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MINISTRY OF HEALTH, ETHIOPIA

# National Healthcare Associated Infections (HAIs) Surveillance Guideline

May 2023
Addis Ababa, Ethiopia

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# Foreword

Infections that originate within health care facilities have always posed major problems in delivering safe health care services. These infections which can be blood-borne, airborne, or transmitted directly through physical contact, endanger the safety of anyone who enters the health care setting: patients and their families, clients, and health care workers. Collectively these infections are named as Healthcare Associated Infections (HAIs).

HAIs can lead to prolonged hospital stays, long-term disabilities, financial burdens for health care facilities, additional costs for patients and their families, and often to avoidable morbidity and deaths.

Infection prevention and control (IPC) is a practical, evidence-based approach protecting patients and health workers from being harmed by preventable HAIs. Effective IPC requires sustained action at all levels of the health care system.

The Ethiopian Ministry of Health, recognizing the critical role of IPC in preventing HAIs, had been engaged in the development and launching of national level IPC guidance documents in collaboration with all relevant stakeholders.

Accordingly, the country now owns a National Infection Prevention and Control Policy, Strategy and Strategy Roadmap which are now being used to implement IPC program across all the health tier system of the country.

As a means of tracking the implementation of the strategy guidances and roadmap activities in an organized way, the country had also developed and launched the national IPC M&E plan which is under implementation.

HAIs can cause serious harm and even death to patients and increase the cost and length of stay in healthcare facilities. Therefore, it is important to prevent and control HAIs through effective surveillance and infection prevention practices.

A country needs to have a surveillance guidance document for HAIs to establish a national baseline of HAI incidence and prevalence, to identify trends and patterns of HAI occurrence, to evaluate the impact and effectiveness of HAI prevention interventions, and to inform policy and resource allocation decisions.

An HAIs surveillance guidance document facilitates collaboration and communication among different stakeholders involved in HAIs prevention and control, such as healthcare providers, public health authorities, researchers, and patients.

With this intent, it has become an imperative to design, develop and launch HAI surveillance guidance document which would provide HAIs case definitions, criteria, methods, and procedures for identifying, diagnosing, and reporting HAIs. This HAIs surveillance guidance document will also help to ensure comparability and validity of HAIs data across different healthcare settings and regions.

In conclusion, I wish to extend my heartfelt gratitude to all individuals and institutions that have contributed to the development of this National Healthcare Associated Infection Surveillance Guidance document.

**Abas Hassen, PhD**
**Lead Executive Officer, Health System Innovation and Quality**
**Ministry Of Health Ethiopia**

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# Abbreviations and Acronyms

| | |
|---|---|
| AMR | Anti-Microbial Resistance |
| AST | Anti-Microbial Susceptibility Testing |
| BSI | Bloodstream Infections |
| CAUTI | Catheter Associated Urinary Tract Infection |
| CLABSI | Central Line Associated Bloodstream Infection |
| CASH | Clean and Safe Healthcare Facilities |
| EHRIG | Ethiopian Health Center Reform Implementation Guideline |
| EHSTG | Ethiopian Health Service Transformation Guideline |
| EQA | External Quality Assurance |
| HCWs | Healthcare Workers |
| HCFs | Healthcare Facilities |
| HAIs | Healthcare Associated Infections |
| IPC | Infection Prevention and Control |
| IEC | Information Education and Communication |
| IT | Information Technology |
| ICU | Intensive Care Units |
| IQA | Internal Quality Assurance |
| IPC FLAT | IPC Facility Level Assessment Tool |
| LQAS | Lots Quality Assurance Sampling |
| MRN | Medical Record Number |
| MRSA | Methicillin-resistant Staphylococcus aureus |
| PT | Proficiency Testing |
| RRT | Rapid Response Team |
| RTI | Respiratory Tract Infections |
| RDQA | Routine Data Quality Assurance |
| SWOT | Strength, Weakness, Opportunities and Threats |
| SSI | Surgical Site Infections |
| UTI | Urinary Tract Infections |
| WaSH | Water Sanitation and Hygiene |

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# Definition of Key Terms

**Healthcare Associated Infections –** an infection that occur in patients while they are receiving healthcare, particularly it is an infection which occurs after 48 hrs. of hospital admission, up to 3 days after discharge, or up to 30 days after operative procedures

**Surveillance –** the ongoing, systematic collection, analysis, interpretation of health data essential to the planning, implementation, and evaluation of public health practice closely integrated with the timely dissemination of these data to those who need to know

**HAIs Surveillance –** a surveillance of selected high impact healthcare associated infections with the primary objective of using surveillance data in improving IPC practices within a healthcare facility and making healthcare facilities safer for patients, visitors, healthcare workers and for the community at large.

**Outbreak -** an increased frequency of a disease above the threshold in a given population which refers to a limited geographic area.

**Infection Prevention and Control (IPC) -** a practical, evidence-based approach preventing patients and health workers from being harmed by avoidable infections.

# About the Document

This document is intended to serve as a guide for health care professionals in general, and for IPC professionals in particular, to ensure that the critical elements and methods of surveillance for health care-associated infections (HAIs) are incorporated into their practice. It provides guidance for each of the surveillance system's building blocks, including planning, data collection, interpretation, analysis, and communication, in order to inform infection prevention and control practices that will result in effective infection control in healthcare settings.

The principles and practices outlined in this document are based on a review of the best available scientific evidence as well as the expert opinions of experts in infectious diseases, infection prevention and control, public health, and epidemiology. This document's recommendations will be reviewed and updated as new information becomes available.

The types of health care settings to which this document's guidance applies are hospitals (tertiary care, community care, mental health, rehabilitation, etc.) practicing healthcare services in the country.

The document focuses on the surveillance of infections that occur during health-care delivery rather than the processes that contribute to changes in the risk of acquiring health-care-associated infections. Process monitoring, such as hand hygiene and sterilization techniques, is addressed through practice audits in the health care setting, rather than through the outcome surveillance systems described in this guide.

The document neither does specify how much surveillance should be conducted in individual facilities nor include specific surveillance recommendations for antibiotic-resistant microorganisms or organisms like clostridium difficile.

Any healthcare facility that plans to design and conduct HAI control surveillance work based on the recommendations of this guidelines needs to have established facility level infection prevention and control program in compliance with national recommendations.

# 1. Introduction

## 1.1. Epidemiology of Healthcare Associated Infections

Healthcare-associated infections (HAIs) are preventable infections that a patient can encounter in a healthcare facility while receiving medical care (1, 2). It occurs after 48 hrs. of hospital admission, up to 3 days after discharge, or up to 30 days after operative procedures (2); Surgical site infection (SSI), urinary tract infection (UTI), bloodstream infection (BSI), and pneumonia or respiratory tract infection (RTI) being the commonest types (1).

According to the World Health Organization (WHO) 2019 HAI fact sheet report, one hundred million patients were affected each year globally. This report added that the point prevalence of HAI was estimated in the ranges between 3.5–12% and 5.7–19.1% in developed and low- and middle-income countries, respectively (3). In Sub-Saharan Africa, HAI prevalence is estimated between 1.6% and 28.7% (4).

In many African countries, infection prevention and control measures are not fully implemented in health facilities. When WHO assessed clinics and hospitals across the continent for these measures, only 16% of the nearly 30,000 facilities surveyed had assessment scores above 75%. Many health centers were found to lack the infrastructure necessary to implement key infection prevention measures, or to prevent overcrowding. Only 7.8% (2213) had isolation capacities (5, 6) and just a third had the capacity to triage patients (7). In addition, across Africa, antimicrobial resistance (AMR), including those associated with healthcare infections, is a growing concern. According to the WHO, one of the key strategies for limiting transmission of AMR in the healthcare setting is the effective use of IPC measures.

The above situation is further complicated as in many countries surveillance systems providing reliable data on HAI do not exist and the burden of HAI is largely underestimated and practically unknown by healthcare professionals and policy makers.

In the Ethiopian context, different studies have been conducted to find the overall prevalence of HAIs and its types. The overall prevalence of HAI was found in the range of 9 to 35.8% (8–11). Concerning types of HAI, SSI (13.5 to 52%) [8, 10-11], RTI (5 to 19%) [10, 17], UTI (9.5 to 48%) (9, 10-11), and BSI (4.3 to 46.6%) (12-13) are the predominated HAIs in the country. However, all the studies showed great variation across geographical setting and time periods. This discrepancy between studies makes it difficult to extrapolate the national prevalence. The multicenter point prevalence survey of Antibiotics use, and health facility care acquired infections in selected public hospitals in Ethiopia indicated that the most common indication for antibiotics was Healthcare Associated Infections (HAIs) (39.6%).

Moreover, HAIs increase morbidity, mortality, long-term disability (14), hospital stay (15), microbial resistance to antibiotics (16), and healthcare costs for patients and their families (17). Besides, it upsurges the financial burden on the healthcare system (14).

To combat against the situations described above, in 2004, WHO launched the "clean care is safer care" initiative with the intent of reducing HAI through improved hand hygiene practice in healthcare settings (18).

At the time, in line with the WHO infection prevention and control policy recommendations, Ethiopia developed its first Infection Prevention and Control (IPC) guidelines for use in healthcare facilities in 2004(19). Based on its health policy recommendations, the country never hesitated to strive the promotion of preventive measures including the prevention of HAIs as attested by the recommendations laid out in a variety of health care guidance documents such as Ethiopian Hospital Reform Implementation Guideline (EHRIG), Ethiopian Health Service

Transformation Guideline (EHSTG), Ethiopian Health Center Reform Implementation Guideline (EHCRIG), IPC and Patient Safety guidelines, IPC reference manual, IPC training materials, and initiatives like Water, Sanitation and Hygiene (WaSH), Clean and Safe Healthcare facility (CASH) within the limits of availability of resources.

The country reached the pinnacles of its IPC efforts by recently developing, endorsing, and launching of the National IPC Policy, IPC Strategy, IPC Strategy Roadmap and National IPC M&E plan. However, there was a limited effort in the prevention of HAIs. Thus, the decades of efforts of the country to prevent and control infections, has paved the way to developing this National Guidelines on HAIs Surveillance.

## What is Surveillance?

The Center for Disease Control and Prevention (CDC-USA) defined epidemiological surveillance as "the ongoing, systematic collection, analysis, interpretation of health data essential to the planning, implementation, and evaluation of public health practice closely integrated with the timely dissemination of these data to those who need to know" (16). There are two key aspects of surveillance systems:

There are two key aspects of surveillance systems:

- Surveillance is an organized and ongoing component of a program to improve a specific area of population health.
- Surveillance systems go beyond the collection of information. It's a mechanism by which the knowledge gained through surveillance is delivered to those who can use it to direct resources where needed to improve health.

## 1.2. SWOT Analysis

The SWOT analysis presented below is taken from national IPC strategy document as this guideline is being developed in line with the recommendation the national IPC policy document.

*Table 1 - SWOT analysis*

| 1. Surveillance of HAI's | | |
|---|---|---|
| **Internal factors** | **Strength** | **Weakness** |
| | • Presence of IPC policy and related working documents<br>• Presence of research and surveillance coordinating body at national and regional level which can support facility level HAI's surveillance.<br>• The existence of preliminary works and establishment of IDSR in hospitals<br>• The presence of antimicrobial resistance surveillance system implementation in selected health hospitals across the country. | • Absence of HAIs' surveillance plan, monitory, and reporting and handling mechanism at all health system<br>• Poor understanding of the importance, capacity (human, laboratory and supplies) to perform and commitment of facility managers to do periodic HAI's surveillance and AMR stewardship.<br>• Lack of HAI's process and outcome indicators at national, regional and hospital level |
| **External factors** | **Opportunity** | **Threats** |
| | • Presence of partner showing interest in promoting and implementing AMR<br>• Presence of existing routine data collection mechanism (DHIS2)<br>• Established health emergency and surveillance department at all health system level | • Emerging and re-emerging infectious disease outbreaks<br>• Limited budget and capacity to do periodic HAI's surveillance |

## 1.3. Rationale

The National IPC Policy provides basic guidance on the need for collaboration between MOH and the RHBs for establishing a robust national HAIs surveillance system for the monitoring of HAIs and identification of the pathogens and conditions to be placed under surveillance. This system will generate quality data on HAIs that will lead to a proper investigation of outbreaks and implementation of prevention and control measures by policy makers and healthcare workers lending itself to the need for the development of National HAIs Surveillance Guidelines.

The second imperative at healthcare facilities level is, the need to generate regular reports of comparative data on the levels of healthcare associated infections within the health facilities that can be available timely for treating clinicians and make them aware of local bacterial pathogen types and their resistance profiles, that will enable them to make better empirical treatment choices where necessary and to assess implications of their treatment choices and

infection control practices.

In addition, a meta-analysis of studies in Ethiopia showed only half of healthcare workers practiced safe infection prevention practices with variations by geographic region and from facility to facility. In terms of knowledge, studies have revealed that 15.3%–46.3% of healthcare workers in Ethiopia were not knowledgeable about infection prevention. Lack of knowledge among healthcare workers and poor prevention strategies in the facilities may potentially lead to a high risk of infection transmission in healthcare settings.

Finally, without existing (baseline) data;

1. It is difficult to know if improvement may be needed;
2. Outbreaks may also be missed, and
3. The effect of improvement strategies may not be appreciated.

Hence, creating standardized practice, proper data management, and evidence-based decision making have to be laid out in the National Guidance of HAIs Surveillance on which so far has not been provided.

The MOH recognizing the complexity of putting together an effective national HAI surveillance system has developed this National HAIs Surveillance Guideline in which the envisioned context-sensitive HAI surveillance approach, data management & use, step wise implementation approaches, roles and responsibilities of key stakeholders, M & E, and quality improvement approaches are outline accordingly in the following sections in this guideline.

## 1.4. Purpose of the Document

The purpose of this HAIs surveillance guideline is to

- Provides guidance on the overall HAI Surveillance system design and implementation approaches
- Introduces context –sensitive standardized HAI surveillance case definitions and Protocols
- Outlines guidance on communication among Healthcare cadres while implementing HAI surveillance
- Provides guidance on integration of HAI surveillance into existing workflows
- Provides guidance on how best to link HAI surveillance and prevention activities
- Designates the roles and responsibilities of key stakeholders
- Describes HAIs data management and M & E systems.

# 2. Objectives

## 2.1. General Objective

The general objective of establishing national HAI surveillance system is to establish a robust surveillance system on priority HAIs which will serve as a basis for strengthening infection prevention and control practices in healthcare facilities.

## 2.2. Specific Objectives

The following are specific objectives of establishing the national HAI surveillance system:

- To standardize HAIs surveillance system across the healthcare system of the country
- To estimate the burden of HAIs in healthcare facilities.
- To detect and investigate clusters of cases, outbreaks, and exposures of infectious diseases.
- To strengthen HAIs detection capacity of healthcare facilities
- To initiate the establishment of HAIs Surveillance networks among healthcare facilities in Ethiopia.
- To encourage research on HAIs as well as the surveillance system
- To establish a link between HAIs surveillance and other related surveillance systems across the healthcare delivery system
- To provide data for monitoring and evaluation of impact of IPC interventions.
- To disseminate HAIs surveillance results to be used by HCWs and Decision makers at all levels.

# 3. Scope and Target Audiences

This surveillance guideline applies to all levels of the healthcare tier system that fall within the jurisdiction of the Ministry of Health- Ethiopia and the Regional Health Bureaus in the country. Other health care facilities that do not fall under the jurisdiction of the Ministry of Health and Regional Health Bureaus may also use this surveillance guideline for establishing and implementing HAI surveillance works.

However, the guidance in this document is not intended as a guide for infection surveillance during community outbreaks. The intended users for this guidance include infection control specialists, infectious disease specialist, epidemiologists, clinicians, Microbiologists, researchers, hospital management, regional and national policy makers and the public at large. And also, it can serve as a resource for anyone seeking to improve their understanding of health care-associated infections surveillance.

# 4. Methodology

This section will provide the detailed descriptions of the different methods and approaches of HAIs Surveillance in healthcare facilities. The section will address types of surveillance, prioritizing HAI, target population (HCFs), case definition, protocol, data management, outbreak management, networking, and communication.

## 4.1. Types of Surveillance

There are several ways to classify HAI surveillance methods which are discussed in the below sections.

### 4.1.1. Active and Passive Surveillance

#### 4.1.1.1. Active Surveillance

Active HAI surveillance system involves actively looking/search for cases of patients who acquire HAIs through trained healthcare workers such as IPC professionals in which the reporting system frequency is regularly observed. In this type of surveillance system, individual cases serve as an alarm for healthcare professionals. Moreover,

This form of surveillance produces more complete and comprehensive information; but the data aggregation is more complex compared with that of passive surveillance; this necessitates a significant increase in time and resources.

Sentinel surveillance is a type of disease surveillance which focuses on disease detection activities among specific subpopulations. Sentinel populations are often chosen based on attributes that make the disease easier to detect or the subjects more convenient to sample. Sentinel surveillance systems can detect pathogen spread into new areas, changes in prevalence or incidence of a pathogen over time, the rate and direction of pathogen spread, and the efficacy of control interventions.

#### 4.1.1.2. Passive surveillance

Passive surveillance refers to regular collection and reporting of data without active search for cases using routine health care system by health care provider, who may not be formally trained and who do not have a primary surveillance role. Although passive HAI surveillance is less expensive than active surveillance due to less labor and resource intensive, there is an inherent bias as the data source is more likely to be voluntarily report data indicating the absence rather than presence of HAI, as the latter could put the reporting source in a negative light. However, Passive surveillance is the most common type of surveillance in humanitarian emergencies and most surveillance for communicable diseases is passive.

### 4.1.2. Patient-based and laboratory-based surveillance

HAI surveillance can also be classified as patient-based, or laboratory based according to the types of data generated from the surveillance systems.

#### 4.1.2.1. Patient-based

Patient based surveillance is a type of surveillance in which we count HAI based on case definition, assess risk factors, and monitor patient care procedures and practices for adherence to infection control principles. This kind of surveillance requires ward rounds and discussion with caregivers. Prospective clinical (patient-based) surveillance is considered the

reference method or 'gold standard' for HAI surveillance but requires substantial resources.

#### 4.1.2.2. Laboratory-based

This kind of surveillance is based on the detection of the finding from laboratory tests of clinical specimens in addition to patient case definition data. Laboratory based surveillance can be conducted by healthcare facility laboratory, national public health laboratory or other laboratories like regional, district and other governmental, non-governmental and private health facility laboratories. These laboratories focus on defining characteristics of pathogens isolated, identifying, and sub-typing such as serotype, antimicrobial resistance profile, and genotype and compile the results with patient data to determine association between pathogens identified and infections.

### 4.1.3. Prospective and retrospective surveillance

#### 4.1.3.1. Prospective surveillance

In order to investigate for potential HAIs, prospective surveillance data is gathered on ongoing basis, by monitoring the patients throughout their hospital stay. Although it involves more resources because all patients must be followed to detect all HAIs, it may be more reliable than other approaches in cases with inadequate documentation. So, in this type of surveillance, patients are monitored during their hospitalization though in case of SSIs in monitoring is also done during the post-discharge period.

#### 4.1.3.2. Retrospective surveillance

Retrospective surveillance evaluates patient data via chart reviews after patient discharge. Although retrospective surveillance takes fewer resources, it will be ineffective if medical records are not fully documented.

### 4.1.4. Priority directed and comprehensive surveillance

#### 4.1.4.1. Priority-directed

Priority-directed surveillance, which is also called targeted/focused or surveillance by objective, is a surveillance method that is focused on certain health care setting areas (e.g., intensive care unit), patient populations (e.g., surgical patients) and/or infection types (e.g., bloodstream infections, indwelling catheter-associated urinary tract infections), that have been identified as a priority within the health care setting.

Its core principle is based on defining surveillance objectives and it mainly focuses on specific events, processes, organisms, and/or patient.

#### 4.1.4.2. Comprehensive

Comprehensive surveillance also called hospital-wide ("whole-house") surveillance of all admitted patients which permits determination of an overall facility HAI rate, i.e., overall percentage of patients with an HAI during the surveillance period. In general, this practice is discouraged for several reasons. Apart from being extremely labor intensive and overall, HAI rates may not accurately convey the relative importance of certain HAIs compared with others and does not allow for risk stratification or adjustment.

### 4.1.5. Risk adjusted and crude rates

#### 4.1.5.1. Risk-adjusted rates

In risk adjusted rate, rates are adjusted for variations in the distribution of the main risk factors linked to an event's occurrence, which enables inter- and intra-facility rate comparisons. Since, hospitals and their patient populations vary significantly, it is now common practice to calculate and report risk-adjusted infection rates.

#### 4.1.5.2. Crude rates

Crude rate is defined as the total number of events, or count, divided by the mid-year total population of the selected health facility and multiplied by a constant, which is a multiple of 10. Crude rates assume equal distribution of risk factors for all events in which such rates cannot be used for inter-facility comparisons. Since there are variation in terms of service type and patient volume.

### 4.1.6. Incidence and prevalence rates

#### 4.1.6.1. Incidence rate

Incidence refers to the occurrence of new cases of disease or injury that occur in a population at risk over a specified period. Thus, incidence gives information about the risk of developing the HAIs. Therefore, we only count new HAI occurrences that take place during a specified time period. Incidence is the most commonly used approach to determine the occurrence of HAIs in the health facility; facility shall use this estimator to response the occurrence of health care associated infection.

#### 4.1.6.2. Prevalence rate

Prevalence is defined as the total number of HAIs present in a population at any given time, whether at a certain point in time or during a predetermined period of time. Data on prevalence give a sense of how widespread HAIs is and may have an impact on how quickly the patients may get the assistance it needs.

## 4.2. Prioritizing Healthcare Associated Infections

Prioritizing surveillance activities is essential for effective allocation of resources to maximize the benefits of reducing HAI among patients admitted to health care facilities. Prioritizing healthcare associated infections to be monitored by surveillance activity may be determined by several factors depending on the context of the health facility which includes the following but not limited to:

- **Mandatory or required** - the healthcare setting may be obliged to do surveillance on specific HAIs to comply with routine reporting requirement.
- **Incidence -** a particular type of healthcare associated infection may be of special concern in the health care setting due to its increased number of cases.
- **Communicability -** due to its communicability, a particular pathogen might be of concern in the health care setting.
- **Cost (healthcare facility and patient) -** the infection has associated impacts and costs

indicated by:

  - The frequency of which the infection results in mortality (its case-fatality ratio)
  - Prolonged hospital stay resulting from the infection the excess treatment costs associated with the infection.
  - Occupational infections of health care workers.
- **Effectiveness of intervention -** surveillance for a particular infection will assess the effectiveness of IPC interventions.
- **Early detection -** Syndromic surveillance (e.g., urinary tract infections) is recommended in healthcare facilities and has the added benefit of detecting important health care-associated infections.
- **Pathogen with high public health concern** (reportable diseases under the national surveillance system) – a healthcare associated infection surveillance might consider pathogens of special public health importance such as Carbapenem Resistant organisms and infections having preventive measures might be considered.
- **Availability of resources –** human, financial, technology and materials required for surveillance might be considered.

## 4.3. HAI surveillance priority areas (target population)

- Surveillance for all types of infections is rarely done in all healthcare setting services and procedure areas. This is important in all settings but especially in settings where resources are scarce, while planning surveillance, priority service provision areas are:
- High-risk areas such as intensive care and postoperative units including post cesarean section.
- High-risk patient populations such as immuno-compromised patients and neonates.
- High-risk procedures (e.g., major surgeries).
- Diseases present in the hospital and community with potential to rapidly spread through the hospital.

## 4.4. Case definition

Case definitions are a set of criteria used in making a decision as to whether an individual has a disease or health event of interest. Establishing a case definition is an imperative step in quantifying the magnitude of disease in a population. Case definitions are used in ongoing HAI surveillance system to track the occurrence and distribution of HAIs within a given area, as well as during outbreak investigations.

A case definition must be clear, simple, and concise, allowing it to be easily applied to all individuals in the population of interest. It typically includes both clinical and laboratory characteristics, which are ascertained by one or many methods that might include diagnosis by a physician, completion of a survey, or routine population screening methods. Individuals meeting a case definition can be categorized as "confirmed," "probable," or "suspected."

During an outbreak of disease, a case definition is developed at an early stage of the outbreak investigation, facilitating the identification of individual cases. While the same criteria apply for developing a case definition in routine surveillance system, in an outbreak investigation a

case definition may also include information regarding person, place, and time. Healthcare facilities shall use case definition as per the national HAI surveillance guidance.

## 4.5. Protocol

A protocol can be defined as a systematic description of procedures to be used in research or non-research study. The quality of HAIs surveillance protocol is often improved when goal, objectives and methods are clearly thought and thoroughly and described. A written protocol facilitates high quality implementation of HAI surveillance.

In developing protocols health facilities have to stick to the national and international standards; protocol for each HAI surveillance should at least include the following contents; title, protocol summary, investigators & collaborators role and responsibility, introduction, literature review, justification for HAI surveillance, intended use of HAI surveillance findings, objectives, detailed methods for the HAIs surveillance implementation strategy depicted in section VI, case definitions, information management system, quality control and assurance, limitations, disseminations, notification and reporting of the surveillance results, anticipated inventions resulting from HAI surveillance findings, references and appendix documents.

## 4.6. Data management and reporting at all levels

Data will be collected from patients diagnosed with prioritized HAI using lab based and patient approaches through appropriate electronic or manual data capturing systems depending on the capacity of the healthcare facility. Then the following data management components must be addressed; data organization, analysis, quality assurance, reporting, assuring of privacy, access, sharing and information use.

Whether using lab-based or patient approach, healthcare facilities would use the following data flow mechanism as depicted in the following diagram.

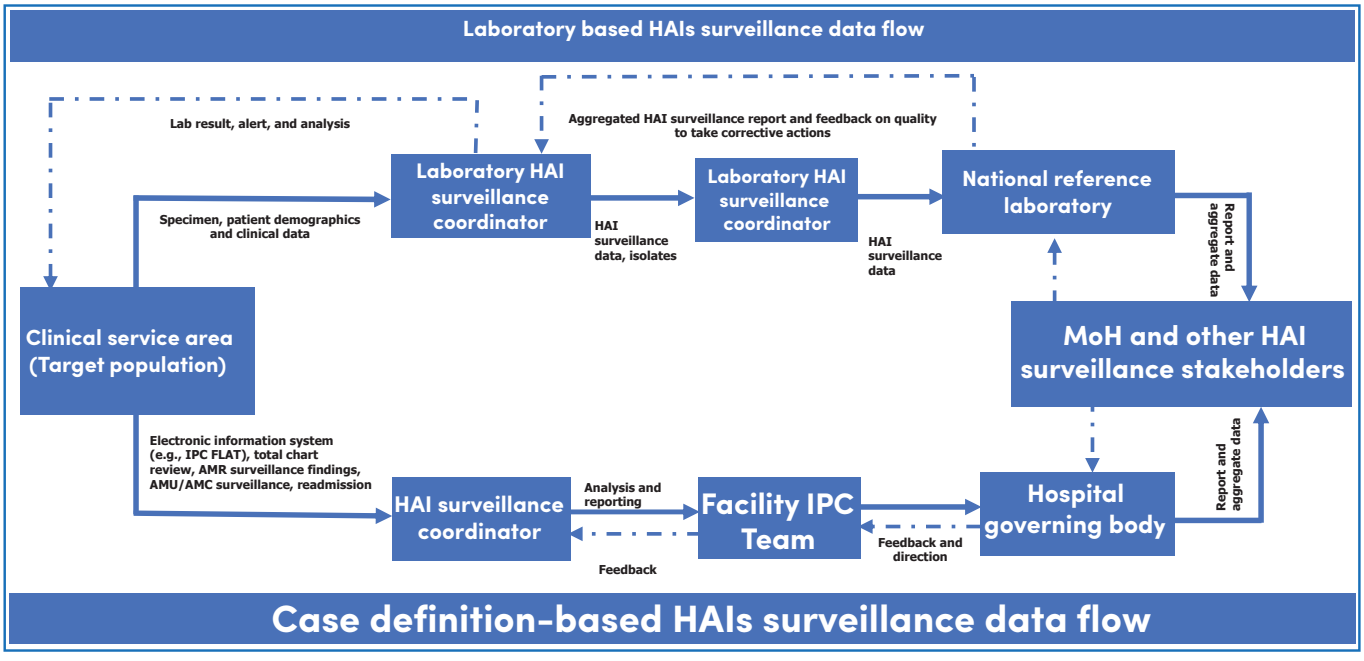


*Figure 1 - Data/information flow for laboratory based and patient-based HAIs surveillance*

*system*

## 4.7. Outbreak Management

An outbreak is defined as an increased frequency of a disease above the threshold in a given population which refers to a limited geographic area.

The majority of outbreak investigations involve the following steps: preparing for the investigation, establishing the existence of the HAI outbreak through rapid assessment, verifying the diagnosis of the HAI outbreak, establishing a case definition, finding cases, and developing a line list, conducting descriptive epidemiology to determine the individual characteristics of the cases, observing changes in disease frequency over time and differences in disease frequency based on location and developing hypotheses about the cause or source, evaluating the hypotheses & then refining the hypotheses and conducting additional studies when necessary, implementing control and prevention measures, communicating the findings and maintaining surveillance system.

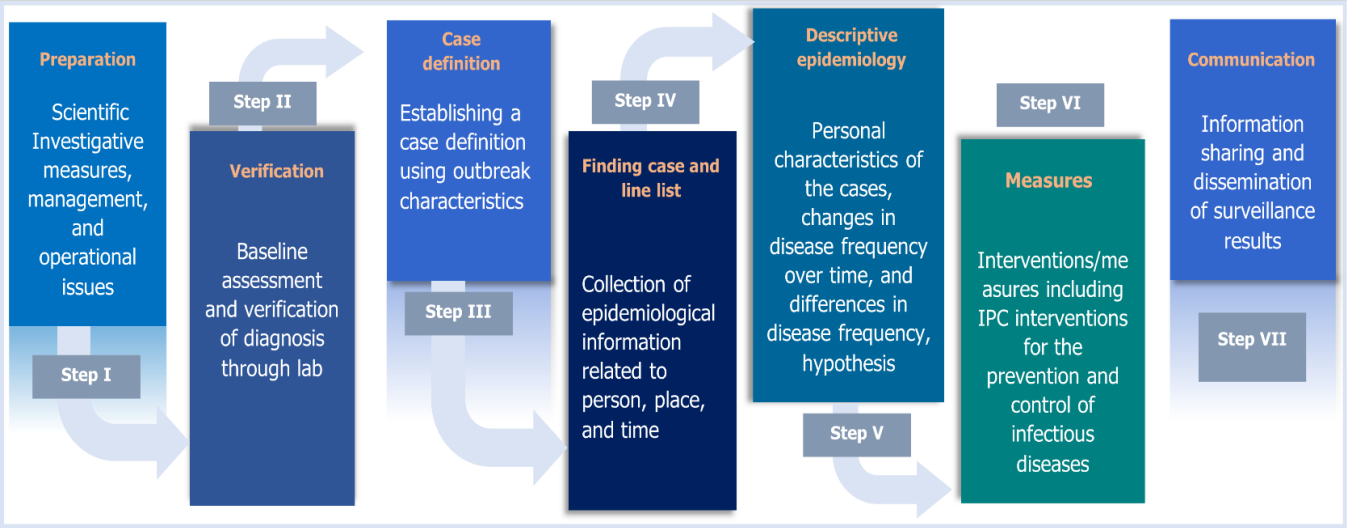


*Figure 2 - Summary of outbreak management steps, May 2023*

## 4.8. Networking, Communication, Dissemination and Advocacy

### 4.8.1. Networking

The network among HAIs surveillance participating healthcare facilities at local and national level strengthen coordination between all key stakeholders at local, national, and international level. This will help to enhance the capacity of implementing HAI surveillance system. HAIs surveillance participating healthcare facilities will also communicate through various forums like monthly, quarterly, or annual review meeting and experience sharing visits.

The networking will be coordinated by national HAI surveillance coordinating team. At national level the coordinating team will participate in technical working groups, other surveillance system forums (e.g., national AMR surveillance system) and also participate in international HAIs surveillance network.

### 4.8.2. Communication

Surveillance data should be communicated between internal facility departments and external health facilities. Communication of HAIs surveillance data can take place in electronic, or paper format and it is recommended for use in improving IPC practice to reduce facility level rates of infection from the surveyed pathogen. Ultimately the production and dissemination of surveillance data and use for program improvement constitutes the end goal of an effective surveillance system.

#### 4.8.2.1. Communication at the health care facility level

Communication of HAI rates takes place first at the healthcare facility level, between departments (laboratory, wards, ICU etc.), IPC team and healthcare facility leaderships. This type of communication provides a facility level view of the risk of HAIs in the health care setting over a specified period of time.

Healthcare providers will be communicated about the HAI surveillance activities using available platforms like review meetings. And this communication, often in the form of a quarterly report, should outline any changes to the risk of infection across all patient care areas that are covered by the HAIs surveillance system.

To assist clinicians and health care facility leaderships to understand the interpretation of HAI rates, it is also important to describe where this rate is situated relative to previous surveillance intervals or in relation to other facilities. Whenever possible, the IPC team should employ visual aids, such as bar or pie charts, graphs, and tables, in order to display surveillance data. Important trends, such as an increasing HAI rate, may be quickly identified.

#### 4.8.2.2. Communication at National/Regional/Zonal/Woreda level

The HAI surveillance report at each level should offer a more detailed analysis of the specific types of infections affecting patients served by these particular care areas and disaggregated by healthcare facilities. Information is generally presented as a written report.

Such reports may be distributed at regular program-specific committee meetings and could be used in a workshop, for example, which might comprise of leaderships of healthcare system at all levels, health care providers and the IPC Teams.

The information provided in surveillance reports can also be used to direct resource allocation in IPC. This information should be directed to those able to effect change in the health care setting's practices.

All information provided in surveillance reports must be clear, easy to follow and provide only the information required. Information should be presented using a standardized format, as healthcare managers and/or healthcare providers often have little time available for an in-depth review of the data.

#### 4.8.2.3. Communication of special alerts and outbreaks

Timely communication of alerts to health care providers following identification of an emerging risk of infection is important. For example, if the IPC team detects a sharp increase in the rate of HAIs in a particular department of their facility, and if once the outbreak is identified, they may issue a facility-wide alert documenting the increase of HAIs and the alert should present

only key information and should be communicated quickly and effectively.

This alert may also serve as an opportunity to remind healthcare providers on adherence to IPC practices, such as hand hygiene compliance and routine HAIs screening practices for patients admitted to that specific department/ward.

Any additional IPC precautions instituted in response to this increase in HAI rate may also be outlined in this alert. If a reportable disease according to the national standard is identified, the healthcare provider in that health facility should notify IPC unit.

Laboratory identification and detection of extensive and pan drug resistant bacterial pathogens repeatedly from specific wards and patient population should be also communicated on time to control the spread to other wards and patients.

### 4.8.3. Dissemination

HAIs surveillance report will be disseminated through annual or biannual review meetings to all local, national, and international key stakeholders. In addition, the national HAI surveillance findings will be disseminated through IEC materials (e.g., brochures, flyers, posters, and leaflets, presenting at national conferences and meetings of professional associations, presenting HAI surveillance program results to local community groups and other local stakeholders, creating toolkits of training materials and curricula for other scholarly communities.

A telegram channel will be created for participating health facilities and periodically findings will be posted to learn lessons from each other. Besides, different national HAI surveillance system technical proceeding reports shall be written and published in international peer-reviewed journals to share the experiences of the HAI Surveillance System implementation to the wider scientific community.

### 4.8.4. Advocacy and awareness creation

HAI surveillance findings will be disseminated to the high-level officials to get their attention to strengthen all types of supports required for HAIs surveillance. On top of this the brief information will be disseminated to the general public through electronic (mainstream and social media) and print medias.

### 4.8.5. Using HAI surveillance data for research purposes

According to the WHO guidelines on the ethical issues in public health surveillance, the data generated from surveillance have often served as a foundation for important public health research (WHO,2017) .

Sharing of surveillance data for research purposes requires appropriate safeguards, such as ethical oversight, anonymization, and data security. Surveillance data should be used only for research projects that have been reviewed and approved by an appropriate research ethics committee or another appropriate body, consistent with international and local requirements on the ethical conduct of research.

Before surveillance data are shared with researchers, there should be agreement about: appropriate data uses, restrictions on data re-sharing, adequate acknowledgement of the data source in publications, and data destruction conditions at the end of the research phase.

# 5. Data Management and Use

Healthcare associated infections (HAIs) data management is the comprehensive approach that involves data collection, cleaning, analysis, interpretation, and dissemination of information. It informs decision making at all levels of healthcare system. Further provides communication and use of information required for patient care to improve the effectiveness and efficiency of the health services and linking to continuous quality improvement.

Data management process includes data collection, identifying data source, reporting, data organization, analysis, interpretation, data quality management and use, ethical consideration and data storage.

## 5.1. Data source

Data source is a location where data is initially generated from specific recording tools (e.g., registers, tally sheets, electronic tools etc.,) designed for the HAI surveillance program which will further be used as an input for analysis, interpretation and informed decision making.

### 5.1.1. Laboratory based data

The data source for laboratory-based surveillance is patient clinical data, request form, the registration or logbook designed specifically to record HAI surveillance data (see annex). These data will be collected from specimen collected for the microbiological laboratory analysis. For the laboratory specimen collection and analysis standard operating procedure will be used across the laboratories involved in HAIs surveillance to maintain data similarity. (See SOP annex).

### 5.1.2. Patient based data

The data source for patient-based surveillance is patient chart (medical records), logbook or other medical records which are stated in implementation standard protocol (annexed).

## 5.2. Data collection

Data collection is the process of gathering quantitative and qualitative data on a specific variable to answer relevant questions with the aim of measuring the magnitude of HAIs and Surveillance program results.

Data can be collected in a continuous and/or periodic manner in which the choice of data collection methods is linked to frequency of decision making, complexity, and cost of data collection.

The following section will address facility level data collection for ongoing program monitoring of selected HAIs for both laboratory based and patient-based HAI surveillance methodologies using input, process, output, and outcome indicators.

### A. Numerator Data Collection

The numerator for HAI surveillance is the number of cases the infection of interest (e.g., SSI) occurs among the population at risk during a specific time interval. Numerator data are collected by using a written, standardized surveillance case definition to determine which cases are included and which are not.

Any trained health personnel can screen data sources for HAI, or automated screening of

electronic databases may be used, as long as the clinician makes the final determination of presence of HAI according to the criteria for defining HAI.

### Minimum Numerator Data Set

- Demographic – MRN name, date of birth/ Age, gender, hospital identification number, Time and admission date, date of discharge
- Infection –date of onset , site of infection, patient care location of HAI on set
- Risk factors – devices, procedures, other factors associated with HAI
- Laboratory – pathogens, antibiogram, serology, pathology
- 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
    a. Laboratory and radiology/imaging results
    b. Nursing and physician's notes and consults
    c. Admission diagnosis
    d. History and physical examination findings
    e. Records of diagnostic and surgical interventions
    f. Temperature chart
    g. Information on administration of antibiotics

## B. Denominator Data Collection

Denominator data may be collected by someone other than the IPC expert as long as that person is trained. When denominator data are available from electronic data bases (e.g., patient tracking systems, respiratory therapy database), these sources may be used as long as the counts are not substantially different from those collected manually.

### Minimum Denominator data Set

1. Counts of the cohorts of patients at risk of acquiring HAI
2. For device-associated HAI incidence density rates: record daily the total number of patients and total number central line-days, and urinary catheter-days in the patient care area(s) under surveillance; sum these daily counts at the end of the surveillance period for use as denominators
3. For SSI rates to be stratified by factors: record information on operative procedures selected for surveillance (e.g., type of procedure, date, risk factors, etc.)

### Sources of denominator data

1. For device-associated incidence density rates: visits to patient care areas to obtain daily counts of the number of patients admitted and the number of patients with each of the commonly used devices associated with HAI (i.e., one or more central line, or indwelling urinary catheter)
2. For SSI rates: detailed logs from the operating room for each operative procedure

### Minimum data set for selected HAI and laboratory request form

The data set for both laboratory and patient base surveillance should have the following minimum data elements.

Minimum data set for Healthcare Associated Infection Surveillance (Laboratory request form).

- Hospital Profile
- Patient information (i.e., Name, Age, Gender, MRN, Address)
- Sender's information (Name, phone number)
- Type of specimen submitted
- Specimen collection date
- Specimen collection time
- Date and time of admission
- Location of the patient
- Current antibiotics taken
- Diagnosis
- Clinical history
- Culture observations and work-up:
- Final culture identification report
- Final test done by
- Reviewed & released by

### Minimum data set for HAI Surveillance

- Hospital profile
- Patient information/demographic information (Name, Age, Gender,)
- Patient admission data (date and time, Diagnosis)
- Exposure data (Contact risk)
- Antimicrobial use data
- Laboratory data

- Microorganism and antimicrobial resistance data
- Procedures'-, duration of the procedure, wound classification, Type of Anesthesia, Emergency/elective,
- Device related information (Type and Date)
- For post-discharge detected SSI, sources include records from surgery clinics, emergency departments.
- HAI Type

## 5.3. Data organization

Data organization is the process of classifying and categorizing data from multiple sources to create unified sets of information for both operational and analytical uses.

All data collected should be regularly consolidated into a format suitable for analysis. In order to do this successfully it is necessary to organize them systematically from the moment of receipt.

Depending on the aim of the analysis, aggregated data can be reported by different stratifying variables, i.e. type of HAIs, service delivery points, health facilities, or other existing health system hieratical structures, or alternatively by patient demographics (for example age groups, gender, comorbidities, and risk factors etc.)

- Organization of HAIs data shall be a computerized and IT supported.
- HAIs surveillance data shall be stored in both electronic and paper-based formats.

## 5.4. Data analysis and interpretation

Data analysis is the process of finding patterns and trends in the data, which is a crucial step in the HAI surveillance process. Data interpretation is the process of reviewing data and arriving at relevant conclusions using various analytical methods. Analysis shall be done at all levels routinely for identifying areas for improvement regarding the outcome of the planned actions and the findings are shared with the health facility administration, relevant staff, and different stakeholders for further program monitoring and planning improvement.

### Calculation of HAIs metrics

One of the common HAIs indicators shall be presenting the rate of HAIs at health facility or service areas. A rate indicates a relationship between two measurements with different units of measure and is used in HAI surveillance to describe HAIs in patient populations of different sizes and in different time periods.

A rate has three components:

- **Numerator:** the number of infections
- **Denominator:** the number of patients at risk
- **Constant:** a multiple of 10 that results in a number greater than zero.

Mathematically, the rate is calculated as the numerator ÷ denominator x constant. Rates

are generally expressed according to the denominator and the constant used e.g, per 100 surgical procedures or per 1,000 central line days.

*Table 2 - Commonly used HAIs Metrics*

| Incidence rates | Expression |
|---|---|
| Surgical Site Infection (SSI) rates | # of infections /# of procedure) x 100 procedures |
| Health care associated-bloodstream infection (sepsis), Central line blood stream infection | (# of infections/# of patient-days) x 1,000 |
| Catheter- associated Urinary Tract infection (CAUTI) rates | # of CAUTI /#of indwelling urinary catheter-days) x 1,000 |
| Ventilator-associated pneumonia (VAP) rates | (# of VAP/# of ventilator-days) x 1,000 |
| Central line-associated blood stream infection (CLABSI) rates | # of CLABSI /#of central line-days) x 1,000 |
| Multidrug-resistant organism (MDRO) rates (e.g., methicillin-resistant Staphylococcus aureus [MRSA] rates) | (# of MDRO infections/# of patient-days) x 1,000 |

### HAIs data presentation

Converting HAIs data into information should be facilitated by using appropriate tools for presentation and analysis.

Data can be reported via:

- Tabular presentation (e.g., in summary tables and listing reports).
- Spatial presentation (e.g., in charts, graphs, and maps created using a GIS).
- Textual
- Electronic analysis tools (e.g., with pivot tables).

## 5.5. Data Quality Management

A well-functioning HAI's data management system yields high-quality and comprehensive data and information that is essential for enabling effective surveillance and management. No matter how rich or complete the data set, it's no good if it doesn't deliver insights. There should be a system to maintain the data quality.

### 5.5.1. HAI surveillance data quality dimensions

HAIs data quality should meet at least the following five dimensions: accuracy, completeness, timeliness, validity, and consistency.

### Accuracy

The term "accuracy" refers to the degree to which information accurately reflects an event or object described which reflects the truth. Training and evaluation, including the use of data quality indicators can help to assess and improve data accuracy.

### Completeness

Data is considered "complete" when all data variables for cases are entered. Let's say that we ask the providers to record surgical outcomes. There might be missed records about the outcome of the surgery and treatment given, that means the data is incomplete.

There are things that should be done to improve HAIs data completeness.

- The data collection format should contain all data sets needed , and field tested (piloted) before use to prevent the "garbage in garbage out" risk
- Providing specific training on HAI's data recording system to the health care providers.
- There should be an assessment whether all of the requisite information is available, and whether there are any missing elements.
- Regular reporting of the data in a way to detect most frequently incomplete information.
- Provide immediate corrective action to the health care providers.
- Promote good data recording and using culture.

### Timeliness

Data are timely when they are available and disseminated at the time the programme needs them. Timeliness is particularly important in surveillance because of the focus on ongoing tracking of HAI events.

If the information isn't ready exactly when it is needed, it doesn't fulfill that dimension. In addition, the information is said to be timely (timeliness) when it is up to date (current) and consistent with the current research evidence.

### Validity

In the context of surveillance, validity describes the ability to capture the 'true value' of the disease burden, such as incidence or prevalence, which is useful for the analysis of surveillance data. The 'true value' should be viewed in the context of a surveillance system. Validity may relate only to a limited number of cases, e.g., those diagnosed by health services covered by surveillance systems. Validity is a data quality dimension that refers to information that doesn't conform to a specific format or doesn't follow reporting rules.

- To meet this data quality dimension, one must check if all the required information follows a specific format or reporting rules. Thus, all health care workers need to follow the required procedure to complete the HAIs data reporting forms.

### Consistency

At many health facilities, the same information may be stored in more than one place. If that information matches, it's considered "consistent." For example, if the laboratory result says the patient is positive for a given test, yet the patient chart saying different, that's inconsistent.

To resolve issues with inconsistency,

- Review the lab data and the patient chart to see if they're the same in every instance.
    - Are there any instances in which the information conflicts with itself?

- Conduct regular LQAS

- Document the laboratory result and other investigation, and the physician examination result in a HAIs reporting format that is prepared for the surveillance system.

### 5.5.2. Internal and External Data Quality Assurance

#### Internal Quality Assurance (IQA)

Internal quality control monitors the daily precision and accuracy of recording system, laboratory analysis, personnel, and laboratory instruments (media, equipment etc.).

- The IQA standard operating procedure (SOPs) should be in place for the laboratory participating in HAI surveillances
- The clinical bacteriology laboratory IQA is done by laboratory personnel on a regular basis for laboratory materials, reagents, chemicals, and reference strains according to the SOPs.
- The IQA results should be registered, signed by supervisor, and documented.
- For the patient -based HAIs surveillance the patient chart must be checked for all data quality dimension by the HAI team or committee on a daily basis.
- The facility shall implement LQAS as per the national health data quality guideline recommendation.

#### External quality Assurance

The external quality assessment (EQA) Proficiency Testing (PT) is useful for a comparison of a laboratory's testing procedures to other laboratories across the world. Comparisons can be made to a peer group of laboratories or to a reference laboratory which allows laboratory to maintain long term accuracy in reporting patients' laboratory results.

- EQA will be achieved through two mechanisms: monthly confirmatory testing of isolates submitted by HAI surveillance sites and proficiency testing (PT) panels sent to the HAI surveillance laboratories from an accredited vendor. These programs will be used to monitor the quality of the bacteriological data generated by the laboratories and to measure the progress made by any capacity building initiatives for bacteriology and antimicrobial susceptibility (AST) improvement.
- Bacterial identification and AST confirmatory testing is a continuous activity in which each HAI surveillance site submits a specific subset of isolates to the national referral laboratory on a monthly basis. Submitted isolates then undergo re-identification and AST for quality assurance, and reports of results and scores are shared back to the HAI surveillance sites laboratories. The laboratories must perform a root cause analysis on all discordant results and, when possible, implement corrective action to prevent the same error from occurring in the future. The HAI surveillance sites laboratories are encouraged to request assistance from the national reference laboratory in these tasks. Instructions for submission of isolates and corresponding SOPs can be found in Compiled Guidance: Confirmation Testing Program.
- The national/regional M &E Team conduct HAI RDQA as per the national health data quality guideline recommendation.

### Data security

There should be a mechanism to protect the surveillance data security through various systems.

- Develop office rules or procedures to ensure that the person responsible for the data is the only one allowed or able to modify the data. However, other members of the team should have access to the data in case they need or desire this. One approach is to make regular up-to-date copies and to provide clear instructions on where to obtain them.
- The paper-based data should be stored in cabinet or locker that can be locked.

## 5.6. HAIs Surveillance Data Use

HAIs surveillance data use focuses on the data communication and use for informed decision making. Data should be converted into information for health-related decision making in a format that meet the needs of multiple users (i.e. policymakers, managers, providers, and communities).

This includes considerations, such as provider awareness and capacity to use for the improvement of the day-to-day activities. Therefore, the data generated from the facility should primarily be used by that facility to improve the quality IPC practice.

Facility leaders must play a key role in the introduction of HAI's data use. They must clearly communicate the goals of data use to staff, provide ample opportunities for training in these systems, and finally utilize the data to communicate with relevant stakeholders (i.e., all health system levels – (woreda health office, Zonal health department, regional health office), and monitor performance.

The HAIs surveillance system should promote the use of data for decision making and communicate the HAI surveillance results through the following ways:

- Preparing regular reports of the HAIs data
- Producing technical reports
- Generating fact sheets
- Integration with the routing health information system (i.e., DHIS2)
- There should be Meetings organized at all levels to communicate the HAIs surveillance result.
- When needed, the data shall be further analyzed and communicated to the scientific community through peer-reviewed journals.
- Establish standard procedure to share HAI surveillance data. Use the form attached in the annex (I-V).

## 5.7. HAIs Surveillance Data Reporting

The reporting period for the HAIs surveillance data shall be every month and should be aligned with the national HMIS reporting period. Each health facility should follow the standard reporting system presented in this document to the report relevant bodies to do plan of action. Send the data to the more central level in the required format and in accordance with the reporting schedule.

## 5.8. Ethical consideration of managing HAI surveillance data

Establishment of HAI surveillance is to improve healthcare quality, ensure patient safety and reduce harm to the patient who attends healthcare facilities. So usually, HAI surveillance data findings will be primarily shared for key stakeholders such as healthcare professionals, department head and senior management team. Furthermore, if incase HAI data is required for research undertaking purposes the required procedures have to be kept and official ethical clearance has to be granted from the responsible body.

## 5.9. Data backup and depositions

HAI data generated at all healthcare facilities will be sent to MOH and saved for later analysis in WHONET (WHONET is a free Windows-based database software developed by the World Health Organization). HAI data backup system will be both web-based and offline system based. HAIs database will be archived both at all sites and nationally on the working computers. These databases must be placed on separate external hard disk like CDs and memory sticks on monthly basis.

# 6. Implementation Approach

## 6.1. Planning and Preparation

The HAI surveillance implementation will follow a phase-based approach. Scaling up of implementation will be based on the experience obtained from the implementation of the first phase. Protocol/SOP will be prepared to guide the implementation of HAI surveillance at facility level. Plan of action would be prepared to guide the implementation of the HAIs surveillance at each level. The surveillance plan of action would address:

- Purpose, objectives, use of data
- Responsible surveillance team
- Methodology
- Timeline
- Monitoring & Evaluation
- Reporting and feedback

## 6.2. Priority HAIs

Prioritized HAIs are Surgical site infections (SSI), Bloodstream infections (BSI), and Catheter Associated urinary tract infections (UTI) are the prioritized HAIs to be measured in the surveillance population during the first phase of the HAIs Surveillance implementation.

These HAIs have been selected for the first phase of the surveillance by taking the following factors into consideration:

- Frequency of HAI and/or medical risks to patients
- Costs of HAI (e.g., treatment, length of stay, mortality, severity).
- Feasibility implementing preventive measures.

Case Definition and protocols - a standardized case definitions and protocols shall be used across the selected hospitals to enables HCWs to classify and count cases consistently and to ensure the comparability of the results among the hospitals. The case definition of the selected HAIs is annexed with this document.

## 6.3. Facility selection criteria

As mentioned in the above section, due to human, technical and financial resource constraints, MoH will select 10 hospitals for the first phase of implementation which will be categorized in two groups.

The 1st group of facilities comprises tertiary level hospitals that have the capability to include laboratory data into HAI surveillance system. These facilities are required to have a functional microbiology laboratory with capacity to perform a routine bacteria identification and Antimicrobial Susceptibility Testing (AST). These sites will be hospitals which have been participating in AMR surveillance system.

The 2nd group of hospitals comprises general and primary hospitals that have the ability of initiating patient-based HAI surveillance.

Furthermore, selection of hospitals to initiate HAI surveillance program in phase one will be determined the following criteria:

### I. For case definition-based HAI surveillance

- A Facility leadership buy-in to implement national HAI surveillance guidance.
- A Facility that has strong IPC program (with best IPC FLAT score)
- A Facility that is committed to dedicate trained personnel responsible for HAI surveillance activities.
- A Facility that has the capacity to avail resources including human, supply, and other logistics for establishing an effective surveillance system
- A Facility with basic ICT infrastructure to securely manage HAIs surveillance data.
- A Facility that has prior experience to collect data on HAIs surveillance.
- A Facility that provides service for ICU, major and minor surgery, and inpatient service,
- A Facility has or can establish a mechanism to follow admitted patients after discharge (e.g. telephone contact/follow-up)

### II. For laboratory-based HAI surveillance

In addition to all the requirements listed above for patient-based HAIs surveillance, the following additional criteria are required:

- A facility that has functional Microbiology laboratory (to be assessed) with the capacity to conduct bacterial identification and AST.
- A facility which is among AMR surveillance sites.
- A facility with EQA participating laboratory.

## 6.4. Target population

Considering the complex nature of establishing HAI surveillance and the human and financial resource implications, the target population for HAIs should be prioritized. The target population is classified based on the two groups of HAI surveillance programs. Accordingly, for:

To conduct HAI surveillance, the target population includes:

1. ICU
2. Medical ward
3. Surgical ward and
4. Maternity ward

## 6.5. Conducting point prevalence survey

Before the start of the actual HAI surveillance, point prevalence HAI survey will be conducted at each selected hospital at the same time. Point prevalence survey is very important to set the baseline of the extent of the problem and to identify the type of infections and microorganisms that are most prevalent in the hospitals. Furthermore, it helps to design intervention strategies for the prevention and control of HAIs through improved adherence to IPC practice. The point surveillance survey will be conducted according to the HAI standard survey protocol annexed (annex V) in this document. The materials and tools to conduct PPS shall be developed entailing the following components: PPS protocol and data entry forms, PPS codebook, including case definitions of HAI and Standardized training material.

## 6.6. Capacity building

### A. Administrative Infrastructure

1. Provide and implement evidence-based guidelines that address HAIs

   1.1. Necessary guidelines, tools, protocols, and SOPs required for the implementation of surveillance would be printed and readily available.

2. Ensure monitoring adherence to practice as per the SOPs.

### B. Health workforce development

**Training:**

- Ensure provision of regular periodic training to health care workers
- Provide regular mentorship, supportive supervision and feedback to health care providers who participate in patient care.

### C. Equipment and Supplies

- Ensure necessary supplies and equipment for any procedure of care for selected HAIs are readily available

### D. IT infrastructure

- Hospitals implementing HAI surveillance shall have the IT infrastructures for electronically documenting the minimum data sets and other relevant information.
- Provide technical assistance to improve service quality and patient safety.

## 6.7. Coordination of surveillance implementation sites

- An HAI surveillance focal should be formally assigned to coordinate all activities of the surveillance activities.
- Multidisciplinary IPC committee will be responsible for data collection, analysis, interpretation, and dissemination of findings. It is recommended that the team consist of an IPC practitioner, epidemiologist, physician, a microbiologist/lab Technologist, tropical and Infectious diseases specialist and a nurse lead with clinical experience.
- The facility management and key stakeholders at facility level will be adequately

oriented.

- The surveillance team will be given protected time for surveillance responsibilities and training in hospital epidemiology/surveillance methods.
- Regular supervision would be conducted by the national/regional IPC team to ensure standard implementation of the surveillance system & the data collected is of good quality.

# 7. Roles and Responsibilities

## 7.1. Ministry of Health

Ministry of health will have the role of overall coordination of the program through its medical services directorate which will have the following roles and responsibilities.

### 7.1.1. Health System Innovation and Quality Lead Executive Office

- Assign national HAI surveillance coordinator.
- Establish strong and functional governance structures at all levels.
- Allocate resource as available for the surveillance system strengthening.
- Develop updated guideline when necessary.
- Develop capacity building initiatives for health workforce at regional, zonal/sub city, woreda health office and surveillance implementation sites.
- Strengthen rapid response team (RRT) to confirm the existence of outbreak and mobilize resource as necessary.
- Coordinate response operations with partners and other governmental stakeholders
- Establish and ensure functionality of HAI surveillance steering, advisory committee and TWG at ministry level.

### 7.1.2. National HAIs Surveillance Steering Committee

- Steering committee chaired by a medical services director and organized from ministry directorates, Agencies associations and partners who have a stake on the HAI surveillance program.
- Responsible for coordination, advocacy and mobilize resources
- Provide strategic directions for advisory committee.
- Monitor and evaluate HAI surveillance implementation.
- Decides to organize annual summit and review workshops to share best experiences and lessons learnt.

### 7.1.3. National HAI Surveillance Coordinator

- Oversee and coordinate implementation of HAI surveillance and capacity building initiatives.
- Monitor and evaluate surveillance program implementation at national level.
- Support selection of HAI surveillance sites and facilitate program initiation at the selected health facilities.
- Develop necessary agreements (MOU, TORs) for the implementation.
- Ensure availability of HAI surveillance guidance, protocol, and tools
- Participate in national and international HAI surveillance networks.

- Facilitate and organize annual HAI surveillance meetings with all stakeholders.

## 7.2. Ethiopian Public Health Institute (EPHI)

- Engages in the national HAI surveillance steering and advisory committee.
- Provides technical support when necessary.
- Responds to notifications on HAIs notifiable conditions/outbreaks.
- Serves as a resource and coordination point for laboratory services.
- Provides training, mentorship, and technical support for microbiology laboratory quality management to reliably perform standardized bacterial identification and antibiotic susceptibility testing (AST)
- Organizes or facilitates participation in external quality assurance system.
- Lead the laboratory-based surveillance internal quality assurance in the healthcare facility.

## 7.3. Ethiopia Pharmaceuticals Supply Services (EPSS)

- Promote and ensure rational use of drugs
- Engage in national HAI surveillance steering committee
- Use HAI surveillance data estimate for forecasting medical supplies
- Procures and avail basic supplies, reagents, and equipment necessary for surveillance program implementation.
- Ensure quality, safety, and efficacy of essential pharmaceuticals used for HAI management

## 7.4. Ethiopia Food and Drug Authority (EFDA)

- Regulate and evaluate drug use and consumption
- Ensure safety, efficacy, and security of pharmaceutical products & health services of surveillance sites
- Update standard treatment guideline and ensure implementation

## 7.5. Regional Health Bureaus (RHBs)

- Coordinates partners and national governmental stakeholders at regional level
- Assign IPC coordinating team/focal person at regional health bureau level
- Monitor trends in HAI epidemiology and related behavioral risk factors
- Monitor prevention and containment activities as per the surveillance report
- Use HAI analyzed surveillance data for resource allocation and further improvement

planning

- Share HAI surveillance report to the next level
- Provide support for HAI surveillance implementing hospitals
- Liaison with MOH for mobilization of additional resource and supports as needed

## 7.6. Zonal/Sub-city/Town/Woreda Health Offices

- Coordinates partners and governmental stakeholders at each level
- Analyze and monitor trends in HAI surveillance report and related behavioral risk factors
- Monitor prevention and containment activities as per the surveillance report
- Analyze and use HAI surveillance data for resource allocation and further improvement planning
- Share HAI surveillance report to the next level
- Provide support to facilities for HAI surveillance implementation
- Request regional health bureau when additional resource and support needed

## 7.7. Health Facilities

### 7.7.1. Hospitals

- Generate the required data and report to the next level timely.
- Ensure adequate staff, appropriate resources to conduct HAI surveillance activities.
- Establish and ensure functionality of committees for Infection prevention control
- Perform data validation and data quality assessment using LQAS.
- Establish systems to enable facility level HAIs surveillance program monitoring and evaluation
- Provide proper information about the clinical and public health management to patients
- Establish communication and networking among laboratory, IPC team, and clinicians
- Establish/strengthen RRT to conduct outbreak investigation
- Properly use analyzed data for action through continuous quality improvement
- Identify and implement public health intervention measures as appropriate
- Use surveillance report for informed decision making

### 7.7.2. IPC Committee

- Provide technical advice and recommendations to hospital SMT about HAI surveillance implementation.

- Propose intervention based on HAI trend for decision and follow required actions to be undertaken
- Evaluate overall surveillance activities and give timely feedback for the focal in charge and HCWs
- Provide timely information, advice, and education to foster the HAI surveillance implementation
- Evaluate consumption and use of antimicrobial utilization
- Develop updated facility context guides and SOPs to prevent and contain of HAIs
- Ensure availability of adequate resources for surveillance implementation
- Monitor accuracy, completeness, and timely submission of HAI surveillance data
- Analyze, interpret, and disseminate the surveillance reports
- Follow continuous quality improvement activities based on the surveillance findings

### 7.7.3. HAI Surveillance Focal

- Be a member of facility IPC team
- Lead, coordinate, promote, monitor, and evaluate overall HAI surveillance activities in the facility
- Facilitate the implementation of different capacity building initiatives as needed
- Monitor data collection conducted as per the recommendation of implementation protocol
- Control surveillance data quality, analyze and interpret the findings
- Conduct quality improvement activities based on the HAI surveillance report
- Sharing HAI surveillance data with the hospital IPC team, clinical departments and next level
- Identify clusters/outbreaks of HAIs and report and respond as per the protocol
- Ensure an adequate supply of guideline, SOP and data collecting tools

### 7.7.4. Clinical Microbiology Laboratory Section/Department

- Be a member of facility IPC committee
- Ensure for quality sample collection as per the protocol
- Immediately communicate with clinicians about inappropriate specimens.
- Conduct IQA and EQA to improve service quality
- Identify bacteria pathogens and perform antimicrobial susceptibility test (AST)
- Record and report laboratory results

- Communicate laboratory findings to surveillance focal, clinician and IPC team whenever cluster of extensive and pan-drug resistance pathogen identified
- Monitor availability of microbiology laboratory supplies regularly
- Ensure and arrange the existence of backup laboratory service system

## 7.8. Health Science Teaching Institutions

- Conduct and disseminate applied research and evaluation on HAI surveillance
- Support the development of standardized training materials

## 7.9. Professional Associations

- Provide technical advice and support
- Support in research and evidence generation
- Build capacity of health care workers
- Advocate on public health threats of HAIs

## 7.10. Non-governmental Organizations and Partners

- Being an active member of national HAI advisory committee
- Provide technical and financial support to build capacities at all levels.
- Actively collaborate and work with national and sub-national IPC program.

The organogram below depicts the governance structure for the establishment and implementation of the national HAIs surveillance program.

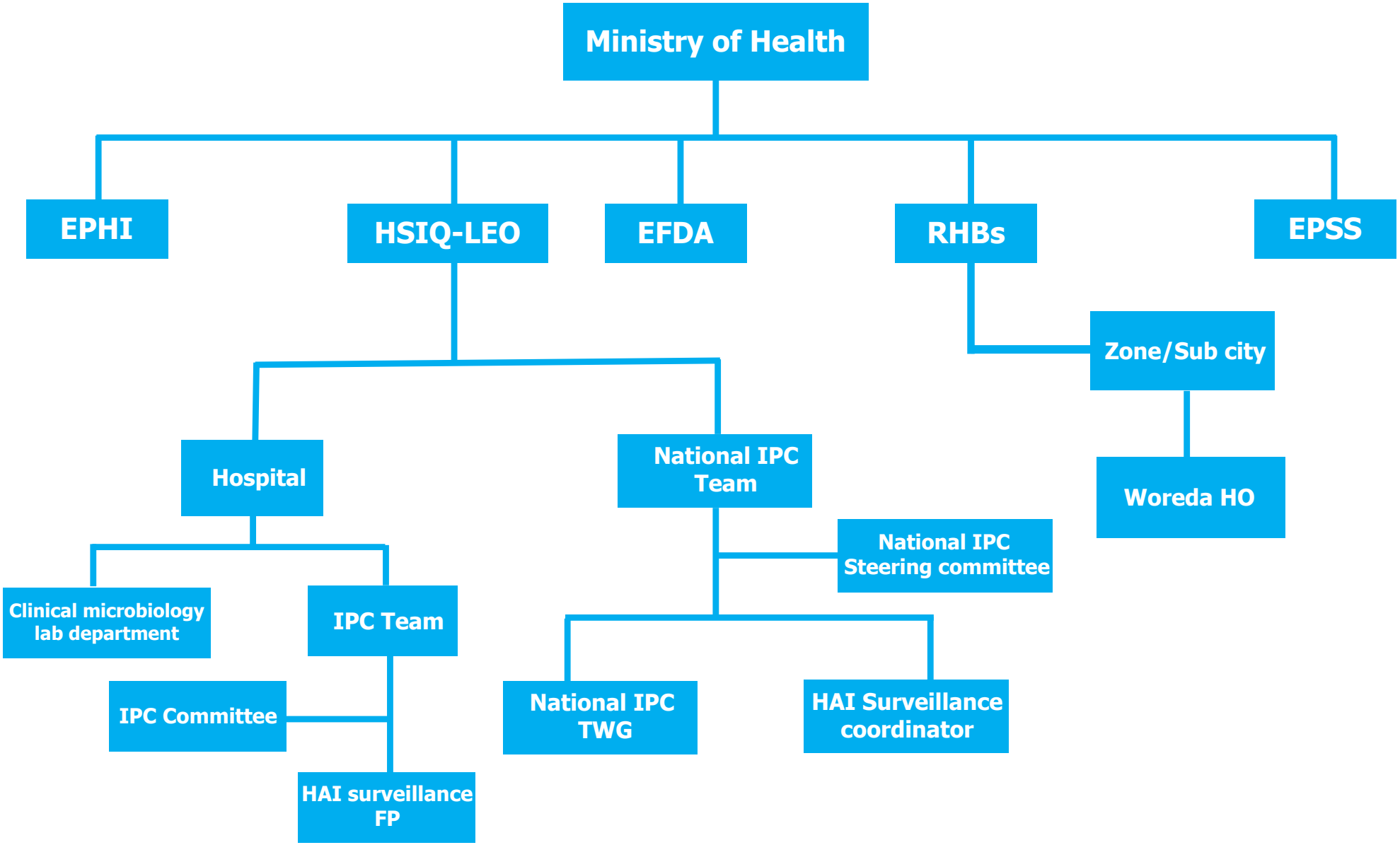


*Figure 3 - Organogram of governance structure of the national HAI surveillance system, May 2023*

# 8. Monitoring and Evaluation

In the context of HAIs surveillance implementation, monitoring is a continuing function that uses the systematic collection of data on specified HAIs surveillance indicators to inform the decision-making process at all levels and stakeholders of the ongoing implementation of the HAIs surveillance and its extent of progress and achievement of results. This includes a routine collection of patient-level data and HAIs surveillance program implementation processes information.

Evaluation is a periodic systematic assessment of HAIs surveillance implementation, its design, and results. The aim is to figure out the relevance and fulfillment of HAIs surveillance objectives, as well as efficiency, effectiveness, impact (overall goal), and sustainability of the program.

HAIs surveillance implementation evaluation provides information that is credible and useful, enabling the incorporation of lessons into decision-making at each level of health care system.

### Dimensions of HAIs surveillance M&E

Based on the overall purpose and aims of the HAIs surveillance, the monitoring and evaluation approach of HAIs surveillance includes the following dimensions for the needs of decision-makers at different levels in the Ethiopian health system to answer the objectives questions. These are:

### HAIs Surveillance Implementation Process Monitoring & Evaluation

**HAIs surveillance system establishments**: Ensure availability of HAIs surveillance system is in place through regular monitoring of HAIs surveillance plan, budget, trained human resources, HAIs, surveillance M&E tools, and relevant laboratory supplies and equipment for HAIs surveillance activity implementations.

**Obtaining baseline data**: before starting HAIs surveillance implementation, baseline data need to be obtained through PPS for comparison and interpretation of changes in practice performance, change in the health outcome, and changes in end-user knowledge and understanding.

**Routine data collection:** routine data collection using the respective HAIs surveillance minimum dataset and their data sources outlined in the data management section.

**Reporting**: regular HAIs surveillance data compilation and reporting to the next level based on data quality dimensions.

**Capacity building initiatives**: HAIs surveillance monitoring data on capacity building need assessment, and implementation including material and technical such as training, clinical and Laboratory mentorship, supportive supervision, review meeting, and other related activities.

### HAIs Surveillance outcome Monitoring & Evaluation

**HAIs rate:** figure out the magnitude of prioritized HAIs to inform decision-makers at all levels about the burden of the problem and its implication in decision making.

**HAIs Surveillance Program Evaluation**: mid-term and end-term evaluation of the first phase HAIs surveillance implementation will be conducted in line with the national IPC strategy evaluation timeline. The findings and lessons learned from the evaluation will be used for improving HAIs surveillance implementation efficiency and effectiveness.

## HAIs Surveillance Indicators

HAIs surveillance indicators are used to measure HAIs surveillance implementation outcomes, and HAIs magnitudes to reveal the burden of HAIs in health facilities.

*Table 3 - HAIs Surveillance Objectives, Expected Results, and Indicators Matrix*

| S.N. | HAI Surveillance Objectives | Result | Indicators |
|---|---|---|---|
| 1 | To estimate the burden of HAIs in healthcare facilities | Reduced the burden of HAIs in the healthcare facilities | Surgical site infection (SSI) rates<br>Bloodstream infections (BSI) rates<br>Catheter-associated UTI (CAUTI) rates |
| 2 | To detect and investigate clusters of cases, outbreaks, and exposures of HAIs | Improved detection of outbreaks and clusters of HAIs<br>Improved outbreak investigation capacity | % of health facilities with improved detection of outbreaks<br>% of health facilities with an improved capacity of outbreak investigation.<br>Number of suspected outbreaks investigated and responded |
| 3 | To strengthen HAIs detection capacity of healthcare facilities | Improved HAIs detection capacity by healthcare providers. | % of health facilities with impro<br>HAIs detection capacity |
| 4 | To initiate the establishment of HAIs Surveillance networks among healthcare facilities in Ethiopia | networked HAIs surveillance sites | number of health facilities tha<br>engaged in HAIs surveillance n |
| 5 | To encourage research on HAIs surveillance system | Improved research on HAIs surveillance | # of research conducted on HAIs<br># of research conducted on a surveillance system. |
| 6 | To establish a link between HAIs surveillance and other related surveillance systems across the healthcare delivery system | Improved linkage of HAIs surveillance with other related surveillance systems across the healthcare system. | Number of surveillances linked with HAI surveillance . |
| 7 | To provide data for monitoring and evaluation of impact of IPC interventions. | Improved infection prevention and control practices at the health facility | Number of QI projects conducted to improve HAIs surveillance |
| 8 | To disseminate HAIs surveillance results to be used by HCWs and Decision makers at all levels. | Improved quality information used for decision making | # of performance review meetings in which HAIs surveillance disseminated |

# 9. Quality Improvement in HAI Surveillance

Beyond establishing surveillance systems, quality improvement methods provide the means by which providers can review and respond appropriately to information from their surveillance systems. Reviewing and responding to surveillance systems information is necessary to control and respond to infection outbreaks, as well as bringing awareness to providers of any existing issues in their healthcare delivery processes that contribute to the occurrence of HAIs.

Using improvement methods, providers are able not only to respond to outbreaks of HAIs but can build resilience to infection outbreaks by continuously improving the quality and safety of care delivery processes to reduce and prevent their occurrence.

Quality improvement methods allow us to review the surveillance process in a way that monitors adherence to best practices and guidelines, as well as understand where issues exist in the processes. After identifying areas of failure in the process, changes are introduced to improve the processes.

The quality of HAI surveillance system can be improved through regular assessment and planning for continues improvement focusing on the following aspects.

- Adherence to guidelines, SOP, protocols
- Application of evidence based best practices.
- Documentation of best practices
- Leadership commitment and stewardship
- Linking the HAIs surveillance with facility level Quality and Clinical
- Data recording and management process
- HCWs HAI detection capacity improvement
- Teamwork and communication

Furthermore, use of surveillance data from one's own facility, demonstrating the effect of IPC practices on HAIs, can be successful in building awareness of the benefits of preventive practices. The implementation of HAIs quality improvement activities at facility level demands strong collaboration between the IPC team and the Quality units.

Finally, it is necessary to follow the national healthcare quality improvement approaches that are Model for improvement and Kaizen stipulated in the National Healthcare Quality and

Patient Safety Strategy developed, endorsed and launched by the MOH-Ethiopia.

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# 11. Appendices

## 11.1. Appendix I – General protocol for surveillance for Healthcare-Associated infections

### List of abbreviations

| | |
|---|---|
| AMR: | antimicrobial resistance |
| BSI: | bloodstream infection |
| CDC: | United States Centers for Disease Control and Prevention |
| CLABSI: | central-line associated bloodstream infection |
| CAUTI: | catheter-associated urinary tract infection |
| DHQP: | Division of Healthcare Quality Promotion |
| DUR: | device utilization rate |
| ECDC: | European Centre for Disease Prevention and Control |
| HAI: | healthcare-associated infection |
| HAI-Net: | Healthcare - Associated Infections Surveillance Network |
| ICU: | intensive care unit |
| MDRO: | Multi-drug resistant organism |
| NCEZID: | National Center for Emerging and Zoonotic Diseases |
| NHSN: | National Healthcare Safety Network |
| NICU: | neonatal intensive care unit |
| PICU: | pediatric intensive care unit |
| SSI: | surgical site infection |
| UTI: | urinary tract infection |
| VAP: | ventilator associated pneumonia |

### 11.1.1. Background

Healthcare-associated infections (HAIs) lead to substantial morbidity and mortality in middle and lower-income countries; at least 5-10% of patient admissions are complicated by an HAI. The available literature shows that HAI incidence rates in developing countries are at least three times higher than incidence rates in the United States [1]. According to a resent systematic review done in Ethiopia, The pooled prevalence of healthcare-associated infection was 16.96%. Specifically, surgical site infection (39.66%), urinary tract infection (27.69%), bloodstream infection (19.9%), dual infections (SSI and UTI) (14.01%), were the commonest types of healthcare-associated infection, the overall prevalence was highest in surgical, gynecology, and obstetrics ward indicating the national prevalence of healthcare-associated infection remains high. The most common type of HAI was surgical site infection, followed by urinary tract infection, bloodstream infection [2].

HAIs can be caused by bacteria, viruses, or fungi. The most common types of infections, bloodstream infections (BSI), pneumonia (e.g., ventilator-associated pneumonia [VAP]), urinary tract infections (UTI), and surgical site infections (SSI) globally, which are primarily caused by bacteria. These bacteria are often resistant to multiple antibiotics, which can severely limit treatment options, complicate medical management, and prolong hospital stays. In developing countries, the burden, severity, and economic impact of HAIs is believed to be underestimated, although existing data are limited to address these issues, a prospective, multisite HAI surveillance project is recommended to provide the necessary data, such as antimicrobial resistance (AMR) results and HAI incidence rates, for facilities and public health authorities to guide evidence-based recommendations for HAI prevention and control.

The proposed HAI event types for initial surveillance are surgical site infections, BSIs, including central-line associated BSIs (CLABSI), and UTIs, including catheter-associated UTIs (CAUTI). But following this general protocol health facilities can develop other HAI protocol in addition .This surveillance network shall provide baseline data on rates of these HAIs in Ethiopia and serve as a platform for measuring the impact of prevention strategies, such as device insertion and safe surgery checklists, IPC practices on HAI rates and patient outcomes.

### 11.1.2. Objectives

The surveillance system is designed to accomplish four main objectives:

- Identify the most frequent pathogens causing HAIs and their antibiotic susceptibility patterns to guide antimicrobial treatment decisions.
- Determine the burden and outcomes of HAIs using standardized metrics that generate comparable data to be shared across participating hospitals in Ethiopia.
- Provide platform for measuring impact of prevention strategies on HAI rates and patient outcomes.
- Identify potential risk factors associated with HAIs to target interventions.

### 11.1.3. Purpose

This protocol guides HAI surveillance staff to follow standardized data collection, analysis, interpretation, presentation and reporting. This shall ensure comparability of data within and between sites over time. This protocol can be used by IPC committee, Surveillance focal persons, infection control practitioners and others health care workers involved in HAI surveillance, as

well as by stakeholders and end users of surveillance data as a way to understand how HAI data are collected and how rates are generated. This protocol contains detailed information for setting up HAI surveillance and instructions that an assigned individual in charge of the surveillance system should follow.

### 11.1.4. Surveillance settings

Surveillance shall occur in high rates of device utilization inpatient service areas like ICU, surgical, medical, Gynecology/Obstetrics and pediatrics wards. Prior to the initiation of surveillance activities, a review of hospitals designated as potential surveillance sites should be completed to determine if they have the capacity to perform surveillance activities.

### 11.1.5. Surveillance events

The Protocol to be developed for HAIs can be used alone or together depending on the priorities and capacities of the implementing facility. The surveillance definitions listed in the Protocol were adapted from different international guidelines such as; European Centre for Disease Prevention and Control's (ECDC) HAI-Net [3] and the United States Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) [4]. Case definitions in such protocol shall be used for the purpose of surveillance only and not for diagnosis and treatment.

### 11.1.6. Key Terms

**Infection window period** - the 7-day timeframe in which all criteria of the case definition must be met. It includes the date of the first positive diagnostic test (defined as the laboratory specimen collection date), and the 3 calendar days before and the 3 calendar days after.

Diagnostic tests to define infection window period include:

- Laboratory procedure
- Imaging test
- Procedure

**Note:** The first positive diagnostic test must be used to meet case definition criteria.

<table>
<tr><td rowspan="6">Infection Window Period</td><td></td><td rowspan="3">3 Days before</td></tr>
<tr><td></td></tr>
<tr><td></td></tr>
<tr><td>• date of the first positive diagnostic test is as an element of the site-specific criteria<br><br>or<br><br>• In the absence of diagnostic test use the date of the first documented localized sign and symptom that is used as an element of the site-specific criteria</td><td></td></tr>
<tr><td></td><td rowspan="3">3 Days After</td></tr>
<tr><td></td></tr>
<tr><td></td></tr>
</table>

N.B. It is important to use the first diagnostic test that creates an infection window period

during which all elements of the criterion can be found.

**Date of Event -** the date when the first criteria used to meet the case definition occurs for the first time within the window period.

**Note:** If the first criteria to meet the case definition is a laboratory diagnostic test, the date of the test (defined as the laboratory specimen collection date) should be reported as the date of event (not the date that test results were obtained).

**Healthcare-associated Infection -** a case where the date of event occurs > 2 calendar days after hospital admission, with date of hospital admission as Day 1.

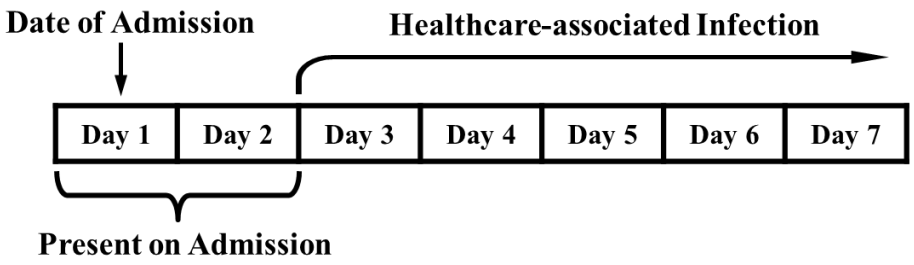


*Figure 4 - Calendar days consideration for HAIs*

**Present on Admission -** a case where the date of event occurs ≤ 2 calendar days after hospital admission, with date of admission as Day 1.

**Event Timeframe -** a 14 calendar day timeframe (date of event = Day 1 of the 14-day timeframe) during which the HAI event is considered to be occurring and no new infections of that same HAI type are reported. Any additional organisms isolated within this timeframe from the same type of infection are added to the original event.

### Examples of Applying the Event Timeframe:

- The date of event for a patient's BSI is June 1 when a blood culture positive for Staphylococcus aureus was collected. Streptococcus pneumoniae is then isolated from blood cultures collected on June 10 from the same patient (within the Event Timeframe which spans June 1 – 14) and should be added to the original BSI event. It is important to remember that the Event Timeframe remains the same, a new Event Timeframe is not constructed around the second positive blood culture in this example.
- The date of event for a patient's BSI is June 1 when a blood culture positive for Staphylococcus aureus was collected. On June 20, another positive blood culture is collected from the same patient. This collection date is outside the Event Timeframe of June 1 – 14. Regardless of whether or not the organism(s) isolated is different from those isolated previously, if the remaining BSI criteria are once again met, a new BSI event should be reported with a new date of event.

**Surveillance Unit -** the unit in which surveillance is occurring, this unit shall have staff trained to carry out these surveillance activities.

### 11.1.7. Surveillance methods

The process of conducting surveillance requires active, patient-based, prospective identification of cases and collection of denominator data by staff trained in HAI surveillance. Hospital staff shall be trained on implementation of the HAI surveillance protocol, including details on how to identify cases. Each HAI event Protocol includes corresponding case definitions and additional event-specific methods for case reporting and data analysis. Sub appendix 1 outlines the broad steps involved in case finding and denominator collection. Each surveillance site should adapt these steps to reflect institutional realities and share with surveillance staff prior to the initiation of surveillance.

#### Assessments

Hospitals need to conduct PPS and infection control assessment before initiating surveillance system to determine the HAIs rates in the hospital and to evaluate IPC compliance and identify gaps in standard.

#### Point prevalence survey

Hospital shall follow a protocol to conduct point prevalence survey for HAIs before setting up HAI surveillance.

#### Infection control assessment

Infection control practices should be assessed and re-assessed regularly, or more frequently if needed, to evaluate progress of IPC practices, as poor IPC practice leads to increased number of HAIs.

### 11.1.8. Case finding

Surveillance staff shall evaluate all patients and seek out possible cases in the ICUs and wards under surveillance by actively looking at a variety of patient data sources, such as admission, discharge, or transfer records, laboratory records, and patient charts, including history and physical exam notes, nurses/physicians notes, temperature charts, etc.

Laboratory Surveillance staff shall engage with the clinical laboratory serving their facility to utilize microbiology Laboratory in order to identify positive cultures of specimen relevant to the HAI under surveillance (e.g., blood for BSI surveillance). For each positive culture, staff shall incorporate additional clinical data to determine if the case definitions are met. For case definitions that do not require positive cultures, staff shall use other laboratory diagnostic methods (e.g., gram stain) and clinical data to determine if the case definitions are met.

#### Surveillance Unit

Laboratory-based surveillance should be used with the medical records and patient charts should also be used to gather surveillance data and it is the primary mode for surveillance staff to identify patients who meet case definitions involving clinical diagnosis or other laboratory diagnostic methods. It is recommended that surveillance staff follow participating ICUs and wards or communicate with clinical staff on a daily basis to evaluate patients who may meet the case definition. If any are identified, the surveillance staff should verify that the case definition is met and that all criteria occurred within the window period.

### 11.1.9. Case reporting

Once surveillance staff have evaluated all patients in the ICUs and wards under surveillance and identified cases meeting the HAI event case definition, a standardized case report form should be used to collect all required data. Each HAI event Protocol includes corresponding case report forms and instructions for their completion.

Case report forms should not be submitted until the end of the Event Timeframe in order to allow for any additional laboratory data to be entered along with patient outcome data. Outcomes of transfer, discharge, or death occurring during the Event Timeframe, should be recorded in real time on the case report form. If at the end of the Event Timeframe, the patient remains in the surveillance unit, this should be indicated on the case report form. At this stage, no additional follow-up is required unless laboratory results taken during the Event Timeframe have not yet been received.

ICU and ward nurses and physicians should be familiar with the case definitions of the HAI(s) under surveillance, assist in identifying patients that potentially meet the definition, and notify surveillance Focal for further confirmation and report. They should also help in collecting denominator data.

#### Case Reporting Rules

All cases meeting all of the following must be reported:

- Date of event > 2 calendar days from hospital admission, with date of hospital admission as Day 1 (see healthcare-associated infection definition)
- Date of event >2 calendar days from date of surveillance unit admission, with the date of surveillance unit admission as Day 1
- Date of event does not occur within the Event Timeframe of a previously identified case of the same event type

If the case does not meet all of the above, do not report.

#### Interpretation and Reporting of Laboratory Results

- Report genus and species identification. No additional comparative methods (e.g., morphology) should be reported.
- If the organism from one culture is identified to both genus and species level and the companion culture identifies only the genus with or without other attributes (e.g., Staphylococcus epidermidis is same as Staphylococcus spp.) then report at the species level

*Table 4 - Reporting of culture result*

| Culture Report | Companion Culture Report | Report as... |
|---|---|---|
| Coagulase-positive staphylococci | *S. aureus* | *S. aureus* |
| *S. epidermidis* | *Coagulase negative Staphylococcus* | *S. epidermidis* |

- For isolated organisms of the same genus and species level, report the resistance profile of the more resistant organism. Example: Methicillin-resistant Staphylococcus

aureus (MRSA) and Methicillin-sensitive Staphylococcus aureus (MSSA) are isolated. Staphylococcus aureus and the MRSA resistance profile are reported.

### Denominator Data

Denominator data are collected for the purposes of calculating the incidence rates of HAI events. These include patient-days (a count of the total number of patients per day that were located in the surveillance unit) and, for certain Protocol, device-days (a count of the total number of patients per day that had a specific invasive device). Denominator data should be collected at the same time, every day for each participating unit under surveillance. Each HAI event Protocol includes a form for the collection of denominator data specific to that Protocol, instructions for its completion, and instructions for the calculation of denominator days and incidence rates.

### Surveillance on Multiple HAI Protocol

When more than one HAIs are identified then report forms applicable to each should be used. If surveillance is being conducted on SSI, BSI and UTI, and HAI event case definitions are met, the SSI, BSI and UTI case report forms should be completed, regardless of whether or not the pus, urine, and blood culture isolates match. The form for collecting denominator data for both BSI and UTI protocols can be found in Appendix 2 along with instructions for its completion.

### Case ID and Related information's

To protect patient Confidentiality, patient names must not be collected on the case report forms. Rather, a unique Case ID can be used for each reportable event. The Case ID is automatically generated by the surveillance system's online data reporting system or can be manually given and shall contain hospital number, surveillance unit number, event number, and the type of HAI being reported. There shall be a different Case ID for each event reported. To allow for the surveillance staff on duty to assign or match Case IDs with patient identifiers, the Case ID and Patient Register table in Appendix 3 is provided. The table should be accessible for surveillance staff, but stored in a secure location (i.e. in a locked drawer) to protect patient privacy.

## 11.1.10. Laboratory

The microbiology laboratory shall play an essential role in surveillance. Much of the case finding shall be conducted by based on microbiology reported results. In order for improved comparability of results across sites, laboratories should provide documentation of the thresholds they are using for antimicrobial susceptibility testing. Therefore, ongoing communication and collaboration with the lab is essential.

## 11.1.11. Data management and analysis

Organizing the flow of surveillance data from the primary sources (e.g. medical or laboratory records) through analysis and report dissemination is a key component of an HAI surveillance system. All participating sites should 1) identify person(s) responsible for data management (including data collection, data entry, data validation and analysis) and 2) develop or adopt detailed SOPs to outline how data should flow within the system. Participating hospitals shall report surveillance data, including cases and denominators, on a regular basis (e.g., monthly) and shall include "zero-reporting" in the case of no reportable events during that time frame.

These data shall be reported to the next higher level via an online data reporting system from secure computers by designated hospital surveillance staff or the health care facility may use manual reporting. MOH and technical partners shall perform data cleaning, validation, and analysis and disseminate reports to each participating hospital. Each HAI event Protocol includes instructions for the calculation of incidence rates. The appendix 2 (denominator data collection) and Appendix 3 (Case id and patient register) attached in this protocol shall be used as it is but can be modified according to the specific HAI selected by the hospital.

As surveillance shall be conducted for HAI events potentially associated with invasive devices, the device utilization rate (DUR) should be calculated to contextualize the HAI incidence. The DUR can be used to assess the proportion of days in which patients were exposed to devices that put them at risk for a device-associated infection. This is important because facilities that use invasive devices likely have a higher HAI rate. The DUR can be calculated by dividing the number of device-days by number of patient-days as shown on the formula below.

### 11.1.12. Monitoring and evaluation of surveillance

Data validation is a necessary element to assure quality, accuracy, and reliability of reported public health surveillance information. Validation activities should include: 1) review of data collected in case report forms against primary data sources (e.g. patient chart) to ensure the completeness of data collection; 2) review of events entered into surveillance database to determine if they meet the HAI surveillance definitions, 3) review of microbiology results and comparison with reported cases to ensure sensitivity of the system, and 4) monitoring trends of patient-days and central line-days to ensure accurate denominator collection and avoid internal errors (for example, the number of central line-days does not exceed patient-days).

These can be done periodically and reports on errors or misclassified cases should be distributed to and discussed with the appropriate personnel. The overall purpose of data validation is to monitor use of HAI definitions and the accuracy of data submitted by hospitals to MoH, assess reporting hospital surveillance system capacity, and identify opportunities to improve future data collection and reporting. The MoH and technical partners, shall conduct regular HAI surveillance support visits that include an assessment of hospital surveillance practices, a review of laboratory data and medical records to assess completeness of case reporting, and a review of submitted surveillance data to validate its accuracy.

Standardized medical record review procedures to ensure that the HAI surveillance is sufficiently sensitive to detect HAI events are another potential tool to monitor the performance of the surveillance system. Consideration should be given to having periodic independent evaluations by outside experts for assessment of critical HAI surveillance parameters like sensitivity and positive predictive value of the surveillance program, in conjunction with questionnaires or key informant interviews to evaluate the knowledge, attitudes and practices of the surveillance personnel.

### 11.1.13. Data usage and ownership

Data generated as part of this surveillance are intended for internal use within the specified heath care facility and country to define the scope and magnitude of HAIs. Facility-level data may be used to implement infection control quality improvement measures at an individual facility. Data ownership shall reside at MoH. The MoH surveillance coordinators team may consult with technical partners, but ownership is Ministry of Health-based and led as appropriate in-country.

### 11.1.14. Roles and Responsibilities

Hospitals to implement HAI surveillance they should include the following staffs with listed roles and responsibilities

### 11.1.15. Hospitals

Hospitals need to identify the staff members that shall oversee the surveillance system, collect, and enter surveillance data and clearly lay out expected roles and responsibilities for these staff members. Tools/resources needed to complete their assigned job should be provided. At minimum the following personnel shall need to be identified.

#### 11.1.15.1. Hospital HAI surveillance focal

A designated contact person at the participating facility assigned to coordinate HAI surveillance. This individual ensures that the surveillance staff at their facility are conducting regular reporting of HAI events and denominator data from all intensive care units (ICUs) and wards under surveillance. Additional responsibilities might include following up with surveillance staff to reconcile missing or conflicting data identified by the data manager, disseminating HAI reports to relevant stakeholders at the hospital, and facilitating monitoring and evaluation visits.

#### 11.1.15.2. Surveillance staff

Designated staff member(s) responsible for conducting the day-to-day activities of HAI surveillance in each participating intensive care unit and wards. In general, these activities will include case finding, data collection, case determination, and recording surveillance data (e.g., on case report forms). In order to seek out possible cases in the ICUs and wards under surveillance these persons shall evaluate a variety of patient data sources daily. These data sources may differ between sites, but will likely include patient medical records (e.g., discharge paperwork, nursing notes), laboratory data, and discussion with the clinical care team. Surveillance staff should be familiar with the HAI protocol, case finding flowcharts, and case definitions.

#### 11.1.15.3. Data manager

Designated staff member(s) from the facility HIS (health information system) team responsible for inputting surveillance data into a database purposely created for this surveillance activities for analysis, generation of reports. Once surveillance data is collected (both numerator and denominator data), data must be prepared for use. This will be through entry of data into an electronic database which will allow for easy data cleaning, validation, and analysis. Data entry, data analysis, and surveillance report preparation should be the responsibility of a person with sufficient experience in data management to complete the job and may occur in collaboration with surveillance staff and hospital coordinators. Reports of surveillance data should be prepared on monthly basis so that they can be shared with the relevant stakeholders

#### 11.1.15.4. ICU and wards' clinical staff

Additionally, though not dedicated surveillance system personnel, the clinical staff in the ICUs and wards under surveillance also have roles in HAI surveillance implementation. Nurses and physicians staffing the ICUs and wards should be aware of the surveillance that is ongoing. These staff should be familiar with the case definitions of the HAI(s) under surveillance in order to assist in identifying patients that potentially meet the case definition and notifying

surveillance staff for further confirmation and report. Clinical staff may be tasked with collection of denominator data, especially on weekends or holidays when surveillance staff may not be in the hospital.

#### 11.1.15.5. Laboratory staff

The laboratory staff is expected to perform the test requested and report timely to the units sent samples for test. The lab technicians will assist surveillance staff in availing records, case identification and reporting.

#### 11.1.15.6. Partners working on HAI surveillance activities

Partners will provide technical assistance to the team in charge of the surveillance system with all aspects of the surveillance project. This may include initial facility assessments related to infection control practices, training of hospital staff, preparation of necessary project materials including case report forms, database management and analysis, and creation of bi-monthly reports and summary reports for internal use and publication. They will also participate in initial hospital practices assessment and regular monitoring, evaluation, and data validation activities to ensure completeness and accuracy of data collected during surveillance. Additionally, partners will provide access to subject matter expertise on HAI surveillance and IPC.

### 11.1.16. Ethical consideration and review

This protocol describes a public health surveillance activity which is considered public health practice and not research. Individual patient consent shall not be collected as a prerequisite of collecting necessary data to monitor HAI incidence. The surveillance activity requires all patients housed in the ICU and wards at any given time as patient level data (e.g. laboratory results, symptoms) are gathered to determine whether a patient is a case and further data collection needed. Every effort will be made to protect patient privacy and confidentiality during this surveillance. Individual patients or their families will not be contacted. Electronic and physical security measures will be taken to ensure protection of potentially identifiable data. Electronic data will be stored in a database housed on a certified secure server and will be accessed via password protected computers or tablets. Data collected on print out reporting forms will be stored in a secure lockable file cabinet.

### 11.1.17. References


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## Sub appendix 1: Case Finding and Denominator Data Collection

### Collection of case (numerator) data

Although standard operation procedures for the surveillance staff shall likely differ from facility to facility, depending on clinical information systems, staff support, and the HAI(s) under surveillance, the following general steps shall be necessary to collect case (numerator) data:

1. Review the latest microbiology records on a daily basis in order to ascertain positive cultures or diagnostic tests of specimens relevant to the HAI(s) under surveillance.

   This may involve visiting the lab itself to review culture results (e.g., in a logbook). Alternatively, in some places with a laboratory information system that can be queried, the lab may be able to pull a daily list of positive results for the surveillance staff.

2. For each positive result, identify the corresponding patient and ensure they were residing in the surveillance unit prior to or at the time when the specimen was collected.

3. Review the clinical and laboratory data of each identified patient and the Case ID and Patient Register to determine if the positive result is the first positive diagnostic test. The positive result might not be the first positive diagnostic test if:

   A. The positive result belongs to a patient already under surveillance for the same HAI (e.g., a second positive blood culture in a patient who is already under surveillance for a bloodstream infection) and falls within the Event Timeframe (a 14-day timeframe when no new events of the same type can be recorded[1]) OR

   B. Earlier positive results exist that meet the surveillance criteria and do not fall inside a previous Event Timeframe in which case those would be the first positive diagnostic test.

4. Once the first positive diagnostic test is identified, use the date of specimen collection2 for that test to create the window period (3 calendar days before and the 3 calendar days after the specimen collection date, 7-day timeframe)

<table>
<tr><td rowspan="4"><u>Infection Window Period</u></td><td colspan="2"></td><td rowspan="3"><u>3 Days before</u></td></tr>
<tr><td colspan="2"></td></tr>
<tr><td colspan="2"></td></tr>
<tr><td colspan="3">• date of the first positive diagnostic test is as an element of the site specific criteria<br><br><u>or</u><br><br>• In the absence of diagnostic test use the date of the first documented localized sign and symptom that is used as an element of the site specific criteria</td></tr>
<tr><td colspan="2"></td><td><u>3 Days After</u></td></tr>
</table>

1. If the positive diagnostic test (e.g. blood culture) belongs to a patient already under surveillance for that same HAI, and the specimen collection date for that test is within the Event Timeframe, then the result should be added to the case report form already created for that patient

2. The case definition for BSI due to common commensal bacteria requires the same common commensal to be isolated from ≥ 2 positive blood cultures (See protocol rules for two matching blood cultures) that were collected on the same or consecutive days. If collected on consecutive days, then the collection date of the first positive culture is the date first diagnostic test.

5. Once the window period has been created, use the patient's clinical information to identify the date of event (when the first criteria used to meet the case definition occurs for the first time within the window period).

**Note:** The first criteria used to meet the case definition may be a symptom or may be the positive laboratory result.

6. Use the date of event to determine if the infection is healthcare-associated (date of event occurs > 2 calendar days after hospital admission, with date of hospital admission as Day 1)

    A. If the infection is not healthcare-associated, the infection should not be included in surveillance, do not continue.

7. If the infection is healthcare-associated, determine if the date of event falls within the Event Timeframe of a previous event of the same type (e.g. fever occurring in a patient who is already under surveillance for a urinary tract infection).

    If the date of event falls within the Event Timeframe of a previous event of the same type, the infection should not be included in surveillance, do not continue.

8. If the date of event does not fall within the Event Timeframe of a previous event, determine if the patient's date of event occurs >2 calendar days from their admission to the surveillance unit (date of surveillance unit admission = Day 1).

    If the patient's date of event does not occur >2 calendar days from their admission to the surveillance unit, then the infection should not be included in surveillance, do not continue.

9. If the patient's date of event occurs >2 calendar days from their admission to the surveillance unit, review the clinical data to verify that all criteria of the surveillance definition are met within the window period. This includes evaluation for any relevant devices (e.g., central lines).

    A. If all criteria of the surveillance definition are not met within the window period, the infection should not be included in surveillance, do not continue.

    B. Note: Surveillance staff may need to follow a patient for a series of days (until the end of the window period) to determine whether they develop clinical criteria to meet the case definition during that time. Keeping track of patients that potentially meet the case definition should be done in a systematic way by surveillance staff.

10. Once cases are identified, construct an Event Timeframe for each case (a 14-day calendar day timeframe, with date of event as Day 1). During this time the HAI event for which the case definition was met is considered to be occurring and no new infections of that same type can be reported.

11. Surveillance staff shall need to keep track of all patients meeting the surveillance case definition and follow up on each patient daily for the entire duration of the Event Timeframe. During this time the following events should be recorded and added to the case report form:

    A. If any additional organisms are isolated within the Event Timeframe, from the same type of culture as was used to meet the original case definition (e.g., additional

positive blood cultures from a BSI case) add these to the case report form.

**B.** If a patient is transferred, discharged, or dies during the Event Timeframe the outcome should be recorded in real time on the case report form (e.g., if the patient is discharged on hospital day 10, the outcome should be recorded then). However, if the patient remains on the surveillance unit at the end of the Event Timeframe, that should be indicated on the case report form and follow up is considered complete.

**12.** Once patient outcome is recorded and the case report form is complete, surveillance staff should submit the completed case report form to the appropriate personnel for data entry and safekeeping.

**13.** Additional steps for BSI Surveillance:

**A.** Once a case is identified, after constructing the Event Timeframe, construct the Secondary BSI Attribution Period. This period spans the window period and the Event Timeframe and shall be a variable number of days depending on when the date of event occurs within the window period (see protocol for details)

**B.** Surveillance staff must evaluate BSI cases daily during the Secondary BSI Attribution Period for any culture-positive infections at other body sites in order to determine whether they meet criteria for a secondary BSI (see protocol for details).

## Collection of denominator data

Denominator data allows for the calculation of incidence rates from surveillance data. Depending on the type of HAI surveillance occurring, several different types of denominator data may be collected in order to calculate the HAI incidence rates of interest. The data can be collected by surveillance staff or other personnel. Any location participating in surveillance must make a plan for how to collect denominator data correctly. This includes the following:

**1.** At the same time every day, including weekends and holidays, use the appropriate denominator form to collect denominator data from the ICU under surveillance.

**2.** If multiple wards are under surveillance, a different denominator form should be filled for each unit under surveillance.

**3.** Completed denominator forms should be submitted for data entry on a regular basis (e.g., monthly).

## Sub appendix 2: Denominator Data Collection Forms

## Denominators for HAI Surveillance

## (BSI and UTI)

**Instructions for filling out this form:** This form should be completed at the same time every day for each participating ICU. Count the total number of patients in the ICU and record the number under "Number of Patients." For BSI surveillance, count the number of patients with a central line and record the number under "Number of patients with ≥1 central lines." For UTI surveillance, count the number of patients with an indwelling urinary catheter and record the number under "Number of patients with urinary catheter." All relevant counts should be performed at the same time by visiting each patient and checking for the presence of any central lines or urinary catheter before moving on to the next patient.

*Table 5 - Denominator data collection form for BSI and UTI*

| **Hospital Name:** **Surveillance Unit Number:** **Month:** **Year:** | | | |
|---|---|---|---|
| **Date** | **Number of Patients** | Number of patients with ≥1 **central lines** | Number of patients with **urinary catheter** |
| **1** | | | |
| **2** | | | |
| **3** | | | |
| **4** | | | |
| **5** | | | |
| **6** | | | |
| **7** | | | |
| **8** | | | |
| **9** | | | |
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| **16** | | | |
| **17** | | | |
| **18** | | | |
| **19** | | | |
| **20** | | | |
| **21** | | | |
| **22** | | | |
| **23** | | | |
| **24** | | | |
| **25** | | | |
| **Totals** | | | |
| | Patient-days: | Central-line days: | Urinary Catheter days: |

## Denominators for Neonatal Intensive Care Unit (NICU)

## (BSI and UTI)

**Instructions for filling out this form:** This form should be completed at the same time every day for each participating NICU. Count the total number of neonates in the NICU and record the number under "Pt" according to the neonate's birthweight. (Note: this is not the neonate's current weight). For BSI surveillance, count the number of neonates with one or more central line, including umbilical catheter, and record the number under "CL." For UTI surveillance, count the number of neonates with a urinary catheter and record the number under "UC." All relevant counts should be performed at the same time by visiting each neonate and checking the birthweight and the presence of any central lines or urinary catheter before moving on to the next neonate.

| **Hospital Name:** | | | | **Surveillance Unit Number:** | | | | | | **Month:** | | | **Year:** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Birth Weight Categories** | | | | | | | | | | | | | | | |
| **Date** | **A = ≤750 g** | | | **B = 751-1000 g** | | | **C =1001-1500 g** | | | **D = 1501-2500 g** | | | **E= >2500 g** | | |
| | Pt | CL | UC | Pt | CL | UC | Pt | CL | UC | Pt | CL | UC | Pt | CL | UC |
| **1** | | | | | | | | | | | | | | | |
| **2** | | | | | | | | | | | | | | | |
| **3** | | | | | | | | | | | | | | | |
| **4** | | | | | | | | | | | | | | | |
| **5** | | | | | | | | | | | | | | | |
| **6** | | | | | | | | | | | | | | | |
| **7** | | | | | | | | | | | | | | | |
| **8** | | | | | | | | | | | | | | | |
| **9** | | | | | | | | | | | | | | | |
| **10** | | | | | | | | | | | | | | | |
| **11** | | | | | | | | | | | | | | | |
| **12** | | | | | | | | | | | | | | | |
| **13** | | | | | | | | | | | | | | | |
| **14** | | | | | | | | | | | | | | | |
| **15** | | | | | | | | | | | | | | | |
| **16** | | | | | | | | | | | | | | | |
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| **19** | | | | | | | | | | | | | | | |
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| **22** | | | | | | | | | | | | | | | |
| **23** | | | | | | | | | | | | | | | |
| **24** | | | | | | | | | | | | | | | |
| **25** | | | | | | | | | | | | | | | |
| **Total** | | | | | | | | | | | | | | | |

## 11.2. Appendix II - Protocol for of Healthcare-Associated BSI Surveillance

### List of Abbreviations

| | |
|---|---|
| BSI: | Bloodstream infection |
| CDC: | United States Centers for Disease Control and Prevention |
| CL: | Central line |
| CLABSI: | Central-line associated bloodstream infection |
| DHQP: | Division of Healthcare Quality Promotion |
| DUR: | Device utilization rate |
| ECDC: | European Centre for Disease Prevention and Control |
| HAI: | Healthcare-associated infection |
| HAI-Net: | Healthcare-Associated Infections Surveillance Network |
| ICU: | Intensive care unit |
| NHSN: | National Healthcare Safety Network |
| NICU: | Neonatal intensive care unit |
| PICC: | Peripherally inserted central catheters |
| PICU: | Pediatric intensive care unit |
| UTI: | Urinary tract infection |

### 11.2.1. Introduction

This protocol describes the methods to conduct surveillance for healthcare-associated bloodstream infections (BSI) in intensive care unit (ICU) and ward settings to ensure standardized application of case definitions, data collection, and reporting procedures. This protocol should be used in conjunction with the National HAIs Surveillance Guideline and of the General protocol for HAIs Surveillance. This protocol may also be used by stakeholders and end users of HAI surveillance data to understand how the BSI data is collected and how the rates are generated.

### 11.2.2. Surveillance settings

The ICU, surgical, medical, Gyne/Obs and pediatric wards are identified for the BSI Surveillance due to the high rates of device utilization.

### 11.2.3. Definitions

The following definitions have been adopted from the United States Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) [1]. The case definitions are for the purpose of surveillance only and are not meant to serve as clinical definitions for use in diagnosis and treatment.

### 11.2.4. BSI Definition

The case definition for BSI is focused on healthcare-associated laboratory-confirmed bloodstream infection (BSI).

### Blood stream Infection (BSI)

- **BSI for Recognized Pathogens:**

A patient with one or more positive blood cultures for a recognized pathogen known to cause BSIs. An abbreviated list of recognized pathogens is included as part of Appendix 1.

- **BSI for Common Commensals:**

Patients > 12 months of age

- A patient with ≥ 2 matching positive blood cultures for a common commensal

**AND**

- At least one of the following signs or symptoms:
  - Fever (>38°C)
  - Hypotension

Patients ≤ 12 months of age

- A patient with ≥ 2 matching positive blood cultures for a common commensal

**AND**

- At least one of the following signs or symptoms:

- Fever (>38oC)
- Hypotension
- Hypothermia (<36oC)
- Apnea
- Bradycardia

**Note:** A common commensal is an organism which can commonly exist on body surfaces without causing disease. It is often referred to as a "contaminant" when isolated in blood culture, but can also be associated with true bloodstream infections, especially when isolated from patients with significant healthcare exposure or found in repeated blood cultures. **See Appendix 1** for list of commonly isolated commensal organisms.

**Rules for two matching blood cultures:**

- **Samples taken at the same time:**
    - Should be from different sites (e.g., one from right arm and other from left arm) using a separate sterile needle and syringe for each blood draw

**OR**

- If samples taken from the same site, there must be:
    - Two separate blood draws each using a separate sterile needle and syringe
    - Site disinfection between draws

- **Samples taken at different times:**
    - Second sample collection must be on the same day or next day (consecutive days)

**Note:** For two matching blood cultures, one or both samples may be drawn from a central line. If both blood culture samples are taken from the central line they can be taken from the same lumen or different lumens (if there is a multi-lumen central line in place).

### 11.2.5. Additional definitions

BSIs may be considered a primary infection (originating in the bloodstream) or a result of dissemination from an infection occurring at another body site. Thus, BSI events can be classified as either primary or secondary. Primary BSI can be further classified by device association, either as central line-associated BSI (CLABSI) or non-central line associated primary BSI. Secondary BSIs cannot be classified as central line associated (e.g., no secondary CLABSI definition should be used), as an infection at another body site argues against a primary BSI due to catheter presence. For the purpose of surveillance, identified BSIs will be classified using the following definitions: Primary BSI, central line-associated BSI (CLABSI) and Secondary BSI.

**Primary BSI:** a BSI without a matching positive culture taken from another body site (e.g., sputum, pus, urine) within the Secondary BSI Attribution Period.

**Secondary BSI Attribution Period** is defined as a timeframe that includes the window period (+/- 3 calendar days from date of first positive diagnostic test) and the Event Timeframe (14 calendar days, date of event = Day 1).

**Central line-associated BSI (CLABSI):** Primary BSI can be further described as central line-associated BSI (CLABSI). A CLABSI is defined as a primary BSI meeting the following criteria:

- A central line in place for >2 calendar days on the date of event, with day of device placement being Day 1,

**OR**

- A central line in place for >2 calendar days that had been removed on the date of event or the day before the date of event

**Note:** If a central line is removed and reinserted on the same or following day, in the same or different site, it is considered as one continuous central line.

A **Central line** 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. Central lines can be:

- **Temporary central line:** A non-tunneled, non-implanted catheter (e.g., peripherally inserted central catheters [PICC lines], short term lines put in commonly in ICUs for acute management).
- **Permanent central line:** Includes:
  - Tunneled catheters (including certain long-term dialysis catheters)
  - Implanted catheters (including ports such as port-a-cath)

**Note:** 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.

The following are considered great vessels for the purpose of reporting central line association and counting central-line (device) days:

- Aorta
- Pulmonary artery
- Superior or inferior vena cava
- Brachiocephalic vein
- Internal jugular vein
- Subclavian vein
- External and common iliac vein
- Femoral vein
- Umbilical artery/vein (in neonates)

The following devices are not considered central lines:

- Extracorporeal membrane oxygenation (ECMO) catheters
- Femoral arterial catheters
- Intra-aortic balloon pump (IABP) devices
- Hemodialysis reliable outflow (HeRO) dialysis catheters
- Impella heart devices

**Secondary BSI:** a BSI with a matching positive culture taken from another body site (e.g., sputum, urine) within the Secondary BSI Attribution Period or strong clinical evidence exists that bloodstream infection was secondary to another infection site, invasive diagnostic procedure or foreign body (ECDC).

**Secondary BSI Attribution Period** is defined as a timeframe that includes the window period (+/- 3 calendar days from date of first positive diagnostic test) and the Event Timeframe (14 calendar days, date of event = Day 1).

*Table 6 - Example for applying the Secondary BSI Attribution Period*

**Example: Applying the Secondary BSI Attribution Period**

| Day | Clinical / Laboratory Criteria | Window Period | Event Timeframe | Secondary BSI Attribution Period |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | Fever > 38°C | | Date of Event | |
| 5 | 2 (+) Blood cultures: *Streptococcus viridians* | 1st (+) diagnostic test | | |
| 6 | | | | |
| 7 | | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | (+) Sputum culture: *Streptococcus viridians* | | | Matching (+) culture from other body site |
| 12 | | | | |
| 13 | | | | |
| 14 | | | | |
| 15 | | | | |
| 16 | | | | |
| 17 | | | | |
| 18 | | | | |

**Explanation:**

- The window period is constructed around Day 5 because the first positive

diagnostic test, the matching positive blood cultures for Streptococcus viridians, occurred on Day 5.

- The first case definition criteria to occur within the window period were fever on Day 4. Thus date of event is Day 4.
- All case definition criteria occurred within the window period, thus BSI case definition was met.
- The BSI event is a secondary infection because the positive sputum culture matched the positive blood cultures, and occurred within the Secondary BSI Attribution period.

### 11.2.6. Surveillance method

The process of conducting BSI surveillance in this protocol requires active, patient-based, prospective identification of cases and collection of denominator data by trained healthcare providers (Member of HAIs Surveillance Team) for 90 consecutive days biannually.

### 11.2.7. Case finding

See Appendix 5 for the BSI case finding flowchart. Refer to Section 5.2, Case Finding, in *Surveillance for Healthcare-Associated Infections (HAI), general protocol.*

### 11.2.8. Case reporting for BSI

Once surveillance staff have evaluated all patients in the surveillance unit under surveillance and identified cases meeting the BSI case definition, the BSI case report form in Appendix 2 will be used to collect all required data. For each positive blood culture that was collected within the 14-day Event Timeframe, the isolated organism(s) and antimicrobial susceptibility testing results will be recorded in the Organism ID and Susceptibility Testing section of the case report form. The instructions for completion of the BSI case report form can be found in Appendix 3. They contain brief instructions for collection and entry of required data for the form.

***For Case Reporting Rules, Interpretation and Reporting of Laboratory Results, and Case ID and Patient Register refer to Section 5.3, Case Reporting, in Surveillance for Healthcare-Associated Infections (HAI) in Intensive Care Units***

**Additional Reporting Rules Specific to BSI:**

- Matching common commensals represent a single criterion. If the matching common commensals came from blood cultures collected on consecutive days (See: Rules for two matching blood cultures), then the collection date of the first culture is the date assigned to the criteria.
- If only one blood sample is culture positive for a common commensal (a second blood sample was negative or never collected), this sample should not be reported for purposes of BSI surveillance.
- Catheter tip cultures should not be used to determine whether a patient has BSI.

### 11.2.9. Denominators (for calculation of incidence rates)

Central line-days and patient-days are the denominators used to determine BSI and CLABSI

incidence rates. Denominator data should be collected at the same time every day for each participating unit or ward under surveillance. The denominator forms for collection of patient-days and central line-days can be found in Appendix 4.

- **Central line-day** denominator data is calculated as the number of patients with one or more central lines on each unit under surveillance, each day. Surveillance staff should record the number of patients in the surveillance unit who have a central line in place. If a patient has more than one central line in place, they still only count as one central line day.
- **Patient-days** denominator data is calculated as the total number of patients per day in the unit under surveillance. Patient-days should be collected at the same time as central line-days.
    - **NICU patient days:** If feasible, participating hospitals conducting surveillance in NICUs may choose to collect the denominator data stratified by birth weight categories using the NICU denominator form in Appendix 4, or they may choose to use the regular/non-stratified denominator data collection form. NICUs collecting the denominator data by birth weight category will be able to stratify HAI rates by five birth weights.

### 11.2.10. Analysis plan

BSI will be stratified by central line association and further as primary or secondary infections and proportions will be calculated and compared. Using numerator and denominator data, incidence will be calculated for total BSI, total CLABSI, and the primary subsets of each, as described below.

**Calculation of Incidence**

- **Total BSI rate:** BSI per 1000 patient days. Divide the total number of reported BSI by the number of patient-days and then multiply by 1000.
- **Primary BSI rate**: Primary BSI per 1000 patient days. Divide the number of primary BSI by the number of patient days and then multiply by 1000.
- **Total CLABSI rate:** CLABSI per 1000 central line days. Divide the total number of reported CLABSI by the number of central line days and then multiply by 1000.

### 11.2.11. Device Utilization Rate (DUR)

The device utilization rate (DUR) is used during reporting to contextualize the BSI incidence. This is important because facilities that have high rates of central line usage (the most important risk factor for BSI in ICUs) will likely have higher BSI and CLABSI rates. The DUR can be calculated by dividing the central line-days by patient-days as shown on the formula below.

### 11.2.12. References

1. Centers for Disease Control and Prevention. National Healthcare Safety Network: Acute Care Hospital Surveillance for Central Line-associated Bloodstream Infections; Available from: http://www.cdc.gov/nhsn/acute-care-hospital/clabsi/index.html.

## Sub appendices

### 11.2.13. Sub appendix 1: Organism Classification

*Table 7 – Abbreviated List of Recognized Pathogens*

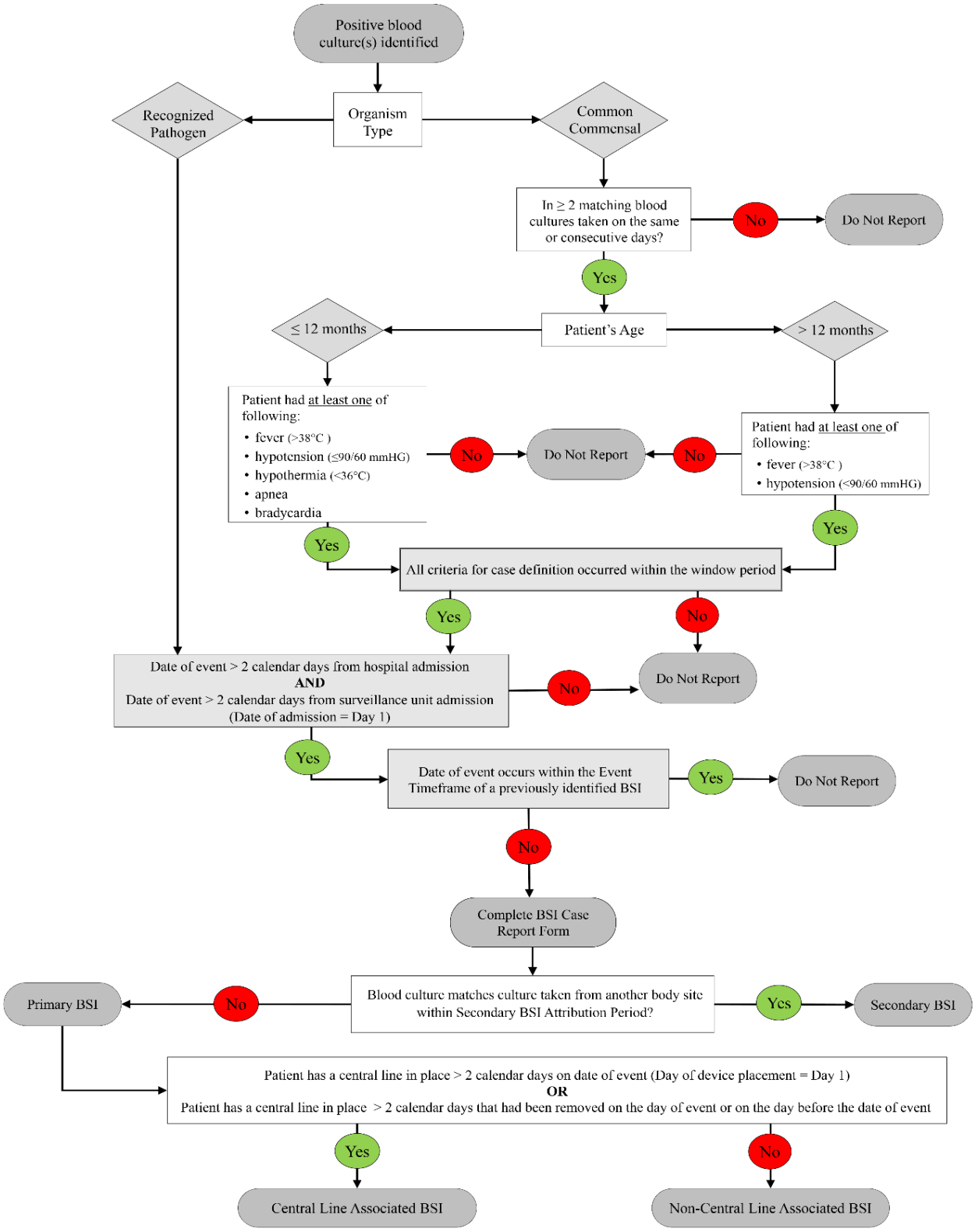
| | | |
|---|---|---|
| *Acinetobacter baumanii* | ***Escherichia coli*** | ***Staphylococcus aureus*** |
| *Burkholderia cepacia* | *Klebsiella oxytoca* | *Candida albicans* |
| *Citrobacter freundii* | *Klebsiella pneumoniae* | *Candida* spp. |
| *Citrobacter koseri* | *Moraxella catarrhalis* | |
| *Enterobacter aerogenes* | *Proteus* spp. | |
| *Enterobacter cloacae* | ***Pseudomonas aeruginosa*** | |
| *Enterococcus faecalis* | *Serratia marcescens* | |
| *Enterococcus faecium* | *Streptococcus agalactiae* | |

Abbreviated List of Common Commensals

| | | |
|---|---|---|
| Bacillus species, not *B. anthracis* | Coagulase-negative *Staphylococcus* | Micrococcus species |
| Corynebacterium species, not *C. diphtheriae* | Propionibacterium species | *Streptococcus viridians* |

A complete list of common commensals available at: http://www.cdc.gov/nhsn/XLS/master-organism-Com-Commensals-Lists.xlsx. If an organism is not included on the complete list of common commensals, it must be treated as a recognized pathogen.

## 11.2.14. Sub appendix 2: Case Finding Flowchart for BSI




**Note:** If a central line is removed and reinserted on the same or following day, in the same or different site, it is considered as one continuous central line.

*Figure 5 - Case finding flowchart for BSI*

### 11.2.15. Sub appendix 2: BSI Case Report Form

*Table 8 - BSI Case Report Form*

| | | |
|---|---|---|
| Record Case ID generated by online reporting system: _____BSI | | |
| Hospital Name: | | |
| Sex: □ Male □ Female | Age: __ | Birth weight:_____grams (NICU only |
| Date of hospital admission: ____ /_____ /_____<br>Date of admission to surveillance unit: ____ /_____ /_____ | | |
| Location prior to hospital admission: | □ Home / Community □ Unknown | □ Another hospital |
| List all other Case IDs assigned to this patient since hospital admission: | | |
| **1. BSI Details** | | |
| Date of event *(dd/mm/yyyy)*: | ____ /_____ /_____ | |
| List all locations, in chronological order, where patient was housed on the date of event: | _____<br>_____<br>_____ | |
| List all the locations, in chronological order, where patient was housed on the day **before** the date of event: | _____<br>_____<br>_____ | |
| **2. Invasive Devices: Central Lines** | | |
| Did the patient have a central line in place at any time on<br>• The date of event **or**<br>• The day before the date of event? | □ Yes<br>□ No *(skip to 3, Infections at Other Body Sites)*<br>□ Unknown *(skip to 3, Infections at Other Body Sites)* | |
| If **YES,** was the central line in place for >2 calendar days? | □ Yes<br>□ No *(skip to 3, Infections at Other Body Sites)*<br>□ Unknown | |

| | |
|---|---|
| If **YES,** type(s) of central line(s) in place<br>*(check all that apply)* | □ Non-tunneled short-term catheter (e.g., double or triple lumen)<br>□ Peripherally inserted central catheter (PICC)<br>□ Port-a-cath<br>□ Hemodialysis catheter □ Tunneled catheter<br>□ Umbilical catheter □ Unknown<br>□ Other, specify: _____ |
| Location(s) of central line(s) in place<br>*(check all that apply)* | □ Jugular □ Brachial<br>□ Subclavian □ Umbilical<br>□ Femoral □ Unknown<br>□ Other, specify: _____ |

| **3. Infections at Other Body Sites** | | | | |
|---|---|---|---|---|
| Was a positive, **matching** culture obtained from another body site(s) during the Secondary BSI Attribution Period? | □ Yes<br>□ No *(skip to 4, Outcome)*<br>□ Unknown | | | |
| If **YES**, specify specimen(s) collected, date(s) of culture, and organism(s).<br>□ Urine<br>□ Respiratory<br>□ CSF<br>□ Other: _____ | Specimen Collected | | Date of specimen collection | Organism |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| **4. Outcome** | |
|---|---|
| Patient Outcome<br>*(check one)* | □ Still in surveillance unit<br>□ Transferred to other ward/unit within the hospital<br>□ Transferred to other hospital<br>□ Discharged<br>□ Died<br>□ Unknown |

**Continue to next page to report organisms and antimicrobial susceptibility results**

| 5. Organisms and Antimicrobial Susceptibility | |
|---|---|
| Type of laboratory-confirmed BSI<br><br>(See Appendix 1 of this protocol) | □ Recognized Pathogen (**ONE** positive blood culture required)<br><br>□ Common Commensal (**TWO** matching positive blood cultures required) |

**Enter collection dates and organisms from ALL positive blood cultures collected during the Event Timeframe in the table below.**

Attach a copy of the laboratory's AST report for each blood organism to the CRF. If this is not possible, enter AST results in the table using information from the laboratory.

(AST Result: S=susceptible, I=intermediate, R=resistant, S-DD=susceptible, dose-dependent)

| Blood Collection Date | Organism Name | Antimicrobial Name | AST Result |
|---|---|---|---|
| _____ | _____ | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
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| | | | |
| | | | |

### 11.2.16. Sub appendix 3: Instructions for Completing BSI Case Report Form

*Table 9 - Instruction for completing BSI case report form*

| Data Field | Instructions for Data Collection |
|---|---|
| Case ID | The online reporting system will automatically create a Case ID for each infection when it is entered. Write the Case ID provided by the online reporting system in the space provided. |
| Hospital Name | |
| Sex | |
| Date of Birth/Age | Record the date of the patient birth using this format: DD/MM/YYYY. |
| Birth Weight | Required only for neonates housed in neonatal intensive care unit. |
| Date of Hospital Admission | Record the date of the hospital admission using this format: DD/MM/YYYY. |
| Location prior to hospital admission | Check one. Indicate the location the patient was in immediately prior to admission to the hospital. |
| Date of admission to Surveillance Unit | Record the date as DD/MM/YYYY. |
| Other Case IDs assigned to this patient since admission | Required only if Case ID previously assigned.<br><br>Check patient register for all case IDs this patient has been assigned since their date of current hospital admission. In the space provided, list all Case IDs that apply. If unknown, write "Unknown" |
| Date of event | Record the date as DD/MM/YYYY.<br><br>Enter the date when the first criteria used to meet the case definition occurred.<br><br>Note: If the first criteria to meet the case definition is a laboratory diagnostic test, the laboratory specimen collection date should be reported as the date of event. |
| Locations where patient was housed on the date of event | In the provided space, list all the locations in the hospital where the patient was housed on the date of event in chronological order. If unknown, write "Unknown" |
| Locations where patient was housed on the day before the date of event | In the provided space, list all the locations in the hospital where the patient was housed on the day before the date of event in chronological order. If unknown, write "Unknown" |
| Did the patient have a central line in place at any time on the date of event or day before the date of event? | Check one.<br><br>If "No," skip to Section 3, Infections at Other Body Sites. |

| | |
|---|---|
| Was the central line in place for >2 calendar days? | Required if central line in place at any time on date of event or day before.<br><br>Check one.<br><br>If "No," skip to Section 3, Infections at Other Body Sites.<br><br>Note: If a central line is removed and reinserted on the same or following day, in the same or different site, it is considered as one continuous central line. |
| Type(s) of central line(s) in place | Required if patient had central line in place for >2 calendar days.<br><br>Search the medical record for central lines that were in place for > 2 days and in place at any time on the date of event or the day before the date of event. Check the type(s) of the central lines that apply. If "Other," specify on the line provided. Do not document 'brand names' in 'other'. |
| Location(s) of central line(s) in place | Required if patient had central line in place for >2 calendar days.<br><br>Search the medical record for central lines that were in place for > 2 days and in place at any time on the date of event or the day before the date of event. Check the locations(s) of the central lines that apply. If "Other," specify on the line provided. |
| Was a positive, matching culture obtained from another body site(s) during the Secondary BSI Attribution Period? | Check one.<br><br>If "Yes," list Specimen Collected, Date of Culture, and Organisms Isolated in the table provided.<br><br>If "No," skip to Section 4, Outcome. |
| Specimen Collected, Date of culture, and Organism | Required if there was a positive culture from another body site that matches any of the blood cultures obtained within the secondary BSI Attribution Period.<br><br>Fill out table for each positive culture obtained from another body site<br><br>Record the date as DD/MM/YYYY. |
| Patient Outcome | Required. Check one.<br><br>Within the Event Timeframe (14 calendar days, date of event = Day 1) record when the patient is transferred, discharged, or dies. If at the end of the Event Timeframe (14 calendar days), the patient remains in the surveillance unit, mark "Still in surveillance unit." |
| Type of laboratory-confirmed BSI | Required. Check one.<br><br>Remember that BSIs with common commensal organisms must have two or more matching positive blood cultures to meet the case definition. An abbreviated list of common commensal organisms is provided as Appendix 1 of this BSI protocol. |

| | |
|---|---|
| Organisms and Antibiotic Susceptibility Testing Results | Report all organisms from positive blood cultures collected during the Event Timeframe (14 calendar days, date of event = Day 1) in this section.<br><br>**For each positive blood culture:**<br><br>• Record date of blood culture collection as DD/MM/YYYY<br><br>• Record the organism's name in the space provided. Specify the organism's species if known, otherwise report as spp.<br><br>• Attach a copy of the organism's antibiotic susceptibility testing (AST) results from the laboratory, if possible.<br><br>• If it is not possible to obtain a copy of the organism's AST results from the laboratory, then record the AST results for up to 10 drugs in the space provided. Use the following codes:<br><br>  ○ S = susceptible<br><br>  ○ I = intermediate<br><br>  ○ R = resistant<br><br>  ○ S-DD = susceptible, dose-dependent<br><br>• Blood culture collection dates and organism names must be recorded on the case report form even if AST results are attached in a separate report from the laboratory. |

### 11.2.17. Sub appendix 4: Denominator Data Collection Forms

**Denominators for BSI Surveillance**

**Instructions for filling out this form:** This form should be completed at the same time every day for each participating surveillance unit. Count the total number of patients in the ICU and record the number under "Number of Patients." Count the number of patients with a central line and record the number under "Number of patients with ≥1 central lines." All relevant counts should be performed at the same time by visiting each patient and checking for the presence of any central linesbefore moving on to the next patient.

*Table 10 - Denominator data collection form for BSI*

| Hospital Name: | Surveillance Unit Number: | Month: | Year: |
|---|---|---|---|
| **Date** | **Number of Patients** | Number of patients with ≥1 **central lines** | |
| **1** | | | |
| **2** | | | |
| **3** | | | |
| **4** | | | |
| **5** | | | |
| **6** | | | |
| **7** | | | |
| **8** | | | |
| **9** | | | |
| **10** | | | |
| **11** | | | |
| **12** | | | |
| **13** | | | |
| **14** | | | |
| **15** | | | |
| **16** | | | |
| **17** | | | |
| **18** | | | |
| **19** | | | |
| **20** | | | |
| **21** | | | |
| **22** | | | |
| **23** | | | |
| **24** | | | |
| **25** | | | |
| **26** | | | |
| **27** | | | |
| **28** | | | |
| **29** | | | |
| **30** | | | |
| **Totals** | | | |
| | Patient-days: | Central-line days: | |

## Denominators for Neonatal Intensive Care Unit (NICU)

**Instructions for filling out this form:** This form should be completed at the same time every day for each participating NICU. Count the total number of neonates in the NICU and record the number under "Pt" according to the neonate's birth weight. (Note: this is not the neonate's current weight). For BSI surveillance, count the number of neonates with one or more central line, including umbilical catheter, and record the number under "CL." All relevant counts should be performed at the same time by visiting each neonate and checking the birth weight and the presence of any central lines before moving on to the next neonate.

*Table 11 - Denominators for Neonatal Intensive Care Unit (NICU)*

| Hospital Name: | Surveillance Unit Number: | Month: | Year: | |
|---|---|---|---|---|
| **Birth Weight Categories** | | | | |

| **Date** | **A = ≤750 g** | | **B = 751-1000 g** | | **C =1001-1500 g** | | **D = 1501-2500 g** | | **E= >2500 g** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Pt | CL | Pt | CL | Pt | CL | Pt | CL | Pt | CL | |
| **1** | | | | | | | | | | | |
| **2** | | | | | | | | | | | |
| **3** | | | | | | | | | | | |
| **4** | | | | | | | | | | | |
| **5** | | | | | | | | | | | |
| **6** | | | | | | | | | | | |
| **7** | | | | | | | | | | | |
| **8** | | | | | | | | | | | |
| **9** | | | | | | | | | | | |
| **10** | | | | | | | | | | | |
| **11** | | | | | | | | | | | |
| **12** | | | | | | | | | | | |
| **13** | | | | | | | | | | | |
| **14** | | | | | | | | | | | |
| **15** | | | | | | | | | | | |
| **16** | | | | | | | | | | | |
| **17** | | | | | | | | | | | |
| **18** | | | | | | | | | | | |
| **19** | | | | | | | | | | | |
| **20** | | | | | | | | | | | |
| **21** | | | | | | | | | | | |
| **22** | | | | | | | | | | | |
| **23** | | | | | | | | | | | |
| **24** | | | | | | | | | | | |
| **25** | | | | | | | | | | | |
| **26** | | | | | | | | | | | |
| **27** | | | | | | | | | | | |
| **28** | | | | | | | | | | | |
| **29** | | | | | | | | | | | |
| **30** | | | | | | | | | | | |
| **31** | | | | | | | | | | | |
| **Total** | | | | | | | | | | | |

## 11.3. Appendix III - Surgical site infection (SSI) surveillance protocol

### 11.3.1. Introduction

Surgical site infections (SSIs) are among the most common healthcare-associated infections (HAIs) in low- and middle-income countries (LMIC) with an incidence over three times higher than rates seen in developed nations.

This protocol for surgical site infection (SSI) surveillance is designed to support the implementation of the National HAI surveillance guidelines. Conducting high-quality SSI surveillance is crucial to detect the magnitude of the problem and assess the impact of any prevention/improvement intervention.

This protocol provides a practical, reproducible, and low-resource demanding SSI surveillance methodology with the goal of providing actionable information for surgical site infection prevention at the lowest cost in resources and staff effort by:

- Targeting surveillance efforts
- Using revised SSI surveillance definitions
- More directly connecting SSI surveillance to SSI prevention activities

### 11.3.2. Objectives

- Provide an economical methodology for the systematic collection, analysis, and presentation of actionable information on the occurrence of surgical site infections (SSI)
- Guide the targeting of infection prevention and control (IPC) activities and the monitoring and measurement of results
- Provide a safer surgical context for patients

### 11.3.3. Minimum criteria

This protocol recommends three minimum criteria to be met before starting SSI surveillance activities:

1. Assessment of the resources required for the proposed surveillance activities with ensured availability of estimated requirements for at least 1-year (See: Structural Surgical Surveillance Assessment)
2. Review of current surgical practices to ensure that relevant STRONGLY recommended practices for the prevention of surgical site infection with an evidence GRADE score of MODERATE – HIGH are being followed. If not, priority should be given to correcting deficient practices before the utilization of resources for surveillance (see WHO Global Guidelines for the Prevention of Surgical Site Infection)
3. Established Infection Prevention and Control (IPC) Program with the willingness and ability to act based on surveillance results.

### 11.3.4. Surveillance Strategy/Approach

A well thought out surveillance strategy will help to determine resource requirements, plan for implementation, and anticipate system limitations. The following sections will walk you

through useful considerations in defining an SSI specific surveillance strategy.

### 11.3.5. Surveillance Period

Implementation of surveillance activities can be as a continuous surveillance system or as a time-limited or period surveillance system.

Continuous surveillance activities are ongoing and integrated into 'regular daily duties' within a facility. Continuous SSI surveillance has several important advantages and is often preferred by those planning surveillance programs; however, continuous surveillance can be costly in both staff time and resources.

Time-limited or period surveillance limits surveillance activities to a defined time period (for example, a single month per year), which can result in substantial resource savings. While period surveillance is unable to detect changes occurring between surveillance periods and has limited use in outbreak detection, period-based systems are useful in monitoring changes over time and for surveillance systems that require a level of data collection/effort that is not sustainable over an extended period.

This protocol recommends time-limited or periodic surveillance (time to be determined).

### 11.3.6. Patient-level risk

Each patient comes to a surgical procedure with an existing or baseline risk of complication – including surgical site infection. This is considered patient-level risk and is generally not changed by the hospital setting or IPC practices. Because a main goal of surveillance is to decrease the risk of infection, patient-level risk should be controlled. One of the easiest ways to control patient-level risk is to group patients with similar patient-level risk together.

Grouping patients with similar patient-level risk is usually done by:

1. Measuring patient-level risk using on a validated patient risk assessment tool
    - One well validated risk assessment tool is the American Society of Anesthesiologist (ASA) Physical Status Classification System
    - All patient-level assessment tools require detailed data on patient preexisting conditions and their current state of health. In setting where these data are not collected as part of standard clinical care, determining patient-level risk can require substantial effort
2. Target surveillance to surgical procedures where the need for the procedure is independent of (not strongly related to) patient-level risk.
    - C-section and hernia repair are examples of surgeries where the need for the surgical procedure is unlikely to increase patient-level risk
    - In most settings, no additional data collection is needed to control patient-level risk by careful selection of a target surgical population for surveillance

### 11.3.7. Procedure related risk

In addition to patient-level risk, each procedure has a baseline level of infection risk called procedure related risk. Two important procedure related risk measures are:

- Wound class (clean, clean-contaminated, contaminated, and dirty wounds)
- Length of the surgical procedure

It is important to understand procedure related risk because comparing procedures with very different infection risk (for example, comparing infections in clean wounds to infections in dirty wounds) is not meaningful.

While the information needed for individual wound classification and length of each surgical procedure is often unavailable, each surgical procedure has an expected wound classification that can be used for some control of procedure related risk.

### 11.3.8. Target Surgical Population

To maximize any observable change following IPC improvement, an ideal surgical population for surveillance will have a low baseline risk of infection. Surgeries in which patient-level risk is independent of the need for the procedure and wound classification is typically clean are most likely to be low-risk and should be prioritized. Appendix 1 (Table 1) provides a list of common surgical procedures with patient-level risk independence and expected wound classification summarized.

Based on the considerations presented in table 1, recommended targeted surgical populations for new SSI surveillance programs include:

- Post-cesarean section (C-section) patients
- Patients post Inguinal/Umbilical Hernia Repair

Additionally, C-section and Hernia repair are among the most common surgical procedures performed in many resources limited settings {Grimes, 2012 #197}.

Due to the high and consistent volume of C-section procedures are a good initial choice for new SSI surveillance programs. Box 1 summarizes some benefits of targeting post C-section patients.

**Benefits of starting SSI surveillance in post C-section patients**:

- Increased comparability
  (Patients have similar risk of infection)
- Improved targeting of recommendations
  (If problems are found, finding solutions is easier)
- Decreased system complexity
  (Surveillance is easier in smaller groups of patients and staff)

One simple and effective way to have additional control for **procedure related risk** in both C-Section and post-hernia repair patients is to group procedures as **emergent** versus **elective**. A simple definition of these is provided as Box 2.

General definition of emergent versus elective procedures for the control of procedure related risk for SSI surveillance:

Emergent Procedures: Procedure done urgently, usually to prevent immediate death or disability, often limiting the pre-surgical procedures done

Elective Procedures: Procedure planned with all pre-surgical procedures done

### 11.3.9. Surveillance Method

#### 11.3.9.1. Case definition

**Symptom based case definition for SSI**

Within 30 days of the C-section, observed or reported by the patient:

A purulent (pus) discharge in, or coming from, the wound (including evidence of an abscess)

OR

Painful, spreading (worsening) erythema (redness, swelling, warmth) surrounding the surgical site with evidence of fever (either measured or by report of symptoms of a fever such as sweating, shivering)

The simplified symptom-based case definition provided in Box 3 is based on definitions proposed by the WHO Practical Guide for Prevention of Hospital-acquired Infections, the UK Surgical Infection Study Group (SISG), and the UK National Prevalence Survey Study (NPS). This case definition represents the most commonly accepted standalone components of surgical wound infection used in relevant published studies {(WHO), 2002 #425; Ayliffe, 1993 #173; Peel, 1991 #88; Bruce, 2001 #44}.

#### 11.3.9.2. Case finding

Case finding is the process of identifying patients that meet the surveillance case definition. Because many surgical site infections will occur after discharge, **post-discharge case finding is essential to measure SSI rates in a meaningful way {Petherick, 2006 #47}**. This means that point prevalence surveys (PPS) looking at healthcare associated infections may not capture SSI cases well.

**Patient follow-up and case finding: In-patient**

In-patient surgical patient follow-up and case finding should start as soon after the surgical procedure as possible. Recommended procedures for in-patient follow-up and case finding are:

- Before discharge, start the **Surgical Patient Tracking and Data Collection Form (Appendix 2)** for each patient in the target population. You will use this form record information for the 30-day follow-up period.
- Patients should be checked daily for either meeting the surgical site infection case definition, death, or discharge. Record new information on the Surgical Patient Tracking and Data Collection Form
- Just before discharge, meet each patient face-to-face for a final wound assessment

and to provide a written information sheet outlining signs and symptoms of infection and contact information to use if symptoms occur or the patient has concerns. **(Appendix 4)**

- At discharge, patients enter post-discharge surveillance

**Patient follow-up and case finding: Post-discharge**

Post-discharge case finding involves staff contacting patients at specified time points after their procedure to ask about wound healing. Procedures for post-discharge follow-up and case finding are:

- Decide when patients will be contacted. For surveillance, a single contact at the end of the follow-up period (approximately 30 days after procedure) may be sufficient and can help reduce the reporting minor symptoms consistent with normal healing common earlier.
- Use the **SSI Patient Follow-up Script** to guide the patient interview and record answers.
- Use interview answers to compete the **Surgical Patient Tracking and Data Collection Form**.

### 11.3.9.3. Collection of Denominator Data

The total number of target procedures performed is the denominator used to determine the SSI incidence rate. The **Denominator Data Collection Form (Appendix 3)** is provided to help collect this information.

Denominator data must be collected by both the primary subgroup (emergent / elective) as well as for any additional subgroups of interest. Therefore, each subgroup used can substantially increase the amount of work required for surveillance.

### 11.3.10. Data Use

One of the most important surveillance activities is the use of data to encourage and guide changes for improved patient outcomes and the protection of populations. All too often, however, the use of surveillance data is overlooked in the planning of new surveillance programs. Explicit planning for data use, before any data is collected, will help to avoid the waste of resources.

The SSI surveillance finding will be used at the health facility, RHB and MoH level to improve the quality of IPC and resource allocation.

### 11.3.11. Confidentiality

Patients should always be assured of anonymity regarding collection of data. Surgeons should also be assured of anonymity in overall reporting.

### 11.3.12. Data entry

Once the form has been completed, this information should be entered in the surveillance database as soon as possible – tick 'yes/no' on the paper copy once this is done. The hard copy of the form should be kept for reference and audits. Notes on data entry are in the Epi-info database manual found on the WHO web pages.

### 11.3.13. Analysis of SSI surveillance data

The major two key output numbers to be used for analysis of SSI will be: Number of patients who developed SSI (Numerator) and Number of patients who have had surgery (Denominator). These are normally used together to calculate incidence.

To calculate the SSI incidence rate: Divide the total number of patients who developed SSI (as a Numerator) by total number of patients who have had the surgery (as Denominator) during the surveillance period (Example - by month) and then multiply by 100.

Incidence= (# of SSI cases detected during the surveillance period ) X 100

(# total number of target surgeries performed during the surveillance period)

Example Surveillance Data (Total SSI Incidence Rate)

- The following section illustrates the calculation and display of incident rates using example data from a facility performing SSI surveillance targeting patients post C-section.

**Note: Data for illustration only – Hypothetical data (Data that are not real)**

Monthly surveillance data for SSI following C-section at Facility A, January through October

*Table 12 - Hypothetical data set for calculating SSI rate*

| Months | **C-sections** | **Infections** | **SSI Rate** |
|---|---|---|---|
| **January** | 106 | 7 | (7/106)*100 = 6.6 |
| **February** | 109 | 15 | (15/109)*100 = 13.76 |
| **March** | 105 | 13 | (13/105)*100 = 12.38 |
| **April** | 98 | 15 | (15/98)*100 = 15.31 |
| **May** | 85 | 6 | (6/85)*100 = 7.06 |
| **June** | 106 | 19 | (19/106)*100 = 17.92 |
| **July** | 108 | 20 | (20/108)*100 = 18.52 |
| **August** | 93 | 11 | (11/93)*100 = 11.83 |
| **September** | 96 | 12 | (12/96)*100 = 12.5 |
| **October** | 105 | 13 | (13/105)*100= 12.38 |
| **November** | | | |
| **December** | | | |

If we want to see the trends by month we can use line graph as shown below from the above hypothetical data

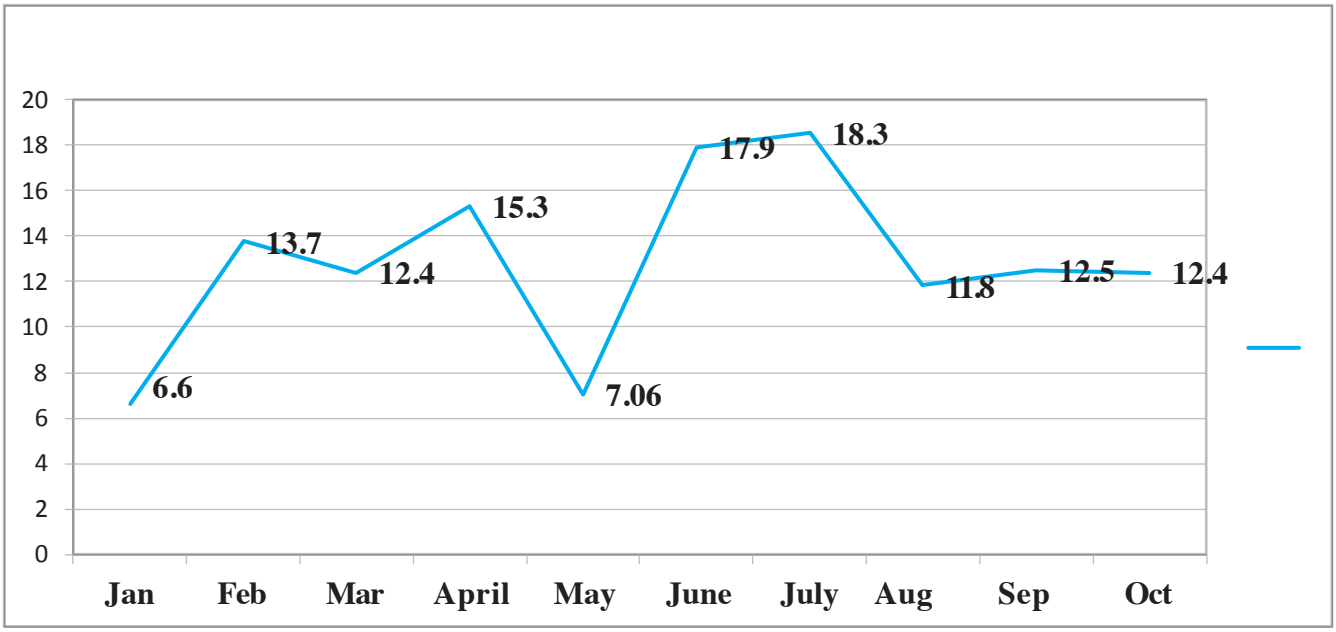



*Figure 6 Total Incidence SSI rate by month – Facility A, January through October*

### 11.3.14. Interpretation and feedback of surveillance data

- The Data results should be interpreted carefully to identify at-risk populations and procedures and assess the impact of prevention measures. However, such interpretation should also carefully consider other factors that may influence surveillance results.
- Analysis should include calculation by subgroup (for example, emergent versus elective procedures).

The structure of the facility and program goals should guide selection subgroups. Possible subgroups may include:

- The surgical team
- Clinic versus hospital-based procedures
- Patient age group
- Difference in surgical practice thought to impact risk (for example, different methods of antimicrobial prophylaxis or skin preparation).

This kind of chart only needs to be updated monthly, and the number of SSI cases lags a month behind the number of operations due to the 30-day surveillance. Note: as this is only showing the number of cases from one hospital, there can be large month-to-month fluctuations due to random variation.

- **Hospitals/departments meetings** is used to report monthly SSI data, ideally with some case notes of patients who have developed a SSI. This approach will also be very useful while using a 'learning from defects' tool and in the meetings dedicated to its use. Larger meetings or seminars to discuss changes in practices across a department can be organized separately with key staff.

- **Direct discussion with individual surgeons**. Open discussion with the clinical team involved so that lessons can be learned where possible. Letting a surgeon know when a case they have operated on has developed an SSI is helping them to improve their own practice.

### 11.3.15. References


1. Global guidelines for the prevention of surgical site Infection. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/250680/1/9789241549882-eng.pdf?ua=1, accessed 22 February 2018).

2. CDC/NHSN surveillance definitions for specific types of infections. Atlanta (GA): Centers for Disease Control and Prevention; 2017 (https://www.cdc.gov/nhsn/pdfs/pscmanual/17ps cnosinfdef_current.pdf, accessed 22 February 2018).

## Sub appendices

### Sub appendix 1

*Table 13: Generalized association between patient-level risk and the need for surgery and expected wound classification by common surgical procedure groups*

| Surgical Procedure | Patient-level Risk Independent | Patient-level Risk Related | Expected Wound Classification |
|---|---|---|---|
| Cesarean Section (elective) | X | | Clean |
| Inguinal Hernia Repair (elective) | X | | Clean |
| Umbilical Hernia Repair (elective) | X | | Clean |
| Thyroid surgery (non-oncological) | X | X* | Clean |
| Open Fracture Reduction (no open wound) | X | | Clean |
| Trauma (open wound) | X | X† | Contaminated |
| Appendectomy | X | | Clean-contaminated Contaminated |
| Hysterectomy (non-oncological) | X | | Clean contaminated |
| Cardiac Procedures | | X | Clean |
| Orthopedic Procedures (non-traumatic) | | X | Clean |
| Gastrointestinal Procedures | | X | Clean-contaminated Contaminated |
| Neurosurgical Procedures | | X | Clean |
| Oncology Procedures | | X | Clean – Contaminated |

* The need for thyroid procedures is age related and older age can increase patient-level risk of surgical complication. If age is controlled (for example by limiting surveillance to individuals <50 years of age), thyroid surgery may be a viable target surgical population for surveillance

† While suffering trauma is generally not related to patient-level risk, some traumatic injuries themselves will increase patient-level risk of surgical complication.

## Sub appendix 2:

*Table 14 – Surgical Patient Tracking and Data Collection Form*

| Patient ID | Patient name | Contact Number | Other Contact Info | Age (years) | Gender | Surgical procedure | Context | Procedure Date (dd/mm/yyyy) | Follow-up end date (dd/mm/yyyy) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | [ ] F<br>[ ] M | [ ] Procedure<br>[ ] Procedure | [ ] Elective<br>[ ] Emergent | __ /__ /____ | __ /__ /____ |
| Discharge date (dd/mm/yyyy) | SSI definition met | Date SSI definition met (dd/mm/yyyy) | Symptoms / Criteria | Sought Care | Infection Diagnosed | Treatment: Antibiotics | Treatment: Interventions | | |
| __ /__ /____ | [ ] Yes<br>[ ] No | __ /__ /____ | [ ] Pus from wound<br>[ ] Worsening erythema<br>[ ] Fever<br>[ ] Other:<br>_____ | [ ] Yes<br>[ ] No | [ ] Yes<br>[ ] No | [ ] Yes<br>[ ] No | [ ] None<br>[ ] Yes* | | |
| **Follow-up Complete** | **Complete date (dd/mm/yyyy)** | **Final outcome** | Death Date (dd/mm/yyyy) | Notes: | | | | | |
| **[ ] Yes**<br>**[ ] No** | __ /__ /____ | **[ ] No SSI**<br>**[ ] Yes SSI**<br>**[ ] Died**<br>**[ ] Unknown** | __ /__ /____ | | | | | | |

| Patient ID | Patient name | Contact Number | Other Contact Info | Age (years) | Gender | Surgical procedure | Context | Procedure Date (dd/mm/yyyy) | Follow-up date (dd/mm/yyyy) |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | [ ] F<br>[ ] M | [ ] Procedure<br>[ ] Procedure | [ ] Elective<br>[ ] Emergent | __ /__ /____ | __ /__ /____ |
| Discharge date (dd/mm/yyyy) | SSI definition met | Date SSI definition met (dd/mm/yyyy) | Symptoms / Criteria | Sought Care | Infection Diagnosed | Treatment: Antibiotics | Treatment: Interventions | | |
| __ /__ /____ | [ ] Yes<br>[ ] No | __ /__ /____ | [ ] Pus from wound<br>[ ] Worsening erythema<br>[ ] Fever<br>[ ] Other: Notes | [ ] Yes<br>[ ] No | [ ] Yes<br>[ ] No | [ ] Yes<br>[ ] No | [ ] None<br>[ ] Yes* | | |
| **Follow-up Complete** | **Complete date (dd/mm/yyyy)** | **Final outcome** | Death Date (dd/mm/yyyy) | Notes: | | | | | |
| **[ ] Yes**<br>**[ ] No** | __ /__ /____ | **[ ] No SSI**<br>**[ ] Yes SSI**<br>**[ ] Died**<br>**[ ] Unknown** | __ /__ /____ | | | | | | |

## Surgical Patient Tracking and Data Collection Form Dictionary

**Patient ID**: A unique patient identifier that links to patient records at the facility. This unique identifier should not be included in analytic database.

**Patient name**: Used for patient tracking and follow-up

**Contact Number**: The contact number the patient prefers be used for follow-up calls

**Other Contact Info**: Space for other relevant information useful for follow-up call

**Patient age**: Record in years

**Gender**: Female or Male (Female is preselected)

**Surgical procedure**: Specify the procedure performed (C-section is preselected)

**Context**: Indicate 'Elective' if procedure was scheduled and standard preoperative activities were completed. Indicate 'Emergent' if procedure was not scheduled and/or standard preoperative activities were not completed. Context is used to adjust for procedure-level risk

**Procedure Date**: The date the C-section was performed

**Follow-up end date**: The last day of the 30-day follow-up period for the patient [Procedure date + 30 days]

**Discharge date:** The date the patient was discharged from the hospital

**SSI Definition Met**: (Yes; No) Was the SSI case definition met?

**Date SSI definition met**: If met, the date the surgical site infection case definition was met

**Symptoms / Criteria**: Indicate the symptoms documented or reported by the patient (selected all symptoms reported or documented). If 'Other' used – write the symptom reported in space provide or in 'Notes' area

**Sought Care**: (Yes; No) Was health care sought for possible wound infection or difficulty with wound healing?

**Infection Diagnosed**: (Yes; No) Was a wound infection diagnosed by a health care provider? Patient report of being told the wound was infected by health care professional is sufficient to indicate 'Yes'.

**Treatment Antibiotics**: (Yes; No) Were antibiotics taken as treatment for possible wound infection or for difficulty in wound healing? Antibiotics **do not** need to have been prescribed by a health care provider.

**Treatment Interventions**: (Yes; No) Were other treatments (either community or healthcare based) received for treatment of possible wound infection or for difficult in wound healing?

**Follow-up Complete**: (Yes; No) Was follow-up completed? Select 'Yes' if patient was contacted and interviewed at approximately 30 days after C-section. If 'No' give reason in 'Notes' area.

**Complete date**: The date follow-up was completed

**Final Outcome**: Indicate the final determination of if SSI occurred within 30-days of post-

surgical procedure follow-up (No SSI, Yes SSI, Died, Unknown/Lost to follow-up)

**Death date**: If patient died before follow-up was completed, the date patient died

**Notes**: Area for any relevant notes

## Sub appendix 3: Denominator Data Collection Tool

Instruction: SSI surveillance denominator data is obtained by counting entries on **Surgical Patient Tracking and Data Collection Forms** by subgroup for the surveillance period. If available, denominators should be compared to counts obtained from an independent data source – for example the surgical log.

First day of surveillance period: _____

Last day of surveillance period: _____

1. Number of procedures of interest performed during the surveillance period:

   a. Total target procedures performed: Number _____

2. Number of surgical procedures by primary analytic subgroup (i.e., procedure-related risk groups):

   **Emergent procedures are unscheduled surgical procedures – usually done with limited or no pre-procedure activities**

   **Elective procedures are scheduled surgical procedure – done with standard pre-procedure activities**

   a. Target Procedure – Emergent: Number _____

      Target Procedure – Elective: Number _____

1. (OPTIONAL) Number of surgical procedures by second subgroup of interest (defined by the structure of facility and the goals of the program)

   a. Target Procedure, Subgroup 2 (Exposed) – Emergent: Number _____

      Target Procedure, Subgroup 2 (Exposed) – Elective: Number _____

      Target Procedure, Subgroup 2 (Not Exposed) – Emergent: Number _____

      Target Procedure, Subgroup 2 (Not Exposed) – Elective: Number _____

## Sub appendix 4: Post-discharge Follow up script

Hello, this is [**YOUR NAME**] from [**HEALTH FACILITY**]. My records show that you had a [**NAME OF PROCEDURE**] on [**DATE OF OPERATION**]. Is this correct?

[ ] Yes Corrected information:

[ ] No (specify)

[ ] Report that patient has died (date of death: ____ / _____ / _____)

Thanks for that, I am calling today to check that you are doing well and that your wound has healed as it should. Do you have 5 to 10 minutes to answer a few questions?

**If not a good time, note a better time to call: _____**

Your answers are very important to us and combined with hundreds of others will help to improve the quality care at [**HEALTH FACILITY**]. I want to assure you that all your responses will be kept confidential.

I would like to start with asking about fluid that may have come from your wound. A small amount of clear or bloody fluid from a healing wound is normal. I am interested in fluid we call **pus** that is a sign of an infection in your wound. Pus is usually thick and cloudy or milky and can sometimes have an unpleasant smell.

1. At any point did you see pus coming from your surgical wound? [[symptom_pus]]
   - □ Yes*
   - □ No [**SKIP TO QUESTION 5**]
2. What color was the pus?
   - □ Clear [clarify, puss is typically not clear]
   - □ Cloudy
   - □ Yellow
   - □ Green
   - □ Red/bloody [clarify, pus is not usually described as mainly bloody
3. Did the pus have a bad smell?
   - □ Yes
   - □ No
4. What was the date when you noticed the pus coming from the surgical wound? [[SSI _ date]]
   - □ (dd/mm/yyyy) ____ / ____ / _____

I am now going to ask you about redness, swelling, and pain around your wound.

5. Did you notice redness around your wound that got worse instead of better? [[symptom _ erythema]]

   - ☐ Yes*
   - ☐ No

6. Did the area around your wound ever become swollen? By swollen I mean an enlargement of the wound area or the affected part of the body causing pain or limited your movement. [[symptom _ erythema]]

   - ☐ Yes*
   - ☐ No [clarify, if #5 = yes, confirm there was **NO swelling noted**]

7. While there was redness and/or swelling around the wound, did you have pain at the site that was worse than you expected? [[symptom _ erythema]]

   - ☐ Yes*
   - ☐ No [clarify, if #5 and #6 = YES, confirm there was **NO pain noted**] [**SKIP TO QUESTION 9**]

8. While there was redness and/or swelling around the wound, did you have fever? By fever I mean a measured temperature above $38^0$ C or symptoms of a fever including periods of unusual sweating, shivering, headache, muscle aches, loss of appetite, or general weakness. [[symptoms _ fever]]

   - ☐ Yes*
   - ☐ No [clarify, if #5, #6, and #7 are YES, confirm there was **NO fever or symptoms of fever**] [SKIP TO QUSTION 11]

9. What was the date when you measured or noticed your fever? [[fever _ date]]

   - ☐ (dd/mm/yyyy) ____ / ____ / _____

10. At any point did you seek health care for treatment of your surgical wound? [[SSI _ care]

    - ☐ Yes
    - ☐ No

11. Did the health care provider tell you that your wound was infected? [[SSI _ dx]]

    - ☐ Yes
    - ☐ No
    - ☐ Unknown

12. Did you take antibiotics to treat the infection? [[SSI _ abx]]

    - ☐ Yes
    - ☐ No

□ Unknown

**13.** Did you have any other treatments done to help your wound infection? [[SSI _ treatment]]

□ No

□ Yes (specify): _____

Thank you for taking the time to answer these questions. Do you have any questions for me? If you think of any questions later you can reach our team at: _____
_____

## 11.4. Appendix IV - Protocol for Surveillance of Healthcare-Associated Urinary Tract Infections

**List of Abbreviations**

| | |
|---|---|
| CDC: | United States Centers for Disease Control and Prevention |
| CAUTI: | Catheter-associated urinary tract infection |
| CFU: | Colony forming unit |
| DHQP: | Division of Healthcare Quality Promotion |
| DUR: | Device utilization rate |
| ECDC: | European Centre for Disease Prevention and Control |
| HA: | Healthcare-associated |
| HAI: | Healthcare-associated infection |
| HAI-Net: | Healthcare-Associated Infections Surveillance Network |
| ICU: | Intensive care unit |
| NHSN: | National Healthcare Safety Network |
| NICU: | neonatal intensive care unit |
| PICU: | pediatric intensive care unit |
| UTI: | urinary tract infection |
| WBC: | white blood cells |

### 11.4.1. Introduction

UTIs are common infections that happen when microorganism, often from the skin or rectum, enter the urethra, and infect the urinary tract. The infections can affect several parts of the urinary tract, but the most common type is a bladder infection (cystitis). Kidney infection (pyelonephritis) is another type of UTI. They're less common, but more serious than bladder infections. UTIs are the most common type of HAIs.

This protocol describes the methods to conduct surveillance for healthcare-associated UTI in intensive care unit (ICU) and wards to ensure standardized application of case definitions, data collection, case reporting, analysis, and data use procedures. This protocol should be used in conjunction with the overview protocol Surveillance for Healthcare-Associated Infections (HAI) in Intensive Care Units and wards by infection control practitioners, health care workers (HCWs), program managers and others to improve quality of UTI care and prevention of HA UTI. This protocol can be used by stakeholders and end users of surveillance data for program planning and resource allocation.

### 11.4.2. Surveillance settings

Surveillance shall occur in high rates of device utilization service areas like ICU, surgical, medical, Gynecology/Obstetrics and pediatrics wards. Please refer to the general protocol regarding selection criteria of health facilities (section 3).

### 11.4.3. Definitions

The following definitions have been adapted from the European Centre for Disease Prevention and Control's (ECDC) HAI-Net [1] and the United States Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) [2]. The case definitions are for the purpose of surveillance only and are not meant to serve as clinical definitions for use in diagnosis and treatment.

### 11.4.4. UTI surveillance definitions

#### Microbiologically confirmed UTI (UTI-A)

A patient with the following feature:

- a positive urine culture of no more than two species of organisms
- at least one organism with ≥$10^5$ CFU/ml

  **or**

- at least two urine cultures with repeated isolation of the same pathogen with ≥ $10^2$ CFU/ml (but <$10^5$ CFU/ml) obtained via urinary bladder catheterization (e.g., straight catheterization)

  **or**

- urine culture with < $10^5$ CFU/ml of a single pathogen in a patient being treated with antimicrobial agent for a urinary tract infection

  **AND**

At least one of following with no other recognized cause:

- fever (>38°C)
- suprapubic tenderness
- urgency
- frequency
- dysuria
- Bloody urine

### Non-Microbiologically confirmed UTI (UTI-B)

- A patient with at least two of the following with no other recognized cause:
  - fever (>38°C core)
  - suprapubic tenderness
  - urgency
  - frequency
  - dysuria
  - Bloody urine

  **AND**

- At least one of following:
  - positive dipstick for leukocyte esterase and/or nitrate
  - pyuria (urine specimen with ≥ 10 WBC/ml or ≥ 3 WBC/high-power field of unspin urine)
  - organisms (e.g., bacteria) seen on Gram stain of unspin urine

### 11.4.5. Additional definitions

**Indwelling Urinary Catheter:** a drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and connected to a drainage bag. This is also called a Foley catheter. Condom or straight in-and-out catheters are not included nor are nephrostomy tubes or suprapubic catheters unless a Foley catheter is also present.

**Catheter-associated UTI (CAUTI):** A patient who meets the definition for microbiologically confirmed UTI (UTI-A) and additionally meets one of the following criteria in any age group:

- An indwelling urinary catheter in place for **>2** calendar days on the date of event, with day of device placement being Day 1,

  **OR**

- An indwelling urinary catheter in place for **>2** calendar days that had been removed on the date of event or the day before the date of event

**Note:** If a catheter is removed and reinserted on the same or following day, it is considered as one continuous usage.

### 11.4.6. Surveillance methods

The process of conducting UTI surveillance in this protocol requires active, patient-based, prospective identification of cases and collection of denominator data by staff trained in HAI surveillance.

### 11.4.7. Case Finding

See Appendix 4 for the UTI case finding flowchart. Refer to Case Finding, in *Surveillance for Healthcare-Associated Infections (HAI), general protocol* 11.1.7

### 11.4.8. Case Reporting for UTI

Once surveillance staff have evaluated all patients in the ICUs and wards under surveillance and identified cases fulfilling the UTI case definition, the UTI case report form in Appendix 1 will be used to collect all required data. The isolated organism(s) and antimicrobial susceptibility testing results will be recorded in the Organism ID and Susceptibility Testing section) of the case report form. The instructions for completion of the UTI case report form can be found in Sub Appendix 2. They contain brief instructions for collection and entry of required data for the form. A copy of lab request and report forum should be attached to case reporting form.

For Case Reporting Rules, Interpretation and Reporting of Laboratory Results, and Case ID and Patient Register refer to, Case Reporting, in *Surveillance for Healthcare-Associated Infections (HAI), general protocol 11.1.8*

**Additional Reporting Rules Specific to UTI:**

- Single urine cultures with > 2 organisms are routinely regarded as contaminated cultures and should not be used for UTI surveillance

**Example:** *Klebsiella pneumoniae*, *E. coli*, and *Citrobacter freundii* are isolated from a urine culture on March 1, this culture should be regarded as contaminated and not used in surveillance.

- If > 2 organisms are isolated over multiple urine cultures, the case definition can still be met.

**Example:** *Klebsiella pneumoniae* and *Citrobacter freundii* are isolated from a urine culture on March 1, and an additional *E. coli* is isolated from a different culture on March 3. All culture results meeting the established case definitions can be used and added to the event.

- If the UTI case definition is met via culture data, all organisms that are seen on gram stain or isolated by culture should be reported, including organisms such as Candida species.

### 11.4.9. Denominators (for calculation of incidence rates)

The denominator should be the "population at risk" for developing disease, i.e., persons who have the potential to get UTI. Urinary catheter days and patient-days are the denominators used to determine UTI and CAUTI incidence rates. Denominator data should be collected at the same time every day for each participating unit or ward under surveillance. The denominator

forms for collection of patient-days and urinary catheter-days can be found in Appendix 3.

- **Urinary Catheter-day** denominator data is calculated as the number of patients with an indwelling urinary catheter in each ward under surveillance, each day. Surveillance staff should record the number of patients in the surveillance departments who have an indwelling urinary catheter in place.

- **Patient-days** denominator data is calculated as the total number of patients per day in the unit under surveillance. Patient days should be collected at the same time as urinary catheter-days.

- **NICU patient days:** Participating hospitals conducting surveillance in NICUs collect the denominator data stratified by birth weight categories using the NICU denominator form in Appendix 4,. NICUs collecting the denominator data by birth weight category will be able to stratify HAI rates by five birth weights.

### 11.4.10. Analysis plan

UTI will be stratified by type (UTI-A and UTI-B) as well as by catheter association. Incidence will be calculated for each UTI subset using numerator and denominator data as described below.

**Calculation of Incidence**

- **Total UTI rate:** UTI per 1000 patient days. Divide total number of reported UTIs (UTI-A and UTI-B) by the number of patient-days and then multiply by 1000.
    - UTI-A incidence: UTI-A per 1000 patient-days. Divide the number of reported UTI-A by the number of patient-days and then multiply by 1000.
    - UTI-B incidence: UTI-B per 1000 patient-days. Divide the number of reported UTI-B by the number of patient-days and then multiply by 1000.
- **Total CAUTI rate:** CAUTI per 1000 urinary catheter-days. Divide the total number of reported CAUTI by the number of urinary catheter-days and multiply by 1000.
    - CAUTI incidence: CAUTI UTI-A per 1000 urinary catheter-days. Divide the number of reported CAUTI UTI-A by the number of urinary catheter-days and then multiply by 1000.

- **Device Utilization Rate (DUR)**

The device utilization rate (DUR) is used during reporting to contextualize the UTI incidence. This is important because facilities that have high rates of indwelling urinary catheter usage will likely have higher UTI and CAUTI rates. The DUR can be calculated by dividing the urinary catheter days by patient-days as shown on the formula below.

### 11.4.11. Reporting and trend analysis

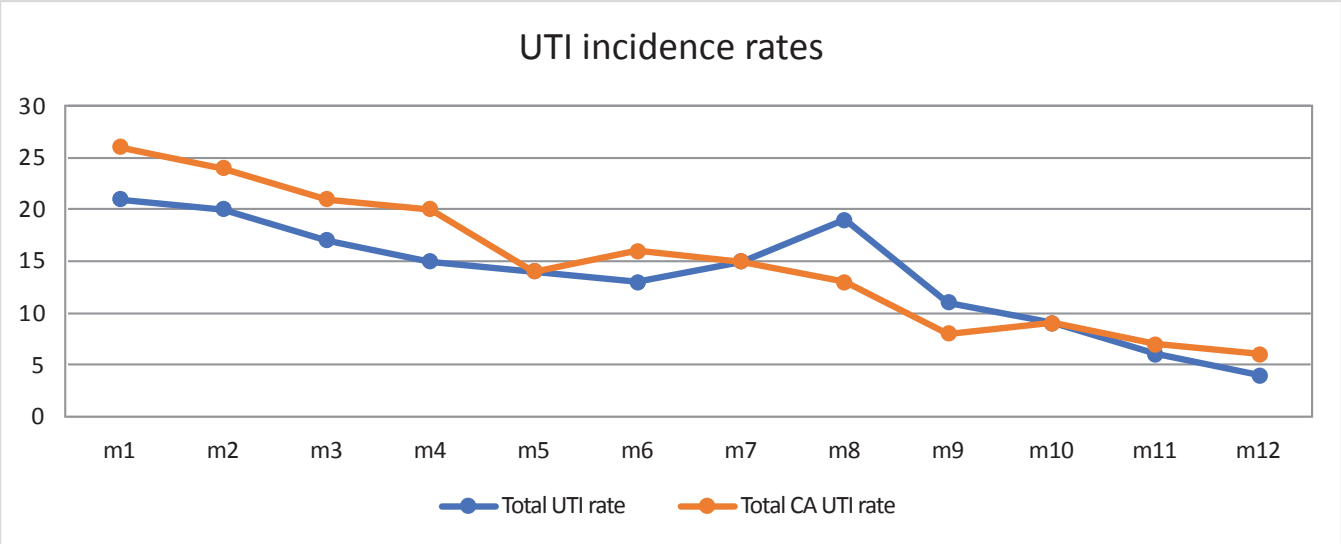
HAIs surveillance point of contacts from each participating health facility will generate monthly report and submit to IPC committee. The IPC team will compile and send quarterly reports to next level reporting hierarchy. During the same time period, regional health bureaus should compile and submit the report to MOH and EHPI. UTI incidence rate will be analyzed overtime to look for trends. The data will be analyzed by months and weeks. As the program continues

to mature, it will be further analyzed by quarter and year. The following table will be used to compare UTI rates over months.

*Table 15 - Template table for comparing UTI rates over months*

| Rates | July | August | Sept | Oct | Nov | Dec | Jan | Feb | March | April | May | June |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| UTI rate | | | | | | | | | | | | |
| CAUTI rate | | | | | | | | | | | | |

Data shall be presented using table and graphs. Trend analysis of monthly UTI rate shall be done yearly using line graph. Comparison of the UTI rates can be presented using bar graphs. Please refer to the below line graph as an example.




### 11.4.12. Dissemination

Findings of the UTI surveillance should be utilized at different levels. The health facilities should use it to improve quality of care and infection prevention activities. Regional health bureaus and MOH can use the data to prepare and update IPC standards and quality of care practice. Partners use the data for monitoring of their activities and allocate resources as required as well as provide technical assistance for the health system.

### 11.4.13. References


1. European Centre for Disease Prevention and Control. Healthcare-associated Infections Surveillance Network (HAI-Net): European surveillance of healthcareassociated infections in intensive care units; Available from: http://ecdc.europa.eu/en/publications/Publications/healthcare-associated-infections-HAI-ICU-protocol.pdf.

2. Centers for Disease Control and Prevention. National Healthcare Safety Network: Acute Care Hospital Surveillance for Urinary Tract Infections; Available from: http://www.cdc.gov/nhsn/acute-care-hospital/cauti/index.html.

## Sub appendices

### Sub appendix 1: UTI Case Report Form

*Table 16 – UTI case reporting form*

| | | |
|---|---|---|
| Record Case ID generated by the reporting system: _____ _____ - UTI | | |
| Hospital Name: | | |
| Sex: Male □ Female □ | Age ____ | Birth weight: _____ grams (NICU only) |
| Date of hospital admission: ____ /_____ /_____<br>Date of admission to surveillance unit: ____ /_____ /_____ | | |
| Location prior to hospital admission: | □ Home / Community | □ Another health facility □ Unknown |
| List all other Case IDs assigned to this patient since hospital admission: | | |
| **1. UTI Details** | | |
| Date of event *(dd/mm/yyyy)*: | ____ /_____ /_____ | |
| List all locations, in chronological order, where patient was housed on the date of event: | _____<br>_____<br>_____ | |
| List all the locations, in chronological order, where patient was housed on the day **before** the date of event: | _____<br>_____<br>_____ | |
| **2. Invasive Devices: Urinary Catheters** | | |
| Did the patient have a Foley catheter in place at any time on:<br>• The date of event **or**<br>• The day before the date of event? | □ Yes<br>□ No *(skip to 3, Outcome)*<br>□ Unknown *(skip to 3, Outcome)* | |
| If **YES,** was the Foley catheter in place for >2 calendar days? | □ Yes<br>□ No<br>□ Unknown | |
| **3. Outcome** | | |
| Patient Outcome<br>*(check one)* | □ Still in surveillance unit<br>□ Transferred to other health facility<br>□ Transferred to other ward/unit within the hospital<br>□ Discharged<br>□ Died<br>□ Unknown | |

**Continue to next page to report organisms and antimicrobial susceptibility results**

| 4. Organisms and Antimicrobial Susceptibility | |
|---|---|
| Type of UTI | □ Microbiologically confirmed (UTI-A)<br>□ Non-microbiologically confirmed (UTI-B) |

**Enter collection dates and organisms from ALL positive urine cultures collected during the Event Timeframe in the table below.**

Attach a copy of the laboratory's AST report for each urine organism to the CRF. If this is not possible, enter AST results in the table using information from the laboratory.

(AST Result: S=susceptible, I=intermediate, R=resistant, S-DD=susceptible, dose-dependent)

| Urine Collection Date | Organism Name | Antimicrobial Name | AST Result |
|---|---|---|---|
| _____ | _____ | | |
| | | | |
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| | | | |
| | | | |
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## Sub appendix 2: Instructions for Completing UTI Case Report Form

| Data Field | Instructions for Data Collection |
|---|---|
| Case ID | The online reporting system will automatically create a Case ID for each infection when it is entered. Write the Case ID provided by the online reporting system in the space provided. |
| Hospital Name | |
| Sex | |
| Age | Record the age of the patient |
| Birth Weight | Required only for neonates housed in neonatal intensive care unit. |
| Date of Hospital Admission | Record the date of the hospital admission using this format: DD/MM/YYYY. |
| Location prior to hospital admission | Check one. Indicate the location the patient was in immediately prior to admission to the hospital. |
| Date of admission to Surveillance Unit | Record the date as DD/MM/YYYY. |

| | |
|---|---|
| Other Case IDs assigned to this patient since admission | Required only if Case ID previously assigned.<br><br>Check patient register for all case IDs this patient has been assigned since their date of current hospital admission. In the space provided, list all Case IDs that apply. If unknown, write "Unknown" |
| Date of event | Record the date as DD/MM/YYYY.<br><br>Enter the date when the first criteria used to meet the case definition occurred.<br><br>Note: If the first criteria to meet the case definition is a laboratory diagnostic test, the laboratory specimen collection date should be reported as the date of event. |
| Locations where patient was housed on the date of event | In the provided, list all the locations in the hospital where the patient was housed on the date of event in chronological order. If unknown, write "Unknown" |
| Locations where patient was housed on the day before the date of event | In the provided, list all the locations in the hospital where the patient was housed on the day before the date of event in chronological order. If unknown, write "Unknown" |
| Did the patient have a Foley catheter in place at any time on the date of event or day before the date of event? | Check one.<br><br>If "No," skip to Section 3, Outcome.<br><br>Note: A Foley catheter is an indwelling urinary catheter inserted into the urinary bladder through the urethra. Condom, nephrostomy, and suprapubic catheters are not included unless a Foley catheter is also present. |
| Was the urinary catheter in place for >2 calendar days? | Required if urinary catheter in place at any time on date of event or day before. Check one.<br><br>Note: If a Foley catheter is removed and reinserted on the same or following day, it is considered as one continuous usage. |
| Patient Outcome | Required. Check one.<br><br>Within the Event Timeframe (14 calendar days, date of event = Day 1) record when the patient is transferred, discharged, or dies. If at the end of the Event Timeframe (14 calendar days), the patient remains in the surveillance unit, mark "Still in surveillance unit." |
| UTI Type | Required. Check one. |

| | |
|---|---|
| Organisms and Antibiotic Susceptibility Testing Results | Report all organisms from positive urine cultures collected during the Event Timeframe (14 calendar days, date of event = Day 1) in this section.<br><br>For each positive urine culture:<br><br>Record date of urine culture collection as DD/MM/YYYY<br><br>Record the organism's name in the space provided. Specify the organism's species if known, otherwise report as spp.<br><br>Attach a copy of the organism's antibiotic susceptibility testing (AST) results from the laboratory, if possible.<br><br>If it is not possible to obtain a copy of the organism's AST results from the laboratory, then record the AST results for up to 10 drugs in the space provided. Use the following codes:<br><br>S = susceptible<br><br>I = intermediate<br><br>R = resistant<br><br>S-DD = susceptible, dose-dependent<br><br>Urine culture collection dates and organism names must be recorded on the case report form even if AST results are attached in a separate report from the laboratory. |

## Sub appendix 3: Denominator Data Collection Forms

### Denominators for UTI Surveillance

**Instructions for filling out this form:** This form should be completed at the same time every day for each participating ICU and wards. Count the total number of patients in the ICU and wards and record the number under "Number of Patients." Count the number of patients with an indwelling urinary catheter and record the number under "Number of patients with urinary catheter." All relevant counts should be performed at the same time by visiting each patient and checking for the presence of a urinary catheter before moving on to the next patient. This form should be used separately for UTI-A and UTI-B

*Table 17 - Denominator data collection form for UTI*

| Hospital Name: | Surveillance Unit Number: | Month: | Year: |
|---|---|---|---|
| **Date** | **Number of Patients** | Number of patients with **urinary catheter** | |
| **1** | | | |
| **2** | | | |
| **3** | | | |
| **4** | | | |
| **5** | | | |
| **6** | | | |
| **7** | | | |
| **8** | | | |
| **9** | | | |
| **10** | | | |
| **11** | | | |
| **12** | | | |
| **13** | | | |
| **14** | | | |
| **15** | | | |
| **16** | | | |
| **17** | | | |
| **18** | | | |
| **19** | | | |
| **20** | | | |
| **21** | | | |
| **22** | | | |
| **23** | | | |
| **24** | | | |
| **25** | | | |
| **26** | | | |
| **27** | | | |
| **28** | | | |
| **Totals** | | | |
| | Patient-days: | Urinary Catheter days: | |

## Denominators for Neonatal Intensive Care Unit (NICU)

**Instructions for filling out this form:** This form should be completed at the same time every day for each participating NICU. Count the total number of neonates in the NICU and record the number under "Pt" according to the neonate's birthweight. (Note: this is not the neonate's current weight). Count the number of neonates with a urinary catheter and record the number under "UC." All relevant counts should be performed at the same time by visiting each neonate and checking the birthweight and the presence of a urinary catheter before moving on to the next neonate.

| Hospital Name: | Surveillance Unit Number: | Month: | Year: |
|---|---|---|---|

| **Birth Weight Categories** | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Date** | **A = ≤750 g** | | **B = 751-1000 g** | | **C =1001-1500 g** | | **D = 1501-2500 g** | | **E= >2500 g** | |
| | Pt | UC | Pt | UC | Pt | UC | Pt | UC | Pt | UC |
| **1** | | | | | | | | | | |
| **2** | | | | | | | | | | |
| **3** | | | | | | | | | | |
| **4** | | | | | | | | | | |
| **5** | | | | | | | | | | |
| **6** | | | | | | | | | | |
| **7** | | | | | | | | | | |
| **8** | | | | | | | | | | |
| **9** | | | | | | | | | | |
| **10** | | | | | | | | | | |
| **11** | | | | | | | | | | |
| **12** | | | | | | | | | | |
| **13** | | | | | | | | | | |
| **14** | | | | | | | | | | |
| **15** | | | | | | | | | | |
| **16** | | | | | | | | | | |
| **17** | | | | | | | | | | |
| **18** | | | | | | | | | | |
| **19** | | | | | | | | | | |
| **20** | | | | | | | | | | |
| **21** | | | | | | | | | | |
| **22** | | | | | | | | | | |
| **23** | | | | | | | | | | |
| **24** | | | | | | | | | | |
| **25** | | | | | | | | | | |
| **26** | | | | | | | | | | |
| **27** | | | | | | | | | | |
| **28** | | | | | | | | | | |
| **Total** | | | | | | | | | | |

## Sub appendix 4: Case Finding Flowchart for UTI

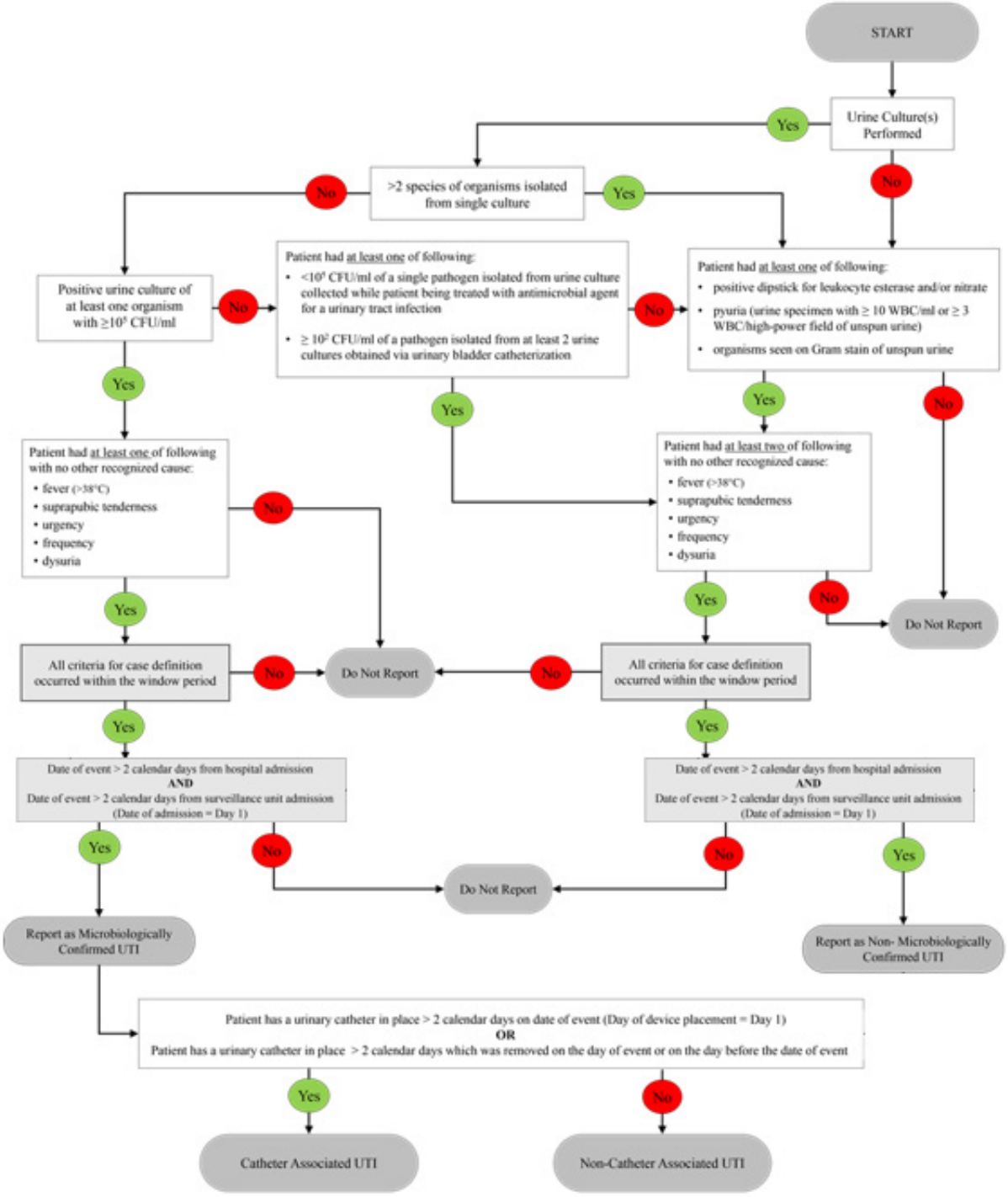


*Figure 7 - Case Finding Flowchart for UTI*

## 11.5. Appendix V - Point Prevalence Survey Protocol for Healthcare-Associated Infections (HAI) in Ethiopia

### 11.5.1. Background

The Ethiopian Ministry of Health (MoH) has developed Healthcare-associated infections (HAIs) surveillance guideline on establishing HAI systems in the country. One of the initial tasks in putting together facility HAI systems is organizing and conducting point prevalence surveys to determine the baseline infection rate of the pathogen under inquiry.

A point prevalence survey (PPS) is a count of the number of patients with a particular condition/ treatment (in this case a healthcare-associated infection at a particular time (in this case a day), as a proportion of the total number of patients who are hospitalized at that time.

A PPS only counts the condition/treatment 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.

PPS is a time and cost-effective method which estimates the burden of HAIs and related risk factors, especially in hospitals with limited resources. It serves as evidence for policymakers to act upon and plan effective ways to reduce HAIs in hospitals.

### 11.5.2. PPS Objectives

- To estimate the point prevalence of HAIs within the surveyed hospitals
- To characterize care infrastructure, patients, invasive procedures, and types of microorganisms responsible for HAIs
- To use the PPS results as an input for establishment of HAI surveillance system
- To provide standardized methodology and tools to estimate the prevalence HAIs

### 11.5.3. Point prevalence survey approach

This PPS approach is customized from the ECDC PPS document for HAIs and antimicrobial use guideline.

### 11.5.4. Hospital selection

Based on the guidelines on HAIs in Ethiopia, ten hospitals (Pilot Sites) have been selected and grouped into two groups when conducting PPS on HAIs. The first group includes five hospitals that have no functional microbiology laboratory to perform culture. The PPS in these hospitals will be focused on patient clinical data to detect the occurrence of HAIs.

The second group also includes five hospitals, and these hospitals have functional microbiology laboratory with supplies and personnel able to perform culture of all specimens and full bacterial identification and antimicrobial susceptibility testing. Both groups of hospitals included in the HAI PPS have an IPC team, capacity for data entry and transfer, and the second group of hospitals run ICUs, surgical, medical, Gyn/Obs wards.

### 11.5.5. Ward selection

**Included**: The hospital wards to be included in the PPS are ICUs, surgical, medical, and maternity, will be used for the HAIs PPS

**Excluded**: are accident and emergency departments (except for wards attached to departments where patients are monitored for more than 24 hours).

### 11.5.6. Patient selection

**Included**: All patients admitted to the selected ward before or at 8 a.m. and not discharged from the ward at the survey time will be included into PPS. This means that patients transferred in/out after 8 a.m. from/to another ward should not be included. The neonates on maternity and pediatric wards if born before/at 8 a.m. will be included. The patients' inclusion and exclusion criteria into the PPS are indicated in the figure below (taken from ECDC PPS for HAIs and antimicrobial uses protocol)

**Excluded:**

- Patients undergoing same day treatment or surgery;
- Patients seen at outpatient department;
- Patients in the emergency room;
- Dialysis patients (outpatients).

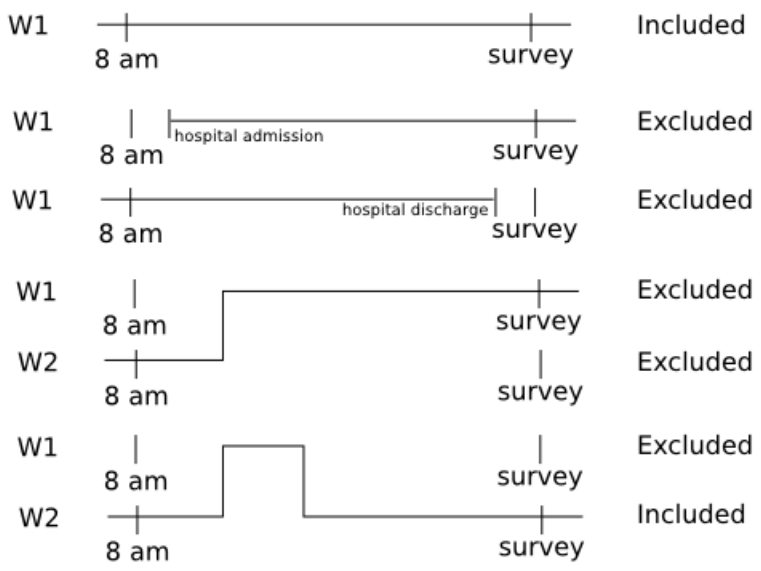


*Figure 8 - Types of cases to be included and excluded in PPS survey*

### 11.5.7. HAIs categories

An HAI is an infection developed during hospitalization. Major and specific HAI site definitions are adapted from the Centers for Disease Control and Prevention's (CDC's) 2008, and National Healthcare Safety Network (NHSN) case definitions. The ECDC groups HAIS into 13 broad categories based on the main physiological systems and surgical interventions. These are:

- Bloodstream infection
- Bone and joint infections
- Cardiovascular system infections
- Central nervous system infections

- Clinical sepsis
- Eye, ear, nose, throat, and mouth infections
- Gastrointestinal infection
- Lower respiratory tract infections other than pneumonia
- Pneumonia
- Reproductive system infections
- Skin and soft tissue infections
- Surgical site infections
- Urinary tract infections

**E. Definition of drug resistant organisms (for the second groups of hospitals)**

- Definition of organisms multidrug resistant (MDR), extensive drug resistant (XDR) and pan drug resistant (PDR) will be defined according to guidelines compiled by the European Center for Disease prevention and Control (ECDC) and the Center for Disease Control and Prevention (CDC).

### 11.5.8. Sample design

All eligible patients within the selected wards will be included on the day of data collection.

### 11.5.9. Data collection and processing

#### 11.5.9.1. Data collection

**When -** Data will be collected in a single day for each ward/unit. The total time frame for data collection for all wards of a single hospital should not exceed two to three weeks.

**Who will collect the data -** The data for PPS will be collected by the hospital infection prevention and control team as well as the ward team in charge of the patient care are involved.

**Training of surveyors – T**raining needs to be provided for the surveyors of the participating hospitals by National HAI surveillance coordinators prior to the point prevalence survey.

#### 11.5.9.2. Data processing

The collected data be entered and analyzed in a computer system, using data entry and analysis tool (e.g. excel,), by the hospital staff after data verification. Data should be exported by the hospitals and transferred to the surveillance coordinator in the IPC team at the MOH. The surveillance coordinator at MOH will compile and analysis the data received from hospitals. The PPS findings will be disseminated in technical report form or through workshops

### 11.5.10. Data collection tools

The PPS data collection tools are customized from ECDC Point prevalence survey of healthcare-

associated infections and antimicrobial use document. The tools are used to for hospital, wards and patients data collection.

### 11.5.10.1. Preparation phase

During the preparation phase, the training material will be developed, and training will be given for the surveyors in advance and prior to one day prior to PPS. The surveillance team will provide data collection tools for the surveyors. General information regarding the hospitals and wards will be collected days before PPS.

### 11.5.10.2. Case finding algorithm for HAIs on PPS day

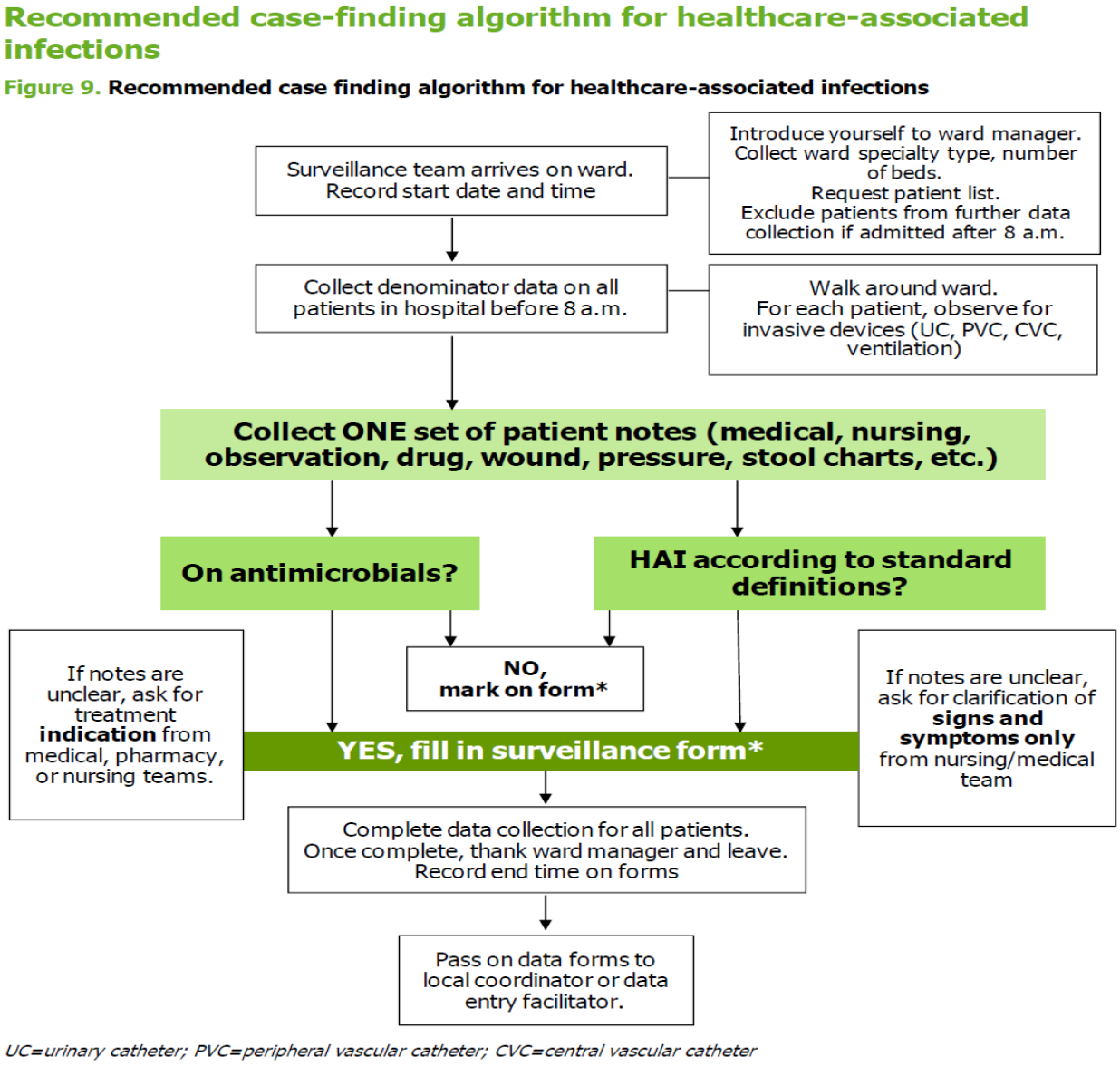


*Figure 9 - Case finding algorithm for HAIs on PPS day*

**Source:** Adopted from European Centre for Disease Prevention and Control. Point prevalence survey of healthcare associated infections and antimicrobial use in European acute care hospitals – protocol version 6.1 Stockholm: CDC; 2022.

## 11.5.11. Sub appendices

### Sub appendix A. Hospital data collection forms

*Table 18 – Hospital data collection form for PPS*

| | | | |
|---|---|---|---|
| Hospital information | | | |
| Hospital name | | | |
| Survey date ( dd/mm/yyyy) | | | |
| Hospital size (total number of bed) | | | |
| Number of ICU beds | | | |
| Number of Inpatient beds | | | |
| Excluded wards from PPS | | | |
| Region /City | | | |
| Total Number of Beds in included wards | | | |
| Number of patients included in PPs : | | | |
| Hospital types | Primary | | |
| | General | | |
| | Specialized | | |
| Number of discharges/admissions per year | | | |
| Number of patient days in year | | | |
| Alcohol hand rub consumption letter per year | | | |
| Number observed hand hygiene opportunities per year | | | |
| Number of blood culture set per year | | | |
| Is there an isolation room for transmission-based precautions (e.g., Airborne...) | Yes | | |
| | No | | |
| **Infection prevention and control(IPC) program** | | | |
| Is there an annual IPC plan approved by hospital CEO or a senior executive officer? | | Yes | |
| | No | | |
| Is there an annual IPC report approved by hospital CEO or a senior executive officer? | | Yes | |
| | No | | |
| Ward indicator data collected at **hospital level** | | Number | Total |
| Number of beds with AHR dispensers at point of care | | | |
| Number of beds assessed for presence of AHR dispensers | | | |
| Number of patient rooms in hospital | | | |
| Number of single patient rooms in hospital | | | |
| Number of beds occupied at 00:01 on the day of PPS | | | |
| Number of beds assessed for occupancy at 00:01 on the day of PPS | | | |

## Sub appendix B. Hospital data collection forms (Multimodal strategies)

Hospital Name_____

Survey dates: From ____ /_____ /_____ to ____ /_____ /_____

*(dd/mm/yyyy)*: *(dd/mm/yyyy)*:

**Point prevalence survey of HAI**

Optional: IPC FLAT Eth

□ Yes □ No

*Table 19 - Multimodal strategies for implementation of IPC interventions (patients' data (IPC FLAT core component 5)*

| No. | Multimodal strategies for implementation of IPC interventions | Yes | No |
|---|---|---|---|
| 1. | Do you use multimodal strategies for implementation of IPC interventions? | | |
| 2. | Do your multimodal strategies include any or all of the following elements: | | |
| 2.1 | **System change:** | | |
| | Element not included in multimodal strategies=N | | |
| | Interventions to ensure the necessary infrastructure and continues availability of supplies are in place=L1 | | |
| | Interventions to ensure the necessary infrastructure and continues availability of supplies are in place to addressing ergonomics and accessibility (e.g.: best placement of central venous catheter set and tray)=L2 | | |
| 2.2 | **Education and training:** | | |
| | Element not included in multimodal strategies=N | | |
| | Written information and/or oral instruction and/or E-learning only= L1 | | |
| | Additional interactive training sessions (includes simulation and/or bedside training)=L2 | | |
| 2.3 | **Monitoring and feedback:** | | |
| | Element not included in multimodal strategies=N | | |
| | Monitoring compliance with process or outcome indicators (e.g. audits of hand hygiene or catheter practice) =L1 | | |
| | Monitoring compliance and providing timely feedback of monitoring results to healthcare workers and key players=L2 | | |
| 2.4 | **Communication and reminders:** | | |
| | Element not included in multimodal strategies=N | | |
| | Reminders, posters, or other advocacy awareness–raising tools to promote the intervention=L1 | | |

| | | | |
|---|---|---|---|
| | Additional methods/initiatives to improve team communication across units and disciplines (e.g. by establishing regular case conference and feedback rounds) =L2 | | |
| 2.5 | **Safety climate and culture change:** | | |
| | Element not included in multimodal strategies=N | | |
| | Managers /leaders show visible support and act as champion and role models, promoting and adaptive approach and strengthening a culture that support IPC, patient safety and quality=L1 | | |
| | Additional teams and individuals are empowered so that they perceive ownership of intervention (e.g. by participatory feedback rounds) =L2 | | |
| 3. | Is multidisciplinary tea used to implement IPC multimodal strategies? | | |
| 4. | Do you regularly link to colleagues from quality improvement and patient safety to develop and promote IPC multimodal strategies? | | |
| 5. | Do these strategies include bundles or checklists? | | |

Comments / obsevations _____
_____

**Definition of hospital data**

**Hospital size:** Total number of beds in the hospital. Include all beds that may generate (in) patient-days and admissions/discharges. Exclude beds which are exclusively used for day cases (e.g., day-care wards).

**Number of acute care beds.** Number of acute care beds in the hospital (in accordance with to national definition)

**Specify excluded wards.** Specify which wards were excluded; free text; please use specialty codes if possible.

**Total number of beds in included wards:** Sum of the number of beds in wards that were included in the PPS.

**Total number of patients included in PPS:** Sum of the number of patients included in the PPS; variable used to double-check the exhaustiveness of reported data, i.e. the sum of a ward's total number of patients in the light protocol option, or the total number of individual patients in the standard protocol option.

**Hospital type:** Hospital type – PRIM: primary, SEC: secondary, TERT: tertiary, SPEC: specialized (definitions see below), missing=UNK; include specialization if applicable; report the hospital type of the hospital site (single hospital) or of the administrative hospital group/ trust, depending on the level for which hospital indicators, patient, antimicrobial use and HAI data are reported.

**1 Primary:**

**2 General:**

**3 Specialty:**

**Sub appendix C. Ward data form**

*Table 20 - Ward data form*

Hospital name_____

| Ward specialty | Number of patients in ward |
|---|---|
| Medical | |
| Surgical | |
| ICU | |
| Maternity | |
| | |
| | |
| | |
| | |
| | |
| | |

| | Number | Year |
|---|---|---|
| Number of patient-days in ward/year | | |
| Alcohol hand rub (AHR) consumption in ward liters/ year | | |
| N of hand hygiene opportunities observed/year | | |
| Number of beds in ward | | |
| N of beds with AHR dispensers at point of care | | |
| Number of HCWs on ward at time of PPS | | |
| Number of HCWs on ward carrying AHR dispensers | | |
| Number of rooms in ward | | |
| Number of single rooms in ward | | |
| Number of beds occupied at 00.01 (PPS starting time) on the day of PPS | | |

This form will be filled separately for each ward separately

**Definition of ward data**

**Survey date.** Date on which the data were collected in the ward. Data from a single ward should be collected on one day; date dd/mm/yyyy.

**Ward specialty.** Main ward specialty (≥ 80% of patients requiring this specialty), If fewer than 80%, report 'mixed ward' (MIX), ICU=Intensive Care, MED=Medical SUR=Surgical, OTH=Other, MIX=Mixed.

**Number of patients in ward by specialty:** Number of patients admitted to the ward before or at 8 a.m. and not discharged from the ward at the time of the survey, recorded separately for each specialty.

**Post-prescription review of antimicrobials in ward:** Is there a formal procedure to review the appropriateness of an antimicrobial within 72 hours from the initial order in this ward (post-prescription review)? A formal post-prescription review procedure should be documented and adopted by the hospital management and should be performed by a person or team other than the treating physician. The procedure should at least address the prescription of broad-spectrum or reserve antimicrobials. Yes/no

**Number of patient days in ward:** Number of patient days in one year for current ward (data from previous year if available, specify year in second column).

**Alcohol hands rub: consumption in wards (liters/year)**. Number of liters of alcohol hand rub delivered to the ward in one year. Provide data for the same year as the number of patient-days in the ward.

**Number of hand hygiene opportunities observed in ward/year**. Number of hand hygiene opportunities observed in the current ward in one year. Provide data for previous year or the most recent data available (specify year in second column). A hand hygiene opportunity is a moment during healthcare activities when hand hygiene is necessary to interrupt germ transmission by hands [14]. Report the total number of observed opportunities for hand hygiene (=the denominator of hand hygiene compliance), not only the compliant observations.

**Number of beds in ward with AHR dispensers at the point of care:** Number of beds in the ward with alcohol hand rub (AHR) dispensers available at the point of care as recommended by the 2009 WHO Guidelines on Hand Hygiene in Health Care. AHR dispensers at the entrance of the patient room only are not considered as 'available at the point of care'. The 'point of care' is the place where three elements come together: the patient, the HCW, and care or treatment involving contact with the patient or his/her surroundings (within the patient zone).

**Number of HCWs on ward at time of PPS**: Number of healthcare workers (HCWs) on ward at the time of PPS. The purpose of this variable is to measure the denominator of those carrying AHR dispensers. Therefore, HCWs should not be included if there is no information on the carriage of alcohol hand rub dispensers.

**Number of HCWs on ward carrying AHR dispensers**: Number of HCWs on ward carrying AHR dispensers (e.g., in their pockets).

**Number of rooms in ward**: Total number of rooms in the ward on the PPS day.

**Number of single rooms in ward**: Total number of single-bed rooms in the ward on the PPS day. Rooms with more than one bed that are designated for use as single occupancy and isolation rooms (e.g., for infection control purposes) should be included.

**Number of beds occupied at 00:01 on the day of PPS**: Number of ward beds occupied at midnight on the day of the PPS (can also be measured at midnight after the PPS took place).

**Comments/observations**: Free text field to report, for example, feasibility issues, data quality problems, or specific epidemiological information for the current ward.

## Sub appendix D. Patient data

*Table 21 – Patient data*

| | | |
|---|---|---|
| Hospital Name | | |
| Ward name | | |
| Survey date ( dd/mm/yyyy) | | |
| Medical record number | | |
| Age in year | | |
| Age if <2 years old/ Month | | |
| Sex | | |
| Date of hospital admission | | |
| Consultant or patient specificity | | |
| If neonatal birth weight in gram | | |
| Surgery since admission | No surgery | |
| | Type of surgery | |
| Central vascular catheter | Yes | |
| | No | |
| | Unknown | |
| Central vascular catheter | Yes | |
| | No | |
| | Unknown | |
| Intubation | Yes | |
| | No | |
| | Unknown | |
| Patient receives antimicrobial | Yes | |
| | No | |
| Patient has active HAI | Yes | |
| | No | |

| Antimicrobial (generic or brand name) | Route | Indications | Diagnosis (site) | Reason in notes | Changed (Reason +notes) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| | HAI1 | | | | HAI2 | | | |
|---|---|---|---|---|---|---|---|---|
| Case definition | | | | | | | | |
| Relevant device | Yes | | | | Yes | | | |
| | No | | | | No | | | |
| | Unknown | | | | Unknown | | | |
| Present on admission | Yes | | | | Yes | | | |
| | No | | | | No | | | |
| Date of onset | | | | | | | | |
| Origin of infection | Current hospital | | | | Current hospital | | | |
| | Other hospital | | | | Other hospital | | | |
| | Unknown | | | | Unknown | | | |
| HAI associated to current ward | Yes | | | | Yes | | | |
| | No | | | | No | | | |
| | Unknown | | | | Unknown | | | |
| If BSI: source | | | | | | | | |
| **Microorganisms** | MO code | AMR | | PDR | MO code | AMR | | PDR |
| | | Tested antibiotics | SIR | | | Tested antibiotics | SIR | |
| Microorganisms 1 | | | | | | | | |
| Microorganisms 1 | | | | | | | | |
| Microorganisms 1 | | | | | | | | |
| | | | | | | | | |

**Definition of patient data**

**Hospital code:** Hospital identifier/code assigned by national/regional PPS coordinating centre; unique code per surveillance/PPS network.

**Ward name**: Abbreviated name of hospital ward: essential for linking between denominator and HAI/AU data; should be used consistently on all forms and should remain the same in different PPS periods/years.

**Ward specialty**: Main ward specialty (≥ 80% of patients requiring this specialty). If fewer than 80%, choose mixed ward (MIX). See more details under ward data and specialty code list. This variable can be omitted from the patient data if ward data are provided. If ward data are not provided, it should be added on the patient form.

**Survey date**: Date on which data were collected in this ward. Data from a single ward should be collected on one day (dd/mm/yyyy). This variable can be omitted from the patient data if ward data are provided. If ward data are not provided, it should be added on the patient of Medical record number. Any missed patient number makes it possible to establish a link between patient data and HAI or antimicrobial use data. Not the actual patient identifier.

**Age in years**: Patient age in years.

**Age in months**: Patient age in months if the patient is younger than two years old. Sex. Gender of the patient: M (male), F (female), or UNK (unknown).

**Date of hospital admission**: Date on which the patient was admitted to the hospital for the current hospitalization (dd/mm/yyyy).

### 11.5.12. References


1. ECDC TECHNICAL DOCUMENT Point prevalence survey of healthcare associated infections and antimicrobial use in European acute care hospitals Protocol version 6.1, ECDC PPS 2022-2023

2. Magiorakos AP, Srinivasan A, Carey RB, Carmeli Y, Falagas ME, Giske CG, Harbarth S, Hindler JF, Kahlmeter G, Olsson-Liljequist B, Paterson DL, Rice LB, Stelling J, Struelens MJ, Vatopoulos A, Weber JT, Monnet DL. Multidrug-resistant, extensively drug-resistant and pandrug-resistant bacteria: an international expert proposal for interim standard definitions for acquired resistance. Clin Microbiol Infect. 2012 Mar;18(3):268-81. doi: 10.1111/j.1469-0691.2011.03570.x. Epub 2011 Jul 27. PMID: 21793988

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