وزارة الصحة
Ministry of Health

KINGDOM OF SAUDI ARABIA
Ministry of Health- Riyadh KSA
General Directorate of Infection Prevention and Control

GDIPC Surveillance

Healthcare Associated Infections (HAIs)

Surveillance Manual

Second Edition

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Message from General Director

I am honored to present the second edition of healthcare-associated infections surveillance manual from the General Directorate of Infection Prevention and Control at the Ministry of Health. It has been estimated that 5% to 15% of the patients admitted to healthcare facilities may acquire infections while receiving care at these facilities. Most of these infections can be prevented by adherence to evidence-based infection control practices and care bundles designed to prevent these infections.

The current edition aimed at guiding healthcare workers in Saudi Arabia, especially infection control practitioners, while monitoring healthcare-associated infections across different levels of healthcare facilities. Implementing the definitions and methodology described in this edition will ensure standardized surveillance and fair comparisons of infection rates and preventive practices between different facilities and in the same facility overtime. The second edition included several modifications based on the feedback of fellow professionals.

We hope this manual will help and guide the infection control practitioners to better understand the surveillance definitions, methodology and other related topics which will enhance patient safety and improve patients' outcomes.

Dr. Khalid H. Alanazi
Director General,
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Abbreviations

ABUTI	ASYMPTOMATIC BACTEREMIC UTI
AIDS	Acquired immunodeficiency syndrome
ANC	Absolute neutrophil count
APIC	Association for Professionals in Infection Control and Epidemiology
APRV	Airway pressure release ventilation
ASA	American Society of Anesthesiology
ASC	Active surveillance cultures
ASP	Antimicrobial stewardship program
AST	Active surveillance testing
AUR	Antimicrobial Use and Resistance
AVF	Arteriovenous fistula
AVG	Arteriovenous graft
BAL	Broncho alveolar lavage
C. DIFF	Clostridium difficile
CAUTI	Catheter-associated urinary tract infection
CBAHI	Central Board for Accreditation of Healthcare Institutes
CCU	Coronary care unit
CDC	Centers for Disease Control and Prevention
CDI	Clostridium difficile infections
CFU	Colony forming units
CHG	Chlorhexidine gluconate
CLABSI	Central line-associated bloodstream infection
CLIPS	Central line insertion practice
CO	Community-onset
COVID-19	Coronavirus disease 2019
CPAP	Continuous nasal positive airway pressure
CRE	Carbapenem-resistant Enterobacteriaceae
CRKP	Carbapenem-resistant Klebsiella pneumonia
CSF	Cerebrospinal fluid
DE	Dialysis event
DOE	Date of event
DUR	Device utilization ratio
DVT	Deep venous thrombosis
ECDC	European Centre for Disease Prevention and Control
ECMO	Extracorporeal life support

ELISA	Enzyme-linked immunoassay
EMR	Electronic Medical Record
ENT	Ear, nose, and throat
ETA	Endotracheal aspirate
FIO2	Fraction of inspired oxygen
GCC	Gulf Cooperation Council
GDIPC	General Directorate of Infection Prevention and Control
GIT	Gastrointestinal tract
GVHD	Graft versus host disease
HAI	Healthcare-associated infection
HCW	Health care workers
HD	Hemodialysis
HERO	Hemodialysis reliable outflow
HESN	Health electronic surveillance network
HFO	High frequency oscillatory
HIV	Human immunodeficiency virus
HO	Healthcare facility-onset
HSCT	Hematopoietic stem cell transplantation
IABP	Intra-aortic balloon pump
ICP	Infection control professional
ICU	Intensive care unit
IDSA	Infectious Diseases Society of America
INICC	The International Nosocomial Infection Control Consortium
IP	Infection preventionist
IPC	Infection prevention and control
IPCAF	WHO infection prevention and control assessment framework
IT	Information technology
IVAC	Infection-related ventilator-associated complications
IWP	Infection Window Period
KAP	Knowledge, attitude and practice
LABID	Laboratory-Identified
LCBI	Laboratory-confirmed bloodstream infection
MAP	Mean airway pressure
MBI	Mucosal barrier injury
MDR	Multidrug-resistant
MDRO	Multidrug-resistant organisms
MOH	Ministry of Health

MRSA	Methicillin-resistant staphylococcus aureus
MSSA	Methicillin-sensitive staphylococcus aureus
NHSN	National Healthcare Safety Network
NICU	Neonatal intensive care unit
OR	Operating room
PCR	Polymerase chain reaction
PEDVAE	Pediatric ventilator-associated event
PEEP	Positive end-expiratory pressure
PICU	Pediatric intensive care unit
PPE	Personal protective equipment
PPS	Point prevalence survey
PSB	Protected specimen brushing
PUD	Peptic ulcer disease
PVAP	Possible ventilator-associated pneumonia
QAD	Qualifying antimicrobial day
RIT	Repeat Infection Timeframe
SCA	Specialty care area
SHEA	Society for Healthcare Epidemiology
SIR	Standardized infection ratio
SOT	Solid organ transplantation
SSI	Surgical site infection
SUR	Standardized utilization ratio
SUTI	Symptomatic urinary tract infection
URI	Upper respiratory tract infection
UTI	Urinary tract infection
VAC	Ventilator-associated condition
VAE	Ventilator-associated event
VAP	Ventilator-associated pneumonia
VRE	Vancomycin-resistant enterococci
WBC	White blood cell
WHO	World Health Organization

General Directorate of Infection Prevention and Control

Introduction

General Directorate of Infection Prevention and Control (GDIPC) at the Saudi Ministry of Health (MOH) manages all of hospitals in 20 regions of Saudi Arabia. Healthcare-associated infections (HAIs) are associated with significant morbidity and mortality. Additionally, they increase the length of stay in admitted patients and consequently the cost of healthcare services. Surveillance of healthcare-associated infections can provides the policy maker as well as healthcare providers with infections rates, a critical step in HAI prevention strategies.

Vision

GDIPC is committed to excellence and safety of healthcare services provided by the MOH hospitals across Saudi Arabia through promoting up to date infection practices including surveillance

Mission

GDIPC is committed to provide information that contribute to the delivery of the highest quality health care, by promoting safety and reducing the risk of acquiring and transmitting infections among patients, visitors, healthcare workers and supporting staff at MOH hospitals through ongoing data collection, consolidation, and analysis, followed by the dissemination of guiding information and actions, using sound epidemiological and statistical principles

Target audience

This manual was created to provide the necessary surveillance information for infection control professionals (ICP), epidemiologists, biostatisticians, and any other healthcare professional whose responsibilities include infection prevention at healthcare setting.

Objectives

This manual was created to provide the necessary surveillance information for the following objectives:

- To measure the incidence of HAIs and organisms and establish their endemic rates by using standard definitions and methods to allow benchmarking local, regional, and international.
- To investigate and control hospital clusters or outbreaks of HAI & resistant organisms among patients and personnel.
- To maintain a comprehensive data system to monitor, evaluate, and implement the necessary actions to ensure a safe and healthy environment for patients, personnel, and visitors.
- To monitor antimicrobial susceptibilities and the development of new resistant strains that may pose challenge to healthcare system.
- To analyze temporal trends of aggregated data to ensure patient safety and appropriate allocation of available resources.
- To evaluate new products to be used to control infection throughout the hospital.
- To ensure compliance with national and international regulations.
- To ensure compliance with the requirements of accrediting bodies, including Saudi Central Board for Accreditation of Healthcare Institutes (CBAHI) and international agencies such as the Joint Commission on Accreditation of Healthcare Organizations or the Rehabilitation Accreditation Commission.
- To provide data and statistical analysis for research and publications.

Table of Contents

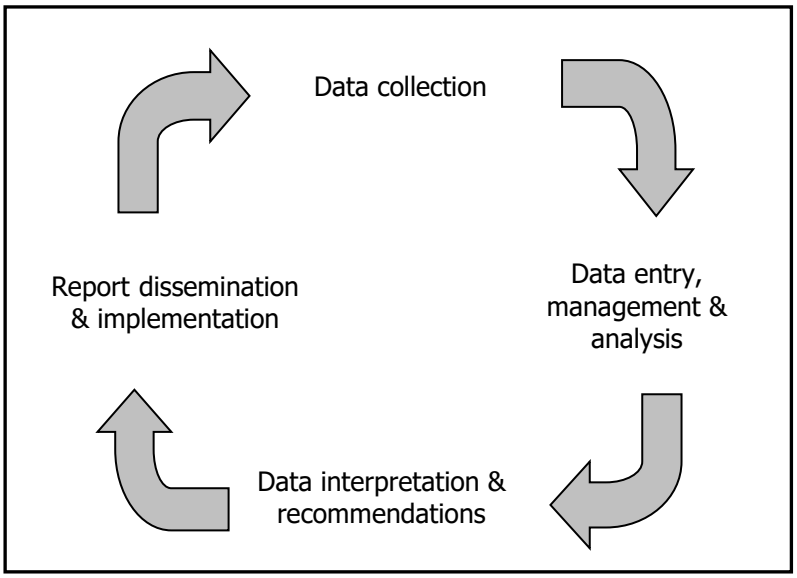
1. Surveillance Definition

Surveillance definition:

Surveillance is a systematic method of ongoing collecting, consolidating, and analyzing data concerning the distribution and determinates of a given disease or event, followed by the dissemination of that information to those who can improve the outcome.

Surveillance cycle:

Surveillance cycle is not complete until data collection is translated into a report and recommendations for implementation as shown in the figure below.



Difference between surveillance and clinical definitions:

Surveillance and clinical definitions are different due to different purposes, as shown below:

	Clinical Criteria	Surveillance Criteria
Main aim	Aim to provide diagnosis and treatment for cared patients	Aim to provide trend for risk assessment, prevention, and policy change
Main focus	Focus on individual patients	Focus on a patient population
Allowance for clinical judgment	Clinical judgment is important	Clinical judgment is absent or minimal

Objectives of HAI surveillance:

Surveillance data can be used to serve several objectives:

- To measure the incidence of healthcare associated infections (HAI) and organisms.
- To establish endemic rates of HAI.
- To early detect, investigate and control hospital outbreaks of HAI.
- To monitor, evaluate, and implement the necessary preventive measures.
- To work on reducing HAI using standard bundles.
- To observe practices, such as hand hygiene and sterilizer performance monitoring, to promote compliance with recommendations and standards.
- To monitor the occurrence of adverse outcomes to identify potential risk factors.
- To prevent and control infections and occupational injuries in healthcare workers (HCWs).
- To monitor antimicrobial susceptibilities.
- To analyze temporal trends of aggregated data.
- To evaluate new products to be used to control infection throughout the hospital.
- To detect and report notifiable diseases to the Ministry of Health (MOH).
- To identify organisms and diseases of epidemiological importance, such as antibiotic-resistant organisms and tuberculosis, to prevent their spread.
- To ensure compliance with national and international regulations.
- To ensure compliance with accrediting agency requirements, such as the Joint Commission on Accreditation of Healthcare Organizations or the Rehabilitation Accreditation Commission.
- To provide information that can be used by responsible partners within/outside the health care facilities to target performance improvement activities.
- To detect a bioterrorist event or an emerging infectious disease.
- To provide data to conduct a facility risk assessment for diseases, such as legionellosis or tuberculosis.

Effectiveness of surveillance:

Surveillance without interventions can result in reduction of rates of infections simply due to change of the behaviors of healthcare providers.

Surveillance would be most effective if the outcome met the following criteria:

- Infections with high prevalence &/or incidence.
- Infections associated with high morbidity &/or mortality.
- Infections associated with long length of stay.
- Infections associated with high treatment cost.
- Preventable infections.

Surveillance design:

Surveillance design is unique and is different from survey and monitoring, as shown below

	Surveillance	Survey	Monitoring
Methods	Making repeated standardized surveys in order to detect possible changes	Making a single observation to measure and record health-related characteristics	Making repeated standardized measurements to detect unacceptable standards
Relation to time	Multiple points of time	One point of time	Multiple points of time
Relation to standards	Usually do not differentiate between acceptable and unacceptable standards	Not applicable	Usually have acceptable and unacceptable standards
Uses	HAI surveillance	Knowledge, attitude and practice (KAP) of hand hygiene in HAI prevention	Monitoring pressure in negative pressure isolation rooms

2. Establishing a Surveillance System

Establishing a surveillance system requires the following steps:

1. Assess the population and identify those at greatest risk for the outcome (e.g. blood stream infection) or process (e.g. central line insertion practices) of interest.
2. Select the appropriate outcome or process to be monitored by surveillance.
3. Select the appropriate surveillance methodology.
4. Create a surveillance manual.
5. Prepare surveillance resources.
6. Assemble surveillance team & engage stakeholders.
7. Train surveillance team.
8. Determine observation location.
9. Determine observation period.
10. Monitor for the outcome or process.
11. Stick to standardized definitions during monitoring.
12. Collect appropriate denominator data.
13. Create and maintain database.
14. Analyze surveillance data.
15. Report and use surveillance information in a timely manner.

1. Assessing the population to survey:

Assess the population and identify those at greatest risk for the outcome (e.g. blood stream infection) or process (e.g. central line insertion practices) of interest.

Indicators that can be used to assess the population to survey:

- What types of patients do we serve?
- What are the most common diagnoses?
- What are our most frequently performed surgical or other invasive procedures?
- Which services or treatments are used most frequently?
- Are there services or treatments that increase the risk of infection for the patient?
- What types of patients increase liability and/or costs for the organization?
- What types of patients with long length of stay in the organization?
- Does the organization's strategic plan focus on particular groups of patients?
- What types of health concerns exist in the community, region, or regulatory environment?
- Which patients are at increased risk for infection or other important outcomes?

Sources of data required to assess the population to survey

- Medical records.
- Financial services.
- Information services.
- Quality/utilization management.
- Surgical database.
- Administrative/management reports.
- Risk management.
- Community agencies.
- Occupational/employee health.
- Human resources records.

Vulnerable patient populations who are higher risk of infection

- Elderly
- Immunosuppressed
- Organ or bone marrow transplant
- HIV / AIDS
- Pregnant women
- Infants and children
- Diabetics
- Alcohol/substance users
- Chronic obstructive pulmonary disease
- Congestive heart failure
- Other chronic illnesses
- Dialysis

2. Selecting the appropriate outcome or process to be monitored by surveillance:

Outcome versus process

- Select the appropriate outcome or process to be monitored by surveillance.
- Examples of outcomes: HAI, infection or colonization with a specific organism, pyrogenic reaction or vascular access infection in hemodialysis patients, sharps injuries, etc.
- Examples of processes: Central line insertion practices (CLIPs), surgical care processes (e.g., preoperative antimicrobial prophylaxis), medication errors, influenza vaccination rates, hepatitis B immunity rates, personnel compliance with protocols, etc.
- Examples of other events: Occurrence of reportable diseases and conditions, communicable diseases in personnel, organisms or syndromes indicative of bioterrorist events, etc.

Selecting the outcome or process should be based on:

- High prevalence &/or incidence.
- High morbidity &/or mortality.
- Long length of stay.
- High treatment cost.
- Preventable.
- Satisfy customer needs / satisfaction.

- Satisfy organizational mission / strategic goals.
- Can be done with available resources.

3. Select Surveillance methodology:

Routine HAI surveillance in most in-patient healthcare facilities should be conducted by ICP in:

1. An active
2. Patient-based
3. Prospective
4. Priority-directed manner
5. That yields risk-adjusted incidence rates

4. Create surveillance manual for:

- Outcome & process
- Methodology
- Location and durations
- Data collection forms
- Data analysis methods
- Benchmarking
- Reporting

5. Prepare surveillance resources:

- Office space
- Computers
- Information technology services
- Administrative services
- Media services
- Folders, papers, pens, cabinets, storage media, pagers
- Microsoft Office (Word, PowerPoint, and Excel) and statistical software

6. Assemble surveillance team & engage stakeholders:

- Hospital epidemiologist
- ICP
- Infection control coordinator
- Data entry clerks
- Biostatistician

7. Train surveillance team:

- Start with recruiting qualified persons
- All must be formally trained in infection prevention and control (IPC) to understand:

✓ Microbiology
✓ Sterilization/ disinfection
✓ Ward practice and risk Assessment
✓ Hospital design and management
✓ Surveillance and research methodology
✓ Short courses, training sessions, campaigns, conferences, diploma, CIC….

8. Determine observation location:

- Inpatient versus outpatient
- Intensive care units versus wards
- Regular wards versus specialty care areas
- Unit-based versus hospital-based

9. Determine observation period:

- It should be sufficient to collect sufficient data. It could be affected by the hospital resources, hospital size, target population, health care priorities …etc.
- The shortest unit time in surveillance is one month

10. Monitor for the outcome or process:

- Develop data collection tools for each surveillance initiative
- Limit data collection to only what is needed for meeting the specific objective
- Design forms considering flow of patient charts / data sources and ease of data recording / entry
- Data collection include numerator and denominator data

11. Stick to standardized definitions during monitoring:

- Use standardized written case definitions to ensure precise surveillance.
- When available and applicable, use previously published, validated definitions
- When historical data are used for internal comparisons or for external comparisons, ensure that the same definitions are used for outcomes and processes and that populations are at similar risk
- If definitions are changed, be aware that such changes compromise the comparability of rates over time.

12. Collect appropriate denominator data:

- Counts of the cohorts of patients at risk of acquiring HAI
- For device-associated HAI incidence rates: record daily the total number of patients and total number of ventilator-days, central line-days, and urinary catheter-days in the patient care area(s) under surveillance
- For SSI rates: record information on operative procedures selected for surveillance (e.g., type of procedure, date, risk factors, etc.)

13. Create and maintain database:

- Type: Microsoft Excel, SPSS, other software
- Separate for each surveillance component
- Names and dates
- Safety
- Storage
- Manuals

14. Analyze surveillance data

- Infection rates
- Device utilization
- Compliance rates of preventive bundles
- Standardized infection ratio
- Benchmarking

15. Report and use surveillance information in a timely manner

- Quarterly reports versus annual reports
- Consider audience
- Consider stakeholders
- Consider units where data were collected

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3. Surveillance Methodology

The patient safety surveillance modules must use the following methodology:

1. Active surveillance
2. Patient-based surveillance
3. Prospective surveillance
4. Targeted surveillance
5. Yields risk-adjusted incidence rates

- This means that the ICP shall seek out infections during a patient's stay by screening a variety of data sources.
- Retrospective chart reviews should be used only when patients are discharged before all information can be gathered.
- Other HCW (other than ICP) may be trained to screen data sources for these infections, but the ICP must make the final determination.
- To minimize the ICP's data collection burden, others may be trained to collect the denominator data (separate forms for device/medication -associated infections).

1. Active versus passive

1. Active surveillance

    - Trained personnel, mainly ICPs, vigorously look for HAI
    - Information accumulated by using a variety of data sources within and beyond the nursing ward

2. Passive surveillance

    - Persons who do not have a primary surveillance role, such as ward nurses or respiratory therapists, identify and report HAI
    - It is acceptable for denominator data

	Active Surveillance	**Passive Surveillance**
Person in charge	Data are collected by trained ICP as part of planned surveillance	Data are reported by non-trained personnel as per reporting regulations
Source of information	Attempt to search multiple data sources	No attempt to search multiple data sources
Time required	Needs more effort and time	Needs less effort and time
Missing data	Few missing events	More missing events
Example	ICP collect CLABSI numerator data	Staff nurse call ICP to report a pneumonia case

2. Patient-based versus laboratory-based surveillance

1. Patient-based surveillance

    - Count HAI, assess risk factors, and monitor patient care procedures and practices for adherence to infection control principles
    - Requires ward rounds and discussion with caregivers

2. Laboratory-based surveillance

    - Detection is based solely on the findings of laboratory studies of clinical specimens

	Patient-based Surveillance	**laboratory-based Surveillance**
Case-finding	Data collected from multiple resources (e.g. visit patient care areas, review charts, & discuss with care giver)	Case-finding based solely on positive lab findings
Surveillance definition	Can verify standard surveillance definition	Usually can NOT verify standard surveillance definition
Uses	Can monitor events, risk factors, and practices	Can NOT monitor risk factors and practices
Example	Device-associate HAI and SSI surveillance	LabID event detection in the MDRO/CDI

3. Prospective versus retrospective surveillance

1. Prospective surveillance

    - Monitor patients during their hospitalization
    - For SSIs, also monitor during the post-discharge period

2. Retrospective surveillance

    - Identify infections via chart reviews after patient discharge

	Prospective Surveillance	**Retrospective Surveillance**
Onset of data collection	Data collection starts before patient discharge	Data collection starts after patient discharge
Ascertainment bias	Less ascertainment bias	More ascertainment bias
Missing data	Few missing events as more resources are available	More missing events as less resources are available
Implementation	Easy to establish	May be difficult to establish

4. Priority-directed versus comprehensive surveillance

1. Priority-directed (also called targeted or focused) surveillance

    - Objectives for surveillance are defined
    - Focus is on specific events, processes, organisms, and/or patient populations

2. Comprehensive surveillance

    - Continuous monitoring of all patients for all events and/or processes
    - Highly personnel resource intensive if done manually

	Targeted Surveillance	**Comprehensive Surveillance**
Focus	Focus on important HAI (e.g. device-associated), locations (e.g. ICUs), and population (e.g. dialysis patients)	Covers all HAIs in all hospital locations and populations
Weight of problems	Weight of problems is respected. Priority & objective directed	Equal weights for different problems
Annual risk assessment	Preceded by annual risk assessment and plan	No need for annual risk assessment and plan
Implementation	Usually feasible & less labor intensive	Usually unfeasible & more labor intensive
Effectiveness	More cost-effective	Less cost-effective

5. Risk-adjusted rates versus crude rates surveillance

1. Risk-adjusted rates

- Rates are controlled for variations in the distribution of major risk factors associated with an event's occurrence
- Such rates allow inter- and intra-facility rate comparisons
- Common methods used for risk-adjustment in HAI surveillance
    - Stratification by location in surveillance of device associated infections
    - Stratification by surgery type in SSI surveillance
    - Stratification by risk index category in SSI surveillance
    - Stratification by birth weight group in neonatal CLABSI and PedVAE
    - Stratification by type of central line in CLABSI in specialty care areas
    - Stratification by vascular access in dialysis event in dialysis centres
    - Standardized infection ratio

2. Crude rates

- Rates assume equal distribution of risk factors for all events
- Such rates cannot be used for inter-facility comparisons

	Adjusted rates	**Crude rate**
Risk factor assumptions	Rates are controlled for variations in the distribution of major risk factor associated with an event's occurrence	Rates assume equal distribution of risk factors for all events
Credibility	Useful for benchmarking	Benchmarking may be misleading
Example	SIR for SSI for patients in surgical ward	SSI rates in all patients in surgical ward

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4. Surveyor Competencies

Competency definition (APIC):

Observable and measurable knowledge, skills, abilities, and personal attributes that improve performance and result in success (doi: 10.1016/j.ajic.2012.03.002)

Updated APIC Competency Model for the ICP

1. Leadership
2. IPC informatics
3. Quality improvement
4. IPC operations
5. Research
6. Professional stewardship

1. Leadership

- **Communication:** The ability to influence, serve as a role model, demonstrate accountability and integrity, and communicate the value of infection prevention to a diverse audience to achieve desired outcomes are all required for leadership competency.
- **Critical thinking skills:** Critical thinking means seeking and using all information to examine a problem or situation and finding solutions through creative application of knowledge, experience, data, and evidence.
- **Collaboration:** ICP's work is executed effectively and sustainably only through working with multiple departments and disciplines to carry out the IPC program's goals.
- **Behavioral science:** Familiarity with psychology and socio-adaptive strategies become valuable because prevention efforts in large part can be behaviorally focused, requiring collaboration, engagement, and communication.
- **Program management:** ICPs also need to be effective and efficient managers of budgets, resources, personnel, and programs.
- **Mentorship:** Effective and timely mentorship can play a critical role in the success of ICPs, especially those new to the profession, because ICPs come to IPC from varied backgrounds from within nursing and non-clinical fields and have not shared standardized training.

2. IPC informatics

- Surveillance Technology
- Electronic Medical Record (EMR)
- Data management, analysis, and visualization
- Applications of novel diagnostic technologies

3. Quality improvement

- ICPs as subject matter experts
- Engaged in performance improvement processes
- Engaged in overall patient safety program
- Data utilization to aid in decision-making and goal setting
- Risk assessment and risk reduction

4. IPC operations

- Epidemiology and surveillance
- Education
- IPC rounds
- Cleaning, disinfection, and sterilization
- Outbreak management
- Emerging technologies
- Antimicrobial stewardship
- Diagnostic stewardship

5. Research

- Evaluation of research
- Comparative effectiveness research
- Implementation and dissemination science
- Conduct or participate in research and evidence-based practices.

6. Professional stewardship

- Ensure that accountability measures are in place
- Ethics
- Ability to quantify the costs and savings of IPC initiatives

- Population health and community infections
- The continuum of care
- Advocacy and role model

Stages of Competency

1. Novice
2. Becoming proficient
3. Proficient
4. Expert

1. Novice ICP

- The Novice ICP has very limited knowledge, skills, experience, and basis in which to have situational awareness in IPC and epidemiology.
- The Novice must rely on rules and concepts to guide their practice and begin to develop their knowledge/skills in the core competencies.

2. Becoming Proficient ICP

- ICP continues to build on their knowledge/skills in the core competencies while developing into an independent practitioner.
- He/she is able to briefly move beyond rule-based thinking to identify common trends that need to be addressed to ensure patient safety.

3. Proficient ICP

- The CIC indicates that the ICP has knowledge required for competent performance in IPC.
- ICP begins to apply the core competencies independently and deepens their knowledge and application of the future-oriented competency domains.

4. Expert ICP

- The Expert ICP shares their knowledge and skills through mentoring, research, publication, collaboration, leadership, and educating other ICPs.

CIC Credential

- CBIC core competencies are evidence-based, reflective of current practice
- ICPs renew and enhance their skills and application of the core competencies throughout their careers.

CIC core competencies

- Identification of infectious disease processes
- Surveillance and epidemiologic investigations
- Preventing/controlling the transmission of infectious agents
- Employee/occupational health
- Management and communication (leadership)
- Education and research

5. Requirements for HESN Plus Enrollment

Health Electronic Surveillance Network (HESN) Plus Program:

It is an integrated national electronic surveillance system that has several domains to uniformly monitor communicable diseases, disease epidemics, immunization, and HAIs across Saudi Arabia. It allows users at different hospitals to continually and uniformly report HAIs to the GDIPC at Riyadh, Saudi Arabia.

Requirements for HESN Plus Enrollment:

Each hospital is eligible for participate in HESN Plus HAIs surveillance plan if the following criteria are met:

- Availability of microbiology laboratory or has signed documented agreement with external or referral laboratory.
- Availability of dedicated surveillance coordinator
- Availability of internet services and adequate number of personal computers
- For device-associated infections:
  - ✓ The hospital should have at least one critical care unit (ICUs, CCU, NICU, etc.)
- For surgical site infections:
  - ✓ The hospital should have a standard operating room (OR) and undergoing at least one recognized surgery.
- For dialysis event:
  - ✓ The hospital should have a dialysis center or unit serving hemodialysis outpatients
  - ✓ Units serving only inpatients do not meet the criteria

Enrollment Application:

If the above criteria are met, the hospital should fill an enrollment application submitted through HESN Plus program and approved by the GDIPC surveillance department. The application is filled electronically and includes the following information:

- Region
- Hospital name
- Total bed capacity
- How many critical care units and how many beds in each one
- Surgical procedures chosen for SSI surveillance according to the protocol
- Name of the surveillance coordinators in the hospital and their contacts
- Other required information

Creation of HESN Plus users:

Infection Control Unit Roles in HESN Plus

1. HESN Plus Infection Control User: Is the employee who works in the healthcare facility and enters the Surveillance information
2. System Manager for a Medical Facility: Is the system administrator at the level of their medical facility
3. Directorate: Is the administrative director of the directorate they are in charge of, and is able to access all data of the medical facilities that fall under their directorate.
4. System Administrator: Is the system administrator for Infection Control and can access data of all medical directorates and facilities.

Submitting a Request to the Infection Control Unit

No facility can use the Infection Control Unit without first submitting a request through HESN+ and having it approved by the Infection Control Unit Administration. The application process is as follows:

1. Click on the Infection Control Unit icon and then on the “Submit Request” button

2. The concerned facility fills in the facility's details on Intensive Care Units (ICUs), Procedures, and Infection Control Administration, and then submits the application. After submitting the application, it will be sent to the Infection Control Administration at the Ministry of Health for review.

Reviewing a Facility's Request

The system administrator user of the Infection Control Unit can view the requests of health facilities submitted through the requests page, and by clicking on the request number, they can preview the facility's request details.

Returning a Request

The system administrator can return a request to the healthcare facility to complete or correct some data as deemed appropriate, in accordance with the standards of the Infection Control Unit. This can be done by clicking the "Return Request" button and adding notes on the edits required to be made by the healthcare facility.

Rejecting a Request

The system administrator can reject the request of a healthcare facility, as deemed appropriate, in accordance with the standards of the Infection Control Administration. This can be done by clicking the "Reject Request" button and adding notes on the rejection of the request.

Approve a Request

The system administrator can approve the request of the healthcare facility, as deemed appropriate, in accordance with the standards of the Infection Control Administration. After approving the request, the healthcare facility will be immediately able to use the Infection Control Unit on the HESN+ platform.

6. Surveillance Plan and Risk Assessment

Infection Control Risk Assessment:

Infection control risk assessment is a coordinated activity to identify the risks for acquiring and transmitting infections based on the patient population served, the types of services provided, and the analysis of surveillance data

Purpose of infection control risk assessment:

1. Evaluation of potential risk for infections, contamination and exposures
    - Based on known risk, historical data and reports in literature
2. Evaluation of harm
    - Life threatening, loss of function, loss of community trust, loss of organization good will, financial threat, legal and/or regulatory issues
3. Evaluation of organization's preparedness
    - To eliminate or mitigate the harm or risk of harm

Components of infection control risk assessment:

1. **Probability of occurrence of the event/condition:** based on known risks, historical data & reports in literature

Rate	Probability of occurrence	Description
0	Never	No possibility to occur
1	Rare	Risk is not expected to occur
2	Maybe	Occur infrequently but remain a possibility, few times per year or per activity
3	Likely	Risk is not a persistent issue, once several times per year month or per activity
4	Expected	Occur frequently, pose a constant threat once or several times per day

2. **Impact of the event/condition at different levels**

- Threat to life and or health
- Disruption of services
- Loss of function
- Prolonged length of stay
- Financial impact
- Legal issues
- Regulatory/accrediting/organizational issues

Rate	Consequence of occurrence	Description
1	Minimal clinical	No real risk or harm
2	Moderate clinical	Minimal real risk or harm
3	Permanent harm	Prolonged length of stay
4	Serious Loss	Permanent injury
5	Life threatening	May cause death

3. Current preparedness of the system

- Status of current plans and implementation
- Training status
- Availability of backup systems
- Community/Public Health resources

Rate	Preparedness level	Description
1	Solid	Risk would be avoided if plan of actions took place
2	Good	Consequences are minimized by the plan of actions
3	Fair	Plan of actions needs to be modified ASAP
4	Poor	Plan of action not enough
5	None	No plan of Action

Example of infection control risk assessment:

Event or Condition	What is probability of event/condition occurring?					What is potential impact of event/condition on patients and staff?					What is organization's preparedness to deal with this event/condition?					Numerical risk level
Level	• Expected	• Likely	• Maybe	• Rare	• Never	• Life threatening	• Serious Loss	• Permanent harm	• Moderate clinical	• Minimal clinical	• None	• Poor	• Fair	• Good	• Solid	Total
	4	3	2	1	0	5	4	3	2	1	5	4	3	2	1	
C-diff infection	4							3					3			36
CABG SSI	4						4					4				64

- Multiply the ratings for each risk in the area of probability, impact and current systems
  - C-diff infection risk: 4x3x3=36
  - CABG SSI risk: 4x4x4=64
- Sort the total score in descending order
- Determine a cut off value below which no action is necessary
- Review with organization for acceptance of priorities

7. Point Prevalence Survey

Point Prevalence Survey (PPS) of HAIs:

- PPS is a count of the number of patients with a particular condition (in this case a HAIs) at a particular time (in this case one day), as a proportion of the total number of patients who are hospitalized at that particular time.
- PPS only counts the condition if present at the time (on the day) of the survey, but does not count if it is present at other times during the patient stay in the hospital.

Objectives of PPS:

- To estimate the overall burden of HAIs
- To describe specific types of HAIs and their causative organisms and associated antimicrobial use
- To set priorities for future surveillance as regards types of HAIs and the units surveyed
- To increase the surveillance skills of ICPs
- Publications

Duration/date of PPS:

- One day
- Choose a day with no much staff leaves
- Avoid days with more scheduled procedures/admissions than usual

Steps of PPS:

1. Creating data collection form
2. Training of ICPs on PPS methodology
3. Training of ICPs on HAI definitions
4. Data collection during the day of the PPS and afterwards if needed
5. Data validation by reviewing positive cases with ID physicians
6. Data entry of validated cases
7. Analysis and report writing

Patients' selection criteria in PPS:

- Inpatients of any age are eligible for inclusion as long as he/she is admitted to the ward/unit before or at 8 a.m. and not discharged from the ward at the time of the survey
- Patients in outpatient clinics, emergency departments (<1 day), same day surgery, and outpatient dialysis patients are excluded

Outcome of PPS:

- The outcome is active HAI infections
- HAI infections: Infections that met the surveillance definition criteria of the National Healthcare Safety Network (NHSN), with onset ≥3 days from admission
- Active infections: Infections that met NHSN surveillance definition criteria, with
  - ✓ Signs or symptoms of infection present on the survey date or
  - ✓ Antimicrobial therapy for an HAI is still being given on the survey date
- Note that all types of HAI infections should be included not only the ones that we regularly do surveillance for as CLABSI or CAUTI

Types of HAIs included in PPS:

☐ Pneumonia □ PVAP of VAE □ Other HAI pneumonia
☐ Blood stream infection □ CLABSI □ Secondary BSI □ Dialysis □ Others
☐ Urinary tract infection □ CAUTI □ Others
☐ Surgical site infection □ Superficial □ Deep □ Organ Surgery: ……
☐ Lower respiratory system infection, other than pneumonia: ……
☐ Gastrointestinal system infection □ Clostridium difficile Infection □ Intra-abdominal infection □ ……
☐ Skin and soft tissue infection □ Burn □ Decubitus ulcer □ Skin/wound □ Breast □ ……
☐ Reproductive tract infection: ……
☐ Bone and joint infection: ……
☐ Central nervous system infection: ……
☐ Cardiovascular system infection: ……
☐ Upper respiratory tract infection (URI): ……
☐ Eye, ENT, or mouth infection other than URI: ……
☐ Others: ……

Exceptions of the ≥3 days rule in HAI:

- Onset ≤2 days BUT the patient was readmitted after discharge within the last 2 days
- Onset ≤2 days BUT the patient was transferred from another hospital
- Onset ≤2 days BUT the patient has Clostridium difficile infection where specimen was collected within 4 weeks from last discharge (community-onset healthcare-associated CDI)
- Onset ≤2 days BUT the patient has surgical site infection occurring after 30/90 days from a relevant surgery

Recurrent HAIs in PPS:

- They are collected in PPS as long as meeting the definition of active infection

Missing data at the date of PPS:

- We should not go prospectively after them
- Results of tests/examinations that are not yet available on the survey date should neither be completed after the survey date nor taken into account when establishing whether the case definition criteria are fulfilled.
- This will probably cause some actual cases of HAI to be discarded, but this can be seen as compensation for the (potentially long) retrospective period preceding the start of the treatment when no more signs or symptoms are present on the survey date.

8. Surveillance Location and Duration

Surveillance is planned based on location and duration

Types of patient care hospital locations

I- Inpatient locations: Locations serving patients whose date of admission to the healthcare facility and the date of discharge are different calendar days.

1. **Intensive care units (ICU):** A care area that provides intensive observation, diagnosis, and therapeutic procedures for adults (Adult ICU), children (Pediatric ICU, PICU), or neonates (Neonatal ICU, NICU) who are critically ill. The critical care could be surgical, medical, trauma, respiratory, neurologic…etc. Care areas that provide step-down, intermediate care or telemetry are not considered ICU.
2. **Specialty care area (SCA):** Hospital location which includes one of the following units: Bone marrow transplant, solid organ transplant, inpatient acute dialysis, hematology/oncology.
3. **Other inpatient:** including any inpatient locations which is not ICU or SCA e.g. inpatient medical, surgical, step down units, and OR. The later may include an operating room, C-Section room, interventional radiology room or a cardiac catheterization lab, or post-anesthesia care unit.

II- Outpatient locations: Locations serving patients whose date of admission to the healthcare facility and the date of discharge are the same calendar day. These may include any outpatient clinic, Outpatient Emergency Department, or same day surgery and its 24-hour observation area

Non-patient care locations

- Community locations: e.g. Home care
- Non-patient care hospital locations: e.g. Laboratory or laundry.

Location is mapped according to acuity level and type of service

80% rule for determining the acuity level of the unit

- The acuity level of unit is determined by the type of care served in that unit.
- That is, if at least 80% of patients are of the same acuity level (for example 80% acute care and 20% non-acute care), that unit is mapped as that acuity level (for example acute care unit). The choice will be based on the list of acuity levels of hospital locations (shown below)
- If the 80% rule does not hold, try splitting the unit into 2 virtual locations. The use of virtual locations is recommended only for units that are geographically split by patient service or those in which beds are designated by service (for example neurology patients are housed in beds 1 thru 10 and the neurosurgery patients are housed in beds 11 thru 20).
- If the 80% rule and virtual locations do not hold, map the unit as mixed acuity unit (comprised of patients with varying levels of acuity)

List of acuity levels of hospital locations:

- Adult critical care units
- Pediatric critical care units
- Neonatal critical care units
- Specialty care areas (SCA)/oncology
- Adult wards
- Pediatric wards
- Neonatal wards
- Step down units
- Mixed acuity units
- Operating rooms
- Chronic care
- Long term acute care
- Rehabilitation
- Outpatient (acute) locations
- Clinic (non-acute) settings

Operating Rooms (OR)

- OR: A patient care area that meets the American Institute of Architects (AIA) criteria for an operating room. This may include an operating room, C-Section room, interventional radiology room, or a cardiac catheterization lab.
- Could be inpatient or outpatient

80% rule for determining the type of unit

- The type of unit is determined by the kind of patients cared for in that unit.
- That is, if at least 80% of patients are of a certain type (for example patients with trauma), that unit is mapped as that type of these patients (for example trauma ICU).
- If the 80% rule does not hold, try splitting the unit into 2 virtual locations. The use of virtual locations is recommended only for units that are geographically split by patient service or those in which beds are designated by service (for example neurology patients are housed in beds 1 thru 10 and the neurosurgery patients are housed in beds 11 thru 20).
- If the 80% rule and virtual locations do not hold, you have two scenarios:
  - ✓ When a unit houses roughly equal populations (for example 50/50 or 60/40 of medical and surgical patients), that unit is mapped as combined patient unit (for example medical/ surgical ICU).
  - ✓ When a unit houses mixed populations but one of them >60% (for example 70% medical and 30% surgical), that unit is mapped as that type of the patient majority (for example medical ICU).

Surveillance location in different types of surveillance

	Locations					
	Inpatients					Out-patients
	Adult ICU	Pediatric ICU	Neonatal ICU	SCA	Other wards	
CLABSI & bundle	Yes	Yes	Yes	Yes	Yes	No
VAE & bundle	VAE	Ped-VAE	Ped-VAE	Yes	Yes	No
CAUTI & bundle	Yes	Yes	No	Yes	Yes	No
DE & bundle	No					Yes
SSI & bundle	Yes					Yes
MDRO & bundle	Yes				Yes	Yes

Surveillance duration:

- The least time period to do surveillance is one month (to allow for denominator collection)
- Usually one quarter (3 months) are enough to give evidence about the rates of infection
- In bigger units shorter duration can be tried and in smaller units longer duration can be tried

9. Healthcare-Associated Infection (HAI)

Infection definition:

- The successful transmission of a microorganism to the host with subsequent multiplication, colonization, and invasion.
- Infection may be clinical or subclinical and may not produce identifiable disease.
- However, it is usually accompanied by measurable host response(s), either through the appearance of specific antibodies or through cell-mediated reaction(s) (e.g., positive tuberculin test results).

Colonization definition:

- The multiplication of a microorganism at a body site or sites without any overt clinical expression or detected immune reaction in the host at the time that the microorganism is isolated.
- Colonization may or may not be a precursor of infection.
- Colonization may be a form of carriage and is a potential source of transmission.

Timelines for Infection and Disease

Infection status	**Latent period:** time interval from exposure to infection to infectiousness	**Infectious period:** time during which the host is infectious
Disease status	**Incubation period:** time from exposure to infection to the development of symptomatic disease	**Symptomatic period:** period in which symptoms of the disease are present.

Mode of transmission of infection:

- It is the method of transfer by which the organism moves from host to susceptible individual
- Transmission could be direct or indirect

1- Direct transmission (person-to-person):

- Droplet contact: coughing or sneezing (1 meter)
- Direct physical contact to infected person secretions, blood, stool/urine (This method includes sexual contact)
- Trans-placental infection

2- Indirect transmission (person-environment-person):

- Airborne transmission - if the microorganism can remain in the air for long periods (TB, varicella, measles)
- Indirect contact - usually by touching soil contamination or a contaminated surface
- Fecal-oral transmission - usually from contaminated food or water sources
- Vector borne transmission - carried by insects or other animals
- Inoculation (devices)

HAI definition:

- A localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s)
- Not present or incubating on admission to the facility
- An infection is considered HAI if the date of event of the NHSN site-specific infection criterion occurs on or after the 3rd calendar day of admission to an inpatient location where day of admission is calendar day 1
- Infections occurring in newborns with date of event on hospital day 1 or day 2 are considered POA. Those with date of event on day 3 or later are HAI. This includes infections acquired transplacentally (for example but not limited to herpes simplex, toxoplasmosis, rubella, cytomegalovirus, or syphilis) or as a result from passage through the birth canal.
- Reactivation of a latent infection (for example but not limited to herpes, shingles, syphilis, or tuberculosis) is not considered to be an HAI

Types of surveillance:

Device-associated infections:

- Central line associated blood stream infection (CLABSI)
- Catheter associated urinary tract infection (CAUTI)
- Ventilator associated events (VAE)
- Dialysis events (DE)

Procedure-associated:

- Surgical Site Infection (SSI)

Others:

- Multidrug-Resistant Organism and Clostridium difficile infections (MDRO/CDI)

Surveillance versus clinical definitions

Surveillance definition is different from clinical definition and can not be unified

	Clinical Criteria	Surveillance Criteria
Use	Clinical care	Surveillance
Focus	Detection of infection in individual patients	Detection of infection in patient population
Purpose	To provide diagnosis and treatment for cared patients	To provide trend for risk assessment, prevention, and policy change
Clinical judgment	Important and is part of diagnosis	Absent and discouraged

10. Infection Pathogens

HAIs are caused by bacterial, fungal, and viral pathogens. The focus here will be on bacterial and fungal pathogens

Difference between Gram-Positive and Gram-Negative Bacteria

	Gram-positive bacteria	Gram-negative bacteria
Gram stain	Appear as purple-colored when examined under the microscope	Appear as pink-colored when examined under the microscope
Cell wall	Composed of thick layers peptidoglycan	Composed of thin layers of peptidoglycan
Toxins	Produce exotoxins	Produce endotoxins
Examples pathogenic	**Pathogenic:** • Staphylococcus aureus • Methicillin Sensitive Staphylococcus aureus • Enterococcus spp. • Clostridium • Streptococcus pneumoniae • Streptococcus spp. **Commensals:** • Coagulase negative Staphylococci • Streptococcus viridans • Diphtheroids • Corynebacterium spp. • Bacillus spp. • Propionibacterium spp. • Aerococcus spp. • Micrococcus spp. • Rhodococcus	• Acinetobacter spp. • Bacteroides spp. • Citrobacter spp. • Enterobacter spp. • Escherichia coli • Fusobacterium spp. • Haemophilus spp. • Klebsiella spp. • Legionella spp. • Peptostreptococcus spp. • Prevotella spp. • Proteus spp. • Providencia • Pseudomonas aeruginosa • Serratia spp. • Stenotrophomonas maltophilia • Veillonella spp.

Most frequent bacterial pathogens causing HAIs

The pathogens causing HAIs (device-associated and SSI) were sorted in descending order according to frequency (Saudi Arabia 2015-2022)

1	Klebsiella spp.	17.2%
2	Pseudomonas spp.	14.4%
3	Staphylococcus aureus	10.6%
4	Escherichia coli	8.0%
5	Enterococcus spp.	7.6%
6	Candida	7.0%
7	Enterobacter spp.	7.0%
8	MRSA	4.7%
9	Acinetobacter spp.	3.9%
10	Stenotrophomonas maltophilia	3.3%
11	Streptococcus spp.	2.5%
12	Coagulase negative staphylococci	2.0%
13	Serratia spp.	1.8%
14	Proteus	1.1%
15	Citrobacter spp.	0.9%
16	Other commensals	0.7%
17	Other intestinal organisms	0.4%
18	Others	7.0%

Commensals organisms

All of the outer surfaces of the human body are covered with agents that normally do no harm and may, in fact, be beneficial. Those commensal organisms on the skin help to break down dying skin cells or to destroy debris secreted by the many minute glands and pores that open on the skin. Many of the organisms in the intestinal tract break down complex waste products into simple substances, and others help in the manufacture of chemical compounds that are essential to human life.

Skin commensals organisms (short list)

- Diphtheroids [Corynebacterium spp]
- Bacillus spp.
- Propionibacterium spp.
- Coagulase-negative Staphylococci [including S. epidermidis]
- Viridans group streptococci
- Aerococcus spp.
- Micrococcus spp.
- Rhodococcus

Intestinal pathogens (MBI pathogens short list)

- Bacteroides spp.
- Candida spp.
- Clostridium spp.
- Enterococcus spp.
- Fusobacterium spp.
- Peptostreptococcus spp.
- Prevotella spp.
- Veillonella spp.
- Enterobacteriaceae

Enterobacteriaceae (short list)

Enterobacteriaceae are a large family of different types of gram-negative, facultatively anaerobic, rod-shaped bacteria that do not form endospores. They include some of the normal inhabitants of the small and large gastrointestinal tracts (as their name said). They are common causes of HAIs and include:

- Citrobacter
- Enterobacter
- Escherichia
- Klebsiella
- Proteus
- Providencia
- Salmonella
- Serratia
- Shigella
- Yersinia

Fungal pathogens (short list)

They can cause HAIs specially in immunocompromised or hospitalized with serious underlying diseases. They include the following groups:

1- Yeast

- Candida:
  - ✓ C. albicans
  - ✓ C. glabrata
  - ✓ C. parapsilosis
  - ✓ C. tropicalis
  - ✓ C. krusei
  - ✓ C. auris
- Cryptococcus:
  - ✓ C. neoformans
  - ✓ C. gattii
- Other yeast:
  - ✓ Pneumocystis
  - ✓ Saccharomyces
  - ✓ Trichosporon

2- Molds:

- Aspergillus:
  - ✓ A. fumigatus
  - ✓ A. flavus
  - ✓ A. niger
  - ✓ A. terreus
- Mucorales:
  - ✓ M. Rhizopus
  - ✓ M. Mucor
- Other molds:
  - ✓ Fusarium spp.
  - ✓ Scedosporium spp.

Dimorphic fungi (endemic mycoses):

Specific fungal pathogens typically causing community-associated infections cannot be used to meet any HAI definition:

- Blastomyces
- Histoplasma
- Coccidioides
- Paracoccidioides
- Cryptococcus
- Pneumocystis.

Viral pathogens (short list)

- Influenza virus
- Respiratory syncytial virus
- Adenovirus
- Parainfluenza virus
- Rhinovirus
- Human metapneumovirus
- Coronavirus

11. Surveillance of Device-Associated HAI

Device-associated infections:

- Device-associated infection is an infection in a patient with a device (e.g., ventilator, central line or indwelling urinary catheter) that was in place for more than 2 calendar days before onset of infection.
- The date of device-associated HAI event is the date the first element used to meet the infection criterion occurs for the first time within the seven-day infection window period.
- If the device-associated HAI develops within 2 calendar days of discharge from a location, it is associated with the discharging location.

Common Criteria for device-associated infections:

The common criteria shown below are applicable for surveillance of device-associated HAI with the exception of VAE. Additionally, these criteria are not applicable to SSI and MDRO (LabID Events). The criteria included the following:

1. Infection Window Period for HAI:

- It is the 7-days during which all site-specific infection criteria must be met.
- It includes the day the first positive diagnostic test that is an element of the site-specific infection criterion, was obtained, the 3 calendar days before and the 3 calendar days after.

2. Date of HAI event:

- It is the date the first element used to meet an NHSN site-specific infection criterion occurs for the first time within the seven-day infection window period

3. Present on admission (POA):

- An infection is considered POA if the date of event of the infection criterion occur
  - Two calendar days before day of admission
  - First day of admission (day 1)
  - Day after admission (day 2)
- Exceptions: SSI, MDRO, CDI, and MRSA bacteremia may occur after patient's discharge from facility and be present upon readmission

4. Healthcare-Associated Infection (HAI):

- An infection is considered HAI if the date of event of the infection at or after the third day of admission of the patient considering the day of admission is day number one
- HAI is a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). Not present or incubating on admission to the facility

5. Transfer Rule:

- If all elements of an HAI were present within 2 calendar days of transfer from one inpatient location to another in the same facility (i.e., on the day of transfer or the next day), the HAI is attributed to the transferring location.
- If all elements of an HAI were present within 2 calendar days of transfer from one inpatient facility to another, the HAI is attributed to the transferring facility
- However, infections cannot be attributed to a location where patients are not housed overnight (like an OR or ED). In this situation, the infection should be attributed to the next inpatient location

6. Multiple Transfer:

- If the patient has been transferred to more than one location on the date of an infection, or the day before, attribute the infection to the first location in which the patient was housed the day before the infection's date of event.

7. Repeat Infection Timeframe (RIT):

- It is a 14-day timeframe during which no new infections of the same type are reported.
- The date of the event is Day 1 of the 14-day RIT.
- Additional pathogens recovered during the RIT from the same type of infection are added to the event.
- The RIT applies during a patient's single admission, including the day of discharge and the day after, in keeping with the Transfer Rule
- An RIT does not carry over from one admission to another even if readmission is to the same facility
- The RIT can apply at the level of specific type of infection with the exception of BSI, UTI, and PNEU where the RIT will apply at the major type of infection.

8. Device removal and reinsertion:

- If central line or urinary catheter were removed and reinserted before a full calendar day without a device (central line or urinary catheter), then continue the day count
- Therefore, if the patient is without a device (central line or urinary catheter) for at least one full calendar day (NOT to be read as 24 hours), then start a new day count.

9. Secondary BSI Attribution Period:

- It is the period in which a positive blood culture must be collected to be considered as a secondary bloodstream infection to a primary site infection
- This period includes the Infection Window Period combined with RIT
- In case of DA HAI: It is 14-17 days in length depending upon the date of event
- In case of SSI: 17-day period that includes the date of SSI event, 3 days prior and 13 days after

10. Pathogen Assignment Guidance:

- Additional pathogens recovered during the RIT from the same type of infection or during the secondary BSI attribution period are added to the event
- Exception: Pathogens excluded from specific infection definitions (e.g., yeast in UTI, Enterococcus spp. in PNEU) are also excluded as pathogens for BSIs secondary to that type of infection
- Secondary BSI pathogens may be assigned to more than one infection source at the same time

11. Microbiologic testing:

- Organisms identified from a specimen by a culture or non-culture based microbiologic testing method is acceptable to meet the HAI definition
- However, for the purpose of meeting the HAI definition culture or non-culture based microbiologic testing method must be performed for purposes of clinical diagnosis or treatment (e.g., not active surveillance culture/testing (ASC/AST).

12. Non-accepted organisms:

- Specific fungal pathogens typically causing community-associated infections cannot be used to meet any HAI definition:
  - Blastomyces
  - Histoplasma
  - Coccidioides
  - Paracoccidioides
  - Cryptococcus
  - Pneumocystis.

11.1 Central line Associated Bloodstream Infection

CLABSI:

- CLABSI is a primary bloodstream infection (BSI) in a patient who had a central line or umbilical catheter
- The central line or umbilical catheter has to be in place for >2 days and in place at the date of event or the day before.
- Primary BSI is a laboratory-confirmed bloodstream infection (LCBI) that is not secondary to an infection meeting CDC/NHSN criteria at another body site.

Surveillance settings:

Surveillance can be done in any inpatient location where denominator data can be collected, this includes

- ICUs
- NICUs
- SCA
- Other inpatient locations
- Inpatients receiving dialysis are included in any CLABSI surveillance in the location in which they are housed, regardless of whether or not the central line is the only central line and only accessed for dialysis

Surveillance methodology

- Active
- Patient based
- Prospective
- Priority-directed targeted
- Yield risk-adjusted incidence rates

Date of event (DOE):

It is the date when the FIRST element used to meet the CLABSI criterion occurs for the first time within the 7-day infection window period.

Central line:

It is 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 CLABSI surveillance:

- Aorta.
- Pulmonary artery.
- Superior vena cava.
- Inferior vena cava.
- Brachiocephalic veins.
- Internal jugular veins.
- Subclavian veins.
- External iliac veins.
- Common iliac veins.
- Femoral veins.
- In neonates, the umbilical artery/vein.

Notes about central line:

- 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 the great vessels or in or near the heart, and be used for one of the purposes outlined above, to qualify as a central line.
- An introducer is considered an intravascular catheter and depending on the location of its tip and use, may be a central line.
- Pacemaker wires and other non-lumened devices inserted into central blood vessels or the heart are not considered central lines, because fluids are not infused, pushed, nor withdrawn through such devices.
- Infusion: 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, IV antimicrobial administration, or blood transfusion or hemodialysis.

The following devices are not considered central lines:

- Arterial catheters unless in the pulmonary artery, aorta or umbilical artery
- Arteriovenous fistula
- Arteriovenous graft
- Atrial catheters
- Extracorporeal life support (ECMO)
- Hemodialysis reliable outflow (HERO) dialysis catheter
- Intra-aortic balloon pump (IABP) devices
- Peripheral IV or Midlines
- Ventricular Assist Device (VAD)

Types of central lines:

- Temporary central line: A non-tunneled, non-implanted catheter.
- Permanent central line: Includes
    - ✓ Tunneled catheters, including certain dialysis catheters.
    - ✓ Implanted catheters (including ports).
- Umbilical catheter: A central vascular device inserted through the umbilical artery or vein in a neonate.

Counting central line days

- If a patient has more than one temporary central line on a given day, this is counted only as one central line day
- If a patient has both a temporary and a permanent central line on the same day, the day is counted as one temporary central line day.
- If an infant has both an umbilical catheter and a non-umbilical central line, count as an umbilical catheter day only

Central line removal and reinsertion:

- If central line was removed and reinserted before a full calendar day without a central line, then continue the day count
- Therefore if the patient is without a central line for at least one full calendar day (NOT to be read as 24 hours), then start a new day count.

Hospital days	1	2	3	4	5	6	7
Central line days	1	2	3	Removal (4)	Re-insertion (5)	6	7

Hospital days	1	2	3	4	5	6	7
Central line days	1	2	3	Removal (4)	---	Re-insertion (1)	2

Location of attribution:

- The inpatient location where the patient was assigned on the date of the LCBI event, which is further defined as the date when the first element used to meet the LCBI criterion occurred.
- OR/Post Anesthesia Care Unit/Recovery Room/dialysis unit /ERs cannot be considered a location of attribution for BSI

Transfer Rule:

- If the date of event for a CLABSI is the day of transfer or discharge, or the next day, the CLABSI is attributed to the transferring location.
- Receiving facilities should share information about such HAIs with the transferring facility to enable reporting.
- Example:
  - ✓ Patient with a central line in place in the SICU is transferred to the surgical ward. The day after transfer is the date of event for an LCBI. This is reported as a CLABSI for the SICU.
  - ✓ Patient with a central line in place is transferred from the medical ward to the coronary care ICU (CCU). An LCBI date of event is on day four in the CCU. The central line is still in place. This is reported as a CLABSI for the CCU because the date of event was not the date of transfer from the medical ward, or the next day.

Multiple Transfers:

- If the patient has been transferred to more than one location on the date of CLABSI, or the day before, attribute the CLABSI to the first location in which the patient was housed the day before the CLABSI's date of event.

Date	3/22	3/23	3/24
Locations	Unit A	Unit A Unit B Unit C	Unit C Unit D *CLABSI was diagnosed*

- CLABSI is attributed to Unit A since Unit A was the first location in which the patient was housed the day before the date of event.

Laboratory-confirmed bloodstream infection (LCBI-1)

Patient of **any age** has a **recognized pathogen** identified from **one or more** blood specimens by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment.

AND

Organism(s) identified in blood is not related to an infection at another site.

Laboratory-confirmed bloodstream infection (LCBI-2)

Patient of **any age** has at least one of the following **signs or symptoms**: fever (>38.0°C), chills, or hypotension.

AND

The same common **commensal** is identified from **two or more** blood specimens drawn on separate occasions, by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment. Criterion elements must occur within the Infection Window Period

AND

Organism(s) identified from blood is not related to an infection at another site.

Laboratory-confirmed bloodstream infection (LCBI-3)

Patient ≤ 1 year of age has at least one of the following **signs or symptoms**: fever (>38.0°C), hypothermia (<36.0°C), apnea, or bradycardia.

AND

The same common **commensal** is identified from **two or more** blood specimens drawn on separate occasions, by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment. Criterion elements must occur within the Infection Window Period

AND

Organism(s) identified from blood is not related to an infection at another site.

Two or more blood specimens drawn on separate occasions:

- The “two or more blood specimens drawn on separate occasions” criterion is met when these two conditions are met:
  1. There is blood collected from at least two separate blood draws on the same or consecutive calendar days
  2. The blood cultures are assigned separate specimen numbers, processed individually, and are reported separately in the final laboratory report. The separate specimen numbers indicate two separate site preparations (decontamination steps) are performed during specimen collection.
- *Separate occasions* are met with different venipunctures, a combination of venipuncture and lumen withdrawal, or different lumens of the same central line), or at different times.
- The guidance above is intended to reduce misidentification of contaminated blood specimens as LCBIs. For example, aseptic technique indicates separate site decontaminations would be performed for blood specimens drawn from different sites
- If both culture sets are positive, there is less chance that contamination was the cause than if 2 positive blood cultures were collected from a single blood draw (in other words, collected using a vacutainer or via venipuncture and attaching multiple bottles after a single decontamination of the site), these specimens would be considered a single access (or the same occasion).

Specimen collection sites:

- Blood specimens drawn through central lines can have a higher rate of contamination than blood specimens collected through peripheral venipuncture.
- However, all positive blood specimens, regardless of the site from which they are drawn or the purpose for which they are collected, must be included when conducting in-plan CLABSI surveillance (for example, weekly blood cultures performed in hematology and oncology locations).
- Catheter tip cultures cannot be used in place of blood specimens for meeting LCBI criteria.

Infection Window Period:

It is the 7-day time period which includes the collection date of the positive blood, the 3 calendar days before and the 3 calendar days after.

Repeat Infection time frame (RIT)

- It is 14-day timeframe during which no new CLABSI of the same type are reported. The date of event is Day 1 of the 14-day RIT.
- Note that only primary BSIs create a BSI RIT. Secondary BSIs do not create a BSI RIT.

Skin commensals organisms

It is applicable for LCBI-2 and LCBI-3. They include

- Diphtheroids [Corynebacterium spp]
- Bacillus spp.
- Propionibacterium spp.
- Coagulase-negative Staphylococci [including S. epidermidis]
- Viridans group streptococci
- Aerococcus spp.
- Micrococcus spp.
- Rhodococcus

Matching organisms:

- If genus and species are identified in both specimens, they must be the same.
    - ✓ Example: Pseudomonas aeruginosa and Pseudomonas aeruginosa
- If one organism is less definitively identified than the other, the lesser identified organism must be identified at least to the genus level and at that level the organisms must be the same.
    - ✓ Example: Pseudomonas species and Pseudomonas aeruginosa.
    - ✓ Exception-1: Staphylococcus and coagulase negative/positive Staphylococcus
    - ✓ Exception-2: Streptococcus species and Streptococcus viridans

- The matching common commensals represent a single element; therefore, the collection date of the first common commensal is the date of the first diagnostic test used to determine the Infection Window Period (IWP).

Examples on matching/non-matching organisms

First culture	Second culture	Sameness	Report as…
Coagulase positive Staphylococci	S. aureus	Different (look at exception above)	S. aureus
S. epidermidis	Coagulase-negative staphylococci	*Same (staph epidermidis is part of Coagulase-negative staphylococci)*	*S. epidermidis*
Enterococcus spp.	*E. faecium*	*Same (genus and species levels)*	*E. faecium*
Bacillus spp.	*B. cereus*	*Same (genus and species levels)*	*B. cereus*
S. salivarius	Strep viridans	*Same (just synonymous names)*	*S. salivarius*

Secondary BSI:

- It is BSI meeting the LCBI criteria BUT is secondary to another site of infection
- One of the following scenarios must be met:
    - ✓ **Scenario 1:** At least one organism from the blood specimen matches an organism identified from the site-specific specimen that is used as an element to meet the NHSN site-specific infection criterion AND the blood specimen is collected during the secondary BSI attribution period (infection window period + repeat infection timeframe).
    - ✓ OR
    - ✓ **Scenario 2:** An organism identified in the blood specimen is an element that is used to meet the NHSN site-specific infection criterion, and therefore is collected during the site-specific infection window period.

Scenarios of secondary BSI:

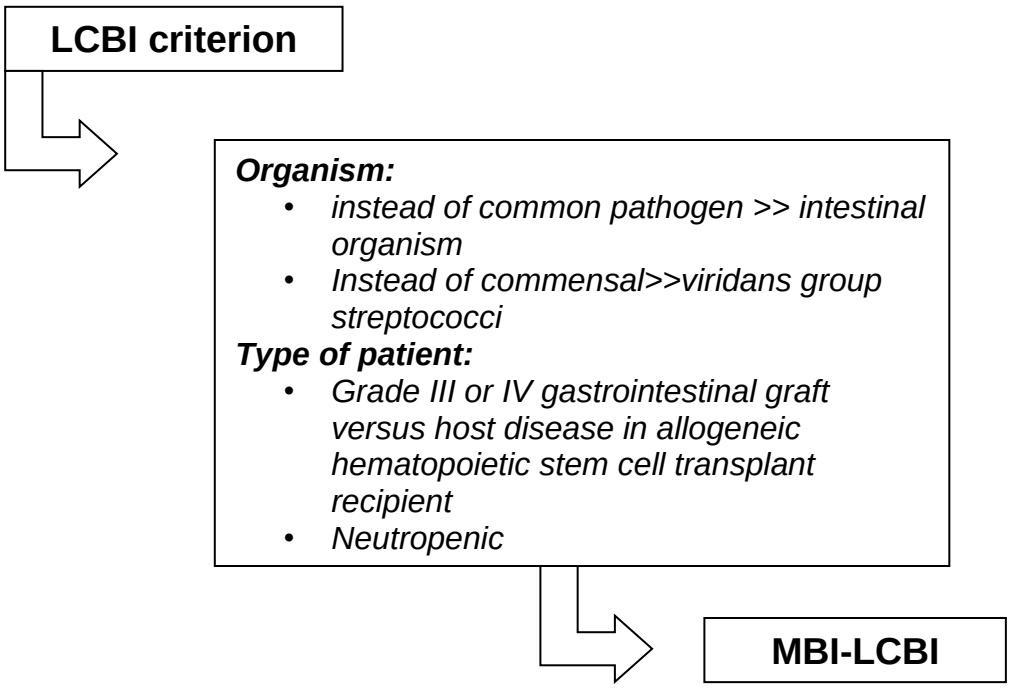
Scenario 1	Scenario 2
Blood specimen must contain at least one **matching** organism of the site specific specimen	Blood specimen must be **an element of the site specific criterion***
And is collected in the secondary **BSI attribution period**	And is collected during the site specific infection's **infection window period**
And an **organism identified from the site specific infection** is used as an element to meet the site specific infection criterion	And an **organism identified in the blood specimen** is an element that is used to meet the site-specific infection criterion

Examples of scenarios of secondary BSI:

Scenario 1	Scenario 2
SSI (SI or DI or OS) • Positive wound • Matching positive blood during BSI attribution period	**IAB criterion 3b** • Fever, nausea or abdominal pain, **positive blood specimen** during IWP and CT scan showing infection in abdominal cavity
SUTI • Positive urine during IWP • Matching positive blood during BSI attribution period	**PNU 2 or 3** (one criterion during IWP) • Infiltrate on chest imaging test, fever, new onset of cough and organism identified from **blood specimen** during IWP
PNU 2 or 3 or PVAP • Positive respiratory specimen during IWP • Matching positive blood during BSI attribution period	**PNU 2 or 3** (Two criteria during IWP) • Infiltrate on chest imaging test, fever, new onset of cough and organism identified from **blood and BAL** specimens during IWP

Mucosal Barrier Injury:

- The mucosal barrier injury (MBI) LCBI meet the need for more specific BSI definition in oncology patients.
- In this population, CLABSI rates are inflated by misclassification of BSI resulting from translocation of intestinal organisms.
- These BSIs are not impacted by CLABSI prevention measures and not associated with the central line
- Mucosal Barrier Injury Laboratory-Confirmed Bloodstream Infection (MBI-LCBI)
    - ✓ Patient who meets LCBI criteria with at least one blood specimen showing intestinal organisms
    - ✓ AND
    - ✓ Patient meets at least one of the following:
        - Grade III or IV gastrointestinal graft versus host disease in allogeneic hematopoietic stem cell transplant recipient
        - Is neutropenic



MBI-LCBI-1

Patient of **any age** meets **criterion 1 for LCBI** with at least **one** blood specimen identified by a culture or non-culture based microbiologic testing method, with **ONLY intestinal organisms** from the MBI-LCBI organisms list.

And

And patient meets **at least one of the following**

1. Is an **allogeneic hematopoietic stem cell transplant** recipient within the past year with one of the following documented during same hospitalization as positive blood specimen:
    a. Grade III or IV gastrointestinal graft versus host disease [GI GVHD]
    b. ≥1 liter diarrhea in a 24-hour period (or ≥20 mL/kg in a 24-hour period for patients <18 years of age) with onset on or within 7 calendar days before the date the positive blood specimen was collected.
2. Is **neutropenic**, defined as at least two separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm3 within a 7-day time period which includes the date the positive blood specimen was collected (Day 1), the 3 calendar days before and the 3 calendar days after

MBI-LCBI-2

Patient of **any age** meets **criterion 2 for LCBI** with at least **two** blood specimens identified by a culture or non-culture based microbiologic testing method, with **only viridans group streptococci and/or Rothia spp.** but no other organisms.

And

And patient meets **at least one of the following**

1. Is an **allogeneic hematopoietic stem cell transplant** recipient within the past year with one of the following documented during same hospitalization as positive blood specimen:
    a. Grade III or IV gastrointestinal graft versus host disease [GI GVHD]
    b. ≥1 liter diarrhea in a 24-hour period (or ≥20 mL/kg in a 24-hour period for patients <18 years of age) with onset on or within 7 calendar days before the date the positive blood specimen was collected.
2. Is **neutropenic**, defined as at least two separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm3 within a 7-day time period which includes the date the positive blood specimen was collected (Day 1), the 3 calendar days before and the 3 calendar days after

MBI-LCBI-3

Patient **≤1 year of age** meets **criterion 3 for LCBI** with at least **two** blood specimens identified by a culture or non-culture based microbiologic testing method, with **only viridans group streptococci and/or Rothia spp.** but no other organisms.
And
And patient meets **at least one of the following**
1. Is an **allogeneic hematopoietic stem cell transplant** recipient within the past year with one of the following documented during same hospitalization as positive blood specimen:
    a. Grade III or IV gastrointestinal graft versus host disease [GI GVHD]
    b. ≥20 mL/kg diarrhea in a 24-hour period with onset on or within 7 calendar days before the date the first positive blood specimen is collected.
2. Is **neutropenic**, defined as at least two separate days with values of absolute neutrophil count (ANC) or total white blood cell count (WBC) <500 cells/mm3 within a 7-day time period which includes the date the positive blood specimen was collected (Day 1), the 3 calendar days before and the 3 calendar days after

Blood specimen collection for MBI-LCBI

- In MBI-LCBI 1, 2 and 3, "No other organisms" means there is no identification of a non-MBI-LCBI pathogen (such as S. aureus) or 2 matching common commensals (such as coagulase-negative staphylococci) collected from the blood on separate occasions that would otherwise meet LCBI criteria. If this occurs, the infection does not meet MBI-LCBI criteria.
- When a blood specimen positive for an organism not included on the NHSN MBI organism list is collected during the BSI RIT of an MBI-LCBI, the initial MBI-LCBI event is edited to an LCBI and the identified non-MBI organism is added.
- MBI-RIT Exception: An MBI-LCBI designation will not change to an LCBI event if the following TWO criteria are met:
    - ✓ The blood culture with the non-MBI organism is collected during an existing BSI (MBI-LCBI) RIT
    - ✓ The blood culture with the non-MBI organism is deemed secondary to an NHSN site-specific infection

Intestinal pathogens (MBI pathogens short list)

- Bacteroides spp.
- Candida spp.
- Clostridium spp.
- Enterococcus spp.
- Fusobacterium spp.
- Peptostreptococcus spp.
- Prevotella spp.
- Veillonella spp.
- Enterobacteriaceae

Enterobacteriaceae (short list)

- Citrobacter
- Enterobacter
- Escherichia
- Klebsiella
- Proteus
- Providencia
- Salmonella
- Serratia
- Shigella
- Yersina

Collection of denominator data for CLABSI

1. **Manual, daily:** patient days and central line days should be collected at the same time, every day, for each location performing surveillance to ensure that differing collection methods don't inadvertently result in device days being > patient days.
2. **Manual, weekly:** patient days and central line days should be collected at the same time on the same designated day, once per week. The idea is to reduce staff time spent collecting surveillance data, once weekly sampling of denominator data is good for
   - For locations with 75 or more device days per month
   - For locations other than specialty care areas/oncology and NICUs
   - If the day designated for the collection of sampled data is missed, collect the data on the next available day instead

3. Electronic sources:

- When patient days and central line days are available from electronic databases, these sources may be used as long as the counts are not substantially different (+/- 5%) from those collected manually.

Analysis of CLABSI

Measure	Calculation	Application
CLABSI Rates	$\frac{\text{The number of CLABSIs for a location}}{\text{The number of central line days for that location}}$ X1000	Location specific measure
MBI-LCBI Rates	$\frac{\text{The number of MBI-LCBIs for a location}}{\text{The number of central line days for that location}}$ X1000	Location specific measure
CLABSI SIR	$\frac{\text{The number of observed CLABSIs}}{\text{The number of predicted CLABSIs}}$	Both location specific and summarized measure
MBI-LCBI SIR	$\frac{\text{The number of observed MBI-LCBIs}}{\text{The number of predicted MBI-LCBIs}}$	Both location specific and summarized measure
Central line DUR	$\frac{\text{The number of central line days for a location}}{\text{The number of patient days for that location}}$	Location specific measure
Central Line SUR	$\frac{\text{The number of observed central line days}}{\text{The number of predicted central line days}}$	Both location specific and summarized measure

SIR, standardized infection ratio; DUR, device utilization ratio; SUR, standardized utilization ratio

- CLABSI rates and central line DUR should be presented by unit (for example, adult ICU, pediatric ICU…etc).
- CLABSI rates and central line DUR in neonatal ICU should be presented by unit and birthweight categories (which includes A = ≤750 g; B = 751-1000 g; C = 1001-1500 g; D = 1501-2500 g; E = >2500 g).
- CLABSI rates and central line DUR in special care areas (such as oncology and transplant units) should be presented by unit and type of catheter (temporary and permanent).

- CLABSI SIR and central line SUR can be presented for single locations and can be summarized across multiple locations, adjusting for differences in the incidence of infection or device utilization (respectively) between different location types.
- In neonatal ICU, CLABSI SIR and central line SUR can be additionally summarized across birthweight categories, adjusting for differences in the incidence of infection or device utilization (respectively) between different birthweight categories.
- In special care areas (such as oncology and transplant units), CLABSI SIR and central line SUR can be additionally summarized across all types of catheter, adjusting for differences in the incidence of infection or device utilization (respectively) between different catheter types.

11.2 Catheter-Associated Urinary Tract Infection

CAUTI:

- CAUTI is defined as a symptomatic urinary tract infection (SUTI) or asymptomatic bacteremic UTI (ABUTI) in a patient who had an indwelling urinary catheter
- Indwelling urinary catheter has to be in place for >2 days and in place at the date of event or the day before.

Surveillance settings:

Surveillance can be done in any inpatient location where denominator data can be collected, this includes

- ICUs
- SCA
- Other inpatient locations
- NICUs (may participate, but only off plan)

Surveillance methodology

- Active
- Patient based
- Prospective
- Priority-directed targeted
- Yield risk-adjusted incidence rates

Date of event (DOE):

It is the date when the FIRST element used to meet the CAUTI criterion occurs for the first time within the 7-day infection window period.

Indwelling urinary catheter:

- Indwelling catheter: A drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a drainage bag (including leg bags).
- These devices are also called Foley catheters.

- Condom or straight in-and-out catheters are not included nor are nephrostomy tubes, ileoconduits, or suprapubic catheters unless a Foley catheter is also present.
- Indwelling urethral catheters that are used for intermittent or continuous irrigation are included in CAUTI surveillance.

Urinary catheter removal and reinsertion:

- If indwelling urinary catheter was removed and reinserted before a full calendar day without a urinary catheter, then continue the day count
- Therefore if the patient is without a urinary catheter for at least one full calendar day (NOT to be read as 24 hours), then start a new day count.

Hospital days	1	2	3	4	5	6	7
Urinary catheter days	1	2	3	Removal (4)	Re-insertion (5)	6	7

Hospital days	1	2	3	4	5	6	7
Urinary catheter days	1	2	3	Removal (4)	---	Re-insertion (1)	2

Repeat Infection time frame (RIT)

- It is 14-day timeframe during which no new CAUTI of the same type are reported.
- The date of event is Day 1 of the 14-day RIT.

Location of attribution:

- The inpatient location where the patient was assigned on the date of the CAUTI event, which is further defined as the date when the first element used to meet the CAUTI criterion occurred.
- OR/Post Anesthesia Care Unit/Recovery Room/dialysis unit /ERs cannot be considered a location of attribution for CAUTI

Transfer Rule:

- If the date of event for a CAUTI is the day of transfer or discharge, or the next day, the CAUTI is attributed to the transferring location.
- Receiving facilities should share information about such HAIs with the transferring facility to enable reporting.
- Example:
  - ✓ Patient in the SICU with a Foley catheter, which has been in place for 5 days, is transferred to a surgical ward.
  - ✓ The next day is determined to be the date of event for a CAUTI.
  - ✓ This is reported as a CAUTI for the SICU

Multiple Transfers:

- If the patient has been transferred to more than one location on the date of CAUTI, or the day before, attribute the CAUTI to the first location in which the patient was housed the day before the CAUTI's date of event.

Date	3/22	3/23	3/24
Locations	Unit A	Unit A Unit B Unit C	Unit C Unit D *CAUTI was diagnosed*

- CAUTI is attributed to Unit A since Unit A was the first location in which the patient was housed the day before the date of event.

1. Symptomatic UTI (SUTI-1a)

Patient must meet 1, 2, and 3 below:

1. Patient of any age had an indwelling urinary catheter that had been in place for > 2 days on the date of event AND was either:
   - Present for any portion of the calendar day on the date of event OR
   - Removed the day before the date of event
2. Patient has at least one of the following signs or symptoms:
   - Fever (>38.0°c)
   - Suprapubic pain or tenderness
   - Costovertebral angle pain or tenderness
   - Urinary urgency (only if catheter is not in place)
   - Urinary frequency (only if catheter is not in place)
   - Dysuria (only if catheter is not in place)
3. Patient has a urine culture with no more than two species of organisms identified, at least one of which is a bacterium $\geq 10^5$ CFU/ml.

2. Symptomatic UTI (SUTI-2)

Patient must meet 1, 2, and 3 below:

1. Patient is ≤1 year and had an indwelling urinary catheter that had been in place for > 2 days on the date of event AND was either:
   - Present for any portion of the calendar day on the date of event OR
   - Removed the day before the date of event
2. Patient has at least one of the following signs or symptoms:
   - fever (>38.0°C)
   - hypothermia (<36.0°C)
   - apnea*
   - bradycardia*
   - lethargy*
   - vomiting*
   - suprapubic tenderness* (*With no other recognized cause)
3. Patient has a urine culture with no more than two species of organisms identified, at least one of which is a bacterium ≥10^5 CFU/ml.

3. Asymptomatic bacteremic urinary tract infection (ABUTI)

Patient must meet 1, 2, and 3 below:

1. Patient of any age with an indwelling urinary catheter has no signs or symptoms of SUTI 1 or 2 according to age
2. Patient has a urine culture with no more than two species of organisms identified, at least one of which is a bacterium ≥10^5 CFU/ml
3. Patient has organism identified from blood specimen with at least one matching bacterium to the bacterium identified in the urine specimen, or meets LCBI criterion 2 (without fever) and matching common commensal(s) in the urine.

Note: All elements of the ABUTI criterion must occur during the Infection Window Period

Comments about CAUTI definition

- The following excluded organisms cannot be used to meet the UTI definition:
  - ✓ Any Candida species as well as a report of “yeast” that is not otherwise specified
  - ✓ mold
  - ✓ dimorphic fungi or
  - ✓ parasites
- “Mixed flora” cannot be reported as a pathogen to meet the CAUTI Criteria.
- An acceptable urine specimen may include these organisms as long as one bacterium of greater than or equal to 100,000 CFU/ml is also present. Additionally, these non-bacterial organisms identified from blood cannot be deemed secondary to a UTI since they are excluded as organisms in the UTI definition.
- Suprapubic tenderness whether elicited by palpation (tenderness-sign) or provided as a subjective complaint of suprapubic pain (pain-symptom), documentation of either found in the medical record is acceptable as a part of SUTI criterion if documented in the medical record during the Infection Window Period.
- Lower abdominal pain or bladder or pelvic discomfort are examples of symptoms that can be used as suprapubic tenderness. Generalized “abdominal pain” in the medical record is not to be interpreted as suprapubic tenderness as there are many causes of abdominal pain and this symptom is too general.
- Left or right lower back or flank pain are examples of symptoms that can be used as costovertebral angle pain or tenderness. Generalized "low back pain" is not to be interpreted as costovertebral angle pain or tenderness.
- Fever and hypothermia are non-specific symptoms of infection and cannot be excluded from CAUTI determination because they are clinically deemed due to another recognized cause.

Collection of denominator data for CAUTI

4. **Manual, daily:** patient days and urinary catheter days should be collected at the same time, every day, for each location performing surveillance to ensure that differing collection methods don't inadvertently result in device days being > patient days.

5. **Manual, weekly:** patient days and urinary catheter days should be collected at the same time on the same designated day, once per week. The idea is to reduce staff time spent collecting surveillance data, once weekly sampling of denominator data is good for

   - For locations with 75 or more device days per month
   - For locations other than specialty care areas/oncology and NICUs
   - It was shown that the use of Saturday or Sunday generate the least accurate estimates, so avoid them
   - If the day designated for the collection of sampled data is missed, collect the data on the next available day instead

6. Electronic sources:

   - When patient days and urinary catheter days are available from electronic databases, these sources may be used as long as the counts are not substantially different (+/- 5%) from those collected manually.

Analysis of CAUTI

Measure	Calculation	Application
CAUTI Rates	$\frac{\text{The number of CAUTIs for a location}}{\text{The number of urinary catheter days for that location}} \times 1000$	Location specific measure
CAUTI SIR	$\frac{\text{The number of observed CAUTIs}}{\text{The number of predicted CAUTIs}}$	Both location specific and summarized measure
Urinary catheter DUR	$\frac{\text{The number of urinary catheter days for a location}}{\text{The number of patient days for that location}}$	Location specific measure
Urinary catheter SUR	$\frac{\text{The number of observed urinary catheter days}}{\text{The number of predicted urinary catheter days}}$	Both location specific and summarized measure

SIR, standardized infection ratio; DUR, device utilization ratio; SUR, standardized utilization ratio

- CAUTI Rates and urinary catheter DUR should be presented by unit (for example, adult ICU, pediatric ICU…etc).
- CAUTI SIR and urinary catheter SUR can be presented for single locations and can be summarized across multiple locations, adjusting for differences in the incidence of infection or device utilization (respectively) between different location types.

11.3 Ventilator-Associated Event

Ventilator-associated Event (VAE):

- VAE events are identified by using a combination of objective criteria: deterioration in respiratory status after a period of stability or improvement on the ventilator, evidence of infection or inflammation, and laboratory evidence of respiratory infection
- Ventilator is defined as a device to assist or control respiration continuously, inclusive of the weaning period, through a tracheostomy or by endotracheal intubation. The ventilator has to be in place for >2 days
- The VAE definition algorithm is for use in surveillance; it is not a clinical definition algorithm and is not intended for use in the clinical management of patients.
- Three tiers of VAE definitions - hierarchical
    - Ventilator-associated condition (VAC)
    - Infection-related ventilator-associated complications (IVAC)
    - Possible ventilator-associated pneumonia (PVAP)

Surveillance settings:

- VAE surveillance can be done in any adult inpatient location where denominator data can be collected.
- Currently it is implemented in adult ICUs and SCA, step-down units, and wards.
- Pediatric and neonatal units should conduct PedVAE surveillance.

Surveillance methodology

- Active
- Patient based
- Prospective
- Priority-directed targeted
- Yield risk-adjusted incidence rates

Ventilator:

- Any device used to support, assist or control respiration (inclusive of the weaning period) through the application of positive pressure to the airway when delivered via an artificial airway, specifically an oral/nasal endotracheal or tracheostomy tube.
- Lung expansion devices such as intermittent positive-pressure breathing (IPPB); nasal positive end-expiratory pressure (nasal PEEP); and continuous nasal positive airway pressure (CPAP, hypoCPAP) are not considered ventilators unless delivered via tracheostomy or endotracheal intubation (e.g., ET-CPAP).
- Patients on Airway Pressure Release Ventilation (APRV) or related modes of mechanical ventilation (e.g., BiLevel, Bi Vent, BiPhasic, PCV+, DuoPAP) are INCLUDED in VAE protocol, but the VAE period of stability or improvement on the ventilator and the period of worsening oxygenation should be determined by changes in FiO2 only, since changes in PEEP may not be applicable to APRV.

Ventilator removal and reinsertion:

- If ventilator was removed and reinserted before a full calendar day without a ventilator, then continue the day count
- Therefore if the patient is without a ventilator for at least one full calendar day (NOT to be read as 24 hours), then start a new day count.
- **Episode of mechanical ventilation:** the period of days during which the patient was mechanically ventilated for some portion of each consecutive day

Hospital days	1	2	3	4	5	6	7
Ventilator days	1	2	3	Extubated (4)	Re-intubated (5)	6	7
Ventilator episodes	1	1	1	1	1	1	1

Hospital days	1	2	3	4	5	6	7
Ventilator days	1	2	3	Extubated (4)	---	Re-intubated (1)	2
Ventilator episodes	1	1	1	1	---	2	2

Date of event (DOE):

- The date of onset of worsening oxygenation
- This is defined as the first calendar day of the required ≥ 2-day period of worsening oxygenation following a ≥ 2-day period of stability or improvement on the ventilator.

Infection Window Period:

- It is usually a 5-day period and includes the 2 days before, the day of, and the 2 days after the VAE event date (i.e., the first day of worsening oxygenation, the day of VAE onset).
- However, it could be shorter if VAE occurs early in the course of mechanical ventilation (cannot include the first 2 days on ventilator)
- The earliest day on which VAE criteria can be fulfilled is day 4 of mechanical ventilation (where the day of intubation and initiation of mechanical ventilation is day 1)
- The earliest date of event for VAE (the date of onset of worsening oxygenation) is day 3 of mechanical ventilation

Ventilator days	10	11	12	13	14	15	16
VAE day	-3	-2	-1	1	2	3	4
Oxygenation	Stable/ improve	Stable/ improve	Stable/ improve	Worsen	Worsen	Worsen	Worsen
DOE		Day2 before	Day1 before	DOE	Day1 after	Day2 after	
Window		1	2	3	4	5	

Ventilator days	1	2	3	4	5	6	7
VAE day	-3	-2	-1	1	2	3	4
Oxygenation	Stable/ improve	Stable/ improve	Stable/ improve	Worsen	Worsen	Worsen	Worsen
DOE		Day2 before	Day1 before	DOE	Day1 after	Day2 after	
Window	Cannot include	Cannot include	1	2	3	4	

Location of attribution:

- The inpatient location where the patient was assigned on the date of the VAE event, which is further defined as date of onset of worsening oxygenation.
- OR/Post Anesthesia Care Unit/Recovery Room/dialysis unit /ERs cannot be considered a location of attribution for VAE

Transfer Rule:

- If a VAE develops on the day of transfer or the day following transfer from one inpatient location to another in the same facility or to a new facility (where the day of transfer is day 1), the event is attributed to the transferring location.
- Example:
  - ✓ Patient on a ventilator in the SICU who has had improving oxygenation for 3 days is transferred to the MICU, still on the ventilator.
  - ✓ On the day of transfer, after the patient has arrived in the MICU, the patient experiences an acute decompensation, requiring an increase of 0.30 (30 points) in FiO2 that persists during the following calendar day.
  - ✓ VAC criteria are met on calendar day 2 in the MICU.
  - ✓ Because the onset of worsening oxygenation occurred on the day of transfer to the MICU, the VAC event is attributed to the SICU.

Multiple Transfers:

- If the patient has been transferred to more than one location on the date of VAE, or the day before, attribute the VAE to the first location in which the patient was housed the day before the VAE's date of event.

Date	3/22	3/23	3/24
Locations	Unit A	Unit A Unit B Unit C	Unit C Unit D *VAE was diagnosed*

- VAE is attributed to Unit A since Unit A was the first location in which the patient was housed the day before the date of event.

Repeat Infection time frame (RIT)

- A new VAE cannot be identified or reported until a 14-day period has elapsed after the day of onset of worsening oxygenation (the event date, day 1).
- However, the period of stability can be diagnosed during the defined 14 days

Secondary BSIs:

- Secondary BSIs may be reported for PVAP events but NOT reported for VAC or IVAC events provided that:

✓ The organism identified from blood specimen matches an organism identified from an appropriate respiratory specimen (respiratory secretions, pleural fluid and lung tissue).

✓ Collection times: respiratory specimen have been collected during the 5-day infection window and the positive blood specimen collected during the 14-day event period starting by the date of event.

✓ In cases where PVAP is met with only the histopathology criterion and there is a positive blood specimen a secondary BSI is not reported.

- Do not limit reporting to just those organisms isolated in culture. For example, influenza A identified by PCR in respiratory specimen and culture of blood specimen, a secondary BSI is reported.

Measurements of oxygen requirement

- **Fraction of inspired oxygen** (FiO2) is oxygen concentration (%) is typically maintained below 0.5 even with ventilation, to avoid oxygen toxicity. Natural air includes 20.9% oxygen, which is equivalent to FiO2 of 0.21.
- **Positive end-expiratory pressure** (PEEP) is the pressure in the lungs above atmospheric pressure applied by a ventilator. A small amount of applied PEEP (0 to 5 cmH2O) is used in most mechanically ventilated patients to mitigate end-expiratory alveolar collapse

Daily minimum PEEP

- The lowest value of PEEP during a calendar day that is set on the ventilator and maintained for at least 1 hour
- In the event that ventilator settings are monitored and recorded less frequently than once per hour or where there is no value that is documented to have been maintained for at least one hour, the daily minimum PEEP is simply the lowest value of PEEP set on the ventilator during the calendar day
- EXAMPLE: The patient is intubated and the PEEP is set at the following values through the remainder of the calendar day:

Time-1	**6:00 PM**	**7:00 PM**	**8:00 PM**	**9:00 PM**	**10:00 PM**	**11:00 PM**
Value-1	10	8	5	5	8	8

Time-2	**6:00 PM**	**7:00 PM**	**8:00 PM**	**9:00 PM**	**10:00 PM**	**11:00 PM**
Value-2	8	5	8	5	8	8

Time-3	**12:00 AM**	**4:00 AM**	**8:00 AM**	**12:00 PM**	**4:00 PM**	**8:00 PM**
Value-3	5	8	5	8	8	10

- In the first example, the daily minimum PEEP for the purposes of VAE surveillance is 5 cmH2O. It was the lowest value that is maintained for one hour
- In the second example, the daily minimum PEEP for the purposes of VAE surveillance is 8 cmH2O. The value 5 cmH2O cannot be used as it was not maintained for one hour
- In the third example, the daily minimum PEEP is 5 cmH2O. PEEP settings are being monitored and recorded every 4 hours; therefore the lowest recorded PEEP setting for the calendar day is the value used in VAE surveillance.

Daily minimum FiO2

- The lowest value of FiO2 during a calendar day that is set on the ventilator and maintained for at least 1 hour
- In the event that ventilator settings are monitored and recorded less frequently than once per hour or where there is no value that has been maintained for at least one hour, the daily minimum FiO2 is simply the lowest value of FiO2 set on the ventilator during the calendar day.
- EXAMPLE: The patient is intubated and the FiO2 is set at the following values through the remainder of the calendar day:

Time-1	**6:00 PM**	**7:00 PM**	**8:00 PM**	**9:00 PM**	**10:00 PM**	**11:00 PM**
Value-1	1.0	0.8	0.5	0.5	0.8	0.8

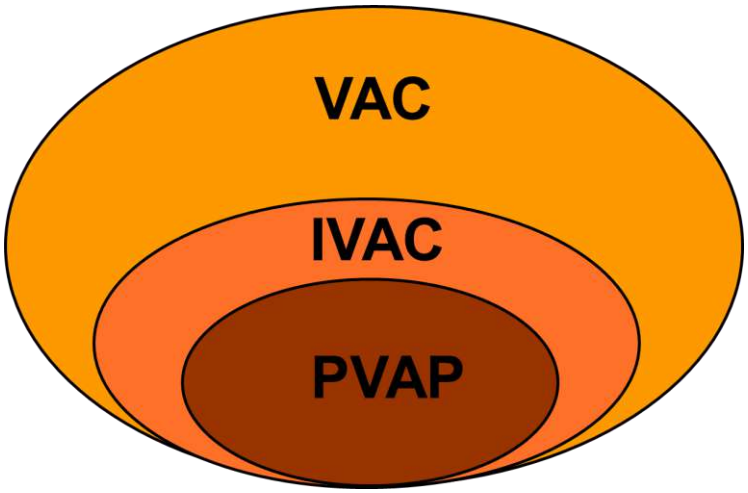
Time-2	**6:00 PM**	**7:00 PM**	**8:00 PM**	**9:00 PM**	**10:00 PM**	**11:00 PM**
Value-2	0.8	0.8	0.5	0.8	0.5	0.8

Time-3	**2:00 PM**	**4:00 PM**	**6:00 PM**	**8:00 PM**	**10:00 PM**	**12:00 AM**
Value-3	1.00	0.60	0.40	0.50	0.55	0.60

- In the first example, the daily minimum FiO2 for the purposes of VAE surveillance is 0.5. It was the lowest value that is maintained for one hour
- In the second example, the daily minimum FiO2 for the purposes of VAE surveillance is 0.8. The value 0.5 cannot be used as it was not maintained for one hour
- In the third example, the daily minimum FiO2 is 0.40. FiO2 settings are being monitored and recorded every 2 hours; therefore, the lowest recorded FiO2 setting for the calendar day is the value used in VAE surveillance.

Layers of VAE events

- **Ventilator-Associated Condition (VAC):** After a period of stability or improvement on the ventilator sustained for ≥ 2 calendar days, the patient has **one** of the following indicators of worsening oxygenation;
  - ✓ Increase in daily minimum FiO2 values of ≥ 0.20 points or
  - ✓ Increase in daily minimum PEEP values of ≥ 3 cm H2O
- **Infection-related Ventilator-Associated Complication (IVAC):** After meeting the criteria of VAC, the patient meets the following **two** criteria;
  - ✓ Temperature > 38 °C or < 36°C, OR white blood cell count ≥ 12,000 cells/mm^3 or ≤ 4,000 cells/mm^3
  - ✓ A new antimicrobial agent(s) is started, and is continued for ≥ 4 calendar days
- **Possible Ventilator-Associated Pneumonia (PVAP):** After meeting the criteria of VAC or IVAC, the patient meets **one** of the following criteria;
  - ✓ **Criterion 1:** Positive culture of respiratory specimens without the requirement for purulent respiratory secretions.
  - ✓ **Criterion 2:** Purulent respiratory secretions plus organisms identified from defined respiratory specimens.
  - ✓ **Criterion 3:** One of the following positive tests: Organism identified from pleural fluid, Lung histopathology, Legionella detection, or viral detection.



1. Ventilator-Associated Condition (VAC)

After a period of stability or improvement on the ventilator sustained for ≥ 2 calendar days, the patient has **one** the following indicators of worsening oxygenation;

- Increase in daily minimum FiO2 values of ≥ 0.20 points or
- Increase in daily minimum PEEP values of ≥ 3 cm H2O

EXAMPLE: In the example below, the baseline period is defined by mechanical ventilation (MV) days 1 through 4 (shaded in light gray), and the period of worsening oxygenation by MV days 5 and 6 (shaded in darker gray), where the daily minimum PEEP is ≥ 3 cmH2O greater than the daily minimum PEEP of the first day in the baseline period. Note that there is no VAC on MV day 3, because PEEP values 0-5 cmH_2O are considered equivalent for the purposes of this surveillance.

Ventilator day	Daily minimum PEEP (cmH_2O)	Daily minimum FIO_2 (%)	VAE
1	0	100%	
2	0	50%	
3	3	50%	
4	5	50%	
5	**8**	50%	VAC
6	**8**	50%	

EXAMPLE: In the example below, the baseline period is defined by mechanical ventilation (MV) days 3 and 4 (shaded in light gray), and the period of worsening oxygenation by MV days 5 and 6 (shaded in darker gray), where the daily minimum FiO2 is ≥ 0.20 (20 points) over the daily minimum FiO2 of the first day in the baseline period.

Ventilator day	Daily minimum PEEP (cmH_2O)	Daily minimum FIO_2 (%)	VAE
1	8	100%	
2	6	50%	
3	5	40%	
4	5	40%	
5	6	**70%**	VAC
6	6	**70%**	

EXAMPLE: In the example below, there is no VAC, because the FiO2 on MV day 4 is higher than the FiO2 on MV day 3 (and therefore not stable or decreasing) – even though the FiO2 on MV days 3 and 4 meets the 20-point threshold when compared with the daily minimum FiO2 on MV days 5 and 6.

Ventilator day	Daily minimum PEEP (cmH_2O)	Daily minimum FIO_2 (%)	VAE
1	8	100%	
2	6	50%	
3	5	35%	
4	5	40%	
5	6	70%	No event
6	6	70%	

2. Infection-related Ventilator-Associated Complication (IVAC):

After meeting the criteria of VAC, the patient meets the following **two** criteria;

- Temperature > 38 °C or < 36°C, OR white blood cell count ≥ 12,000 cells/mm3 or ≤ 4,000 cells/mm3
- A new antimicrobial agent(s) is started, and is continued for ≥ 4 calendar days

New antimicrobial agent:

- Any agent initiated on or after the third calendar day of mechanical ventilation AND in the VAE Window Period
- The agent is considered new for the purposes of this definition if it was NOT given to the patient during the 2-days before the window
- Qualifying Antimicrobial Day (QAD): day on which the patient was administered an antimicrobial agent that was determined to be “new” within the VAE Window Period
- Four consecutive QADs are needed to meet the IVAC antimicrobial criterion
- The requirement for 4 consecutive QADs can be met with 4 days of therapy with the same antimicrobial (with a gap of no more than 1 calendar day between administrations of that antimicrobial) or it can be met with 4 days of therapy with multiple antimicrobial agents, as long as each antimicrobial was started within the VAE Window Period.

Routes of administration of new antimicrobial agent

Route of Administration	Definition
Intravenous	An intravascular route that begins with a vein.
Intramuscular	A route that begins within a muscle
Digestive Tract	A route that begins anywhere in the digestive tract extending from the mouth through rectum.
Respiratory Tract	A route that begins within the respiratory tract, including the oropharynx and nasopharynx.

Qualifying Antimicrobial Day (QAD):

Ventilator days	2	3	4	5	6	7	8
Oxygenation		Stable/ improve	Stable/ improve	Worsen	Worsen		
Antimicrobial agent	Ceftriaxone	Ceftriaxone	Ceftriaxone	Meropenem	Meropenem	Meropenem	Meropenem
QAD				1	2	3	4

- Meropenem is a new start while ceftriaxone is not as it was given to the patient the day before the 5-day period.
- The number of QAD is 4

Ventilator days	2	3	4	5	6	7	8
Oxygenation		Stable/ improve	Stable/ improve	Worsen	Worsen		
Antimicrobial agent	Ceftriaxone	Ceftriaxone	Ceftriaxone	Meropenem	Imipenem	Piperacillin/ Tazobactam	Piperacillin/ Tazobactam
QAD				1	2	3	4

- Meropenem, Imipenem and Piperacillin/ Tazobactam are new start while ceftriaxone is not as it was given to the patient the day before the 5-day period.
- The number of QAD is 4

Ventilator days	2	3	4	5	6	7	8
Oxygenation		Stable/ improve	Stable/ improve	Worsen	Worsen		
Antimicrobial agent			Levofloxacin		Levofloxacin		Levofloxacin
QAD			1	2	3	4	5

- Because there is a gap of no more than 1 calendar day between days of levofloxacin administration, the requirement for 4 consecutive QADs is met
- The number of QAD is 5

Ventilator days	2	3	4	5	6	7	8
Oxygenation		Stable/ improve	Stable/ improve	Worsen	Worsen		
Antimicrobial agent			Vancomycin			Vancomycin	
QAD							

- Because there is a gap of more than 1 calendar day between days of vancomycin administration, the requirement for 4 consecutive QADs is not met
- The number of QAD is 0

3. Possible Ventilator-Associated Pneumonia (PVAP):

After meeting the criteria of VAC or IVAC, the patient meets **one** of the following criteria;

Criterion 1: Positive culture of one of the following specimens, meeting quantitative or semi-quantitative thresholds, without requirement for purulent respiratory secretions:

- Endotracheal aspirate, ≥ 10^5 CFU/ml or corresponding semi-quantitative result
- Bronchoalveolar lavage, ≥ 10^4 CFU/ml or corresponding semi-quantitative result
- Lung tissue, ≥ 10^4 CFU/g or corresponding semi-quantitative result
- Protected specimen brush, ≥ 10^3 CFU/ml or corresponding semi-quantitative result

Criterion 2: Purulent respiratory secretions PLUS organism identified from one of the following specimens (to include qualitative culture, or quantitative/semi-quantitative culture without sufficient growth to meet criterion #1):

- Sputum
- Endotracheal aspirate
- Bronchoalveolar lavage
- Lung tissue
- Protected specimen brush

Criterion 3: One of the following positive tests:

- Organism identified from pleural fluid (where specimen was obtained during thoracentesis or initial placement of chest tube and NOT from an indwelling chest tube)
- Lung histopathology, defined as: 1) abscess formation or foci of consolidation with intense neutrophil accumulation in bronchioles and alveoli; 2) evidence of lung parenchyma invasion by fungi (hyphae, pseudohyphae or yeast forms); 3) evidence of infection with the viral pathogens listed below based on results of immunohistochemical assays, cytology, or microscopy performed on lung tissue
- Diagnostic test for Legionella species

- Diagnostic test on respiratory secretions for influenza virus, respiratory syncytial virus, adenovirus, parainfluenza virus, rhinovirus, human metapneumovirus, coronavirus

Criterion 1-PVAP: Threshold values for cultured specimens used in the diagnosis of pneumonia

Specimen collection/technique	Values*
1. Lung tissue	$\geq 10^4$ CFU/g tissue
2. Bronchoscopically (B) obtained specimens	
• Broncho alveolar lavage (B-BAL)	$\geq 10^4$ CFU/ml
• Protected BAL (B-PBAL)	$\geq 10^4$ CFU/ml
• Protected specimen brushing (B-PSB)	$\geq 10^3$ CFU/ml
3. Non bronchoscopically (NB) obtained (blind)specimens	
• Broncho alveolar lavage (NB-BAL)	$\geq 10^4$ CFU/ml
• Protected specimen brushing (NB-PSB)	$\geq 10^3$ CFU/ml
4. Endotracheal aspirate (ETA)	$\geq 10^5$ CFU/ml

*CFU = colony forming units, g = gram, ml = milliliter

Semi-quantitative results:

- Semi-quantitative Results for cultured specimens such as "moderate" or "heavy" or "many" or "numerous" growth, or 2+, 3+, or 4+ growth can meet Criterion 1 of the PVAP surveillance definition
- Semi-quantitative results for purulent respiratory secretions can meet Criterion 2 of the PVAP surveillance definition

✓ Neutrophils: Many, heavy, numerous, 4+, or ≥ 25 neutrophils per low power field (lpf) [x100]

✓ Squamous cells: No, rare, occasional, few, 1+ or 2+, or ≤ 10 squamous epithelial cells per lpf [x100]

Collection of denominator data for VAE

1. **Manual, daily:**
   - Patient days and ventilator days should be collected at the same time, every day, for each location performing surveillance to ensure that differing collection methods don't inadvertently result in device days being > patient days.
2. **Electronic sources:**
   - When patient days and ventilator days are available from electronic databases, these sources may be used as long as the counts are not substantially different (+/- 5%) from those collected manually.

Analysis of VAE

Measure	Calculation	Application
VAE Rates	$\frac{\text{The number of VAEs for a location}}{\text{The number of ventilator days for that location}}$ X1000	Location specific measure
VAE Rates	$\frac{\text{The number of VAEs for a location}}{\text{The number of ventilator episodes for that location}}$ X100	Location specific measure
VAE SIR	$\frac{\text{The number of observed VAEs}}{\text{The number of predicted VAEs}}$	Both location specific and summarized measure
Ventilator DUR	$\frac{\text{The number of ventilator days for a location}}{\text{The number of patient days for that location}}$	Location specific measure
Ventilator SUR	$\frac{\text{The number of observed ventilator days}}{\text{The number of predicted ventilator days}}$	Both location specific and summarized measure

SIR, standardized infection ratio; DUR, device utilization ratio; SUR, standardized utilization ratio

- VAE rates and ventilator DUR should be presented by unit (for example, adult ICU, pediatric ICU…etc).
- VAE rates and ventilator DUR in neonatal ICU should be presented by unit and birthweight categories (which includes A = ≤750 g; B = 751-1000 g; C = 1001-1500 g; D = 1501-2500 g; E = >2500 g).
- VAE SIR and ventilator SUR can be presented for single locations and can be summarized across multiple locations, adjusting for differences in the incidence of infection or device utilization (respectively) between different location types.
- In neonatal ICU, VAE SIR and ventilator SUR can be additionally summarized across birthweight categories, adjusting for differences in the incidence of infection or device utilization (respectively) between different birthweight categories.

11.4 Pediatric Ventilator-Associated Event

Pediatric Ventilator-Associated Event (PedVAE):

- VAE surveillance in pediatric and neonatal population.
- Detection of a PedVAE is determined by identification of deterioration in respiratory status after a period of stability or improvement on the ventilator using two key parameters.

Surveillance settings:

- VAE surveillance can be done in pediatric and neonatal inpatient location where denominator data can be collected.
- Can be implemented in pediatric and neonatal ICUs and SCA, step-down units, and wards.

Surveillance methodology

- Active
- Patient based
- Prospective
- Priority-directed targeted
- Yield risk-adjusted incidence rates

Eligibility of patients:

- Patients on specific modes of mechanical ventilation:
  - ✓ High frequency oscillatory or jet ventilation (HFO)
  - ✓ Airway pressure release ventilation (APRV)-FiO2 parameter only
- Patients who are receiving a conventional mode of mechanical ventilation while receiving:
  - ✓ Surfactant
  - ✓ Corticosteroids
  - ✓ Prone positioning
  - ✓ Nitric oxide therapy
  - ✓ Helium-oxygen mixture
  - ✓ Epoprostenol therapy

Exclusions:

- Patients on extracorporeal life support or paracorporeal membrane oxygenation
- Non-acute care locations in acute care facilities
- Pediatric patients in adult locations

PedVAE is similar to VAE in the following definitions:

- Ventilator definition
- Date of event: the date of onset of worsening oxygenation
- Location of attribution and transfer rule are similar to VAE
- 14-day event period: 14-day period, starting on the day of onset of worsening oxygenation (the date of event, day 1). A new PedVAE cannot be identified or reported until this 14-day period has elapsed.
- Episode of Mechanical Ventilation: Defined as a period of days during which the patient was mechanically ventilated for some portion of each consecutive day.
- Location of attribution and transfer rule

PedVAE is different from VAE in the following:

- Use of mean airway pressure (MAP) instead of PEEP.
- Locations are only pediatric and neonatal locations.
- No differentiation to VAC, IVAC, PVAP (so it is comparable to VAC in VAE).
- No secondary BSI can be attributed to PedVAE.

Daily Minimum FiO2:

- The lowest value of FiO2 during a calendar day that is set on the ventilator and maintained for > 1 hour.
- If there is no value that has been maintained for >1 hour then select the lowest value available regardless of the period of time in which the setting was maintained
  - ✓ Ventilation initiated late in the calendar day
  - ✓ Ventilation discontinued early in the calendar day
  - ✓ Ventilator settings very unstable throughout the day
- If FiO2 is recorded every 15/30 minutes, 5/3 consecutive recordings of FiO2 are needed to meet the required >1 hour minimum duration.

- Increase in the daily minimum FiO2 of at least 0.25 (25 points) over the daily minimum FiO2 of the first day in the baseline period is one of two criteria that can be used in meeting the PedVAE definition.

Mean Airway Pressure (MAP):

- The average pressure exerted on the airway and lungs from the beginning of inspiration until the beginning of the next inspiration.
- Daily minimum MAP is the lowest value documented during the calendar day (not necessarily maintained for > 1 hour)
- A sustained increase in the daily minimum MAP of ≥ 4 cmH2O following a period of stability or improvement on the ventilator is one of two criteria that can be used in meeting the PedVAE definition.
- For patients < 30 days:
  - ✓ MAP values of 0-8 cmH2O are considered equal to 8 cmH2O
  - ✓ Any day where daily minimum MAP is 0-8 cmH20 will be assigned a daily minimum MAP value of 8 cmH20.
- For patients ≥ 30 days:
  - ✓ MAP values 0-10 cmH2O are considered equal to 10 cmH2O
  - ✓ Any day where daily minimum MAP is 0-10 cmH20 will be assigned a daily minimum MAP value of 10 cmH20.

Baseline Period:

- Baseline period is ≥ 2 calendar days of stable or decreasing daily minimum FiO2 or MAP values and immediately precedes the first day of increased daily minimum MAP or FiO2

Worsening of oxygenation:

- The patient has at least one of the following :
  - ✓ Increase in daily minimum FiO2 of ≥ 0.25 (25 points) over the daily minimum FiO2 of the first day in the baseline period, sustained for ≥ 2 calendar days.

    OR
  - ✓ Increase in daily minimum MAP values of ≥ 4 cmH2O over the daily minimum MAP of the first day in the baseline period, sustained for ≥ 2 calendar days.

PedVAE diagnosis:

- Patient has a baseline period of stability or improvement on the ventilator, defined by ≥ 2 calendar days of stable or decreasing daily minimum FiO2 or MAP values.
- After a period of stability or improvement on the ventilator, the patient has at least one of the following indicators of worsening oxygenation:
  - ✓ Increase in daily minimum FiO2 of ≥ 0.25 (25 points) over the daily minimum FiO2 of the first day in the baseline period, sustained for ≥ 2 calendar days.
  - ✓ Increase in daily minimum MAP values of ≥ 4 cmH2O over the daily minimum MAP of the first day in the baseline period, sustained for ≥ 2 calendar days

Analysis of PedVAE:

Measure	Calculation	Application
PedVAE Rates	$\frac{\text{The number of PedVAEs for a location}}{\text{The number of ventilator days for that location}}$ X1000	Location specific measure
PedVAE Rates	$\frac{\text{The number of PedVAEs for a location}}{\text{The number of ventilator episodes for that location}}$ X100	Location specific measure
Ventilator DUR	$\frac{\text{The number of ventilator days for a location}}{\text{The number of patient days for that location}}$	Location specific measure

- PedVAE rates and ventilator DUR should be presented by unit (for example, pediatric ICU, pediatric cardiac ICU…etc).
- PedVAE rates and ventilator DUR in neonatal ICU should be presented by unit and birthweight categories (which includes A = ≤750 g; B = 751-1000 g; C = 1001-1500 g; D = 1501-2500 g; E = >2500 g).

11.5 Dialysis Events

Dialysis Event (DE):

DE could be one or more of the following types:

- **In-unit IV antimicrobial start:** Include all IV antimicrobial starts, not just those with vancomycin or for a vascular access problem.
- **Positive blood culture:** Include all patients with a positive blood culture even if they did not have an associated hospitalization or in-unit IV antimicrobial start. Include blood cultures taken as an outpatient or within 1 day after a hospital admission. Access-associated bacteremia is a positive blood culture with source identified as the vascular access site or unknown.
- **Pus, redness, or increased swelling at the vascular access site:** Pus is always reportable. Report redness or swelling if it is greater than expected and suspicious for infection.

Surveillance settings:

- Surveillance occurs in outpatient hemodialysis centers.
- These centers may be attached to or affiliated with a hospital, but should serve hemodialysis outpatients.
- Inpatient dialysis is not included in this module

Eligibility of patients:

- Maintenance hemodialysis outpatients.
- Transient Patient: patients transferred from another facility and received in-center hemodialysis at our location on the first two working days of the month.

Non-eligibility of patients:

- If the reverse happen, our patient was transferred to another facility we do not count him/her in our denominator unless he/she received in-center hemodialysis at our location on the first two working days of the month
- Non-hemodialysis (peritoneal dialysis) patients and inpatients are excluded

Surveillance methodology

- Active
- Patient based
- Prospective
- Priority-directed targeted
- Yield risk-adjusted incidence rates
    - ✓ Rates are controlled for variations in the distribution of major risk factors associated with an event's occurrence (e.g. type of event and type of access)
    - ✓ Such rates allow inter- and intra-facility rate comparisons

Date of event (DOE):

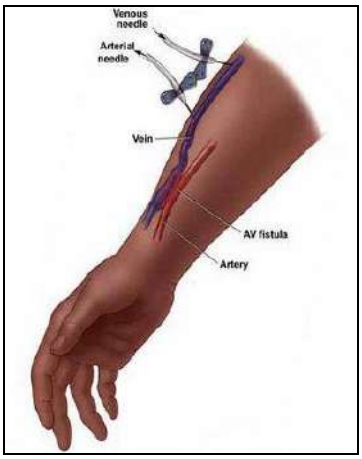
It is the date when the FIRST element used to meet the DE criterion occurs

Event Type	Date of Event Criterion
IV antimicrobial start	Date of first outpatient dose of an antimicrobial course
Positive blood culture	Date of specimen collection
Pus, redness, or increased swelling at the vascular access site	Date of onset of symptoms
Combination	Earliest date of the three types

Vascular access:

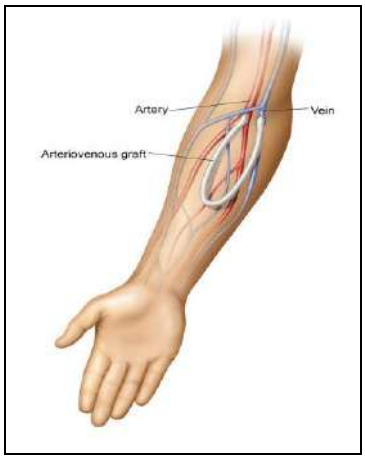
Hemodiaylsis vascular access types, in order of increasing risk of infection, include:

1. Arteriovenous fistulas created from the patient's own blood vessels
2. Arteriovenous grafts often constructed from synthetic materials
3. Tunneled central lines
4. Non-tunneled central lines
5. Post access device



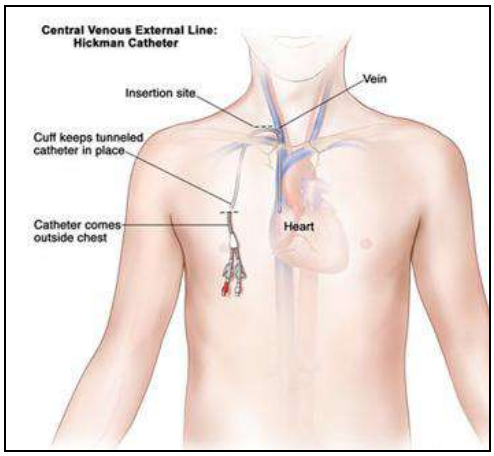
Arterio-venous fistula

A surgically created direct connection between an artery and a vein to provide vascular access



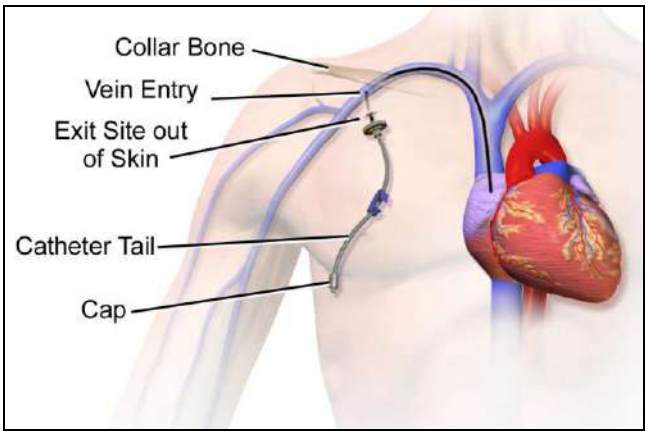
Arterio-venous graft

A surgically created connection between an artery and a vein using implanted synthetic tubing for the purpose to provide a permanent vascular access



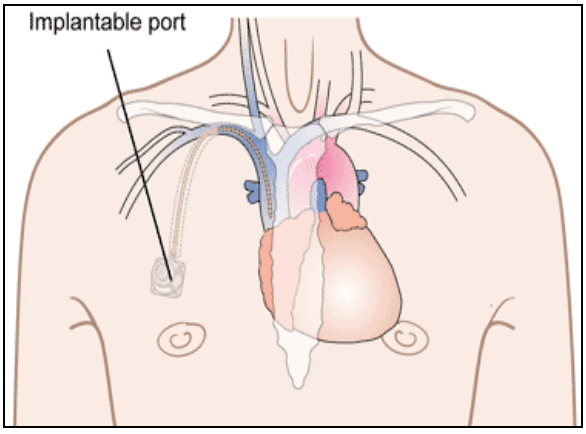
Permanent central line

A central venous catheter that travels a distance under the skin from the point of insertion before terminating at or close to the heart or one of the great vessels (e.g., Hickman® or Broviac® catheters).



Temporary central line

A central venous catheter that travels directly from the skin entry site to a vein and terminates close to the heart or one of the great vessels, typically intended for short term use.

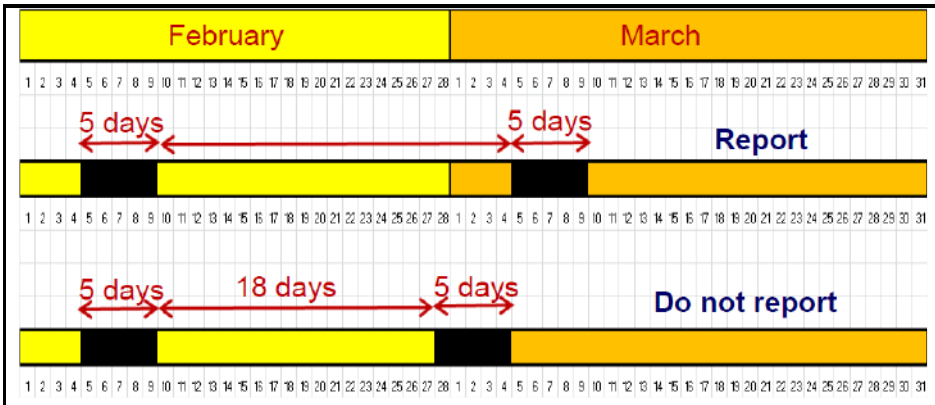


Port access device

A fully implantable access device e.g., Lifesite

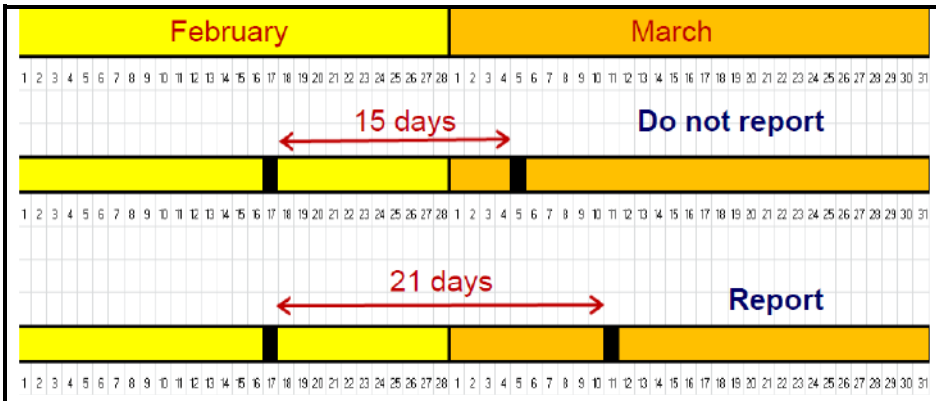
21-day rule:

- 21 or more days must exist between two dialysis events of the same type for the second occurrence to be reported as a separate dialysis event
- The 21-day rule applies across calendar months
- If fewer than 21 days have passed since the last reported event of the same type, the subsequent event is not reported.



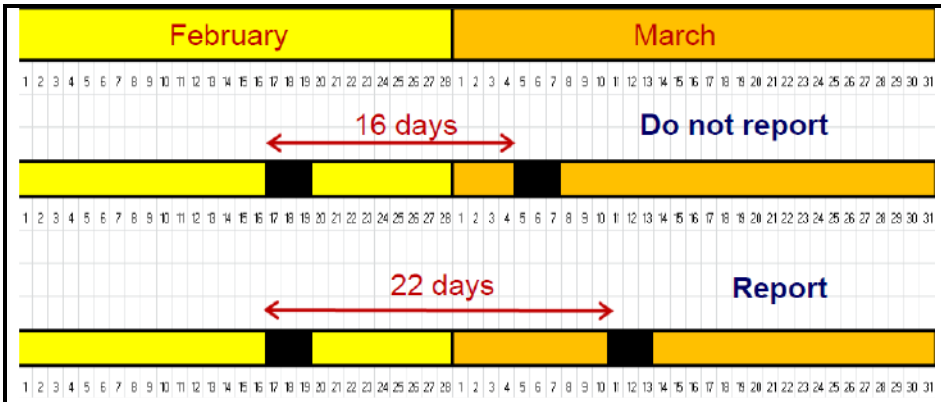
IV antimicrobial start

From the end of one (reported) IV antimicrobial course to the beginning of a second IV antimicrobial star



Positive blood culture

From date of first (reported) culture to date of second culture



Local infection

From onset of first (reported) episode to the onset of a second episode

1- IV antimicrobial start

- Report all starts of intravenous (IV) antibiotics or antifungals administered in an outpatient setting, regardless of the reason for administration (i.e., include IV antimicrobial starts unrelated to vascular access problems) and regardless of the duration of treatment.
- A start is defined as a single outpatient dose or first outpatient dose of a course.
- Report outpatient starts that are continuations of inpatient treatment or another outpatient dialysis facility
- Do not report IV antiviral starts
- There must be 21 or more days from the end of the first IV antimicrobial start to the beginning of a second IV antimicrobial start for two starts to be considered separate dialysis events, even if different antimicrobials are used.
- If IV antimicrobials are stopped for less than 21 days and then restarted, the second start is NOT considered a new dialysis event.
- To apply the 21-day rule to outpatient IV antimicrobial starts that are continuations of inpatient treatment, consider the start day to be the first day of outpatient treatment.
- Inter-facility patient transfers: If a patient at a dialysis facility has an IV antimicrobial start and then transfers to another facility (as a transient or permanent patient) where the antimicrobial is continued, the second facility would report the IV antimicrobial start in their facility as well

2- Positive blood culture

- Report all positive blood cultures collected as an outpatient or collected within the first 2 calendar days after a hospital admission, regardless of whether or not a true infection is suspected, infection is thought to be related to hemodialysis, or treatment is received
- The date of a blood culture result is based on the date the blood specimen was collected, not the date the laboratory reported the result.

- There must be 21 or more days between positive blood cultures for each positive blood culture to be considered a separate dialysis event, even if organisms are different.
- If positive blood cultures occur less than 21 days apart, the second positive blood culture(s) is NOT considered a new dialysis event: add new organisms from these subsequent positive blood cultures to the first report.

Suspected source of the positive blood culture

- **Vascular access:**
  - ✓ If there is objective evidence of vascular access infection and the vascular access is thought to be the source of the positive blood culture.
- **A source other than the vascular access**
  - ✓ If either (a) or (b) is true:
  - ✓ a) a culture from another site (e.g., infected leg wound, urine) shows the same organism found in the blood and the site is thought to be the source of the positive blood culture
  - ✓ b) there is clinical evidence of infection at another site which is thought to be the source of the positive blood culture, but the site was not sampled for culture
- **Contamination:**
  - ✓ If the organism isolated from the blood culture is thought by the physician, infection preventionist, or head nurse to be a contaminant.
  - ✓ Contamination is more likely if the organism is a common commensal and is isolated from only one blood culture.
- **Uncertain:**
  - ✓ Only if there is insufficient evidence to decide among the three previous suspected source categories

3- Pus, redness, or increased swelling at the vascular access site

- Report each new outpatient episode where the patient has one or more symptoms of pus, greater than expected redness or greater than expected swelling at a vascular access site, regardless of whether the patient received treatment.
- There must be 21 or more days between the onset of a first episode and onset of a second episode of pus, redness, or increased swelling at a vascular access site to be considered separate dialysis events
- If an episode of pus, redness, or increased swelling at a vascular access site resolves and then recurs within 21 days, the recurrence is NOT considered a new dialysis event.

Calculated dialysis events:

- Bloodstream infection:
  - ✓ Any positive blood culture
- Local access site infection:
  - ✓ Pus, redness, or swelling of the vascular access site and bloodstream infection is not present.
- Access-related bloodstream infection:
  - ✓ Positive blood culture with the suspected source identified as the vascular access site or uncertain.
- Vascular access infection:
  - ✓ Either a local access site infection or an access-related bloodstream infection.

Numerator data:

- Complete a Dialysis Event form only if a maintenance hemodialysis outpatient has one or more of the following:
  - ✓ IV antimicrobial start
  - ✓ Positive blood culture
  - ✓ Pus, redness or increased swelling at the vascular access site
- If a patient has a positive blood culture and begins IV antimicrobials, these two events would be recorded together on one form.

- When reporting multiple dialysis events together, always use the date from the first event that occurred.
- Refer to dialysis event definitions for the 21-day rule.
- Do not report unrelated dialysis events on the same form.

Number of forms

Scenario	IV antimicrobial start	Positive blood culture	Local infection	Number of forms
One event type	**X**			One form
More than one event type in **related episode** in same month	**X**	**X**		One form
More than one event types in **unrelated episodes** in same month	**X**		**X**	Two forms
Same event type twice in the same month	**XX**			Two forms
Any type of events in different months	**X**	**X**		Two forms

Denominator Data

Vascular Access Type	Number of Chronic Hemodialysis Patients		
	Day-1	Day-2	Total
Arterio-venous fistulas			
Arterio-venous graft			
Permanent central line			
Temporary central line			
Port access device			
Total patients: sum of all patients listed above			

- Record the number of chronic hemodialysis patients with each of the above 5 access types (individually and total) who received hemodialysis at your center on the first two working days of the month.
- Count each patient only once.
- Only chronic hemodialysis outpatients are included, including transient patients.
- A patient must be physically present for in-center hemodialysis on one of these two days to be counted on this form (exclude patients who are hospitalized).
- Exclude also non-hemodialysis patients and inpatients.
- If the patient has multiple vascular accesses (even if not all used), record that patient once, reporting only their vascular access with the highest risk of infection.
- Therefore if a patient has both an implanted access (graft or fistula) and a catheter, count this patient as having the catheter.
- If there are no patients in a given vascular access category, enter 0.
- Accurate data is strictly required in order to produce reliable rates.

Analysis of DE

Measure	Calculation	Application
DE Rates	$\frac{\text{The number of DEs (separately or total)}}{\text{The number of patient-months}}$ X100	Location specific measure
DE SIR	$\frac{\text{The number of observed DEs}}{\text{The number of predicted DEs}}$	Both location specific and summarized measure

SIR, standardized infection ratio

- DE rates should be presented by type of DE events:
  - ✓ In-unit IV antimicrobial start
  - ✓ Positive blood culture
  - ✓ Local infection signs
- DE rates should be stratified by access type:
  - ✓ Catheter (temporary and permanent)

- ✓ AV fistula and AV graft

- DE SIR can be presented for single locations and can be summarized across multiple locations, adjusting for differences in the incidence of infection or device utilization (respectively) between different location types.
- DE SIR can be additionally summarized across different accesses, adjusting for differences in the incidence of infection between different access types.

11. Surgical Site Infection

Surgical Site Infection (SSI):

Infection occurs within 30 or 90 days (according to the operative procedures) after an operative procedure that involves the skin or subcutaneous tissue (superficial incisional SSI), deep soft tissue (deep incisional SSI), or any other part of the body that is opened or manipulated during the operative procedure (organ/space SSI).

Surveillance Settings:

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

Surveillance Methods:

- Active
- Patient based
- Prospective
- Priority-directed targeted
- Yield risk-adjusted incidence rates

Surveillance Requirements:

- Select at least one NHSN operative procedure category for at least one month
- A procedure must meet the NHSN definition of an operative procedure in order to be included in SSI surveillance.
- All procedures included in the NHSN monthly surveillance plan are followed for superficial incisional, deep incisional, and organ/space SSI events and the type of SSI reported must reflect the deepest tissue level where SSI criteria is met during the surveillance period.
- SSI events where infection present at the time of surgery (PATOS) are reported with SSI.
- An SSI event is attributed to the facility in which the NHSN operative procedure is performed.

Surveillance Types:

- Concurrent and post discharge surveillance methods should be used to detect SSIs following inpatient operative procedures
- Post-discharge surveillance for outpatient operative procedures.

Post-discharge Surveillance:

- Review of medical records or surgery clinic patient records
  - ✓ Admission, readmission, ED, and OR logs
  - ✓ Patient charts for signs and symptoms of SSI
  - ✓ Lab, imaging, other diagnostic test reports
  - ✓ Clinician notes
- Visit the ICU and wards – talk to primary care staff
- Surgeon surveys by mail or telephone
- Patient surveys by mail or telephone (though patients may have a difficult time assessing their infections).
- Review of medical records or surgery clinic patient records
- Any combination of these methods (or other methods identified by the facility) which has the capacity to identify all SSIs is acceptable for use; however, NHSN criteria for SSI must be used.

Definition of an NHSN Operative Procedure:

- Takes place during an operation where at least one incision (including laparoscopic approach and cranial Burr holes) is made through the skin or mucous membrane, or reoperation via an incision that was left open during a prior operative procedure
- And takes place in an operating room (OR), defined as 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. This may include an operating room, C-section room, interventional radiology room, or a cardiac catheterization lab.
- Exclusions: Otherwise eligible procedures that are assigned an ASA score of 6 are not eligible for NHSN SSI surveillance.

NHSN Operative Procedure:

Code	Name
AAA	Abdominal aortic aneurysm repair
AMP	Limb amputation
APPY	Appendix surgery
AVSD	AV shunt for dialysis
BILI	Bile duct, liver or pancreatic surgery
BRST	Breast surgery
CARD	Cardiac surgery
CBGB	Coronary bypass with chest & donor incisions
CBGC	Coronary bypass graft with chest incision
CEA	Carotid endarterectomy
CHOL	Gallbladder surgery
COLO	Colon surgery
CRAN	Craniotomy
CSEC	Cesarean section
FUSN	Spinal fusion
FX	Open reduction of fracture
GAST	Gastric surgery
HER	Herniorrhaphy
HPRO	Hip prosthesis
HTP	Heart transplant

Code	Name
HYST	Abdominal hysterectomy
KPRO	Knee prosthesis
KTP	Kidney transplant
LAM	Laminectomy
LTP	Liver transplant
NECK	Neck surgery
NEPH	Kidney surgery
OVRY	Ovarian surgery
PACE	Pacemaker surgery
PRST	Prostate surgery
PVBY	Peripheral vascular bypass surgery
REC	Rectal surgery
SB	Small bowel surgery
SPLE	Spleen surgery
THOR	Thoracic surgery
THYR	Thyroid and/or parathyroid surgery
VHYS	Vaginal hysterectomy
VSHN	Ventricular shunt
XLAP	Exploratory laparotomy

Eligible surgeries under NHSN Operative Procedure:

Code	Name	Description
BRST	Breast surgery	Excision of lesion or tissue of breast including radical, modified, or quadrant resection, lumpectomy, incisional biopsy, or mammoplasty
CARD	Cardiac surgery	Procedures on the heart; includes valves or septum; does not include coronary artery bypass graft, surgery on vessels, heart transplantation, or pacemaker implantation
CBGB	Coronary bypass with chest & donor incisions	Chest procedure to perform direct revascularization of the heart; includes obtaining suitable vein from donor site for grafting

Date of event (DOE):

- For an SSI, the date of event is the date when the first element used to meet the SSI infection criterion occurs for the first time during the SSI surveillance period.
- The date of event must fall within the SSI surveillance period to meet SSI criteria. The type of SSI (superficial incisional, deep incisional, or organ/space) reported and the date of event assigned must reflect the deepest tissue level where SSI criteria are met during the surveillance period. Synonym: infection date.
- All elements required to meet an SSI criterion usually occur within a 7 to 10-day timeframe with no more than 2-3 days between elements.
- The elements must be relational to each other, meaning you should ensure the elements all associate to the SSI, and this can only happen if elements occur in a relatively tight timeframe. Each case differs based on the individual elements occurring and the type of SSI.

Secondary BSI Attribution Period for SSI:

- The secondary BSI attribution period for SSI is a 17-day period that includes the date of SSI event, 3 days prior, and 13 days after.

Denominator for procedure details:

Diabetes:

- The NHSN SSI surveillance definition of diabetes indicates that the patient has a diagnosis of diabetes requiring management with insulin or a non-insulin anti-diabetic agent.
- This includes:
  - ✓ Patients with “insulin resistance” who are on management with anti-diabetic agents.
  - ✓ Patients with gestational diabetes.
  - ✓ Patients who are noncompliant with their diabetes medications.
- The NHSN definition of diabetes excludes patients with no diagnosis of diabetes. The definition also excludes patients who receive insulin for perioperative control of hyperglycemia but have no diagnosis of diabetes.

Duration of operative procedure:

The interval in hours and minutes between the Procedure/Surgery Start Time and the Procedure/Surgery Finish Time

- Procedure/Surgery Start Time: Time when the procedure is begun (for example, incision for a surgical procedure).
- Procedure/Surgery Finish: Time when all instrument and sponge counts are completed and verified as correct, all postoperative radiologic studies to be done in the OR are completed, all dressings and drains are secured, and the physicians/surgeons have completed all procedure-related activities on the patient.

Emergency operative procedure:

- A procedure that is documented per the facility’s protocol to be an Emergency or Urgent procedure.

General anesthesia:

- The administration of drugs or gases that enter the general circulation and affect the central nervous system to render the patient pain free, amnesic, unconscious, and often paralyzed with relaxed muscles. This does not include conscious sedation.

NHSN Inpatient Operative Procedure:

- An NHSN operative procedure performed on a patient whose date of admission to the healthcare facility and the date of discharge are different calendar days.

NHSN Outpatient Operative Procedure:

- An NHSN operative procedure performed on a patient whose date of admission to the healthcare facility and date of discharge are the same calendar day.

Non-primary Closure:

- The closure of the surgical wound in a way which leaves the skin level completely open following the surgery. Closure of any portion of the skin represents primary closure.
- For surgeries with non-primary closure, the deep tissue layers may be closed by some means (with the skin level left open), or the deep and superficial layers may both be left completely open.
- Wounds with non-primary closure may or may not be described as "packed" with gauze or other material, and may or may not be covered with plastic, "wound vacs," or other synthetic devices or materials.

Primary Closure:

- The closure of the skin level during the original surgery, regardless of the presence of wires, wicks, drains, or other devices or objects extruding through the incision.
- This category includes surgeries where the skin is closed by some means. Thus, if any portion of the incision is closed at the skin level, by any manner, a designation of primary closure should be assigned to the surgery.
- Note: If a procedure has multiple incision/laparoscopic trocar sites and any of the incisions are closed primarily then the procedure technique is recorded as primary closed.

Scope:

- An instrument used to reach and visualize the site of the operative procedure. In the context of an NHSN operative procedure, use of a scope involves creation of several small incisions to perform or assist in the performance of an operation rather than use of a traditional larger incision (specifically, open approach).

Trauma:

- Blunt or penetrating injury occurring prior to the start of the procedure
- Complex trauma cases may require multiple trips to the OR during the same admission to repair the initial trauma

SSI Risk Index Category

- ASA score
  - ✓ ASA classification of 3, 4, or 5: give one
- Wound class
  - ✓ Contaminated (Class 3) or Dirty/infected (Class 4) wound class: give one
- Operative duration
  - ✓ Operation lasting more than the duration cut point: give one
- SSI Risk Index Category
  - ✓ Sum up the number of these factors present at the time of the operation

American Society of Anesthesiology (ASA) score :

- Assessment by the anesthesiologist of the patient's preoperative physical condition

  1 = Normally healthy patient

  2 = Patient with mild systemic disease

  3 = Patient with severe systemic disease that is not incapacitating

  4 = Patient with an incapacitating systemic disease that is a constant threat to life

  5 = Moribund patient not expected to survive for 24 hours with or without operation
- Note: Do NOT report procedures with an ASA physical status of 6 (a declared brain-dead patient whose organs are being removed for donor purposes) to HESN+ .

Wound class:

- An assessment of the degree of contamination of a surgical wound at the time of the operation.
- Wound class should be assigned by a person involved in the surgical procedure (for example, surgeon, circulating nurse, etc.).

Wound class	Description
Class I ***Clean***	• An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. • In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. • The following NHSN operative procedure categories are NEVER considered to have a clean wound classification: APPY, BILI, CHOL, COLO, REC (Rectal surgery), SB (Small bowel), and VHYS (Vaginal hysterectomy)
Class II ***Clean-contaminated***	• An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. • Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered.
Class III ***Contaminated***	• Open, fresh, accidental wounds. • In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered are included in this category.
Class IV ***Dirty-infected***	• Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. • This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation.

1. Surgical Site Infection Criteria (SSI)-Superficial incisional SSI

Must meet the following criteria:

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

AND involves only skin and subcutaneous tissue of the incision

AND the patient has at least **one** of the following:

1. Purulent drainage from the superficial incision.
2. Organisms identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture or non-culture based microbiologic testing method, which is performed for purposes of clinical diagnosis or treatment (for example, not active surveillance culture/testing (ASC/AST)).
3. Superficial incision that is deliberately opened by a surgeon, physician* or physician designee AND Culture or non-culture based testing of the superficial incision or subcutaneous tissue is not performed AND Patient has at least one of the following signs or symptoms:
   - Localized pain or tenderness
   - Localized swelling
   - Erythema
   - Heat
4. Diagnosis of a superficial incisional SSI by a physician or physician designee.

The term physician for the purpose of application of the NHSN SSI criteria may be interpreted to mean a surgeon, infectious disease physician, emergency physician, other physician on the case, or physician's designee (nurse practitioner or physician's assistant)

There are two specific types of superficial incisional SSIs:

1. Superficial Incisional Primary (SIP) – a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incisions (for example, C-section incision or chest incision for CBGB)

2. Superficial Incisional Secondary (SIS) – a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (for example, donor site incision for CBGB)

Reporting Instructions for Superficial SSI:

The following do not qualify as criteria for meeting the NHSN definition of superficial SSI:

- Diagnosis/treatment of cellulitis (redness/warmth/swelling), by itself, does not meet criterion “d” for superficial incisional SSI. Conversely, an incision that is draining or that has organisms identified by culture or non-culture based testing is not considered a cellulitis.
- A stitch abscess alone (minimal inflammation and discharge confined to the points of suture penetration)
- For an NHSN operative procedure, a laparoscopic trocar site is considered a surgical incision and not a stab wound.
- A localized stab wound or pin site infection is not considered an SSI; depending on the depth, these infections might be considered either a skin (SKIN) or soft tissue (ST) infection.

2. Surgical Site Infection Criteria (SSI)-Deep incisional SSI

Must meet the following criteria:

The date of event occurs within 30 or 90 days after the NHSN operative procedure (where day 1 = the procedure date)

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

AND the patient has at least **one** of the following:

1. Purulent drainage from the deep incision.
2. A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, physician* or physician designee

   AND organism(s) identified from the deep soft tissues of the incision by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not active surveillance culture/testing (ASC/AST)) or culture or non-culture based microbiologic testing method is not performed. A culture or non-culture-based test from the deep soft tissues of the incision that has a negative finding does not meet this criterion

   AND patient has at least one of the following signs or symptoms: fever (>38°C); localized pain or tenderness.
3. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test.

*The term physician for the purpose of application of the NHSN SSI criteria may be interpreted to mean a surgeon, infectious disease physician, emergency physician, other physician on the case, or physician's designee (nurse practitioner or physician's assistant).

There are two specific types of deep incisional SSIs:

1. Deep Incisional Primary (DIP) – a deep incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (for example, C-section incision or chest incision for CBGB)

2. Deep Incisional Secondary (DIS) – a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (for example, donor site incision for CBGB)

3. Surgical Site Infection Criteria (SSI)-Organ/Space SSI

Must meet the following criteria:

Date of event occurs within 30 or 90 days after the NHSN operative procedure (where day 1 = the procedure date)

AND involves any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure

AND the patient has at least **one** of the following:

1. Purulent drainage from a drain that is placed into the organ/space (for example, closed suction drainage system, open drain, T-tube drain, CT-guided drainage).
2. Organism(s) identified from fluid or tissue in the organ/space by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not active surveillance culture/testing (ASC/AST)).
3. An abscess or other evidence of infection involving the organ/space that is detected on gross anatomical or histopathologic exam, or imaging test evidence suggestive of infection.

AND

Meets at least one criterion for a specific organ/space infection site listed in Table attached. These criteria are found in the Surveillance Definitions for Specific Types of Infections

30-day Surveillance:

Category	Operative Procedure	Category	Operative Procedure
AAA	Abdominal aortic aneurysm repair	LAM	Laminectomy
AMP	Limb amputation	LTP	Liver transplant
APPY	Appendix surgery	NECK	Neck surgery
AVSD	Shunt for dialysis	NEPH	Kidney surgery
BILI	Bile duct, liver or pancreatic surgery	OVRY	Ovarian surgery
CEA	Carotid endarterectomy	PRST	Prostate surgery
CHOL	Gallbladder surgery	REC	Rectal surgery
COLO	Colon surgery	SB	Small bowel surgery
CSEC	Cesarean section	SPLE	Spleen surgery
GAST	Gastric surgery	THOR	Thoracic surgery
HTP	Heart transplant	THYR	Thyroid and/or parathyroid surgery
HYST	Abdominal hysterectomy	VHYS	Vaginal hysterectomy
KTP	Kidney transplant	XLAP	Exploratory laparotomy

90-day Surveillance:

Category	Operative Procedure
BRST	Breast surgery
CARD	Cardiac surgery
CBGB	Coronary artery bypass graft with both chest and donor site incisions
CBGC	Coronary artery bypass graft with chest incision only
CRAN	Craniotomy
FUSN	Spinal fusion
HER	Herniorrhaphy
HPRO	Hip prosthesis
KPRO	Knee prosthesis
PACE	Pacemaker surgery
PVBY	Peripheral vascular bypass surgery
VSHN	Ventricular shunt

Specific Sites of an Organ/Space SSI:

Category	Specific Site	Category	Specific Site
BONE	Osteomyelitis	MED	Mediastinitis
BRST	Breast abscess or mastitis	MEN	Meningitis or ventriculitis
CARD	Myocarditis or pericarditis	ORAL	Oral cavity infection (mouth, tongue, or gums)
DISC	Disc space infection	OREP	Deep pelvic tissue infection or other infection of the male or female reproductive tract
EAR	Ear, mastoid infection	PJI	Periprosthetic joint infection
EMET	Endometritis	SA	Spinal abscess/infection
ENDO	Endocarditis	SINU	Sinusitis
GIT	Gastrointestinal (GI) tract infection	UR	Upper respiratory tract, pharyngitis, laryngitis, epiglottitis
IAB	Intraabdominal infection, not specified elsewhere	USI	Urinary System Infection
IC	Intracranial infection	VASC	Arterial or venous infection
JNT	Joint or bursa infection	VCUF	Vaginal cuff infection
LUNG	Other infection of the lower respiratory tract		

Denominator:

All patients having any of the procedures included in the selected NHSN operative procedure category(s) are monitored for SSI. The Surgical Site Infection (SSI) form is completed for each SSI.

SSI Event Reporting Instructions

1. Infection present at time of surgery (PATOS)

- Must be documented at the start of or during the surgery
- Must be to the same depth as the SSI that is being attributed to the procedures (e.g., if a patient has evidence of an intraabdominal infection at the time of surgery and then later returns with a superficial or deep incisional SSI, so it NOT PATOS
- Previous infection does not need to meet NHSN definition but infection or abscess evidence does need to be noted
- Example:
    - ✓ Patient admitted with an acute abdomen.
    - ✓ Sent to OR for an exploratory laparotomy where there is a finding of an abscess due to ruptured appendix and an APPY is performed.
    - ✓ Patient returns two weeks later and meets criteria for an organ space IAB SSI.
    - ✓ This is PATOS SSI event
- Example:
    - ✓ Patient is admitted with a ruptured diverticulum.
    - ✓ In the OR note the surgeon documents that there are multiple abscesses in the intra-abdominal cavity.
    - ✓ Patient returns three weeks later and meets criteria for a superficial SSI.
    - ✓ This is NOT PATOS SSI event

2. Excluded organisms:

Community associated organisms (organisms belonging to the following genera: Blastomyces, Histoplasma, Coccidioides, Paracoccidioides, Cryptococcus and Pneumocystis) and/or organisms associated with latent infections (for example, herpes, shingles, syphilis, or tuberculosis) are excluded from meeting SSI criteria.

3. Attribution of SSI after multiple types of NHSN procedures are performed during a single trip to the OR:

- Procedure-associated HAIs are attributed to the procedure NOT the location
- 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.
- If more than one NHSN operative procedure 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 Selection Lists to select which operative procedure to report.

NHSN Principal Operative Procedure Category Selection List

Priority	Category	Abdominal Operative Procedures
1	LTP	Liver transplant
2	COLO	Colon surgery
3	BILI	Bile duct, liver or pancreatic surgery
4	SB	Small bowel surgery
5	REC	Rectal surgery
6	KTP	Kidney transplant
7	GAST	Gastric surgery
8	AAA	Abdominal aortic aneurysm repair
9	HYST	Abdominal hysterectomy
10	CSEC	Cesarean section
11	XLAP	Laparotomy
12	APPY	Appendix surgery
13	HER	Herniorrhaphy
14	NEPH	Kidney surgery
15	VHYS	Vaginal hysterectomy
16	SPLE	Spleen surgery
17	CHOL	Gall bladder surgery
18	OVRY	Ovarian surgery

4. Multiple tissue levels are involved in the infection:

The type of SSI (superficial incisional, deep incisional, or organ/space) reported must reflect the deepest tissue level where SSI criteria is met during the surveillance period.

- Report infection that involves the organ/space as an organ/space SSI, whether or not it also involves the superficial or deep incision sites.
- Report infection that involves the superficial and deep incisional sites as a deep incisional SSI.
- If an SSI started as a deep incisional SSI on day 10 of the SSI surveillance period and then a week later (day 17 of the SSI surveillance period) meets criteria for an organ space SSI, the date of event would be the date of the organ/ space SSI.

5. Attributing SSI when several procedures are performed on different dates:

If a patient has several operative procedures performed on different dates, attribute the SSI to the most recently performed operative procedure.

6. Attributing SSI to NHSN procedures that involve multiple primary incision sites:

If multiple primary incision sites of the same NHSN operative procedure become infected, only report as a single SSI, and assign the type of SSI (superficial incisional, deep incisional, or organ/space) that represents the deepest tissue level where SSI criteria is met at any of the involved primary incision sites during the surveillance period. Examples:

- If one laparoscopic incision meets criteria for a superficial incisional SSI and another meets criteria for a deep incisional SSI, only report one deep incisional SSI.
- If one or more laparoscopic incision sites meet criteria for superficial incisional SSI but the patient also has an organ/space SSI related to the laparoscopic procedure, only report one organ/space SSI.
- If an operative procedure is limited to a single breast and involves multiple incisions in that breast that become infected, only report a single SSI.
- In a colostomy formation or reversal (take down) procedure, the stoma and other abdominal incision sites are considered primary incisions. If both the stoma and

another abdominal incision site develop superficial incisional SSI, report only as one SSI (SIP).

7. Attributing SSI to NHSN procedures that have secondary incision sites:

- Certain procedures can involve secondary incisions (specifically the following, BRST, CBGB, CEA, FUSN, PVBY, REC, and VSHN).
- The surveillance period for all secondary incision sites is 30 days, regardless of the required deep incisional or organ/space SSI surveillance period for the primary incision site(s).
- Procedures meeting this designation are reported as only one operative procedure.
- For example:
  - ✓ A saphenous vein harvest incision site in a CBGB procedure is considered the secondary incision site. One CBGB procedure is reported, the saphenous vein harvest site is monitored for 30 days after surgery for SSI, and the chest incision is monitored for 90 days after surgery for SSI. If the patient develops an SSI of the leg site (such as a superficial incisional SSI) and an SSI of the chest site (such as a deep incisional SSI) two SSIs are reported.
  - ✓ A tissue harvest site (for example, Transverse Rectus Abdominis Myocutaneous [TRAM] flap) in a BRST procedure is considered the secondary incision site. One BRST procedure is reported, and if the secondary incision site gets infected, report as either SIS or DIS as appropriate.

8. SSI detected at another facility:

It is required that if an SSI is detected at a facility other than the one in which the operation was performed, SSI event is attributed to the facility in which the NHSN operative procedure is performed.

9. SSI following invasive manipulation/accession of the operative site:

An SSI will not be attributed if the following 3 criteria are ALL met:

- During the post-operative period the surgical site is without evidence of infection and,
- Invasive manipulation/accession of the site is performed for diagnostic or therapeutic purposes (for example, needle aspiration, accession of ventricular shunts, accession of breast expanders) and,
- Infection subsequently develops in a tissue level which was entered during the manipulation/accession.

Analysis of SSI

Measure	Calculation	Application
SSI Rates	$\frac{\text{The number of SSIs detected after a procedure}}{\text{Total number of that procedures examined}}$ X100	Procedure specific measure
SSI SIR	$\frac{\text{The number of observed SSIs}}{\text{The number of predicted SSIs}}$	Both procedure specific and summarized measure

SIR, standardized infection ratio

- SSI rates should be presented by operative procedure (for example, herniorrhaphy, gallbladder surgery, …etc) and by risk index category (0, 1, 2, and 3).
- SSI SIR can be presented for single procedures and can be summarized across multiple procedures, adjusting for differences in the incidence of infection between different procedure types.
- SSI SIR can be additionally summarized across different risk index categories, adjusting for differences in the incidence of infection between different risk index categories.

12. MDRO and CDI

Multidrug-Resistant Organism (MDROs)

MDROs are defined as microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents.

Gram NEGATIVE MDROs
1. CephR –Cephalosporin Resistant Klebsiella
2. CRE – Carbapenem Resistant Enterobacteriaceae
3. MDR Acinetobacter
4. MDR Klebsiella
5. MDR Pseudomonas
Gram POSITIVE MDROs
1. MRSA – Methicillin-Resistant Staphylococcus aureus
2. VRE – Vancomycin Resistant Enterococcus

Gram negative MDROs

Gram negative MDROs include the followings:

1. **CephR-Klebsiella:**

   Klebsiella oxytoca or Klebsiella pneumoniae non-susceptible (resistant or intermediate) to at least one cephalosporin agent (ceftazidime, cefotaxime, ceftriaxone, cefepime, ceftazidime/avibactam, or ceftolozane/tazobactam)

2. **Carbapenem resistant Enterobacteriaceae (CRE):**

   Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Klebsiella aerogenes or Enterobacter spp resistant to at least one carbapenem agent (imipenem, meropenem, doripenem, ertapenem, meropenem/vaborbactam, or imipenem/relebactam) OR by production of a carbapenemase (specifically, KPC, NDM, VIM, IMP, OXA-48) demonstrated using a recognized test (examples:

polymerase chain reaction, metallo-β-lactamase test, modified-Hodge test, Carba-NP).

3. **MDR Acinetobacter:** Any Acinetobacter spp. non-susceptible (resistant or intermediate) to at least one agent in 3 of following 6 antimicrobial classes:

Aminoglycosides: ✓ Amikacin ✓ Gentamicin ✓ Tobramycin	**Cephalosporins:** ✓ Cefepime ✓ Ceftazidime ✓ Cefotaxime ✓ Ceftriaxone	**β-lactam/ β-lactamase inhibitor combination:** ✓ Piperacillin/tazobactam
Carbapenems: ✓ Imipenem ✓ Meropenem ✓ Doripenem	**Fluoroquinolones:** ✓ Ciprofloxacin ✓ Levofloxacin	**Sulbactam:** ✓ Ampicillin/sulbactam

4. **MDR Klebsiella:** Any Klebsiella spp. non-susceptible (resistant or intermediate) to at least one agent in 3 of following 5 antimicrobial classes

Aminoglycosides: ✓ Amikacin ✓ Gentamicin ✓ Tobramycin	**Cephalosporins:** ✓ Cefepime ✓ Ceftazidime ✓ Cefotaxime ✓ Ceftriaxone	**β-lactam/ β-lactamase inhibitor combination:** ✓ Piperacillin/tazobactam
Carbapenems: ✓ Imipenem ✓ Meropenem ✓ Doripenem	**Fluoroquinolones:** ✓ Ciprofloxacin ✓ Levofloxacin	

5. **MDR Pseudomonas:** Any Pseudomonas spp. non-susceptible (resistant or intermediate) to at least one agent in 3 of following 5 antimicrobial classes

Aminoglycosides: ✓ Amikacin ✓ Gentamicin ✓ Tobramycin	**Cephalosporins:** ✓ Cefepime ✓ Ceftazidime ✓ Cefotaxime ✓ Ceftriaxone	**β-lactam/ β-lactamase inhibitor combination:** ✓ Piperacillin/tazobactam
Carbapenems: ✓ Imipenem ✓ Meropenem ✓ Doripenem	**Fluoroquinolones:** ✓ Ciprofloxacin ✓ Levofloxacin	

Gram positive MDROs

Gram positive MDROs include MRSA and VRE.

1. **MRSA:** Includes Staph. aureus that is resistant to oxacillin or cefoxitin or methicillin by standard susceptibility testing methods, or any laboratory finding of MRSA (e.g. PCR or other molecular testing)
2. **VRE:** Any Enterococcus spp. (Enterococcus faecalis, Enterococcus faecium or Enterococcus unspecified – not able to identify specie) that is resistant to vancomycin by standard susceptibility testing methods, or any laboratory finding of enterococcus sp. (PCR or other molecular testing)

Inclusions and Exclusions of the specimens:

Inclusion Criteria	*Exclusion Criteria*
Unique Blood Source: • An MDRO isolated from **blood** in a patient with NO prior positive blood culture for the same MDRO in ≤2 weeks (14 days or less), even across calendar months and different facility admissions • An MDRO isolated from **Non-blood Sample** in a patient with NO prior positive blood culture for the same MDRO in ONE month (30 days or less), even across calendar months and different facility admissions	**Duplicate MDRO Isolates:** • An MDRO isolated from **blood** in a patient with prior positive blood culture for the same MDRO in ≤2 weeks (14 days or less), even across calendar months and different facility admissions • An MDRO isolated from **Non-blood Sample** in a patient with prior positive blood culture for the same MDRO in ONE month (30 days or less), even across calendar months and different facility admissions
Clinical specimen: • Any specimen, obtained for clinical decision making, testing positive for an MDRO	**Surveillance (screening) specimen:** • Any sample collected as a part of active surveillance culture/testing (ASC/AST), i.e. screening or non-clinical decision

Categorization of MDRO by Presentation:

- **Community-Onset (CO):** Any specimen collected for clinical decision making tested positive from outpatient location or an inpatient location in the first 3 days of admission to the facility
- **Healthcare Facility-Onset (HO):** Any specimen collected for clinical decision making tested positive from inpatient location 4 days or more after admission to the facility

Categorization of MDRO by symptoms:

Infection	*Colonization*
• Infection is the entry and multiplication of organisms in the tissue of a host. • Infection may be clinical or subclinical and may not produce identifiable disease. • However, it is usually accompanied by measurable host response(s), either through the appearance of specific antibodies or through cell-mediated reaction(s)	• The multiplication of a microorganism at a body site or sites without any overt clinical expression or detected immune reaction in the host at the time that the organism is isolated. • Colonization may or may not be a precursor of infection. • Colonization may be a form of carriage and a potential transmission source. • Commensal or normal flora are microorganisms present in or on a body site without causing clinical infection.

Difference in timing of HAI and MDRO surveillance

Admission days	*HAI*	*Present on admission*	*MDRO-Community-onset*	*MDRO-Healthcare-onset*
1	Free during the first 2 days	Signs of infection in the first 2 days	Clinical specimen collected in the first 3 days is positive	Clinical specimen collected in the first 3 days is negative
2				
3	Signs of infection on or after 3rd day	Signs of infection may or may not continue on or after 3rd day		
4			Clinical specimen collected after 3rd day is positive or negative	Clinical specimen collected after 3rd day is positive
5				

Clostridium difficile Infection (CDI):

A positive laboratory test result for C. difficile toxin A and/or B, (includes molecular assays [PCR] and/or toxin assays) tested on an unformed stool specimen (must conform to the container) OR A toxin-producing C. difficile organism detected by culture or other laboratory means performed on an unformed stool sample (must conform to the container).

Duplicate C. difficile:

- Any C. difficile toxin-positive laboratory result from the same patient and location, following a previous C. difficile toxin-positive laboratory result within 14 days even across calendar months and readmissions to the same facility location.
- There should be 14 days with no C. difficile toxin-positive laboratory result for the patient and specific location before another C. difficile LabID Event is entered into HESN plus for the patient and location.
- The date of specimen collection of a previously submitted C. difficile LabID Event is considered Day 1.

Categorization of CDI by Occurrence:

- **Incident CDI Assay:** Any positive test for CDI from a specimen obtained >8 weeks after the most recent positive test for CDI (or with no previous positive test for CDI documented) for that patient.
- **Recurrent CDI Assay:** Any positive test for CDI from a specimen obtained >2 weeks and ≤8 weeks after the most recent positive test for CDI for that patient.

Categorizing of CDI by Presentation:

- **Community-Onset (CO):** Any positive test for CDI collected in an outpatient location or an inpatient location ≤3 days after admission to the facility and the patient was not previously discharged from an inpatient location within the same facility within 4 weeks prior to current date of specimen collection.
- **Community-Onset Healthcare Facility-Associated (CO-HCFA):** Any positive test for CDI collected from a patient who was discharged from the facility within 4 weeks prior to current date of stool specimen collection. The previous discharge

must have been from an inpatient location within the same facility (in other words, an outpatient visit does not qualify for this definition).

- **Healthcare Facility-Onset (HO):** Any positive test for CDI collected 4 days or more after admission to the facility.

MDRO/CDI Reporting Methods:

1. **Facility-wide by location:**
   - Report MDRO LabID event and denominator for each location separately and cover all locations in a facility.
   - Must monitor All specimen sources.
   - This reporting method requires the most effort but provides the most detail for local and national statistical data.
2. **Selected locations:**
   - Report MDRO LabID event and denominator from one or more specific locations within a facility.
   - Exception: inpatient rehabilitation units, 24-hour observation, and emergency department
   - Must monitor All specimen sources.
   - This reporting method is ideal for use during targeted prevention programs.
3. **Overall facility-wide:**
   - Report MDRO LabID event and denominator from all inpatient locations AND separately for outpatient locations (emergency department, and 24-hour observation locations)
   - Must monitor All specimen sources.
   - Exception: rehabilitation facility and inpatient psychiatric
4. **Overall facility-wide: Blood Specimens Only**
   - Report MDRO LabID event and denominator from all inpatient locations AND separately for outpatient locations (emergency department, and 24-hour observation locations)
   - Blood Specimens Only.
   - Exception: rehabilitation facility and inpatient psychiatric

MDRO/CDI Reporting Methods:

1. **Laboratory-Identified (LabID) Event:**
    - Include all non-duplicate MDRO isolates from any specimen source and unique blood source MDRO isolates
    - Allows laboratory testing data to be used without clinical evaluation of the patient
    - Provides proxy infection measures of MDRO and/or C. difficile exposure burden, infection burden, and healthcare acquisition
    - ONLY for positive laboratory results (e.g., cultures) that are collected for "clinical" purposes (i.e., for diagnosis and treatment).
2. **Infection Surveillance Reporting:**
    - Enables users to utilize HAI definitions for identifying and reporting infections associated with MDROs and/or C. difficile.
    - Surveillance must occur from at least one patient care area and requires active, patient-based, prospective surveillance of the chosen MDRO(s) and/or C. difficile infections (CDIs) by a trained Infection Preventionists (IP).
    - Infection Surveillance can occur in any inpatient location where such infections may be identified and where denominator data can be collected,
    - Surveillance for all types of HAIs with MDRO selected for monitoring in at least one location in the healthcare facility
    - No active surveillance culture/testing (ASC/AST) results are to be included in this reporting of individual results.

	LabID *MDRO*	**LabID** *CDI*	**Infection**
1. Facility-wide by location	YES	YES	
2. Selected locations	YES	YES	YES
3. Overall facility-wide	YES	YES	
4. Overall facility-wide: Blood Specimens Only	YES		

Active surveillance culture/testing (ASC/AST)

- It is a testing that is intended to identify the presence/carriage of microorganisms for the purpose of instituting or discontinuing isolation precautions
- Can be done in inpatient locations, especially ICUs
- Can target one or more organisms, with the most common being MRSA and/or VRE
- **Patient eligibility for ASC/AST**
  - ✓ All patients in the chosen unit irrespective of the organism history or
  - ✓ All patients in the chosen unit who have NO documented positive infection or colonization of the target organism (such as MRSA or VRE) during the previous 12 months.
- **Timing of ASC/AST**
  - ✓ At admission: Specimens for AST are obtained within 3 days from admission
  - ✓ At both admission and discharge: Specimens for AST are obtained within 3 days from admission and at the time of discharge/transfer in patients who stay of more than 3 days. Discharge/transfer AST should include all discharges (including discharges from the facility or to other wards or deaths) and can include the most recent weekly AST if performed more than 3 days after admission to the patient care location. Discharge/transfer AST should not be performed on patients who tested positive on AST admission.

Admission specimens	Discharge/transfer specimens	Need for isolation at admission	Organism acquisition during stay
Negative	Not done	No	Cannot be assessed
Negative	Negative	No	No
Negative	Positive	No	Yes
Positive	Should not be done	Yes	Not applicable

Analysis of MDRO

Measure	Calculation	Application
MDRO infection incidence rate	$\frac{\text{The number of infections of a certain MDRO type}}{\text{The number of patient days}} \times 1000$	Location-specific measure
MDRO- LabID Event	$\frac{\text{Laboratory-identified MDRO Events}}{\text{The number of patient days, admissions, or encounters}}$	Location-specific measure

MDRO-Infection Surveillance:

- Rate is then stratified by time (e.g., month, quarter, etc.) and patient care location.

MDRO-Laboratory-Identified (LabID) Event:

- These data are used to calculate four distinct proxy measures including:
  - ✓ Admission prevalence rate and
  - ✓ Overall prevalence rate based on clinical testing (measures of exposure burden),
  - ✓ MDRO bloodstream infection incidence rate (a measure of infection burden), and
  - ✓ Overall MDRO infection/colonization incidence rate (a measure of healthcare acquisition).
- LabID Events proxy measures are categorized as healthcare facility-onset (4 days or more days after admission to the facility) versus community-onset (≤ 3 days after admission to the facility).

13. Bundles

Preventive bundle:

A bundle is a structured way of improving the processes of care and patient outcomes

It is a small, straightforward set of evidence-based practices, generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes.

Type of preventive bundle:

- Central line insertion bundle
- Central line maintenance bundle
- Adult ventilator bundle
- Pediatric/neonatal ventilator bundle
- Urinary catheter bundle
- Surgical bundle
- Dialysis bundle

14.1 Central Line Insertion Bundle

Central line bundle:

It is a group of evidence-based interventions for patients with intravascular central catheters that, when implemented together, result in better outcomes (reduce BSI) than when implemented individually.

Objective:

- To reduce the risk of developing CLABSI

Setting:

- Inpatient areas where patients with one or more central lines are hospitalized
- However, the central line bundle was designed to apply in ICUs only (where temporary central line is common)

Sampling:

- Sampling is allowed at the level of days but not the patients.
- Therefore, review all patients in a specific unit with central line for one or two days a week.

Components of central line insertion bundle:

1- Hand hygiene
2- Maximal barrier precautions
3- Chlorhexidine skin antisepsis
4- Optimal catheter site selection, with subclavian vein as the preferred site for non-tunneled catheters
5- Ultrasound guidance to place central venous catheters

1. Hand hygiene

Washing hands or using an alcohol-based waterless hand cleaner helps prevent contamination of central line sites and resultant bloodstream infections. When caring for central lines, indications for hand hygiene include:

- Before and after palpating catheter insertion sites (Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained.)
- Before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter
- When hands are visibly soiled or if contamination is suspected
- Before and after any invasive procedures are done
- In between the patients
- Before donning and after removing gloves

2. Maximal barrier precautions

A key change to decrease the likelihood of central line infections is to apply maximal barrier precautions in preparation for line insertion.

For the operator placing the central line and for those assisting in the procedure, maximal barrier precautions mean strict compliance with hand hygiene and wearing a cap, mask, sterile gown, and sterile gloves. The cap should cover all hair and the mask should cover the nose and mouth tightly. These precautions are the same as for any other surgical procedure that carries a risk of infection.

For the patient, applying maximal barrier precautions means covering the patient from head to toe with a sterile drape, with a small opening for the site of insertion.

3. Chlorhexidine skin antisepsis

Chlorhexidine skin antisepsis has been proven to provide better skin antisepsis than other antiseptic agents such as povidone-iodine solutions.

The technique, for most kits, is as follows:

- Prepare skin with antiseptic/detergent chlorhexidine 2% in 70% isopropyl alcohol.
- Pinch wings on the chlorhexidine applicator to break open the ampule (when ampule is included). Hold the applicator down to allow the solution to saturate the pad.
- Press sponge against skin, and apply chlorhexidine solution using a back-and-forth friction scrub for at least 30 seconds. Do not wipe or blot.
- Allow antiseptic solution time to dry completely before puncturing the site (~ 2 minutes).
- Type of antiseptic solution:
    - Birth weight of ≤1,500 gm or aged less <4 weeks are using 2% aqueous chlorhexidine
    - Birth weight of >1,500 gm and aged less >4 weeks are using 2% chlorhexidine in alcohol as adults and pediatrics.
- **However, skin maturation should be assessed by the treating physician before chlorhexidine use.**

4. Optimal catheter site selection, with avoidance of using the femoral vein for central venous access in adult patients

- Several non-randomized studies show that the subclavian vein site is associated with a lower risk of CLABSI than the internal jugular vein.
- The femoral site is associated with greater risk of infection in adults; specially in overweight adult patients.
- The bundle requirement for optimal site selection suggests that other factors (e.g., the potential for mechanical complications, the risk of subclavian vein stenosis, and catheter-operator skill) should be considered when deciding where to place the catheter.
- In these instances, teams are considered compliant with the bundle element as long as they use a rationale construct to choose the site.
- The physician must determine the risks and benefits of using any vein.
- Absolute contraindications to subclavian approach
  - ✓ Trauma to the ipsilateral clavicle, anterior proximal rib, or subclavian vessels
  - ✓ Anticoagulation therapy or bleeding disorder (Inability to do direct pressure to stop bleeding)
  - ✓ Distorted local anatomy (e.g., vascular injury, prior surgery, radiation history)
  - ✓ Infection at insertion site
  - ✓ Inexperienced operator
  - ✓ Uncooperative patient
  - ✓ Patients with higher risks for pneumothorax or inability to tolerate pneumothorax

5. Ultrasound guidance to place central venous catheters

- High-quality evidence suggested that the use of ultrasound guidance to place central venous catheters can reduce the number of cannulation attempts and mechanical complications.
- Ultrasound guidance should only be implemented when the ultrasound devices are available and the staff are fully trained in its technique.
- Steps of performing ultrasound-guided central venous catheter placement:

1. Identify anatomy of the insertion site and localization of the vein.
    - Identify vein, artery, anatomic structures
    - Check for anatomic variations
    - Use short axis (transverse; A) and long axis (longitudinal; B) view
    - Perform this step before prepping and draping of the puncture site
2. Confirm patency of the vein.
    - Use compression ultrasound to exclude venous thrombosis
    - Use color Doppler imaging and Doppler flow measurements to confirm the patency of the vein and to quantify blood flow
3. Use real-time US guidance for puncture of the vein.
    - Use an aseptic approach
    - Use a short axis/out-of-plane (A) or a long axis/in-plane (B) approach
    - Try to constantly identify the tip of the needle during the needle approach to the vein and puncture of the vein
4. Confirm needle position in the vein.
    - Confirm that the needle tip is placed centrally in the vein before approaching the guide wire
5. Confirm wire position in the vein.

- Confirm the correct position of the guide wire in a short axis (A) and a long axis (B) view

6. Confirm catheter position in the vein.
   - Confirm the correct position of the central venous catheter in the vein in a short axis (A) and a long axis (B) view

Analysis of data:

$$\text{Central line bundle compliance} = \frac{\text{Total number of patients with all compliant applicable bundle components}}{\text{Total number of patients reviewed for the bundle compliance}} \times 100$$

14.2 Central line Maintenance Bundle

Central line Maintenance Bundle:

It is a group of evidence-based interventions for patients with intravascular central catheters that, when implemented together, result in better outcomes (reduce CLABSI) than when implemented individually.

Objective:

- To reduce the risk of developing CLABSI

Setting:

- Inpatient areas where patients with one or more central lines are hospitalized
- However, the central line bundle was designed to apply in ICUs only (where temporary central line is common)

Sampling:

- Sampling is allowed at the level of days but not for the patients.
- Therefore, review all patients in a specific unit with central line for one or two days a week

Components of central line maintenance bundle:

1. **Hand Hygiene and aseptic technique**
   - Hand hygiene before catheter access/manipulation.
   - Scrub the access port with an appropriate antiseptic (chlorhexidine, povidone iodine, or 70% alcohol) and access the port only with sterile devices.
   - Bathe ICU patients >2 months of age with a chlorhexidine preparation on a daily basis.
2. **Daily review / assessment of catheter necessity** with prompt removal of unnecessary lines.
3. **Proper dressing choice:**

- Use chlorhexidine-impregnated dressings only for adult patients (but not pediatric patients) with short term non-tunneled catheters.
- Use transparent semipermeable dressing
- Use gauze only if the site is bleeding or oozing or the patient is diaphoretic

4. Proper frequency of dressing change:

- Replace transparent dressing every 7 days (except in those pediatric patients in which the risk for dislodging the catheter may outweigh the benefit of changing the dressing)
- Replace gauze dressing every 2 days
- Replace immediately dressing that becomes damp, loosened, or visibly soiled

5. Proper replacement of administrative sets:

- In patients not receiving blood, blood products or fat emulsions, replace administration sets that are continuously used, including secondary sets and add-on devices no more frequently than every 4 days, but at least every 7 days.
- If blood or blood products or fat emulsions are administered, change tubing within 24 hours of initiating the infusion.
- If propofol is administered, replace tubing used to administer propofol infusions every 6 or 12 hours or when the vial is changed

Analysis of data:

$$\text{Central line maintenance bundle compliance} = \frac{\text{Total number of patients with all compliant applicable bundle components}}{\text{Total number of patients reviewed for the bundle compliance}} \times 100$$

14.3 Adult Ventilator Bundle

Ventilator bundle:

A ventilator bundle is a group of evidence-based interventions for adult patients with ventilators that, when implemented together, result in better outcomes (reduce VAE/PVAP) than when implemented individually.

Objective:

- To reduce the risk of developing VAE/PVAP

Setting:

- Inpatient areas where adult patients with ventilator are hospitalized

Sampling:

- Sampling is allowed at the level of days but not the patients.
- Therefore, review all patients in a specific unit with ventilator for one or two days a week

Components of adult ventilator bundle:

1- Elevation of the head of the bed to between 30 and 45 degrees
2- Daily “sedative interruption” & daily assessment of readiness to extubate
3- Peptic ulcer disease (PUD) prophylaxis
4- Deep venous thrombosis (DVT) prophylaxis (unless contraindicated)
5- Daily oral care with chlorhexidine

1. Elevation of the head of the bed

- Elevation of the head of the bed is an integral part of the ventilator bundle and has been correlated with a reduction in the rate of ventilator-associated pneumonia.
- The recommended elevation is 30-45 degrees. This help to
  - ✓ Reduce potential for aspiration
  - ✓ Potential to improve ventilation
- However, elevation of the head of the bed issues and concerns
  - ✓ It is uncomfortable for the patient
  - ✓ Causes the patient to slide down in bed
  - ✓ Potential for skin-shearing

2. Daily sedative interruption and daily assessment of readiness to extubate

- Using daily sedative interruptions and assessing the patient’s readiness to extubate are an integral part of the ventilator bundle and have been correlated with reduction in the rate of ventilator-associated pneumonia.
- Include this intervention on the bundle form for initiation and weaning of mechanical ventilation, delivery of tube feedings, and provision of oral care.
- Seven distinct complications associated with mechanical ventilation and critical illness were identified:
  - ✓ Ventilator-associated pneumonia

- ✓ Upper gastrointestinal hemorrhage
- ✓ Bacteremia
- ✓ Barotrauma
- ✓ Venous thromboembolic disease
- ✓ Cholestasis
- ✓ Sinusitis requiring surgical intervention

3. Peptic Ulcer Disease (PUD) Prophylaxis

- Stress ulcerations are the most common cause of gastrointestinal bleeding in intensive care unit patients, and the presence of gastrointestinal bleeding due to these lesions is associated with a five-fold increase in mortality compared to ICU patients without bleeding.
- Applying peptic ulcer disease prophylaxis is a necessary intervention in critically ill patients.
- Prophylactic therapy for stress ulceration has been the potential for increased risk of health care associated pneumonia.
  - ✓ Agents that raise gastric pH may promote the growth of bacteria in the stomach, particularly gram-negative bacilli that originate in the duodenum.
  - ✓ Esophageal reflux and aspiration of gastric contents along the endotracheal tube may lead to endobronchial colonization and pneumonia or may precipitate pneumonia due to the decreased bacterial killing in the low-acid environment. Elevating the head of the bed should reduce the amount of aspiration patients have.
- PUD prophylaxis in the bundle is that provided with medications; H2 blockers are preferred over sucralfate. Proton pump inhibitors may be efficacious, and an alternative to sucralfate or H2 antagonist.

4. Deep Venous Thrombosis (DVT) Prophylaxis

- Applying deep venous thrombosis prophylaxis is an appropriate intervention in all patients who are sedentary.
- The risk of venous thromboembolism is reduced if antithrombotic and thrombolytic therapy is recommended for the prophylaxis of patients undergoing surgery, trauma patients, acutely ill medical patients, and patients admitted to the intensive care unit.
- While it is unclear if there is any association between DVT prophylaxis and decreasing rates of PVAP, our experience is that PVAP rates decreased most dramatically in hospitals where all elements of the ventilator bundle were implemented, including this one. The intervention remains excellent practice in the general care of ventilated patients.
- Important considerations include that the risk of bleeding may increase if anticoagulants are used to accomplish prophylaxis.
- When prophylactic anticoagulation cannot be used because of high risk of bleeding, sequential compression devices may be used. Often, sequential compression devices are not applied reliably to patients when they go to or return from procedures negating their effectiveness.

5. Daily Oral Care with appropriate antiseptic solution

- Dental plaque biofilms are colonized by respiratory pathogens in mechanically ventilated patients.
- Dental plaque develops in patients that are mechanically ventilated because of the lack of mechanical chewing and the absence of saliva, which minimizes the development of biofilm on the teeth.
- Dental plaque can be a significant reservoir for potential respiratory pathogens that cause PVAP.
- Daily Oral Care with appropriate antiseptic solution is recommended.

Analysis of data:

$$\text{Ventilator bundle compliance} = \frac{\text{Total number of patients with all compliant bundle components}}{\text{Total number of patients reviewed for the bundle compliance}} \times 100$$

14.4 Pediatric/Neonatal Ventilator Bundle

Ventilator bundle:

Ventilator bundle is a group of evidence-based interventions for pediatric or neonatal patients with ventilator that, when implemented together, result in better outcomes (reduce-PedVAE) than when implemented individually.

Objective:

- To reduce the risk of developing PedVAE

Setting:

- Inpatient areas where pediatric or neonatal patients with ventilator are hospitalized

Sampling:

- Sampling is allowed but at the level of days not the patients.
- Therefore, review all patients in a specific unit with ventilator for one or two days a week

Components of pediatric/neonatal ventilator bundle:

1- Hand hygiene
2- Semi-recumbent position
3- Mouth rinse with an appropriate solution
4- Appropriate ventilator circuit care
5- Daily assessment of readiness to extubate

1. Hand hygiene

- Hand hygiene before contact with the ventilator

2. Semi-recumbent position

- Elevation of the head of the bed to keep the patient in semi-recumbent position is necessary to reduce the risk of aspiration of gastric content to the airway.
- The recommended elevation is 15-30 degrees for neonates and 30-45 degrees for infants or older children.

3. Mouth rinse with appropriate solution

- Colonization of the oral cavity leads to colonization of the tracheal/tracheostomy tube and the lungs by bacteria
- Mouth rinse with appropriate solution is recommended every 2 to 4 hours with
  - ✓ Pediatric patients: Normal saline or sterile water
  - ✓ Neonatal patients: Maternal colostrum (if available) or sterile water

4. Appropriate ventilator circuit care

- Limit the change of the ventilator circuit only when visibly soiled or more than 1 week
- Draining ventilator condensate away
  - ✓ Keep the ventilator tubing clear of condensation.
  - ✓ Drain ventilator condensate away every 4 hours and before repositioning.
  - ✓ Ensure proper sterilization of reusable respiratory care equipment, using sterile water in humidification system, and periodic drainage of condensate from the breathing circuit, and hand hygiene before and after contact with respiratory equipment

5. Daily assessment of readiness to extubate

- Daily assessment of readiness to extubate is recommended to minimize ventilator days

- However, daily “sedative interruption” is not recommended in pediatric and neonatal patients due to high risk of unplanned extubation

Analysis of data:

$$\text{Ventilator bundle compliance} = \frac{\text{Total number of patients with all compliant bundle components}}{\text{Total number of patients reviewed for the bundle compliance}} \times 100$$

14.5Urinary Catheter Bundle

Urinary catheter bundle:

Urinary catheter bundle is a group of evidence-based interventions for patients with urinary catheter that, when implemented together, result in better outcomes (reduce CAUTI) than when implemented individually.

Objective:

- To reduce the risk of developing CAUTI

Setting:

- Inpatient areas where patients with urinary catheter are hospitalized
- Implementation of these four components of urinary catheter bundle requires a multidisciplinary approach involving physicians, nurses, leaders, and experts in infection prevention and urological care.

Sampling:

- Sampling is allowed at the level of days but not the patients.
- Therefore, review all patients in a specific unit with urinary catheter for one or two days a week

Components of urinary catheter bundle:

1- Avoid unnecessary urinary catheters

2- Insert catheter using aseptic technique

3- Maintain catheters based on recommended guidelines (daily care)

4- Review catheter necessity daily and remove promptly

1. Avoid unnecessary urinary catheters

- No invasive device should ever be used unless absolutely necessary, including urinary catheters.
- Following are the indications for placement of urinary catheters:
  - ✓ Perioperative use for selected surgical procedures
  - ✓ Urine output monitoring in critically ill patients
  - ✓ Management of acute urinary retention and urinary obstruction
  - ✓ Assistance in pressure ulcer healing for incontinent patients
  - ✓ As an exception, at patient request to improve comfort (SHEA-IDSA) or for comfort during end of life care (CDC)
- Perioperative use for selected surgical procedures
  - ✓ Patients undergoing urologic surgery or other surgery on contiguous structures of the genitourinary tract
  - ✓ Anticipated prolonged duration of surgery (catheters inserted for this reason should be removed in post-anesthesia care unit)
  - ✓ Patients anticipated to receive large-volume infusions or diuretics during surgery
  - ✓ Need for intraoperative monitoring of urinary output
- Alternatives to indwelling catheters include the following:
  - ✓ External condom catheters for male patients without urinary retention or bladder outlet obstruction have been shown to have lower risk of bacteriuria or symptomatic UTI. Such catheters are reported by patients to be more comfortable and limit mobility less than indwelling catheters.
  - ✓ Intermittent catheterization several times per day may have the same or lower risk of infection, yet provide the patient with greater mobility and ensure an indwelling catheter is not left in place longer than necessary.

- Placement of catheters for convenience should be avoided at all times, and nursing personnel should be fully educated about all risks associated with catheters, including infections, decreased mobility, and urethral trauma. Patient preference and comfort is an important consideration.

2. Insert urinary catheters using aseptic technique

Make sure that the catheter is inserted only by trained personnel following aseptic technique. Note the following basic elements for insertion:

- Utilize appropriate hand hygiene practice, immediately before insertion of the catheter.
- Insert catheters using aseptic technique and sterile equipment, by using:
  - ✓ Gloves, a drape, and sponges;
  - ✓ Sterile or antiseptic solution for cleaning the urethral meatus; and
  - ✓ Single-use packet of sterile lubricant for insertion.
- Use appropriate technique for catheter insertion
- Use as small a catheter as possible that is consistent with proper drainage, to minimize urethral trauma.

A checklist may be a helpful tool for staff at the time of insertion and may also serve as a data collection tool to assess compliance.

Education and training of staff are fundamental. Organizations should train and verify competency of all clinical staff (nurses, physicians, residents, etc.) who may insert urinary catheters.

3. Maintain catheters based on recommended guidelines

- Appropriate hand hygiene practices are a basic standard of care and should be followed before and after any patient care activity. Standard precautions, including the use of gloves as appropriate, should be used during manipulation of the catheter site or apparatus. Catheter maintenance can be classified in two general categories: routine maintenance and practices that should be avoided.
- Routine maintenance includes
  - ✓ Maintain a sterile, continuously closed drainage system.
  - ✓ Keep catheter properly secured to prevent movement and urethral traction.
  - ✓ Keep collection bag below the level of the bladder at all times.
  - ✓ Maintain unobstructed urine flow.
  - ✓ Empty collection bag regularly, using a separate collecting container for each patient, and avoid allowing the draining spigot to touch the collecting container.
  - ✓ Routine hygiene (e.g., cleansing of the meatal surface during daily bathing) is appropriate. Do not clean the periurethral area with antiseptics to prevent CAUTI while the catheter is in place.
  - ✓ Collection of urine samples should be done by aspirating urine from the needleless sampling port with a sterile syringe/cannula.
- Some practices actually increase the risk of infection or other complications and should be avoided:
  - ✓ Irrigating catheters, except in cases of catheter obstruction;
  - ✓ Disconnecting the catheter from the drainage tubing;
  - ✓ Replacing catheters routinely (in the absence of obstruction or infection); and
  - ✓ Use aseptic technique to replace the collection system.
- Educating all staff and physicians about practices that should occur routinely and those that should be avoided is a fundamental first step.

4. Review urinary catheter necessity daily and remove promptly

- “The duration of catheterization is the most important risk factor for development of infection.”
- If use of an indwelling catheter is necessary, the most important strategy is removing the catheter as soon as possible.
- Daily review of catheter necessity should be conducted for all patients with urinary catheters.

Analysis of data:

$$\text{Urinary catheter bundle compliance} = \frac{\text{Total number of patients with all compliant applicable bundle components}}{\text{Total number of patients reviewed for the bundle compliance}} \times 100$$

14.6 Surgical bundle

Surgical bundle:

The surgical bundle is a group of evidence-based interventions for patients undergoing surgery that, when implemented together, result in better outcomes (reduce SSI) than when implemented individually.

Objective:

To reduce the risk of developing SSI

Setting:

Inpatient or outpatient areas where patients are undergoing surgeries

Sampling:

- Sampling is allowed at the level of procedures

Number of surgeries done	Number of surgical bundle forms
>555	20% (maximum 111 form)
140-555	20%
28-140	Minimum 28 forms
<28	No sampling, review all

Components of Surgical bundle:

1- Appropriate use of prophylactic antibiotics;
   - Selection
   - Timely administration
   - Timely discontinuation

2- Appropriate hair removal

3- Immediate postoperative control of blood-glucose levels in all patients

4- Maintain normothermia during the perioperative period.

5- Use appropriate antiseptic solution

1. Appropriate use of prophylactic antibiotics

- **Appropriate antibiotic selection**

  Prophylactic antibiotic selection for surgical patients consistent with national guidelines. See MOH list of antibiotics for surgical prophylaxis

- **Timely administration**
  - ✓ Prophylactic antibiotic received within 1 hour prior to surgical incision. Superior efficacy is observed if prophylactic antibiotic is administered in less than half an hour.
  - ✓ Due to the longer infusion time required for Vancomycin and fluoroquinolones, it is acceptable to start these antibiotics within 2 hours prior to incision
  - ✓ A single dose of antibiotics is considered sufficient for most procedures.
  - ✓ Repeat doses are indicated for procedures lasting more than 4 hours (2 half-lives antimicrobial of agents) or those with significant blood loss (>1,500 mL).
  - ✓ Always give at least a full therapeutic dose of antibiotic.
  - ✓ Increase dosing of prophylactic antimicrobial agent for morbidly obese patients. Adjust dosing based on patient weight

- **Timely discontinuation**
  - ✓ Prophylactic antibiotics should be discontinued after incisional closure in the operating room
  - ✓ Some guidelines suggest stopping the antimicrobial agents within 24 hours of surgery, but this doesn't add benefits more than stopping after incisional closure
  - ✓ Actually, antibiotics given after closure contribute to increased antimicrobial resistance and increased risk of Clostridium difficile infection and acute kidney injury

2. Appropriate Hair Removal

- Do not remove unless hair will interfere with the operation; if hair removal is necessary, remove outside of the operating room by clipping.
- The use of razors prior to surgery increases the incidence of wound infection when compared to clipping, depilatory use, or no hair removal at all.
- Staff must be trained in the proper use of clippers because an untrained user can damage the skin.

3. Immediate postoperative control of blood-glucose levels in all patients

- The degree of hyperglycemia in the postoperative period is correlated with the rate of SSI in patients undergoing major cardiac surgery.
- Maintain postoperative blood-glucose level between 110 and 150 mg/dl in each of the first two postoperative days.
- Glucose control postoperatively should target all patients especially those with diabetes.

4. Maintain normothermia during the perioperative period

- For procedures not requiring hypothermia, maintain normothermia (temperature >35.5°C) during the perioperative period
- Studies showed the benefits of both preoperative and intraoperative warming in reducing SSI rates and intraoperative blood loss
- Preoperative normothermia may be most beneficial; patients who received 30 minutes of preoperative warming had lower intraoperative hypothermia rates.
- Patients who are hypothermic at the end of surgery may remain hypothermic for up to 5 hours. Although there is no standardized duration of postoperative warming, one study used 2 hours of postoperative warming and showed reduced rates of SSI.

5. Use appropriate antiseptic solution

Patient preparation:

- The most effective antiseptic combination is chlorhexidine-alcohol and to a lesser extent povidone-iodine-alcohol.
- Preoperative skin preparation using alcohol-containing antiseptic skin agents.

- Preoperative vaginal preparation using alcohol-containing antiseptic vaginal preparation agents for patients undergoing cesarean delivery or hysterectomy.

Surgeon preparation:

- Use appropriate antiseptic agent to perform preoperative surgical scrub.
- For most products, scrub the hands and forearms for 2–5 minutes.

Analysis of data:

$$\text{Surgical bundle compliance} = \frac{\text{Total number of patients with all compliant bundle components}}{\text{Total number of patients reviewed for the bundle compliance}} \text{ X100}$$

14.7 Dialysis bundle

Hemodialysis bundle:

The tool can be used by the staff of hemodialysis facilities to help guide their practices.

Objective:

- To reduce the risk of developing bacteremia

Setting:

- Outpatient hemodialysis facilities.

Sampling:

- Sampling is allowed at the level of days but not the patients.
- Review all patients with dialysis access in a specific hemodialysis unit for one or two days a week.

Components of hemodialysis bundle for catheter:

1- Appropriate hemodialysis catheter connection

2- Appropriate hemodialysis catheter disconnection

3- Appropriate hemodialysis catheter exit site care

4- Appropriate dialysis station routine disinfection

5- Appropriate hemodialysis injectable medication preparation

6- Appropriate hemodialysis injectable medication administration

Components of hemodialysis bundle for fistula/graft:

1- Appropriate arteriovenous fistula/graft cannulation

2- Appropriate arteriovenous fistula/graft decannulation

3- Appropriate dialysis station routine disinfection

4- Appropriate hemodialysis injectable medication preparation

5- Appropriate hemodialysis injectable medication administration

Appropriate hemodialysis catheter connection

- Perform hand hygiene
- Don proper PPE (mask with face shield or mask with goggles, plus gown & gloves)
- Provide a mask for the patient
- Scrub dialysis catheter hub and lumens using appropriate disinfectant (chlorhexidine >0.5% with/or 70% isopropyl alcohol) for the recommended time duration (10-15 seconds) and allow to dry before each access.
- Connect catheter to blood lines aseptically
- Attach new caps aseptically whenever remove

Appropriate hemodialysis catheter disconnection

- Perform hand hygiene
- Don proper PPE (mask with face shield or mask with goggles, plus gown & gloves)
- Provide mask for the patient
- Scrub catheter hub with appropriate disinfectant (chlorhexidine >0.5% with/or 70% isopropyl alcohol) and allow to dry
- Disconnect catheter from blood lines aseptically
- Discard tubing in a leak-proof container

Appropriate hemodialysis catheter exit site care

- Perform hand hygiene
- Apply skin antiseptic
- Allow skin antiseptic to dry
- Apply dressing aseptically

Appropriate arteriovenous fistula/graft cannulation

- Perform hand hygiene
- Don proper PPE (mask with face shield or mask with goggles, plus gown & gloves)
- Clean site with 2% Chlorhexidine gluconate wipes or Soap and water
- Apply appropriate skin antiseptic (chlorhexidine >0.5%, 70% isopropyl alcohol or 10% povidone iodine) & allow it to dry
- Do not contaminate needle insertion site (after antisepsis)
- Insert needles & connect to blood lines aseptically

Appropriate arteriovenous fistula/graft decannulation

- Perform hand hygiene
- Don proper PPE (mask with face shield or mask with goggles, plus gown & gloves)
- Disconnect from blood lines aseptically
- Discard tubing in a leak-proof container
- Wear clean gloves (patient and/or staff) to compress site
- Remove needles aseptically
- Apply clean gauze/bandage to site

Appropriate dialysis station routine disinfection

- Don proper PPE (as per indication but at least use gloves)
- Ensure that the patient has left the dialysis station before cleaning
- Discard all single-use supplies, clean and disinfect reusable equipment
- Nursing: Clean and disinfect dialysis station (dialysis machine and bedside table)
- Housekeeping: Clean and disinfect dialysis chair or bed (rails, armrests & mattresses)

Appropriate hemodialysis injectable medication preparation

- Perform hand hygiene
- Prepare medications in clean designated areas
- Inspect all vials
- Prepare medications using aseptic techniques
- Use new needle and new syringe to enter all vials
- Discard all single dose vial(s)
- Discard or properly store all multi dose vial(s)

Appropriate hemodialysis injectable medication administration

- Perform hand hygiene (before and after)
- Use proper PPE (gloves)
- Properly transport medication to patient station
- Disinfect injection port with appropriate antiseptic
- Administer medications using aseptic techniques
- Discard syringe at point of use

Analysis of data:

$$\text{Dialysis bundle compliance} = \frac{\text{Total number of patients with all compliant applicable bundle components}}{\text{Total number of patients reviewed for the bundle compliance}} \times 100$$

14. Surveillance data collection

Surveillance data can be categorized into two groups; numerator or denominator data.

1	25	← Numerator
———	———	← Fraction bar
4	100	← Denominator

15.1 Numerator data

Numerator is the upper portion of a fraction used to calculate a rate or ratio. In surveillance, it is usually the number of cases of a disease or event being studied.

Responsibility of numerator data collection

1. Mainly ICP
2. Personnel other than ICPs may be trained to screen data sources for HAI, or automated screening of electronic databases may be used, as long as the ICP makes the final determination of presence of HAI according to Surveillance definitions of HAI.

Types of numerator data to collect

1. **Demographic data:** name, date of birth, gender, hospital identification number, admission date
2. **Infection**: onset date, site of infection, patient care location of HAI onset
3. **Risk factors**: devices, procedures, other factors associated with HAI
4. **Laboratory**: pathogens, antibiogram, serology, pathology
5. **Radiology/imaging**: X-ray, CT scan, MRI, etc.

Sources of numerator data

1. Admission/discharge/transfer records, microbiology laboratory records
2. Visits to patient wards for observation and discussion with caregivers
3. Patient charts (paper or computerized) for case confirmation

- Laboratory and radiology/imaging results
- Nursing and physician's notes and consults
- Admission diagnosis
- History and physical examination findings
- Records of diagnostic and surgical interventions
- Temperature chart
- Information on administration of antibiotics

4. For post-discharge detected SSI, sources include records from surgery clinics, physician's offices, emergency departments

How an ICP collects numerator data

1. Screens admission/discharge/transfer records for patients admitted with infection and those whose diagnoses put them at risk of acquiring HAI
2. Reviews laboratory reports looking for patients with possible infections (e.g., positive microbiology cultures, positive pathology findings) and converses with laboratory personnel trying to identify patients that might be infected and to identify clusters of infections, especially in areas not targeted for routine HAI surveillance
3. During ward rounds, quickly screens nursing care reports, temperature charts, antibiotic administration sheets, and conversation with nurses and physicians trying to identify patients who might be infected
4. Performs chart review of patients suspected of having HAI: reviews physician's progress notes and nurse's notes, laboratory data, radiology/imaging reports, surgery reports, etc.; if electronic charts are available, these can be reviewed from the ICP's desk, but ward rounds are still essential for surveillance, prevention, and control activities
5. Completes HAI data collection forms/screens as data sources are reviewed

15.2 Denominator data

Denominator is the lower portion of a fraction used to calculate a rate or ratio. The purpose of denominator is to adjust the HAI events and other related numerator data to the counts of the cohorts of patients at risk of acquiring HAI to make fair comparisons

Types of denominator data collection

Surveillance	Types of denominator data
CLABSI	Patient-days and central line-days
CAUTI	Patient-days and urinary catheter-days
VAE	Patient-days, ventilator-days, ventilator episodes
DE	Patient-months
SSI	Number of operative procedures of the same type
MDRO	Patient-days, number of admissions, number of encounters

Responsibility of denominator data collection

1. **Unit staff:**
    - Denominator data may be collected by someone other than the ICP as long as that person is trained.
    - Training should be checked periodically, specially when staff take leaves or in areas of high staff turnover
2. **Electronic sources:**
    - When denominator data are available from electronic databases (e.g., patient tracking systems, respiratory therapy database), these sources may be used as long as the counts are not substantially different (+/- 5%) from those collected manually.
    - When converting from one electronic counting system to another electronic counting system, the new electronic system should be validated against manual counts as above.
    - If electronic counts for the new electronic system are not within 5% of manual counts, resume manual counting and continue working with IT staff to improve design of electronic denominator data extraction (while reporting manual counts) until concurrent counts are within 5% for 3 consecutive months.

Methods of denominator data collection

3. **Manual, daily:** Device-associated denominator data (other than DE) including patient days and device days should be collected at the same time, every day, for each location performing surveillance to ensure that differing collection methods don't inadvertently result in device days being > patient days
4. **Manual, weekly:** Device-associated denominator data (other than DE) including patient days and device days should be collected at the same time on the same designated day, once per week. The idea is to reduce staff time spent collecting surveillance data, once weekly sampling of denominator data is good for
    - For CLABSI and CAUTI denominators only
    - For locations with 75 or more device days per month
    - For locations other than specialty care areas/oncology and NICUs
    - If the day designated for the collection of sampled data is missed, collect the data on the next available day instead
5. **Electronic sources:**
    - When denominator data are available from electronic databases (e.g., patient tracking systems, respiratory therapy database), these sources may be used as long as the counts are not substantially different (+/- 5%) from those collected manually.
6. DE denominator data: record the number of chronic hemodialysis patients with each access type who received hemodialysis at the center during the first two working days of the month
7. SSI denominator data: record information on operative procedures selected for surveillance (e.g., type of procedure, date, risk factors, etc.)

15. Infection control indicators

Infection control indicators have been used to assess the overall activity and efficiency of infection control program. They are no meant to identify or report every infection or infection prevention activity. Several countries and organizations have adopted one of the following infection control indicators;

Domain	Items	Metric expression
Infection prevention	Hand hygiene compliance	100 opportunities
Device-associated HAI	CLABSI rate	1000 central line days
	CAUTI rate	1000 urinary catheter days
	VAE rate	1000 ventilator days
Procedure-associated HAI	SSI: C-section rate	100 C-section procedures done
	SSI: cholecystectomy rate	100 cholecystectomy procedures done
Antimicrobial resistance	MRSA rate	10,000 patient days
	Clostridium difficile rate	10,000 patient days

Suggested Infection control indicators:

1. **Central line-associated bloodstream infection (CLABSI) rate:**
   - It should be done in one or more intensive care unit (ICUs) such as adult medical-surgical ICU or neonatal ICU
   - The rate is expressed as CLABSI events per 1000 central lines days
   - Both average in certain period and quarterly trend are required
2. **Surgical site infection (SSI) rate:**
   - SSI rate should be calculated per surgery and per risk index category
   - It is expressed as SSI events per 100 surgeries done (same type)
   - Suggested surgeries are cesarean section and cholecystectomy
   - Both average in certain period and quarterly trend are required
3. **Hand hygiene compliance:**
   - It should be calculated for the whole hospital, ICU versus non-ICU locations, and by professional category.
   - It is expressed per 100 observed hand hygiene opportunities.
   - Both average in certain period and quarterly trend are required
4. **Multi-drug resistant organisms (MDRO) rate:**
   - It should be calculated for the whole hospital, ICU versus non-ICU locations
   - It is expressed as organism per 10,000 patient days
   - Suggested organism is methicillin-resistant Staphylococcus aureus (MRSA)
   - Both average in certain period and quarterly trend are required

16. Evaluation of surveillance program

Program evaluation:

Program evaluation is a systematic method for collecting, analyzing, and using information to answer questions about projects, policies and programs, particularly about their effectiveness and efficiency.

Types of evaluation:

There are several types of evaluations that can be conducted. Some of them include the following:

1. **Formative evaluation** ensures that a program or program activity is feasible, appropriate, and acceptable before it is fully implemented. It is usually conducted when a new program or activity is being developed or when an existing one is being adapted or modified.
2. **Process/implementation evaluation** determines whether program activities have been implemented as intended.
3. **Outcome/effectiveness evaluation** measures program effects in the target population by assessing the progress in the outcomes or outcome objectives that the program is to achieve.
4. **Impact evaluation** assesses program effectiveness in achieving its ultimate goals.

Process evaluation of surveillance activities

I. Using WHO Infection Prevention and Control (IPC) Assessment Framework (IPCAF) tool:
    1. Organization of surveillance
    2. Priorities for surveillance - defined according to the scope of service
    3. Methods of surveillance
    4. Information analysis and dissemination/data use, linkage, and governance

II. National guide for auditors in infection control auditing strategies for healthcare facilities (ICA tool to evaluate infection control).

Process evaluation of surveillance activities (IPCAF tool)

1. Organization of surveillance

- Is surveillance a defined component of your IPC program?
- Do you have personnel responsible for surveillance activities?
- Have the professionals responsible for surveillance activities been trained in basic epidemiology, surveillance and IPC (that is, capacity to oversee surveillance methods, data management and interpretation)?
- Do you have informatics/IT support to conduct your surveillance (for example, equipment, mobile technologies, electronic health records)?

2. Priorities for surveillance - defined according to the scope of care

- Do you go through a prioritization exercise to determine the HAIs to be targeted for surveillance according to the local needs (e.g. annual risk assessment)?
- In your facility is surveillance conducted for:
  - ✓ Surgical site infections?
  - ✓ Device-associated infections (such as CLABSI, CAUTI, VAE, DE)?
  - ✓ Clinically-defined infections (such healthcare pneumonia)?
  - ✓ Colonization or infections caused by MDR pathogens according to your local epidemiological situation?
  - ✓ Local priority epidemic-prone infections (such as MERS and COVID-19)?
  - ✓ Infections in vulnerable populations (for example, neonates, intensive care unit, immunocompromised, burn patients)?
  - ✓ Infections that may affect health care workers in clinical, laboratory, or other settings (for example, hepatitis B or C, human immunodeficiency virus [HIV], influenza)?
- Do you regularly evaluate if your surveillance is in line with the current needs and priorities of your facility?

3. Methods of surveillance

- Do you use reliable surveillance case definitions (defined numerator and denominator according to international definitions [e.g. NHSN/GCC]) or if adapted, through an evidence-based adaptation process and expert consultation?
- Do you use standardized data collection methods (for example, active prospective surveillance) according to international surveillance protocols (e.g. NHSN/GCC) or if adapted, through an evidence-based adaptation process and expert consultation?
- Do you have processes in place to regularly review data quality (for example, assessment of case report forms, review of microbiology results, denominator determination, etc.)?
- Do you have adequate microbiology and laboratory capacity to support surveillance?
  - ✓ Can differentiate gram-positive/negative strains but cannot identify pathogens
  - ✓ Can reliably identify pathogens (for example, isolate identification) in a timely manner
  - ✓ Can reliably identify pathogens and antimicrobial drug resistance patterns (that is, susceptibilities) in a timely manner

4. Information analysis and dissemination/data use, linkage, and governance

- Are surveillance data used to make tailored unit/facility-based plans for the improvement of IPC practices?
- Do you analyze antimicrobial drug resistance on a regular basis (for example, quarterly/half-yearly/annually)?
- Do you regularly (for example, quarterly/half-yearly/annually) feedback up-to-date surveillance information to:

- ✓ Frontline health care workers (doctors/nurses)?
- ✓ Clinical leaders/heads of department
- ✓ IPC committee
- ✓ Non-clinical management/administration (chief executive officer/chief financial officer)?

- How do you feedback up-to-date surveillance information? (at least annually)
  - ✓ By written/oral information only
  - ✓ By presentation and interactive problem-orientated solution finding

ICA tool for auditing strategies in healthcare facilities

I. IPC administrative measures

1: leadership support

2: IPC department

3: IPC committee

4: IPC program

5: IPC annual plan

6: IPC policies & procedures

7: IPC education & training

II. HAIs surveillance & outbreak management

1: Outbreak management measures

2: Emergency preparedness & response to national infectious diseases' threats

3: Antimicrobial stewardship / antibiogram

4: HAIs surveillance

5: Patient's care bundles for prevention of HAIs & MDROs. There is a written policy and procedure concerning patient's care

Antimicrobial stewardship / antibiogram (sub-elements):

- There is a written policy and procedure for antimicrobial stewardship program (ASP) and authorized ASP committee formulated & approved by ASP committee members that is chaired by clinical pharmacist or infectious disease (ID) consultant with a clear roles and responsibilities and meets on regular basis (at least bi-annually).

- There is a written restricted antibiotics policy implemented in the facility, and it should be developed & followed up by the pharmacy and infectious disease department.
- There is an Interventional policy implemented to Improve antibiotic usage which is developed & approved by the pharmacy department.
- The ASP committee members include: infectious disease physician, pharmacist, microbiologist, IPC practitioner, head of critical care units, head of operating room, head of surgical department, head of nursing services and other departments as needed.
- Antibiogram is regularly discussed by antimicrobial stewardship committee with action plan and interventions to improve the use of antimicrobials and prevent resistance.
- Hospital leaders dedicate necessary human, financial, and information technology resources to the ASP committee (support training ASP/MDROs program-participating in the world awareness antimicrobial week celebrations (WAAW) , assign ID consultant, etc)
- The antibiogram report is prepared & interpreted annually by hospital microbiologist and reported to the hospital IPC department (hospital ≥100 beds) and to the ASP team chairman.
- Education about AMR & optimal antimicrobial prescription are provided regularly to the HCWs at least biannually by the ASP team members (each per their role).

HAIs surveillance (sub-elements):

- There are written policies and procedures for surveillance of health care associated infections, using CDC-NHSN definitions approved by national MOH guidelines (e.g., VAP/VAE, CLABSI, CAUTI, SSI and MDROs according to the hospital's scope of services).
- There is a written policy and procedure for surveillance of dialysis event, using CDC-NHSN definitions which are approved by national MOH guideline.

- Adequate number of computers and a reliable internet service are available for effective implementation of surveillance program without any interruption.
- IPC practitioners are well trained regarding the national approved electronic surveillance platform and familiar with CDC-NHSN definitions approved by national MOH guideline.
- Surveillance system is carried out in all critical care units (active, prospective, targeted and patient based surveillance).
- SSI surveillance is applied according to national MOH guideline (i.e. selecting only 1 - 3 types of high risk procedures or most common surgeries during at least 6 months).
- Hospital has a system for post-operative follow up and communication with post-surgical patients regularly after discharge for any signs and symptoms of surgical site infections including patients with implants.
- Surveillance data (targeted patients, numerators, denominators, and device utilization ratio) are validated by IPC practitioners at least once monthly.
- Surveillance data are regularly collected & reported to MOH through national approved electronic surveillance platform.
- Results of surveillance are regularly analyzed, interpreted, and communicated to HCWs and concerned departments.
- Results of surveillance are regularly reviewed by the IPC committee, and the action plan is developed and followed up accordingly (at least once quarterly).
- Results of surveillance are used to reduce HAIs through well designed quality improvement projects.

Patient's care bundles for prevention of HAIs & MDROs (sub-elements):

- There is a written policy and procedure concerning patient's care
  - ✓ Bundle for prevention of CAUTI
  - ✓ Bundles for prevention of CLABSI

- ✓ Bundles for prevention of VAEs
- ✓ Bundles for the prevention of SSIs
- ✓ Bundles for the prevention of MDROs
- ✓ Bundles for prevention of DE.

Outcome evaluation of surveillance activities

1. **Infection control indicators (mentioned above):**
    - CLABSI rate
    - SSI rate
    - Hand hygiene compliance
    - MDRO rate:
2. **Other common measures:**
    - Rates before and after starting surveillance
    - Rates before and after applying bundles
    - Rates before and after the improvement project
3. **Impact measures:**
    - Hospital length of stay
    - ICU length of stay
    - Cost per admission in different department
    - Attributable mortality

17. Surveillance Data Analysis

As mentioned before, surveillance is a systematic method of ongoing collecting, consolidating, and analyzing data concerning the distribution and determinates of a given disease or event, followed by the dissemination of that information to those who can improve the outcome. Therefore, statistical analysis is an integral part of the surveillance process. Actually weak analysis turns the surveillance activity into data collection activity.

Requirements of data analysis

- Epidemiologist or biostatistician
- Data entry staff
- Computers with excel and SPSS software
- Data collected in standardized data collection forms
- Pre-prepared data entry files for each type of surveillance
- Analysis plans and defined metrics
- Benchmarking

Example of main duties of epidemiologist or biostatistician

- Maintains excellent database quality by performing required data cleaning
- Works with other related personnel in developing appropriate instrument for data collection (both hardcopies and electronic).
- Manages and analyze surveillance data on timely manner
- Produces periodic, annual and sometimes urgent statistical report.
- Provides interpretation of data analysis results with appropriate recommendation
- Supervises statistical assistant(s) and data entry clerk(s).
- Communicates analysis interpretation effectively with relevant staffs at ICP department

18.1 Basic Statistics

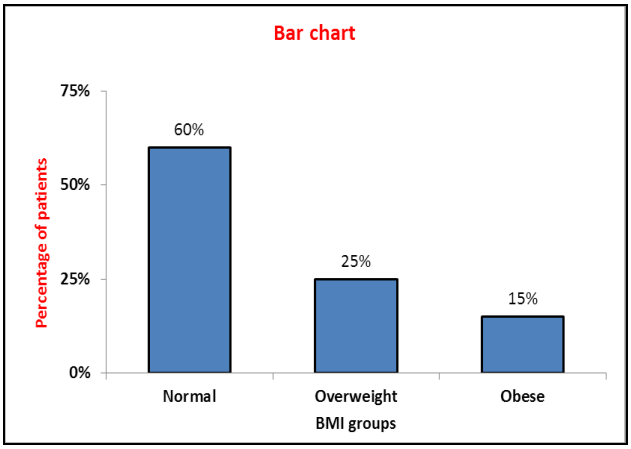
There are two types of statistics, descriptive and inferential. Descriptive statistics provides numerical information about variables (e.g. mean). Inferential statistics makes an assumption about a population based on a sample of the population (Z test).

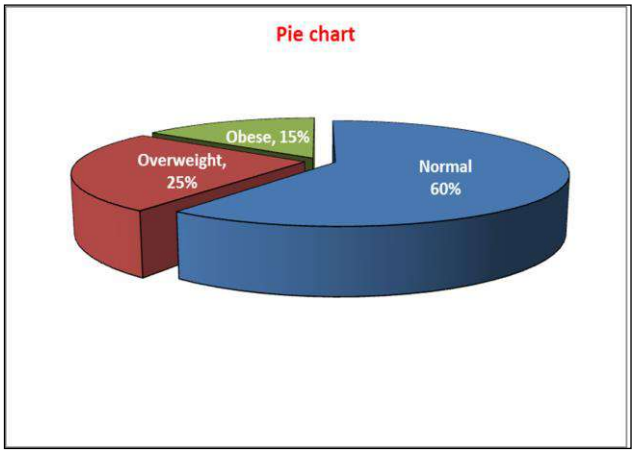
Quantitative data		Categorical data	
Sub-type	**Example**	**Sub-type**	**Example**
Continuous	• Blood pressure • Height & weight • Age	Ordinal (Ordered)	• Grade of breast cancer • Small, medium, large • Educational level
Discrete	• Number of children • Number of attacks of asthma per week	Nominal (Unordered)	• Sex (male/female) • Alive or dead • Blood group O, A, B, AB

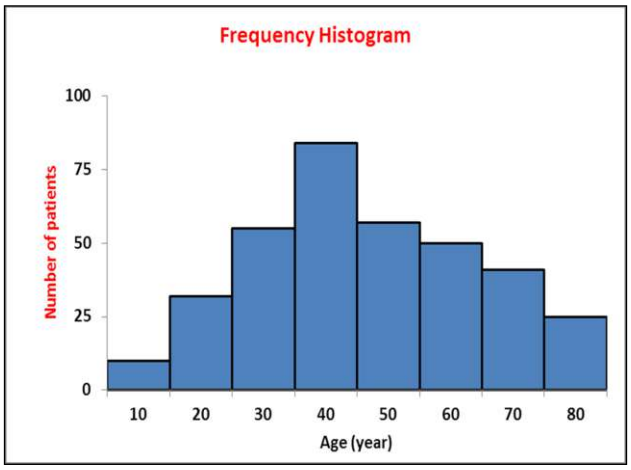
Descriptive Statistics:

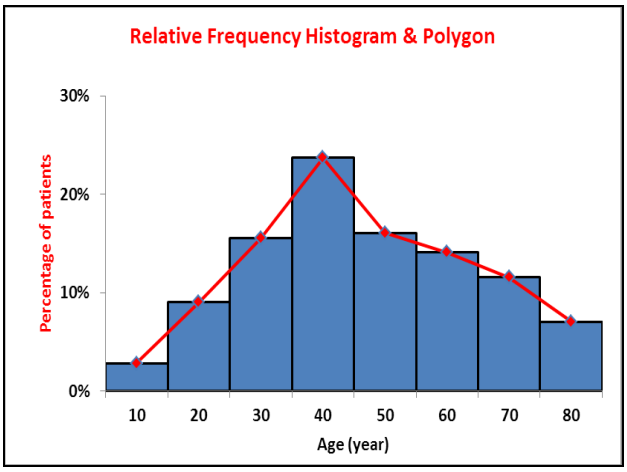
- Frequency table
- Frequency histogram
- Relative frequency histogram
- Frequency polygon
- Relative frequency polygon
- Bar chart
- Pie chart
- Stem-and-leaf display
- Box plot
- Scatter plot

Examples of descriptive Statistics

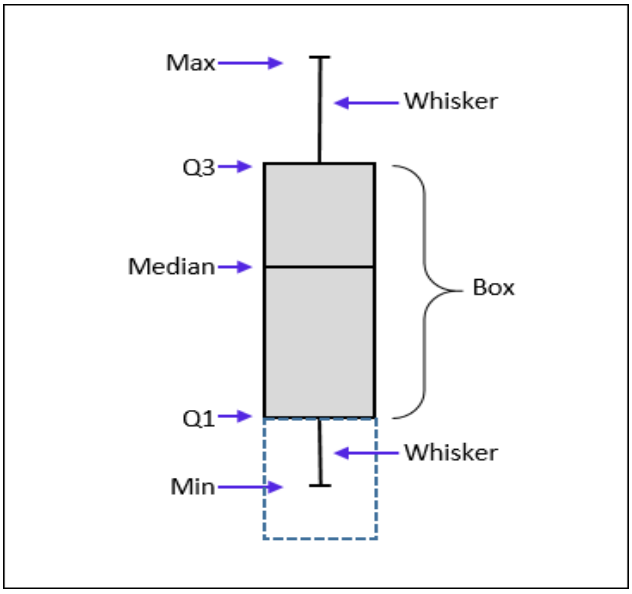








Box plot



Frequency Table

Age Groups	Frequency	Percentage
32 -36.99	2	6.7%
37- 41.99	3	10.0%
42-46.99	4	13.3%
47-51.99	3	10.0%
52-56.99	8	26.7%
57-61.99	3	10.0%
62-66.99	4	13.3%
67-72	3	10.0%
Total	**30**	100.0%

Measures of central tendency:

	Advantages	Disadvantages
Arithmetic mean	• Uses all the data values • Algebraically defined and so mathematically manageable	• Distorted by outliers • Distorted by skewed data
Median	• Not distorted by outliers • Not distorted by skewed data	• Ignores most of the information • Not algebraically defined
Mode	• Easily determined for categorical data	• Ignores most of the information • Not algebraically defined

Measures of variation:

Measure	Definition
Range	The difference between the largest value and the smallest value.
Interquartile range	The difference between the first and the third quartiles (25th and 75th percentiles)
Standard deviation	The mean differences of individual data from the arithmetic mean of all data. It is the square root of the variance.
Variance	The mean of the squares of the deviations from the arithmetic mean of a data set
Standard error of the mean	It is calculated by dividing the standard deviation by the square root of the sample size.
Coefficient of Variation	It is the ratio of the sample standard deviation to the sample mean

Measures of variations:

	Advantages	Disadvantages
Range	• Easily determined	• Uses only two observations • Distorted by outliers • Tends to increase with increasing sample size
Interquartile range	• Unaffected by outliers • Independent of sample size • Appropriate for skewed data	• Clumsy to calculate • Cannot be calculated for small samples • Uses only two observations • Not algebraically defined
Variance	• Uses every observation • Algebraically defined	• Units of measurement are the square of the units of the raw data • Sensitive to outliers • Inappropriate for skewed data
Standard deviation	• Same advantages as the variance • Units of measurement are the same as those of the raw data • Easily interpreted	• Sensitive to outliers • Inappropriate for skewed data

Measures of relative standing:

Measure	Definition
Percentile	Data divided into 100 equal parts by rank (i.e., the kth percentile is that value greater than k% of the others). Example, • 30th percentile means values more than 30% of the values • 90th percentile means values more than 90% of the values
Quartile	Data divided into 4 equal parts by rank: • Q1 (first quartile) is greater than ¼; • Q2 is identical to the median • Q3 (third quartile) is the value greater than ¾ of the others
z score	Measures the distance from the mean in terms of standard deviation

Measures of Frequency:

Rates, ratios, and proportions are used to measure the occurrence and risk of an event in a specific population during a given period.

1. **Rate:** an expression of the frequency with which an event occurs in a defined population, for example, CLA-BSI incidence rate is 5.3 per 1000 patient-days
2. **Ratio:** the value obtained by dividing one quantity by another, for example, the ratio of females to males is 2:1
3. **Proportion:** a type of ratio in which the values in the numerator are included in (i.e., are a subset of) the denominator, for example, 33% of the population is in risk category 1

18.2 Measures of Morbidity and Mortality

Surveillance should yield risk-adjusted incidence rates to allow inter- and intra-facility rate comparisons.

Risk-adjusted rates and crude rates

1. Risk-adjusted rates

- Rates are controlled for variations in the distribution of major risk factors associated with an event's occurrence
- Such rates allow inter- and intra-facility rate comparisons

2. Crude rates

- Rates assume equal distribution of risk factors for all events
- Such rates cannot be used for inter-facility comparisons

Measures of morbidity and mortality

1- Measures of morbidity:

- Incidence rate
- Prevalence rate

2- Measures of mortality:

- Mortality rate
- Case fatality
- Proportionate mortality

Measures of morbidity:

- **Incidence rate:** a measure of the frequency with which an event occurs in a population over a defined time period. The numerator is the number of new cases occurring during the defined time period, and the denominator is the population at risk.
- **Attack rate** is a type of incidence rate used to measure the frequency of new cases of a disease or condition in a specific population during a given (short) period of time; expressed as a percentage.
- **Prevalence rate:** the proportion of persons in a population who have a particular disease or condition (new and previously existing) at a specified point in time or over a specified period of time.

Point prevalence = $\frac{\text{Number of all cases (old and new) in a given point in time}}{\text{Total population at risk at the given point in time}}$
Period prevalence= $\frac{\text{Number of all cases (old and new) in a given period of time}}{\text{Total population at risk at the given period in time}}$
Cumulative incidence= $\frac{\text{Number of new cases in a given period of time}}{\text{Total population at risk during that time}}$
Attack rate= $\frac{\text{Number of new cases in a short period of time}}{\text{Total population at risk during that time}}$
Incidence Density= $\frac{\text{Number of new cases in a given period of time}}{\text{Total person-time of observation}}$

Measures of mortality:

- **Mortality rate:** The frequency of occurrence of death in a defined population during a specified interval.
- **Case fatality:** The proportion of deaths from a certain disease compared to the total number of people diagnosed with the disease for a particular period
- **Proportionate mortality:** It describes the proportion of deaths in a specified population over a period of time attributable to different causes. Each cause is expressed as a percentage of all deaths, and the sum of the causes must add to 100%

Mortality rate = $\frac{\text{Deaths in a given period of time}}{\text{Total population in the given period of time}}$
Case fatality = $\frac{\text{Deaths from a certain disease}}{\text{All patients diagnosed with that disease}}$
Proportionate mortality = $\frac{\text{Deaths from a certain disease in a given period of time}}{\text{Deaths from all causes in the given period of time}}$

18.3 Calculating Infection Rates and Ratios

CLABSI:

- The CLABSI rate 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 Central Line Utilization Ratio 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 and birthweight categories in NICUs.

CAUTI:

- 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.

VAE:

- The VAE rate per 1000 ventilator-days is calculated by dividing the number of VAEs by the number of ventilator-days and multiplying the result by 1000.
- The VAE rate per 100 episodes of mechanical ventilation is calculated by dividing the number of VAEs by the number of episodes of mechanical ventilation and multiplying the result by 100 (episodes of mechanical ventilation).
- 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, specialty care areas, and other adult locations in the institution

DE:

- The numbers of various events (In-unit IV antimicrobial start, positive blood culture, or local infection) are tabulated, and rates of these events per 100 patient-months calculated by dividing the number of events by the number of patient-months and multiplying the result by 100.
- These rates are stratified by vascular access type and compared to the mean rate of all centers combined.

SSI:

- The 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.
- These calculations will be performed separately for the different types of operative procedures and stratified by risk index.
- Standardized infection ratios are also calculated using indirect standardization or multivariate models.

MDRO-Infection Surveillance:

- MDRO infection incidence rate is calculated by dividing the number of infections of a certain MDRO type by the number of patient days and multiplying the results by 10,000.
- Rate is then stratified by time (e.g., month, quarter, etc.) and patient care location.

MDRO-Laboratory-Identified (LabID) Event:

- Numerator data are the Laboratory-identified MDRO Events while denominator data are the number of patient days, admissions, and encounters (for ER and outpatient locations).
- These data are used to calculate four distinct proxy measures including:
  - ✓ Admission prevalence rate and
  - ✓ Overall prevalence rate based on clinical testing (measures of exposure burden),
  - ✓ MDRO bloodstream infection incidence rate (measure of infection burden), and
  - ✓ Overall MDRO infection/colonization incidence rate (measure of healthcare acquisition).
- LabID Events proxy measures are categorized as healthcare facility-onset (4 days or more days after admission to the facility) versus community-onset (≤ 3 days after admission to the facility).

18.4 Calculating SIR

The standardized infection ratio (SIR):

- SIR is a summary measure used to track HAIs at a national, state, or local level over time.
- SIR provides improved risk adjustment and can replace risk-stratified HAI rates.

Calculation of SIR:

$$\frac{\text{Observed HAI events}}{\text{Expected HAI events}}$$

- The observed HAI events: It is the HAI events you detect during surveillance
- The expected HAI events: It can be calculated from the published benchmarking reports of NHSN, INICC, GCC, or Saudi MOH.
- To allow for more precise comparisons, SIRs are calculated only if the number of expected HAIs is ≥1
- When the expected HAI <1, this indicates that the denominator (e.g. number of device days or procedures) in the facility or location is too low to calculate a precise SIR and comparative statistics.

Interpretation of SIR:

- SIR<1 means that after adjusting for differences, fewer HAIs were observed than predicted
- SIR>1 means that after adjusting for differences, more HAIs were observed than predicted
- SIR=1 means that after adjusting for differences, Same HAIs were observed as predicted

Example of SIR calculation:

Assume you have CLABSI rates for 4 ICUs and you want to calculate overall SIR for CLABSI at your hospital compared with published NHSN rates

1- Abstract the published NHSN rates corresponding to the above four ICUs (e.g. medical cardiac ICU is 2.0 per 1000 central line days)

2- Calculate the expected CLABSI rates for each ICU separately by multiplying the observed central lines days in each unit with its corresponding published NHSN rates (e.g. in medical cardiac ICU 380 X 2.0 /1000 = 0.76)

3- Sum up expected CLABSI events in the four ICUs (e.g. 0.76 + 0.67 + 0.94 + 1.78 = 4.15)

4- Calculate the SIR by dividing observed CLABSI events by expected CLABSI events (e.g. 8 / 4.15 = 1.93)

5- Interpret the SIR: Your hospital had 93% more CLABSIs than expected assuming your ICUs have CLABSI rates similar to that of NHSN ICUs

Type of ICU	Observed CALBSI events	Observed central line days	Hospital rates	Published NHSN rates	Expected CLABSI events
Medical cardiac	2	380	5.26	2.0	0.76
Medical	1	257	3.89	2.6	0.67
Medical surgical	3	627	4.78	1.5	0.94
Neurosurgical	2	712	2.81	2.5	1.78
Total	8	1976	4.05		4.15

18.5 Comparing Rates

For the purpose of comparing rates, statistical tests can be used to determine whether significant differences exist (by giving approximate p-values). Here are some common terms you will encounter:

Z-test:

- It is a statistical test used to determine if the rate difference between 2 independent groups is large enough to be statistically significant, that is, if the difference is unlikely to have occurred by chance.

P-value:

- It is the probability of obtaining a value of the test statistic at least as extreme as the one that was actually observed, given that the null hypothesis is true.
- P-value (observed level of significance) is compared to α (nominated level of significance)
- Popular levels of significance are 5%
- P<0.05 means that the association (or the difference) is statistically significant and unlikely to be due to chance alone
- P<0.05 does not mean that the association (or the difference) is necessarily clinically significant, large, or important in the common meaning of the word

Misconceptions of p-value:

- P-value <0.05 means clinically significant
- P value <0.05 means the association is strong or the difference is large
- P value <0.05 is still valid with multiple comparisons
- P value >0.05 means no association or difference

Suggestions to overcome pitfalls of p-value:

- Report effect size, a measure of the strength of the relationship between two variables
- Calculate confidence intervals which measure small effect size (associated with large sample) with great confidence
- Report meta-analyses results

Adjustment and Standardization:

- They are methods to allow fair comparisons of rates and ratios
- Comparing rates requires that they be appropriately stratified and/or adjusted by risk to account for differences in the distribution of the important risk factors.

Adjustment:

- It is statistical techniques that try to remove the influence of factors that distort or confound a comparison. It includes the following techniques

Technique	Effect	Example
Restriction	Adjust for(usually) one confounder by excluding unwanted levels of that confounder	• MRSA rates in neonates • CLABSI rates in children
Stratification	Adjust for (usually) one confounder at a time by stratifying the metric by the levels (groups) of that confounder	• SSI rates by risk index categories • CLABSI rates by type of ICU
Standardization	Adjust for (usually) one confounder based on weighted averages	• CLABI SIR for multiple ICUs
Multivariate logistic regression	Adjust for multiple confounders at the same time	• Adjusted odds ratio of catheter type in developing CLABSI

Standardization:

- It refers to methods of adjustment based on weighted averages
- It facilitates fair comparison between two groups with different weights of a certain factor (that influence the rate of interest but which is not the focus of attention) by removing the effect of such factor through creating a weighted-average (summary) rate.
- There is two types of standardization; direct and indirect

	Direct standardization	Indirect standardization
Requirement	Specific rates of the study population	Specific rates of the standard population
Use	Uncommonly used in surveillance	Commonly used in surveillance
Example	Calculating age and sex adjusted rates of infection in a study (adjusted to 2010 US population)	Standardized infection ratio of a hospital compared with NHSN rates (discussed above)

Hypothesis testing

1- The null hypothesis (H0)

- It represents a theory that has been put forward, either because it is believed to be true or because it is to be used as a basis for argument, but has not been proved.
- Example of H0: There is no difference between the infection rate between my hospital and NHSN hospitals

2- The alternative hypothesis (H1)

- It is a statement of what a statistical test is set up to prove
- Example of H1: There is difference between the infection rate between my hospital and NHSN hospitals

Statistical errors:

Type I error and Type II error

		Reality	
		Null True (No difference)	Null False (Difference)
Study conclusion	Null True (No difference)	OK	**Type II error**
	Null False (Difference)	**Type I error**	OK

Type I error, α error, or a "false positive":

- It is the error of rejecting a null hypothesis (conclude that there is difference) when it is actually true (in reality there is no difference).

Type II error, β error, or a "false negative":

- It is the error of failing to reject a null hypothesis (conclude that there is NO difference) when the alternative hypothesis is the true state of nature (in reality there is difference).

18.6 Data Validation

Surveillance data validation:

It is the process of confirming that surveillance data meets the requirements and the standards for which it was intended

Purpose of surveillance data validation:

- Ensure that surveillance data are of high quality: Complete, accurate, and timely
- Ensure that surveillance data are suitable for fair comparison of HAI rates between hospitals
- Provide insights into systematic weaknesses in the surveillance process and suggest how to correct them
- Estimate coefficient of under reporting

Levels of surveillance data validation:

Validation should strive to address data quality across several components that comprise HAI measures. This includes the completeness and accuracy of

- The population denominator at risk for the HAI
- Identified cases
- Reported data elements, including those used for risk adjustment.

Types of surveillance data validation:

1- Intrinsic validation:

- It is an automated process built into a computer application that controls the values and types of data that are entered into the system.
- Point-of-entry validation is a process for routinely checking whether data are reasonable, complete, consistent, and formatted in accordance with system requirements.

- Intrinsic validation serves as a means for detecting and preventing some input errors However, intrinsic validation does not prevent all errors and does not assure the quality and completeness of HAI case ascertainment or the caliber of numerator and denominator data acquisition.

2- Internal validation

- It is a systematic process that enables facility personnel themselves to assess whether sound surveillance methods, optimal healthcare data sources, and the highest caliber data abstraction and entry are in use when numerator and denominator records are completed.
- Investigations of surveillance practices and analysis and follow-up of aberrant or outlying results are the main methods of internal validation.

3- External validation

- It is a survey and audit process conducted by an agency outside the reporting facility (e.g. Ministry of health team), in which a facility's surveillance determinations and methods are assessed by one or more validators who work for the agency and who are trained to evaluate completeness and accuracy of reporting.
- External validation complements internal validation by systematically reinforcing the obligation of facilities to conduct complete and accurate surveillance.
- Findings from external validation can be used to correct misconceptions about definitions, criteria, and data requirements.

4- Validation of internal data against external dataset

- This may involve the acquiring of data from an independent source such as a microbiology laboratory database and the cross-checking of these data with the surveillance data to check for missing infections.
- This could be undertaken on an intermittent basis (e.g. quarterly or annually) or undertaken on a continuous basis, especially if the process can be semi-automated.

5- Validation of ICP surveillance skills

- This may involve a person responsible for collecting surveillance data being externally examined using a standardized assessment tool by an accredited surveyor.
- This may involve case scenarios and require the person to correctly identify the classification of HAI data.
- This may involve inter-rater reliability between two ICPs using kappa statistic

6- Denominator data validation

- The denominator data are usually provided by the medical statistics department of the hospital or unit staff.
- It is important that surveillance personnel are familiar with the way that these data are obtained; have documentary evidence that the extracted data meet the definitions for patient days and device days
- This will usually involve direct communication with those responsible for generating the data extract.
- Comparing electronic and manually collected denominators

Examples of some validation items in CLABSI surveillance:

- Not all positive blood cultures reviewed by ICP (need a list from the laboratory)
- Not all patients on central line included in the surveillance
- Misclassification of primary and secondary BSI due to mismatch of pathogens
- Misclassification of primary and secondary BSI due to missing candida
- Misclassification of primary and secondary BSI due to failure to recognize infections at other sites (such as GIT infections)
- Misclassification of HAI and POA because of wrong window estimation
- Use of current weight group rather than birth weight group in neonatal ICU

- Wrong location of attribution after transfer
- Counting both CLABSI and MBI in the same patient
- Misclassification of LCBI criterion due to failure to distinguish between recognized pathogen and skin contaminant
- Using LCBI criterion 3 outside neonatal ICU
- Central line days more than patient days
- Central line days extremely higher or lower than expected
- Data entry errors (need impendent entry of about 5% of the cases)

18.7 Benchmarking

Benchmarking is the process of "comparing oneself to others performing similar activities, so as to continuously improve." Although it is very appealing to compare one's rates externally with others, comparisons should be made only after ensuring that the several conditions are met.

Benchmarking conditions

- Using standardized case definition
- Using similar data collection methods
- The population and time period for study is well defined.
- The size of the population should be large enough and the duration should be sufficient to allow fair comparisons
- Using same data description methods including:
  - ✓ Similar rate calculation
  - ✓ Similar rate stratification by risk factors
  - ✓ Similar rate stratification by hospital locations
  - ✓ Similar adjusting methods
- Using sound statistical comparisons methods
- Patients confidentiality are safeguarded

Benchmarking Reports

- The National Healthcare Safety Network (NHSN)
- The International Nosocomial Infection Control Consortium (INICC)
- European Centre for Disease Prevention and Control (ECDC)
- World Health Organization (WHO) estimates
- Ministry of health reports

18. Surveillance Reporting

Surveillance report:

- A written report should be developed to provide a mechanism to interpret and disseminate surveillance data
- Tables, graphs, and charts are effective tools for organizing, summarizing, and visually displaying data and should be used as applicable.
- The format and level of detail in each report will depend on the intended audience
- Surveillance is not finished until dissemination of “Surveillance report”

Surveillance report criteria:

- Define the event, population, setting, and time period studied (e.g., surgical site infections in patients undergoing coronary artery bypass graft in hospital A from January through December 2003)
- State the criteria used for defining a case (e.g., NHSN criteria for urinary tract infection)
- Specify the number of cases or events identified and the number in the population studied (e.g., 2 surgical site infections in 179 total hip replacement procedures performed)
- Explain the methodology used to identify cases (e.g., case reports from personnel and review of medical records and laboratory results)
- Identify the statistical methods and calculations used, when appropriate (e.g., fall rate in April = falls in April / # resident days in April x 1000 or 3/414 x 1000 =7.2 falls per 1000 resident-days)
- State the purpose for conducting surveillance (e.g., to reduce the rate of occurrence of an event)
- Interpret the findings in a manner that is understandable to those who read the report

- Describe any actions taken and recommendations made for prevention and control measures
- Identify the author and date of the report
- Identify the recipients of the report

Surveillance report structure:

1- Author information

2- Target audience information

3- Executive Summary

4- Background literature

5- Objectives of the surveillance

6- Methods:

- Define population, setting, and time period studied
- State the criteria used for defining a case
- Explain the methodology used to identify cases
- Describe the statistical methods and calculations used, when appropriate

7- Results:

- Specify the number of cases or events identified and the number in the population studied
- Describe findings using tables, graphs, and charts
- Interpret the findings in a manner that is understandable to those who read the report
- Benchmarking

8- Conclusions and recommendations:

- Describe the main findings

- Describe any actions taken and recommendations made for prevention and control measures

9- References

Surveillance report recipients:

After you prepare the report according to the above criteria (including easy to understand conclusions and recommendations), the following stakeholders (persons/bodies) need to receive a copy of your final report:

- Immediate supervisor, higher rank administration, or any other healthcare facility employee who are required (by your facility local policies) to be informed and/or are authorized to implement the suggested recommendation.
- Healthcare workers who have immediate concern with the report contents (e.g. surgical team who performed the procedures for which you are reporting SSI rates)
- ICPs who are directly involved in data collection as a way to keep them informed as well as promote quality improvements.
- Some reports may need to be reported to the ministry of health or even higher national or international bodies (according to your country health policies e.g. certain outbreaks).

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