 55.69
LAM	Laminectomy	Exploration or decompression of spinal cord through excision or incision into vertebral structures	03.01, 03.02, 03.09, 80.50, 80.51, 80.53, 80.54†, 80.59, 84.60-84.69, 84.80-84.85
LTP	Liver transplant	Transplantation of liver	50.51, 50.59
NECK	Neck surgery	Major excision or incision of the larynx and radical neck dissection; does not include thyroid and parathyroid operations.	30.1, 30.21, 30.22, 30.29, 30.3, 30.4, 31.45, 40.40-40.42
NEPH	Kidney surgery	Resection or manipulation of the kidney with or without removal of related structures	55.01, 55.02, 55.11, 55.12, 55.24, 55.31, 55.32, 55.34, 55.35, 55.39, 55.4, 55.51, 55.52, 55.54, 55.91
OVRY	Ovarian surgery	Operations on ovary and related structures	65.01, 65.09, 65.12, 65.13, 65.21-65.25, 65.29, 65.31, 65.39, 65.41, 65.49, 65.51-65.54, 65.61-65.64, 65.71-65.76, 65.79, 65.81, 65.89, 65.92-65.95, 65.99
PACE	Pacemaker surgery	Insertion, manipulation or replacement of pacemaker	00.50-00.54, 17.51, 17.52, 37.70- 37.77, 37.79-37.83, 37.85-37.87, 37.89, 37.94-37.99
PRST	Prostate surgery	Suprapubic, retropubic, radical, or perineal excision of the prostate; does not include transurethral	60.12, 60.3, 60.4, 60.5, 60.61, 60.62, 60.69



Legacy	Operative		
Code	Procedure	Description	ICD-9-CM Codes
		resection of the prostate.	
PVBY	Peripheral vascular bypass surgery	Bypass operations on peripheral arteries	39.29
REC	Rectal surgery	Operations on rectum	48.25, 48.35, 48.40, 48.42, 48.43, 48.49-48.52, 48.59, 48.61-48.65, 48.69, 48.74
RFUSN	Refusion of spine	Refusion of spine	81.30-81.39
SB	Small bowel surgery	Incision or resection of the small intestine; does not include small-to-large bowel anastomosis	45.01, 45.02, 45.15, 45.31-45.34, 45.51, 45.61-45.63, 45.91, 46.01, 46.02, 46.20-46.24, 46.31, 46.39, 46.41, 46.51, 46.71-46.74, 46.93
SPLE	Spleen surgery	Resection or manipulation of spleen	41.2, 41.33, 41.41-41.43, 41.5, 41.93, 41.95, 41.99
THOR	Thoracic surgery	Noncardiac, nonvascular thoracic surgery; includes pneumonectomy and hiatal hernia repair or diaphragmatic hernia repair (except through abdominal approach.)	32.09, 32.1, 32.20-32.23, 32.25, 32.26, 32.29, 32.30, 32.39, 32.41, 32.49, 32.50, 32.59, 32.6, 32.9, 33.0, 33.1, 33.20, 33.25, 33.28, 33.31-33.34, 33.39, 33.41-33.43, 33.48, 33.49, 33.98, 33.99, 34.01-34.03, 34.06, 34.1, 34.20, 34.26, 34.3, 34.4, 34.51, 34.52, 34.59, 34.6, 34.81-34.84, 34.89, 34.93, 34.99, 53.80-53.84
THYR	Thyroid and/or parathyroid surgery	Resection or manipulation of thyroid and/or parathyroid	06.02, 06.09, 06.12, 06.2, 06.31, 06.39, 06.4, 06.50-06.52, 06.6, 06.7, 06.81, 06.89, 06.91-06.95, 06.98, 06.99
VHYS	Vaginal hysterectomy	Vaginal approach with uterine removal	68.51, 68.59, 68.71, 68.79
VSHN	Ventricular shunt	Ventricular shunt operations, including revision and removal of shunt	02.2, 02.31-02.35, 02.39, 02.42, 02.43, 54.95 [^]
XLAP	Abdominal surgery	Abdominal operations not involving the gastrointestinal tract or biliary system includes diaphragmatic hernia repair through abdominal approach.	53.71, 53.72, 53.75, 54.0, 54.11, 54.12, 54.19, 54.3, 54.4, 54.51, 54.59, 54.61, 54.63, 54.64, 54.71-54.75, 54.92, 54.93



*NOTE: The procedure represented by this ICD-9-CM code can be performed in a number of ways. However, as for all surgeries, if, at the end of the procedure, the skin incision edges do not meet because of wires, devices or other objects extruding through the incision, the incision is not considered primarily closed. Therefore the procedure is not considered an NHSN operative procedure and any subsequent infection is not considered a procedure-associated infection (i.e., not an SSI or PPP).

†NOTE: If this procedure is performed percutaneously, it is not considered an NHSN operative procedure and should not be included in LAM denominator data.

[^]NOTE: Include only if this procedure involves ventricular shunt.

For a complete mapping of all ICD-9-CM codes to their assignment as an NHSN operative procedure category, a surgical procedure other than an NHSN operative procedure (OTH), or a non-operative procedure (NO), see ICD-9-CM Procedure Code Mapping to NHSN Operative Procedure Categories at http://www.cdc.gov/nhsn/library.html.

Definitions:

An NHSN operative procedure is a procedure

1) that is performed on a patient who is an NHSN inpatient or an NHSN outpatient; 2) takes place during an operation (defined as a single trip to the operating room (OR) where a surgeon makes at least one incision through the skin or mucous membrane, including laparoscopic approach, and <u>closes the incision</u> before the patient leaves the OR; and 3) that is included in Table 1.

*NOTE: If the skin incision edges do not meet because of wires or devices or other objects extruding through the incision, the incision is not considered primarily closed and therefore the procedure is not considered an operation. Further, any subsequent infection is not considered a procedure-associated infection (i.e., not an SSI or PPP).

NHSN Inpatient: A patient whose date of admission to the healthcare facility and the date of discharge are different calendar days.

<u>NHSN Outpatient</u>: A patient whose date of admission to the healthcare facility and date of discharge are the <u>same</u> calendar day.

Operating Room (OR): A patient care area that met the Facilities Guidelines Institute's (FGI) or American Institute of Architects' (AIA) criteria for an operating room when it was constructed or renovated.⁷ This may include an operating room, C-Section room, interventional radiology room, or a cardiac catheterization lab.

<u>Implant</u>: A nonhuman-derived object, material, or tissue that is permanently placed in a patient during an operative procedure and is not routinely manipulated for diagnostic or therapeutic purposes. Examples include: porcine or synthetic heart valves, mechanical heart, metal rods, mesh, sternal wires, screws, cements, internal staples, hemoclips, and other devices. Non-absorbable



sutures are excluded because Infection Preventionists may not easily identify and/or differentiate the soluble nature of suture material used.

<u>Transplant</u>: Human cells, tissues, organs, or cellular- or tissue-based products that are placed into a human recipient via grafting, infusion, or transfer. Examples include: heart valves, organs, ligaments, bone, blood vessels, skin, corneas, and bone marrow cells.

<u>Autologous</u> or "autograft" transplants are products that originate from the patient's own body. <u>Non-autologous</u> or "allograft" transplants are tissues or other products derived from another human body, either a donor cadaver or a live donor.

REPORTING INSTRUCTIONS:

- Some products are a combination of human- and nonhuman-derived materials, such as demineralized human bone matrix with porcine gel carrier. When placed in a patient during an operative procedure, indicate "Yes" for both the Implant and Non-autologous Transplant fields.
- Some operative procedures involve placement of both autologous and non-autologous products. For these procedures, indicate "Yes" for Non-autologous Transplant field.

A <u>superficial incisional SSI</u> must meet one of the following criteria:

Infection occurs within 30 days after the operative procedure 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. organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision
- c. at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by surgeon, and is culture-positive or not cultured. A culture-negative finding does not meet this criterion.
- d. diagnosis of superficial incisional SSI by the surgeon or attending physician.

NOTE: There are two specific types of superficial incisional SSIs:

- 1. <u>Superficial Incisional Primary (SIP)</u> a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CBGB)
- 2. <u>Superficial Incisional Secondary (SIS)</u> a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site [leg] incision for CBGB)

REPORTING INSTRUCTIONS:

• Do not report a stitch abscess (minimal inflammation and discharge confined to the points of suture penetration) as an infection.



- Do not report a localized stab wound infection as SSI. While it would be considered either a skin (SKIN) or soft tissue (ST) infection, depending on its depth, it is not reportable under this module.
- "Cellulitis", by itself, does not meet the criteria for Superficial Incisional SSI.
- If the incisional site infection involves or extends into the fascial and muscle layers, report as a deep-incisional SSI.
- Classify infection that involves both superficial and deep incision sites as deep incisional SSI.
- An infected circumcision site in newborns is classified as CIRC. Circumcision is not an NHSN operative procedure. CIRC is not reportable under this module.
- An infected burn wound is classified as BURN and is not reportable under this module

A **deep incisional SSI** must meet one of the following criteria:

Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place 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

patient has at least one of the following:

- a. purulent drainage from the deep incision but not from the organ/space component of the surgical site
- b. a deep incision spontaneously dehisces or is deliberately opened by a surgeon 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.
- c. an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
- d. diagnosis of a deep incisional SSI by a surgeon or attending physician.

NOTE: There are two specific types of deep incisional SSIs:

- 1. <u>Deep Incisional Primary (DIP)</u> a deep incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CBGB)
- 2. <u>Deep Incisional Secondary (DIS)</u> a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site [leg] incision for CBGB)

REPORTING INSTRUCTIONS:

• Classify infection that involves both superficial and deep incision sites as deep incisional SSI.

An <u>organ/space SSI</u> involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure. Specific sites are assigned to organ/space SSI to further identify the location of the infection. The table below lists the specific sites that must be used to differentiate organ/space SSI. An example is appendectomy with



subsequent subdiaphragmatic abscess, which would be reported as an organ/space SSI at the intraabdominal specific site (SSI-IAB). Specific sites of organ/space (Table 2) have specific criteria which must be met in order to qualify as an NHSN event. These criteria are in addition to the general criteria for organ/space SSI and can be found in Chapter 17.

An **organ/space SSI** must meet one of the following criteria:

Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure and

infection involves any part of the body, excluding the skin incision, fascia, or 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 through a stab wound into the organ/space
- b. organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
- c. 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
- d. diagnosis of an organ/space SSI by a surgeon or attending physician.

REPORTING INSTRUCTIONS:

- Occasionally an organ/space infection drains through the incision. Such infection generally
 does not involve reoperation and is considered a complication of the incision. Therefore,
 classify it as a deep incisional SSI.
- Report mediastinitis following cardiac surgery that is accompanied by osteomyelitis as SSI-MED rather than SSI-BONE.
- If meningitis (MEN) and a brain abscess (IC) are present together after operation, report as SSI-IC.
- Report CSF shunt infection as SSI-MEN if it occurs ≤ 1 year of placement; if later or after manipulation/access, it is considered CNS-MEN and is not reportable under this manual.
- Report spinal abscess with meningitis as SSI-MEN following spinal surgery.
- Episiotomy is not considered an operative procedure in NHSN.

Table 2. Specific sites of an organ/space SSI. Criteria for these sites can be found in the NHSN Help System (must be logged in to NHSN) or <u>Chapter 17</u>.

Code	Site	Code	Site
BONE	Osteomyelitis	JNT	Joint or bursa
BRST	Breast abscess or mastitis	LUNG	Other infections of the respiratory
			tract
CARD	Myocarditis or pericarditis	MED	Mediastinitis
DISC	Disc space	MEN	Meningitis or ventriculitis
EAR	Ear, mastoid	ORAL	Oral cavity (mouth, tongue, or gums)
EMET	Endometritis	OREP	Other infections of the male or female
			reproductive tract



Code	Site	Code	Site
ENDO	Endocarditis	OUTI	Other infections of the urinary tract
EYE	Eye, other than conjunctivitis	SA	Spinal abscess without meningitis
GIT	GI tract	SINU	Sinusitis
HEP	Hepatitis	UR	Upper respiratory tract
IAB	Intraabdominal, not specified	VASC	Arterial or venous infection
	else-where		
IC	Intracranial, brain abscess or dura	VCUF	Vaginal cuff

Numerator Data: All patients having the selected operative procedure are monitored for signs of SSI. The *Surgical Site Infection (SSI)* form (CDC 57.120) is completed for each such patient found to have an SSI.

NOTES:

- 1. If a patient has several NHSN operative procedures prior to an infection, report the operative procedure code of the operation that was performed most closely in time prior to the infection date, unless there is evidence that the infection is associated with a different operation.
- 2. If a procedure from more than one NHSN operative procedure category was done through a single incision, attempt to determine the procedure that is thought to be associated with the infection. If it is not clear (as is often the case when the infection is a superficial incisional SSI), or if the infection site being reported is not an SSI, use the NHSN Principal Operative Procedure Category Selection Lists (Table 3) to select which operative procedure to report.

Table 3. NHSN Principal Operative Procedure Category Selection Lists

The following lists are derived from Table 1, NHSN Operative Procedure Categories. The operative procedures with the highest risk of surgical site infection are listed before those with a lower risk.

Priority	Code	Abdominal Operations
1	SB	Small bowel surgery
2	KTP	Kidney transplant
3	LTP	Liver transplant
4	BILI	Bile duct, liver or pancreatic surgery
5	REC	Rectal surgery
6	COLO	Colon surgery
7	GAST	Gastric surgery
8	CSEC	Cesarean section
9	SPLE	Spleen surgery
10	APPY	Appendix surgery
11	HYST	Abdominal hysterectomy
12	VHYS	Vaginal Hysterectomy
13	OVRY	Ovarian surgery
14	HER	Herniorrhaphy



The following	lists are derived from	Table 1, NHSN Operative Procedure Categories. The
operative proc	edures with the highe	st risk of surgical site infection are listed before those
with a lower r	isk.	-
15	CHOL	Gall bladder surgery
16	AAA	Abdominal aortic aneurysm repair
17	NEPH	Kidney surgery
18	XLAP	Laparotomy
Priority	Code	Thoracic Operations
1	HTP	Heart transplant
2	CBGB	Coronary artery bypass graft with donor incision(s)
3	CBGC	Coronary artery bypass graft, chest incision only
4	CARD	Cardiac surgery
5	THOR	Thoracic surgery
Priority	Code	Neurosurgical (Spine) Operations
1	RFUSN	Refusion of spine
2	FUSN	Spinal fusion
3	LAM	Laminectomy
Priority	Code	Neurosurgical (Brain) Operations
1	VSHN	Ventricular shunt
2	CRAN	Craniotomy
Priority	Code	Neck Operations
1	NECK	Neck surgery
2	THYR	Thyroid and or parathyroid surgery

The *Instructions for Completion of Surgical Site Infection* form (Tables of Instructions, Tables 12 and 2a) includes brief instructions for collection and entry of each data element on the form. The SSI form includes patient demographic information and information about the operative procedure, including the date and type of procedure. Information about the SSI includes the date of SSI, specific criteria met for identifying the SSI, when the SSI was detected, whether the patient developed a secondary bloodstream infection, whether the patient died, and the organisms isolated from cultures and the organisms' antimicrobial susceptibilities.

Denominator Data: For all patients having a procedure selected for surveillance during the month, complete the *Denominator for Procedure* form (CDC 57.121). The data are collected individually for each operative procedure performed during the month specified on the *Patient Safety Monthly Surveillance Plan* (CDC 57.106). The *Instructions for Completion of Denominator for Procedure* form (Tables of Instructions, Table 13) includes brief instructions for collection and entry of each data element on the form.

NOTES:



- 1. If procedures in more than one NHSN operative procedure category are performed during the same trip to the OR even if performed through the same incision, a Denominator for Procedure (CDC 57.121) record is reported for <u>each</u> operative procedure being monitored. For example, if a CARD and CBGC are done through the same incision, a *Denominator for Procedure* record is reported for each.
- 2. EXCEPTION: If a patient has both a CBGC and CBGB during the same trip to the OR, report only as a CBGB. Only report as a CBGC when there is a chest incision only. CBGB and CBGC are never reported for the same patient for the same trip to the OR. For bilateral operative procedures see #4 below.
- 3. If procedures of different ICD-9-CM codes from the same NHSN Operative Procedure Category are performed through the same incision, record only one procedure for that category. For example, if your facility is performing surveillance for both CBGB and CARD procedures, and a patient undergoes an aortocoronary bypass of one coronary vessel (36.11, CBGB) and the replacement of both the mitral and tricuspid valves (35.23 and 35.27, both CARD) during the same trip to the OR, you would complete a *Denominator for Procedure* record for the CBGB and another for the CARD.
- 4. If more than one NHSN operative procedure category is performed through the same incision, record the combined duration of all procedures, which is the time from skin incision to primary closure.
- 5. For bilateral operative procedures (e.g., KPRO), two separate Denominator for Procedure (CDC 57.121) records are completed. To document the duration of the procedure, indicate the incision time to closure time for each procedure separately or, alternatively, take the total time for both procedures and split it evenly between the two. See "5" below.
- 6. Laparoscopic hernia repairs are considered one procedure, regardless of the number of hernias that are repaired in that trip to the OR. In most cases there will be only one incision time documented for this procedure. If more than one time is documented, total the durations. In this situation, if more than one of the incisions should become infected, only report as a single SSI. Open [i.e., non-laparoscopic] hernia repairs are reported as one procedure for each hernia repaired via a separate incision, i.e., if two incisions are made to repair two defects, then two procedures will be reported. It is anticipated that separate incision times will be recorded for these procedures. If not, take the total time for both procedures and split it evenly between the two.
- 7. If a patient goes to the OR more than once during the same admission and another procedure is performed through the same incision within 24 hours of the original operative incision, report only one procedure on the *Denominator for Procedure* (CDC 57.121) form combining the durations for both procedures. For example, a patient has a CBGB lasting 4 hours. He returns to the OR six hours later to correct a bleeding vessel. The surgeon reopens the initial incision, makes the repairs, and recloses in 1.5 hours. Record the operative procedure as one CBGB and the duration of operation as 5 hour 30 minutes. If the wound class has changed, report the higher wound class. If the ASA class has changed, report the higher ASA class.



Data Analyses: The SIR is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using SSI probabilities estimated from multivariate logistic regression models constructed from NHSN data during a baseline time period to represent a standard population.

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥ 1 .

While the SSI SIR can be calculated for single procedure categories, and for specific surgeons, the measure also allows you to summarize your data across multiple procedure categories, while adjusting for differences in the estimated probability of infection among the patients included across the procedure categories. For example, you will be able to obtain one SSI SIR adjusting for all procedures reported. Alternatively, you can obtain one SSI SIR for all colon surgeries (COLO) only within your facility.

SSI rates per 100 operative procedures are calculated by dividing the number of SSIs by the number of specific operative procedures and multiplying the results by 100. SSI will be included in the numerator of a rate based on the date of procedure, not the date of event. Rate calculations can be performed separately for the different types of operative procedures and stratified by the basic risk index. SSI rate calculation options are available in the advanced analysis feature of the NHSN application.

- Basic SSI Risk Index. The index used in NHSN assigns surgical patients into categories based on the presence of three major risk factors:
 - 1. Operation lasting more than the duration cut point hours, where the duration cut point is the approximate 75th percentile of the duration of surgery in minutes for the operative procedure.
 - 2. Contaminated (Class 3) or Dirty/infected (Class 4) wound class.
 - 3. ASA classification of 3, 4, or 5.

The patient's SSI risk category is simply the number of these factors present at the time of the operation.

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¹Klevens RM, Edwards JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160-166.

² Emori TG, Gaynes RP. An overview of healthcare-associated infections, including the role of the microbiology laboratory. Clin Microbiol Rev 1993;6(4):428-42.

³ Condon RE, Schulte WJ, Malangoni MA, Anderson-Teschendorf MJ. Effectiveness of a surgical wound surveillance program. Arch Surg 1983;118:303-7.



⁴ Society for Healthcare Epidemiology of America, Association for Professionals in Infection Control and Epidemiology, Centers for Disease Control and Prevention, Surgical Infection Society. Consensus paper on the surveillance of surgical wound infections. Infect Control Hosp Epidemiol 1992;13(10):599-605.

⁵Haley RW, Culver DH, White JW, Morgan WM, Emori TG, Munn VP. The efficacy of infection surveillance and control programs in preventing healthcare-associated infections in US hospitals. Am J Epidemiol 1985;121:182-205.

⁶Centers for Disease Control and Prevention. Guideline for prevention of surgical site infection,1999. Infect Control Hosp Epidemiol, 1999;20(4):247-278.

⁷ Facilities Guidelines Institute. Guidelines for design and construction of health care facilities. American Society for Healthcare Engineering; Chicago IL; 2010.

CAUTI

event category	full term	short term	specifications	standard
healthcare-	urinary tract infection that is	SSI		AHRQ
associated	catheter-associated			
infection				NHSN

implementation guidance				
NHSN guidance included on the next few pages.				
examples				



Catheter-Associated Urinary Tract Infection (CAUTI) Event

Introduction: The urinary tract is the most common site of healthcare-associated infection, accounting for more than 30% of infections reported by acute care hospitals¹. Virtually all healthcare- associated urinary tract infections (UTIs) are caused by instrumentation of the urinary tract.

CAUTI can lead to such complications as cystitis, pyelonephritis, gram-negative bacteremia, prostatitis, epididymitis, and orchitis in males and, less commonly, endocarditis, vertebral osteomyelitis, septic arthritis, endophthalmitis, and meningitis in all patients. Complications associated with CAUTI cause discomfort to the patient, prolonged hospital stay, and increased cost and mortality. Each year, more than 13,000 deaths are associated with UTIs.¹

Prevention of CAUTIs is discussed in the CDC/HICPAC document, *Guideline for Prevention of Catheter-associated Urinary Tract Infections*².

Settings: Surveillance will occur in any inpatient locations where denominator data can be collected, which may include critical intensive care units (ICU), specialty care areas (SCA), stepdown units, and long term care wards. Neonatal units are NOT included. A complete listing of inpatient locations can be found in Chapter 15.

NOTE: It is not required to monitor for CAUTIs after the patient is discharged from the facility, however, if discovered, they should be reported to NHSN. No additional indwelling catheter days are reported.

Requirements: Surveillance for CAUTI is performed in at least one inpatient location in the healthcare institution for at least one calendar month as indicated in the *Patient Safety Monthly Reporting Plan* (CDC 57.106).

Definitions: As for all infections reported to NHSN, infections associated with complications or extensions of infections already present on admission, unless a change in pathogen or symptoms strongly suggests the acquisition of a new infection area not considered healthcare associated. Therefore, infections that become apparent within the first few days of admission must be carefully reviewed to determine whether they should be considered healthcare associated.

<u>Urinary tract infections</u> (UTI) are defined using symptomatic urinary tract infection (SUTI) criteria or Asymptomatic Bacteremic UTI (ABUTI) criteria (Table 1 and Figure 1). Report UTIs that are <u>catheter-associated</u> (i.e. patient had an indwelling urinary catheter at the time of or within 48 hours before onset of the event).



NOTES:

- 1. There is no minimum period of time that the catheter must be in place in order for the UTI to be considered catheter-associated. EXAMPLE: Patient has a Foley catheter in place on an inpatient unit. It is discontinued, and 4 days later patient meets the criteria for a UTI. This is not reported as a CAUTI because the time since Foley discontinuation exceeds 48 hours.
- 2. SUTI 1b and 2b and other UTI (OUTI) cannot be catheter-associated.

Location of attribution: The location where the patient was assigned on the date of the UTI event, which is further defined as the date when the first clinical evidence appeared or the date the specimen use to meet the criterion was collected, whichever came first. EXAMPLE: Patient who had no clinical signs or symptoms of UTI upon arrival to the Emergency Department, has a Foley catheter inserted there before being admitted to the MICU. Within 24 hours of admission to the MICU, patient meets criteria for UTI. This is reported to the NHSN as a CAUTI for the MICU, because the Emergency Department is not an inpatient location and no denominator data are collected there.

TRANSFER RULE EXCEPTION: If a CAUTI develops within 48 hours of transfer from one inpatient location to another in the same facility, or a new facility, the infection is attributed to the transferring location. This is called the <u>Transfer Rule</u> and examples are shown below.

- Patient with a Foley catheter in place in the SICU is transferred to the surgical ward. Thirty six (36) hours later, the patient meets the criteria for UTI. This is reported to NHSN as a CAUTI for the SICU.
- Patient is transferred to the medical ward from the MSICU after having the Foley catheter removed. Within 24 hours, patient meets criteria for a UTI. This is reported to NHSN as a CAUTI for the MSICU.
- Patient with a Foley catheter in place is transferred from the medical ward to the coronary care ICU (CCU). After 4 days in the CCU, the patient meets the criteria for UTI. This is reported to NHSN as a CAUTI for the CCU.
- EXAMPLE: Patient on the urology ward of Hospital A had the Foley catheter removed and is discharged home a few hours later. The ICP from Hospital B calls the next day to report that this patient has been admitted to Hospital B with a UTI. This CAUTI should be reported to NHSN for Hospital A and attributed to the urology ward.

<u>Indwelling catheter</u>: a drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a closed collection system; also called a Foley catheter; does not include straight in-and-out catheters.

Numerator Data: The *Urinary Tract Infection (UTI)* Form (CDC 57.114) is used to collect and report each CAUTI that is identified during the month selected for surveillance. The *Instructions for Completion of Urinary Tract Infection Form* (Tables of Instructions, Tables 5 and 2a) includes brief instructions for collection and entry of



each data element on the form. The UTI form includes patient demographic information and information on whether or not an indwelling urinary catheter was present. Additional data include the specific criteria met for identifying the UTI, whether the patient developed a secondary bloodstream infection, whether the patient died, and the organisms isolated from cultures and their antimicrobial susceptibilities.

Denominator data: Device days and patient days are used for denominators (See Chapter 16 Key Terms). Indwelling urinary catheter days, which are the number of patients with an indwelling urinary catheter device, are collected daily, at the same time each day, according to the chosen location using the appropriate form (CDC 57.117, and 57.118). When denominator data are available from electronic databases, these sources may be used as long as the counts are not substantially different (+/- 5%) from manually collected counts. These daily counts are summed and only the total for the month is entered into NHSN. Indwelling urinary catheter days and patient days are collected separately for each of the locations monitored.

Data Analyses: The SIR is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using CAUTI rates from a standard population during a baseline time period as reported in the NHSN Report.

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥ 1 .

While the CAUTI SIR can be calculated for single locations, the measure also allows you to summarize your data by multiple locations, adjusting for differences in the incidence of infection among the location types. For example, you will be able to obtain one CAUTI SIR adjusting for all locations reported. Similarly, you can obtain one CAUTI SIR for all specialty care areas in your facility.

The CAUTI rate per 1000 urinary catheter days is calculated by dividing the number of CAUTIs by the number of catheter days and multiplying the result by 1000. The Urinary Catheter Utilization Ratio is calculated by dividing the number of urinary catheter days by the number of patient days. These calculations will be performed separately for the different types of ICUs, specialty care areas, and other locations in the institution, except for neonatal locations.

¹Klevens RM, Edward JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160-166.

²Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA. Guideline for prevention of catheter-associated urinary tract infections 2009. Infect Control Hosp Epidemiol. 2010;31(4):319-26.



Table 1: Urinary Tract Infection Criteria

Criterion	n Urinary Tract Infection (UTI)	
	Symptomatic Urinary Tract Infection (SUTI)	
	Must meet at least 1 of the following criteria	
1a	Patient had an indwelling urinary catheter in place at the time of specimen collection and	
	at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C), suprapubic tenderness, or costovertebral angle pain or tenderness and	
	a positive urine culture of $\geq 10^5$ colony-forming units (CFU)/ml with no more than 2 species of microorganisms.	
	OR	
	Patient had indwelling urinary catheter <u>removed within the 48 hours prior</u> to specimen collection and	
	at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C), urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness and	
	a positive urine culture of $\geq 10^5$ colony-forming units (CFU)/ml with no more than 2 species of microorganisms.	
1b	Patient did <u>not</u> have an indwelling urinary catheter in place at the time of specimen collection nor within 48 hours prior to specimen collection and	
	has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C) in a patient that is ≤65 years of age, urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness and	
	a positive urine culture of $\geq 10^5$ CFU/ml with no more than 2 species of microorganisms.	
2a	Patient had an indwelling urinary catheter in place at the time of specimen collection and	
	at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C), suprapubic tenderness, or costovertebral angle pain or tenderness and	
	a positive urinalysis demonstrated by at least 1 of the following findings: a. positive dipstick for leukocyte esterase and/or nitrite	
	b. pyuria (urine specimen with ≥10 white blood cells [WBC]/mm ³ of unspun urine or ≥3 WBC/high power field of spun urine)	



Criterion	Urinary Tract Infection (UTI)
	c. microorganisms seen on Gram stain of unspun urine
	and a positive urine culture of $\geq 10^3$ and $< 10^5$ CFU/ml with no more than 2 species of microorganisms.
	OR
	Patient had indwelling urinary catheter <u>removed within the 48 hours prior</u> to specimen collection and at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C), urgency, frequency, dysuria, suprapubic tenderness, or
	costovertebral angle pain or tenderness and a positive urinalysis demonstrated by at least 1 of the following findings: a. positive dipstick for leukocyte esterase and/or nitrite
	 b. pyuria (urine specimen with ≥10 white blood cells [WBC]/mm³ of unspun urine or ≥3 WBC/high power field of spun urine) c. microorganisms seen on Gram stain of unspun urine
	a positive urine culture of $\ge 10^3$ and $< 10^5$ CFU/ml with no more than 2 species of microorganisms.
2b	Patient did <u>not</u> have an indwelling urinary catheter in place at the time of specimen collection nor within 48 hours prior to specimen collection and
	has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C) in a patient that is ≤65 years of age, urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness and
	a positive urinalysis demonstrated by at least 1 of the following findings: a. positive dipstick for leukocyte esterase and/or nitrite
	b. pyuria (urine specimen with ≥10 WBC/mm³ of unspun urine or ≥3 WBC/high power field of spun urine)
	c. microorganisms seen on Gram stain of unspun urine and a positive urine culture of $\geq 10^3$ and $< 10^5$ CFU/ml with no more than 2 species of microorganisms.
3	Patient ≤1 year of age with or without an indwelling urinary catheter has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C core), hypothermia (<36°C core), apnea, bradycardia, dysuria, lethargy, or vomiting



Criterion	on Urinary Tract Infection (UTI)	
	and a positive urine culture of $\geq 10^5$ CFU/ml with no more than 2 species of	
	microorganisms.	
4	Patient ≤1 year of age with or without an indwelling urinary catheter has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C core), hypothermia (<36°C core), apnea, bradycardia, dysuria, lethargy, or vomiting and	
	a positive urinalysis demonstrated by at least one of the following findings: a. positive dipstick for leukocyte esterase and/or nitrite	
	b. pyuria (urine specimen with ≥10 WBC/mm³ of unspun urine or ≥3 WBC/high power field of spun urine)	
	c. microorganisms seen on Gram's stain of unspun urine and	
	a positive urine culture of between $\ge 10^3$ and $< 10^5$ CFU/ml with no more than two species of microorganisms.	
Criterion	Asymptomatic Bacteremic Urinary Tract Infection (ABUTI)	
	Patient with or without an indwelling urinary catheter has <u>no</u> signs or symptoms (i.e., for any age patient, <u>no</u> fever (>38°C), urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness, <u>OR</u> for a patient ≤1 year of age, <u>no</u> fever (>38°C core), hypothermia (<36°C core), apnea, bradycardia, dysuria, lethargy, or vomiting) and	
	a positive urine culture of >10 ⁵ CFU/ml with no more than 2 species of uropathogen microorganisms* and	
	a positive blood culture with at least 1 matching uropathogen microorganism to the urine culture, or at least 2 matching blood cultures drawn on separate occasions if the matching pathogen is a common skin contaminant.	
	* Uropathogen microorganisms are: Gram-negative bacilli, <i>Staphylococcus</i> spp., yeasts, beta-hemolytic <i>Streptococcus</i> spp., <i>Enterococcus</i> spp., <i>G. vaginalis</i> , <i>Aerococcus urinae</i> , and <i>Corynebacterium</i> (urease positive).	
Comments	Urinary catheter tips should not be cultured and are not acceptable for the diagnosis of a urinary tract infection.	
	 Urine cultures must be obtained using appropriate technique, such as clean catch collection or catheterization. Specimens from indwelling catheters should be aspirated through the disinfected sampling ports. In infants, urine cultures should be obtained by bladder catheterization or suprapubic aspiration; positive urine cultures from bag specimens are unreliable and should be confirmed by specimens aseptically obtained by catheterization or suprapubic aspiration. 	



The state of the s			
Criterion	Urinary Tract Infection (UTI)		
	 Urine specimens for culture should be processed as soon as possible, preferably within 1 to 2 hours. If urine specimens cannot be processed within 30 minutes of collection, they should be refrigerated, or inoculated into primary isolation medium before transport, or transported in an appropriate urine preservative. Refrigerated specimens should be cultured within 24 hours. Urine specimen labels should indicate whether or not the patient is symptomatic. Report secondary bloodstream infection = "Yes" for all cases of Asymptomatic Bacteremic Urinary Tract Infection (ABUTI). Report only pathogens in both blood and urine specimens for ABUTI. Report Corynebacterium (urease positive) as either Corynebacterium species 		
Criterion	unspecified (COS) or, as <i>C. urealyticum</i> (CORUR) if so speciated. Other Urinary Tract Infection (OUTI) (kidney, ureter, bladder, urethra, or		
Criterion	tissue surrounding the retroperineal or perinephric space)		
	tissue surrounding the retroperment of permeanite space)		
	Other infections of the urinary tract must meet at least 1 of the following criteria:		
1	Patient has microorganisms isolated from culture of fluid (other than urine) or		
	tissue from affected site.		
2	Patient has an abscess or other evidence of infection seen on direct examination,		
	during a surgical operation, or during a histopathologic examination.		
3	Patient has at least 2 of the following signs or symptoms with no other recognized cause: fever (>38°C), localized pain, or localized tenderness at the involved site and		
	at least 1 of the following:		
	a. purulent drainage from affected site		
	b. microorganisms cultured from blood that are compatible with suspected site of infection		
	c. radiographic evidence of infection (e.g., abnormal ultrasound, CT scan, magnetic resonance imaging [MRI], or radiolabel scan [gallium, technetium]).		
4	Patient ≤ 1 year of age has at least 1 of the following signs or symptoms with no other recognized cause: fever (>38°C core), hypothermia (<36°C core), apnea, bradycardia, lethargy, or vomiting and		
	at least 1 of the following:		
	a. purulent drainage from affected site		
	b. microorganisms cultured from blood that are compatible with		
	suspected site of infection		
	c. radiographic evidence of infection, (e.g., abnormal ultrasound, CT scan, magnetic resonance imaging [MRI], or radiolabel scan [gallium,		
Commont	technetium]). Papert infactions following circumsision in nowheres as SST CIRC		
Comment	Report infections following circumcision in newborns as SST-CIRC.		



Figure 1: Identification and Categorization of SUTI Indwelling Catheter at the Time of Specimen Collection

Patient had an indwelling urinary catheter at the time of specimen collection

At least 1 of the following with no other recognized cause: Signs and ☐ fever(>38°C) □ suprapubictenderness costovertebral angle pain or tenderness A positive urinalysis demonstrated by at least 1 of the following findings: positive dipstick for leukocyte esterase and/or nitrite □ pyuria (urine specimen with ≥10 WBC/mm³ of unspun urine or ≥3 WBC/high powerfield of spun urine) microorganisms seen on Gram stain of unspunurine A positive urine culture of ≥105 A positive urine culture of ≥103 CFU/ml with no more than 2 and < 105 CFU/ml with no more species of microorganisms than 2 species of microorganisms SUTI - Criterion 2a SUTI - Criterion 1a CAUTI CAUTI

August, 2011



Figure 2: Identification and Categorization of SUTI Indwelling Catheter Discontinued in Prior 48 Hours

Patient had an indwelling urinary catheter discontinued within 48 hours prior to specimen collection

Signs and symptons		
S S		
Urinalysis	positive dipstick for leukoc	h ≥10 WBC/mm³ of unspun urine or ≥3 WBC/high
		\downarrow
Culture	A positive urine culture of ≥10 ⁵ CFU/ml with no more than 2 species of microorganisms	A positive urine culture of ≥10³ and <10⁵ CFU/ml with no more than 2 species of microorganisms
OE	↓	
	SUTI – Criterion 1a	SUTI – Criterion 2a
	<u> </u>	<u> </u>
	CAUTI	CAUTI



Figure 3: Identification and Categorization of SUTI Without Indwelling Catheter at Time of or Within 48 Hours Prior to Specimen Collection

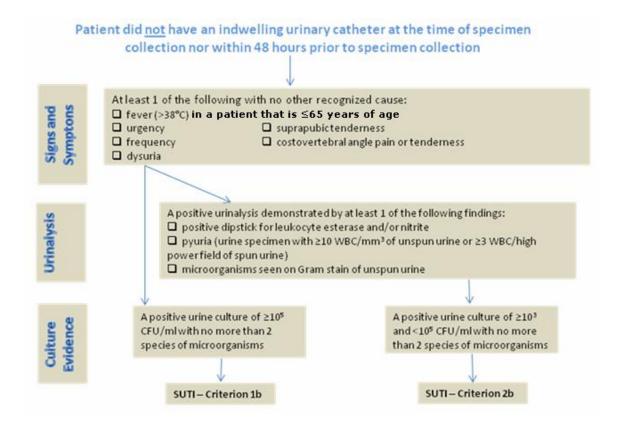




Figure 4: Identification and Categorization of SUTI in Patient ≤1 Year of Age

Patient ≤1 year of age (with or without an indwelling urinary catheter)

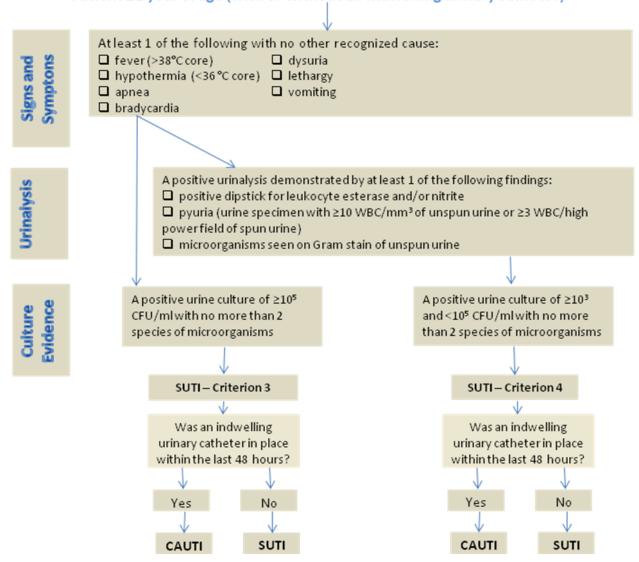
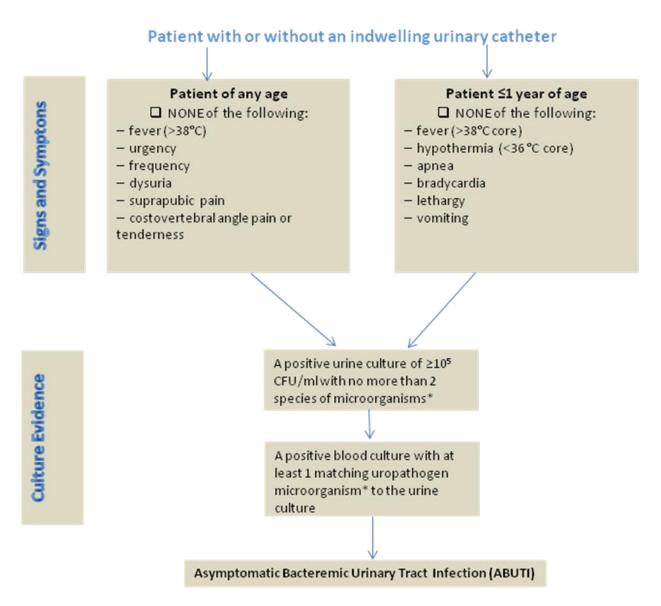




Figure 5: Identification of Asymptomatic Bacteremic Urinary Tract Infection (ABUTI)



*Uropathogen microorganisms are: Gram-negative bacilli, *Staphylococcus* spp., yeasts, beta-hemolytic *Streptococcus* spp., *Enterococcus* spp., *G. vaginalis*, *Aerococcus urinae*, *Corynebacterium* (urease positive)[†].

[†]Report Corynebacterium (urease positive) as either Corynebacterium species unspecified (COS) or, as C. urealyticum (CORUR) if so speciated.

HAI - other

event category	full term	short term	specifications	standard
other	healthcare-associated infection	HAI		NRS

implementation guidance

This area is intended to capture events not previously covered in above categories. Reviewing 2009-2010 data categorical inclusion: *E Coli* in sputum on ventilator, stool infection, necrotizing pancreatitis.

examples

actual sentinel event: A 68 year-old male is admitted with stool impaction and a urinary tract infection. After 4 days in hospital, the patient's condition worsens, and he is subsequently found to have *C difficile* in his stool. The infection results in sepsis and 3-day prolonged hospitalization with admission to intensive care unit.

other - specify

event category	full term	short term	specifications	standard
other	other	other		NRS

implementation guidance

Any unexpected death not elsewhere classified qualifies as a sentinel event and should be reported under the other category with a brief description accompanying it.

examples

actual sentinel event: A patient undergoes a surgical procedure and pre-operative assessment reveals no allergies. The patient receives intravenous Cephalexin and has a subsequent anaphylactic reaction. All attempts are made to revive patient, but they are unsuccessful, and the patient dies.

actual sentinel event: A 62 year-old patient with underlying HTN, diabetes, and obesity is medically cleared for a hip replacement. The patient is anesthetized without complication. An intra-operative cardiac arrhythmia is noted, and the patient is defibrillated without success and is subsequently pronounced dead.

not a sentinel event: 72 year-old Hispanic male diagnosed with end-stage pancreatic cancer agrees to a palliative surgery to improve comfort. The day after surgery, the patient has a cardiac arrhythmia and dies. Death is attributed to the patient's terminal cancer. This does not need to be reported.

glossary

term	definition	
abduction	means the taking away of a person by persuasion, by fraud, or by open force or violence. It includes convincing someone, particularly a minor or a woman he/she is better off leaving with the persuader, telling the person he/she is needed, or that the mother or father wants him/her to come with the abductor.	
adverse	describes a consequence of care that results in an undesired outcome. It does not address preventability.	
associated with	means that it is reasonable to initially assume that the adverse event was due to the referenced course of care; further investigation and/or root cause analysis of the unplanned event may be needed to confirm or refute the presumed relationship.	
authorized	means the guardian or other individual(s) having the legally recognized ability to consent on behalf of a minor or incapacitated individual (surrogate), or person designated by the surrogate to release or consent for the patient.	
decision-making capacity	is the ability to understand information relevant to a decision and the ability to appreciate the reasonably foreseeable consequences of a decision (or lack of a decision).	
deep tissue injury	presents as a purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.	
device	See Medical Device.	
elopement	refers to a situation where a patient or resident who is cognitively, physically, mentally, emotionally, and/or chemically impaired wanders/walks/runs away, escapes, or otherwise leaves a caregiving institution or setting unsupervised, unnoticed and/or prior to their scheduled discharge.	
event	means a discrete, auditable, and clearly defined occurrence.	
healthcare setting	means any facility or office, including a discrete unit of care within such facility, that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence or other care of human illness or injury, physical or mental, including care during and after pregnancy. Healthcare settings include, but are not limited to, hospitals, nursing homes, rehabilitation centers, medical centers, office-based practices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, ambulatory surgical centers, and pharmacies. The boundary of a healthcare setting (the "grounds") is the physical area immediately adjacent to the setting's main buildings. It does not include nonmedical	

	businesses such as shops and restaurants located close to the setting.
high alert medications	are those medications that have a high risk of causing serious injury or death to a patient if they are misused. Examples of high-alert medications include anticoagulants and IV antithrombotics, insulin, cytotoxic chemotherapy, concentrated electrolytes, IV digoxin, opiate narcotics, neuromuscular blocking agents, and adrenergic agonists. The recommended "High Alert Medication List" is available at the Institute for Safe Medication Practices' website, www.ismp.org .
infant	is a child under the age of one year. (SRE 2006; Stedman's online dictionary)
informed consent	involves a process of shared decisionmaking in which discussion between a person who would receive a treatment, including surgery or invasive procedure, and the caregiver/professional person who explains the treatment, provides information about possible benefits, risks and alternatives, and answers questions that result in the person's authorization or agreement to undergo a specific medical intervention. Documentation of this discussion should result in an accurate and meaningful entry in the patient record, which could include a signed "consent form." Signing a consent form does not constitute informed consent; it provides a record of the discussion.
injury	, as used in this report has a broad meaning. It includes physical or mental damage that substantially limits one or more of the major life activities of an individual in the short term, which may become a disability if extended long term. Further, injury includes a substantial change in the patient's long-term risk status such that care or Appendix B - Glossary B-3 National Quality Forum monitoring, based on accepted national standards, is required that was not required before the event. (Of note, states and other entities may use alternate definitions for the term "disability.")
largely preventable	recognizes that some of the events on the SRE list are not universally avoidable, given the complexity of healthcare and current knowledge.
low-risk pregnancy	refers to a woman aged 18-39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancyinduced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.

SENTINEL EVENT REPORTING GUIDANCE GLOSSARY

medical device	is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. ¹
medication error	means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. ²
neonate	is a newborn less than 28 days of age.
patient	means a person who is a recipient of healthcare. A person becomes a patient at the point that they are being "cared for" in the facility. Being "cared for" begins when they are first engaged by a member of the care team, e.g. assessment by the triage nurse in the E.D., walking with the phlebotomist to the lab for a lab draw. A patient is no longer considered a patient at the point that they are no longer under the care of a member of the care team, e.g. the nursing assistant has safely assisted the patient to the car from an inpatient stay; the ambulating patient that does not need assistance leaves the radiology department following an outpatient test. ³
pressure ulcer, stage 3	is defined as full thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon, or muscle is not exposed. Slough may be present. May include undermining and tunneling. The depth of a Stage 3 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue and Stage 3 ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Stage 3 pressure ulcers. Bone/tendon is not visible or directly palpable. ⁴
pressuer ulcer, stage 4	is defined as full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present. Often includes undermining and tunneling. The depth of a Stage 4 pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput, and malleolus do not have subcutaneous tissue and these ulcers can be shallow. Stage 4 ulcers can extend into muscle and/or supporting structures (e.g., fascia, tendon, or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed

	bone/tendon is visible or directly palpable. ⁴	
pressure ulcer, unstageable	is defined as full thickness tissue loss in which the actual depth of the ulcer is completely obscured by slough and/or eschar in the wound bed. Until enough slough and/or exchar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either Stage 3 or Stage 4.4	
preventable	describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure.	
restraints	is defined by The Joint Commission, the Centers for Medicare & Medicaid Services, and by some states. The appropriate source(s) should be consulted for the definition required by the setting and/or jurisdiction in which a presumptive event occurs. In the event none of those definitions apply to an institution, the following definition, which is intended to capture definitions from the named organizations, is offered: Restraints means any method of restricting a patient's freedom of movement that is not a usual and customary part of a medical diagnostic or treatment procedure to which the patient or his or her legal representative has consented; is not indicated to treat the patient's medical condition or symptoms; or does not promote the patient's independent functioning.	
serious	describes an event that can result in death, loss of a body part, disability, loss of bodily function, or require major intervention for correction (e.g., higher level of care, surgery).	
sexual abuse	NRS 200.366 Sexual assault: Definition; penalties. 1. A person who subjects another person to sexual penetration, or who forces another person to make a sexual penetration on himself or herself or another, or on a beast, against the will of the victim or under conditions in which the perpetrator knows or should know that the victim is mentally or physically incapable of resisting or understanding the natu of his or her conduct, is guilty of sexual assault.	
surgery	 NAC 449.9743 "Surgery" defined. (NRS 449.037) "Surgery" means the treatment of a human being by a physician using one or more of the following procedures: 1. Cutting into any part of the body using a scalpel, electrocautery or any other means for diagnosis or the removal or repair of diseased or damaged tissue, organs, tumors or foreign bodies. 2. The reduction of a fracture or the dislocation of a bone, joint or bony structure. 3. The repair of a malformation of the body resulting from an injury, a birth defect or another cause, that requires cutting and manipulation or a suture. 4. An instrumentation of the uterine cavity of a woman for diagnostic or therapeutic purposes, including the procedure commonly known as dilation and curettage. 5. Any instrumentation of, or injection of a substance into, the uterine cavity of a woman to terminate a pregnancy. 6. Any procedure to sterilize a human being. 	

SENTINEL EVENT REPORTING GUIDANCE GLOSSARY

SEINTINEL EVENT REPORTI	NG GOIDANCE GLOSS
	7. An endoscopic procedure.
	8. A laproscopic procedure.
surgery begins	, regardless of setting, at point of surgical incision, tissue puncture, or insertion of instrument into tissues, cavities, or organs.
surgery ends	after all incisions or procedural access routes have been closed in their entirety, device(s) such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating/procedure room.
unambiguous	refers to an event that is clearly defined and easily identified.
unintended retention	of a foreign object refers to a foreign object introduced into the body during a surgical or other invasive procedure, without removal prior to the end of the surgery or procedure, which the surgeon or other practitioner did not intend to leave in the body.

¹ Food and Drug Administration. Available at www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm. Last accessed January 19, 2011.

² National Coordinating Council for Medication Error Reporting and Prevention. Available at www.nccmerp.org/aboutMedErrors.html. Last accessed January 7, 2011.

³ Minnesota Department of Health.

⁴ National Pressure Ulcer Advisory Panel. Available at: www.npuap.org/Final Quick Treatment for web 2010.pdf. Last accessed January 31, 2011.