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هيئة الصحة العامة
PUBLIC HEALTH AUTHORITY

# HAI Surveillance & Outbreak External Validation Manual

Version 2.0
May - 2025

@Saudi_PHA

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# Table of Contents

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# Abbreviations, Terms, and Acronyms

| | |
|---|---|
| **ABUTI** | Asymptomatic Bacteremic Urinary Tract Infection. |
| **BSI** | Bloodstream infection |
| **CAUTI** | Catheter Associated Urinary Tract Infection |
| **CLABSI** | Central line-associated bloodstream infection. A laboratory confirmed bloodstream infection where an eligible BSI organism is identified, and an eligible central line is present on the LCBI DOE or the day before. |
| **DOE** | Date of Event: The first element used to meet an NHSN site-specific infection criterion occurs for the first time within the seven-day infection window period. |
| **External Validation** | Survey and record review process performed by an external agency to assure quality of NHSN surveillance and reporting |
| **EVTs** | External Validation Tools for specific HAI (CLABSI, CAUTI, VAE, SSI, MDRO, DE) |
| **HAI** | Healthcare-associated infection. An infection is considered an HAI if the DOE occurs on or after the 3rd calendar day of admission to the facility (the day of admission to an inpatient location is calendar day 1). All elements used to meet site specific infection criteria must occur during the Infection Window Period. |
| **LabID Event** | A measure developed for easy electronic infection surveillance using laboratory results without the requirement for extensive clinical documentation. |
| **MRN** | Medical record number. |
| **Patient Days** | The number of patients (inpatients and observation patients) housed in a facility inpatient location during the designated counting time each day and summed for a monthly denominator report for device-associated infections (CLABSI, CAUTI, VAE) and LabID Events. |
| **SUTI** | Symptomatic UTI |
| **SSI** | Surgical site infection. |
| **Sampling Frame** | Derived from positive laboratory line listings (blood culture, urine culture, and MDRO positive specimen) or line listing of chosen surgical procedures already entered and available in official platforms during the validation timeframe from which medical records are selected for validation. |
| **VAE** | (NHSN) Ventilator-associated event. An objective surveillance algorithm that can identify a broad range of conditions and complications (including but not limited to pneumonia) occurring in mechanically ventilated adult patients |
| **Validation** | Assurance that reported HAI surveillance & outbreak data meet pre-determined specifications and quality standards. |
| **Validator** | Member of Public Health Authority branches HAI Surveillance & Outbreak Program that reviews a facility's HAI surveillance & Outbreak determinations and methods to evaluate surveillance program quality, data completeness, and reporting. |

# Introduction

Data validation is a process of verifying & checking the accuracy and quality of source data. extremely important to ensure high-quality HAI surveillance data through accountability and by identifying, understanding, and correcting problems related to accurate identification & reporting. Developing a standard approach to HAI data validation is important to ensure accuracy & completeness of national HAI surveillance data reported via electronic platforms. Validation supports accuracy of case findings methods.

This document provides guidance for six healthcare-associated infection (HAI) metrics: Central Line-Associated Blood Stream Infection (CLABSI), Ventilator Associated Events (VAE), Catheter-Associated Urinary Tract Infection (CAUTI), selected Surgical Site Infections (SSIs), Selected MDRO Lab ID Events & Dialysis Events (DE). In addition, it also provides framework for validation of data to ensure if there were any undetected and unreported outbreaks. Timely reported surveillance data helps in early detection of outbreak & further interventions in order to prevent further transmission.

## Purpose & Goals of Data Validation:

**WHAT:** Validation can be defined as confirming or ensuring that data meet pre-determined specifications and quality standards.

**WHY:** To ensure completeness, accuracy & timeliness of HAI Surveillance & Outbreak data in order to generate reliable, actionable nationwide electronic data that motivates infection prevention & control efforts, set infection prevention program priorities and measure the impact of prevention efforts.

**WHO:** External Validation by Public Health Authority (PHA) branches HAI Surveillance & Outbreak Program Coordinators.

**HOW:** Using External Data Validation Tools

**WHEN:** Every Quarter by adopting structured methodology for selection of hospitals.

## External validation:

A survey and review process conducted by external teams related to PHA branches. One or more trained validators review the hospitals surveillance & outbreak determinations and methods to evaluate HAI program quality e.g.

- Knowledge and Practices
- Data completeness and reporting accuracy
- Identifying and correcting shortcoming

# Goals of External Validation

## 1: Evaluate hospital HAI surveillance & Outbreak Process & practices:

- *Assess if IC staff are well trained about HAI Surveillance & Outbreak protocols.*
- *Assess if assigned staff are familiarized with data collection and reporting methods.*
- *Identify common barriers to complete and accurate data collection and reporting.*

## 2: Educate hospital IC staff on HAI Surveillance & Outbreak Protocols:

- *Educate staff about the HAI surveillance methods & Event/s criteria*
- *Educate staff about the outbreak detection, reporting & management protocols.*
- *Improve staff data collection and reporting practices.*
- *Increase staff awareness of reporting data via electronic platforms.*

## 3: Assess and improve the quality of HAI Surveillance data reported via electronic Platforms:

- *Identify under- and over-reported events.*
- *Check the relevant forms in electronic platform to ensure completeness and accuracy.*
- *Identify recurrent errors & provide feedback on how to improve data collection and reporting practices.*

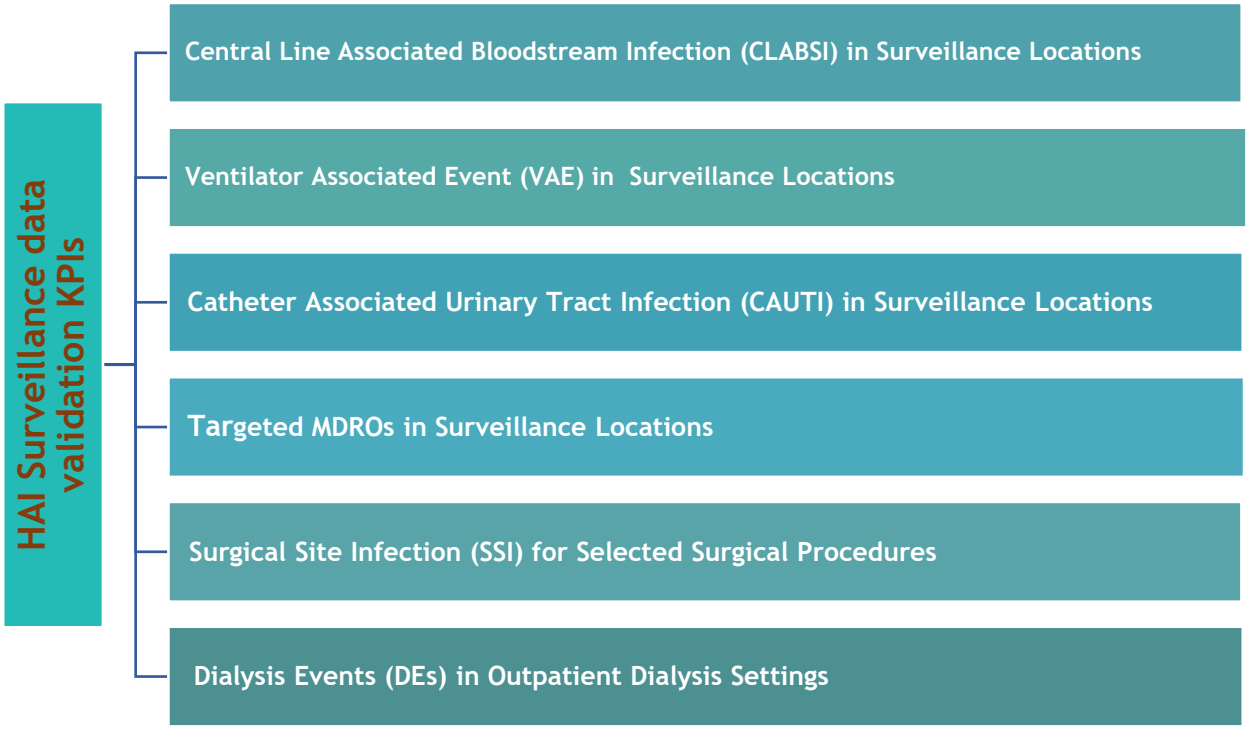
## 4: Seek end user feedback to support continuous improvement:

- *Improve the external validation tools and the corresponding documents.*
- *Develop an optimal and standardized data evaluation methods.*
- *Improve existing HAI event surveillance and reporting resources & technical errors related to electronic data reporting.*

*Comments and Feedback Welcome: PHA HAI Surveillance & Outbreak validation approaches are a work-in-progress and will improve more quickly with generous input and feedback from those implementing the methods.*
*Please direct any comments or suggestions for improvement to the GDIPC@moh.gov.sa with the subject line "HAI Surveillance & Outbreak External Validation Manual."*

## B: External Validation Domains

**Public Health Authority** external validation includes **six metrics** for HAI Surveillance data validation:



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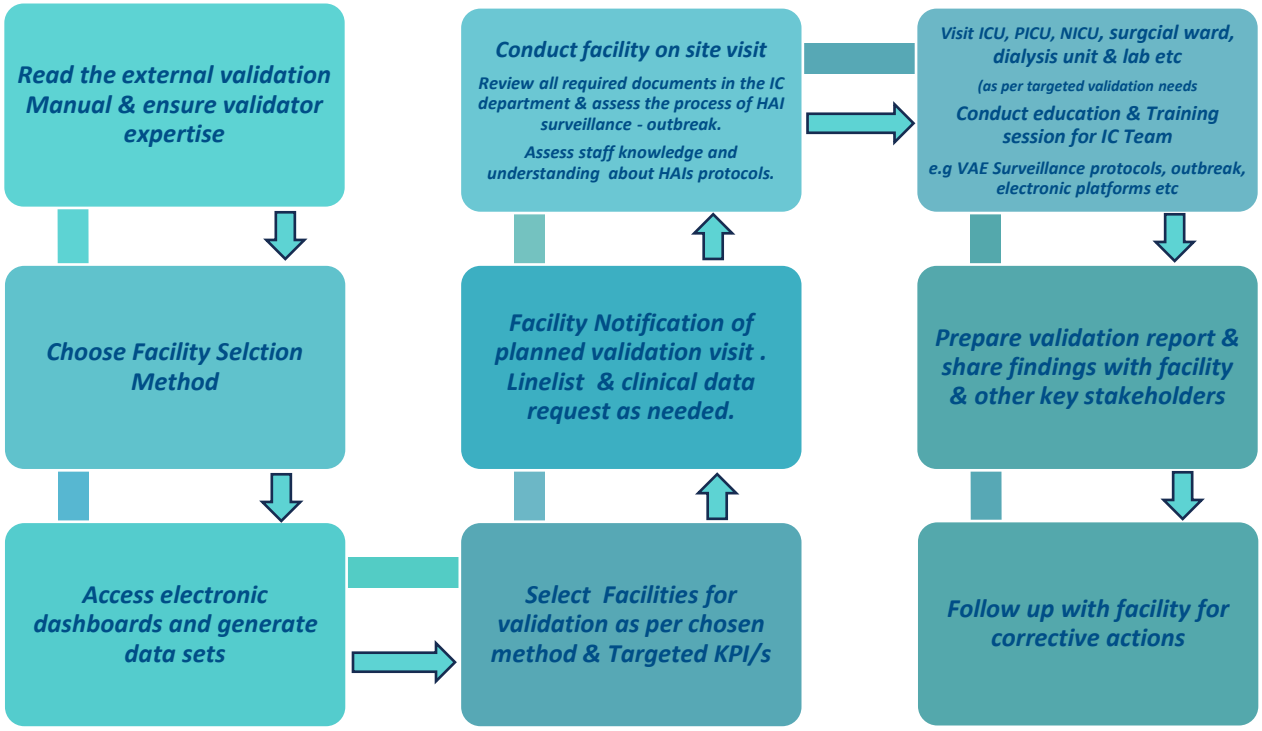
# External Validation Process Flowchart



# Trigger for External Validation

- Continuous review of HAI surveillance data reported via electronic platforms & notice HAI reporting patterns *(High HAI rate - Zero HAI rate etc.)*
- Review data in weekly meetings & decide for hospitals to be selected for validation as per steps mentioned later.

| TRIGGER - I | TRIGGER - II |
|---|---|
| **High HAI Rate** reported for 2 consecutive months | **ZERO HAIs** reported for 2 consecutive months in comparison with high device utilization, large ICU bed size, high volume of Surgical procedures etc. |
| ↓ | ↓ |
| CLABSI And/or CAUTI And/or VAE MDROs And/or SSIs And/or DEs | CLABSI And/or CAUTI And/or VAE MDROs And/or SSIs And/or DEs |
| ↓ | ↓ |
| Choose Hospitals using Method I for hospital Selection | Choose Hospitals using Method II for hospital Selection |
| ↓ | ↓ |
| Conduct virtual meetings with hospitals and assess need for onsite visit | Follow protocols for onsite validation Visit |
| ↓ | ↓ |
| Conduct on site visit using HAI Specific External Validation Tool as needed | Conduct on site visit using HAI Specific External Validation Tool |

***NOTE: Once hospitals are selected based on trigger 1 and/or trigger 2, validate all domains during onsite visit.***

| | External Validation Process Stepwise Approach |
|---|---|
| **A: Pre - visit Preparation:** | |
| ☐ | Read the HAI Surveillance & Outbreak External Validation Manual in its entirety. |
| ☐ | Read PHA HAI Surveillance & Outbreak Manuals & HAI-specific External Validation Tools **(EVTs)** in its entirety. |
| ☐ | Ensure validators are trained in HAI Events Surveillance & Outbreak Management Protocols. |
| ☐ | Review data in official electronic platforms on daily basis and assess the HAI reporting patterns. |
| ☐ | Determine the targeted HAI(s) your branch will validate.(CLABSI,VAE, CAUTI, SSI, MDROs, DEs) |
| ☐ | Determine the method of facility selection and number of facilities that will be included in the validation. |
| ☐ | Determine the periodic validation timeframe. |
| ☐ | Generate datasets from official electronic Platforms. |
| ☐ | Using exported data spreadsheet, make final hospital selection as per chosen method. |
| ☐ | Review & keep record of electronic data for comparison with manual data during visit *(# of HAIs, Patient days, device days etc.)* |
| ☐ | Determine when the site visits will occur. |
| **B: Obtain Facility Participation:** | |
| ☐ | Contact Facility Infection Preventionist requesting site visit and line listing(s) (use *template Letter)* |
| ☐ | Request pre - selected clinical records derived from line list to be available on the day of the site visit. |
| ☐ | Send notification about the planned date & time of validation visit. |
| ☐ | Confirm a day before visit about availability of IC team and requested documents on day of visit. |
| ☐ | Ensure all required items & tools are prepared.*(Laptop, internet access, specific validation tools & training materials etc.)* |
| **C: Conduct on Site Visit:** | |
| ☐ | Introduce yourself & explain purpose of visit in detail. |
| ☐ | Request documentation/training evidence of Infection Control Practitioners (ICPs) training. |
| ☐ | Conduct staff interview using **EVTs** & assess knowledge about surveillance process & methodology. |
| ☐ | Review of facility location mapping, bed size. |
| ☐ | Review data collection tools for numerator & denominator data. |
| ☐ | Compare Manual data with electronic data and calculate 5% tolerance interval. |
| ☐ | Review pre-selected clinical records derived from line list and identify any undetected/missed events. |
| ☐ | Conduct validation rounds to *Adult ICU, PICU, NICU, Surgical ward,* Dialysis unit & Lab as needed. |
| ☐ | Discussion of validation results / provide informal feedback to IC team. |
| ☐ | Conduct Training & Education Session according to selected KPI/s *e.g. CLABSI Protocols, VAE Protocols etc.* |
| **D: Post Visit:** | |
| ☐ | Create Facility Validation report using excel template. |
| ☐ | Share Validation report with facility & key stakeholders. |
| ☐ | Follow up with facility for corrective interventions. |

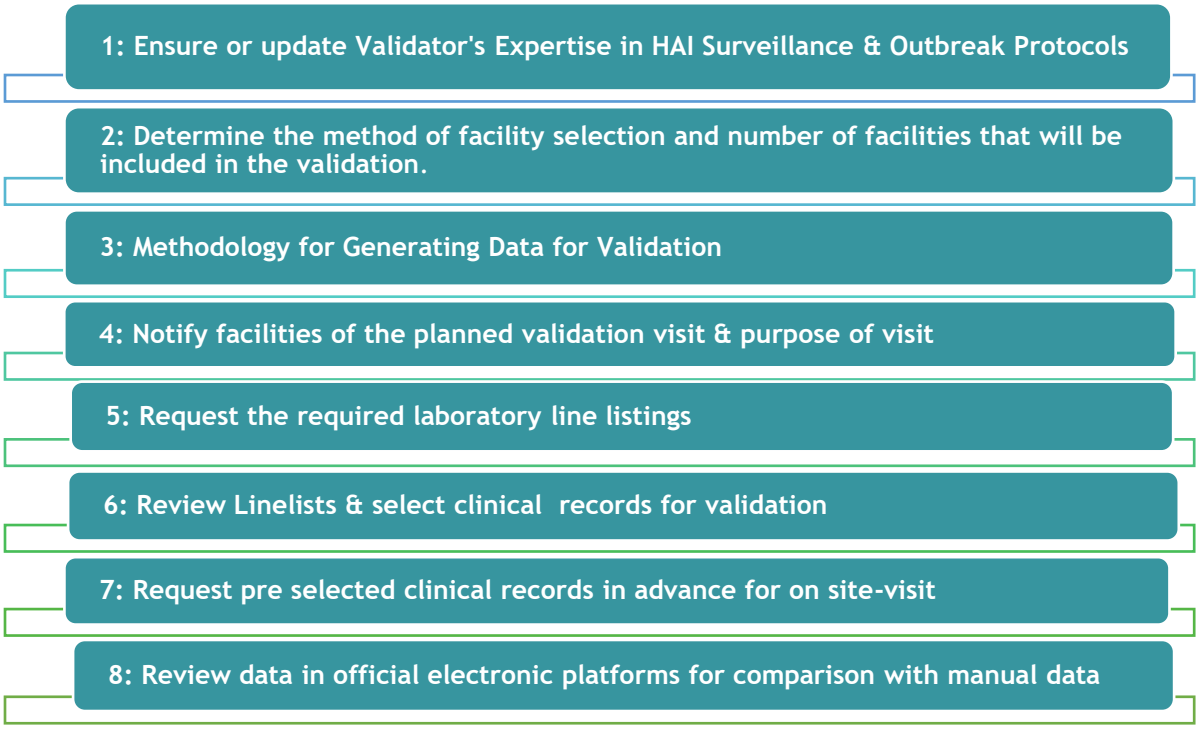
# CHAPTER I

## HAI Surveillance Data Validation Process

*Stepwise Approach*

## A: PRE – VISIT ACTIVITIES

*(To be carried out by PHA branches surveillance team before on site visit)*




## 1) Ensure or Update Validator Expertise in HAI Surveillance & outbreak management Protocols:

- External PHA branches HAI Surveillance program coordinators/validators must ensure expertise in surveillance & outbreak management protocols and acquire validation skills.
- Ensure each coordinator has attended sufficient training courses using online & onsite platforms.
- Validation process must be well understood and implemented in order to ensure standardization in HAI Surveillance & outbreak validation methodology.

# 2) Methodology of Hospitals Selection for validation:

## Method 1: Prioritizing Facilities with Highest Likelihood of Event Occurrence & reported HAI Events

**Targeted selection:**

- This method prioritizes facility selection based on highest likelihood of event occurrence. It is more likely to select facilities with higher patient volume, and thus a higher HAI rate/higher expected number of events.
- Targeted selection of hospitals performing high volume, high risk surgical procedures with highest likelihood of SSI event occurrence are to be validated.
- Refer to table # 1 for number of facilities to be selected.

## Method 2: Prioritizing Facilities with Highest Likelihood of Event Occurrence but with few or ZERO reported events

- This method prioritizes facility selection who have reported zero or very few events and have a high expected number of events.
- Facilities who have high patient volume, ICU bed capacity, high device utilization ratio etc but reported zero or few HAI events.
- HAI data validation efforts have demonstrated that underreporting of HAI events continues to be a concern.
- Refer to table # 1 for number of facilities to be selected.

## Method 3: Stratified Random Sampling :

- ***Applicable to Healthcare Facilities with bed size 200 or less, with small ICU size and low device Utilization ratio)***

**(Total Sample size =15)**

a) **Fewer than 15 facilities: Validate them all**
b) **More than 15 facilities: Divide in Strata 1 & Strata 2 as mentioned below**

Divide the total facilities in the sampling frame into two strata:

a. ***Stratum 1: Includes all facilities in the sampling frame that have a bed size of 1-100***
b. ***Stratum 2: Includes all facilities in the sampling frame that have a bed size of 101-200.***

**Stratum 1: (Bed size 1-100) - *(Choose 5 hospitals)***

***a**. If there are 5 or fewer facilities within Stratum 1, select all facilities within Stratum 1 and proceed to Stratum 2.*
*b. If there are more than 5 facilities within Stratum 1, use the following formula of random selection to get sample size of 5.*

**Example**:

- If the total number of healthcare facilities (HCF) with bed size 1-100 in PHA branch are = 40
- Divide Total HCF/5 = n (40/5 = **8th** )
- Choose every 8th Facility to make complete set of **05 healthcare facilities (HCF)**

### Stratum 2: Bed size (101-200) - *(Choose 10 hospitals)*

a. *If there are 10 or fewer facilities within Stratum 2, select all facilities within Stratum 2.*
b. *If there are more than 10 facilities within Stratum , use the following formula of random selection to get sample size of 10.*

**Example:**

- If the total number of healthcare facilities (HCF) with bed size 101-200 in PHA branch are = 60
- Divide Total HCF/10 = n (60/10 = **6th** )
- Choose every 6th Facility to make complete set of **10 healthcare facilities (HCF)**

**Total Sampling Frame = 15 *(5 facilities from Stratum 1 & 10 facilities from stratum 2)***

### NOTE:

- *PHA Branches coordinators may also choose hospitals based on previous experience in data analysis & reporting patterns in order to prioritize which HAIs to validate.*
- *Some hospitals with small ICU bed size may have high volume of chosen surgical procedures e.g. C-section that may also be included in SSI validation as priority.*
- *Alternatively, branches can focus validation on HAIs with unexpectedly high rates to assist facilities with prevention.*

## Table 1: External Validation Facility Selection Methods Comparison

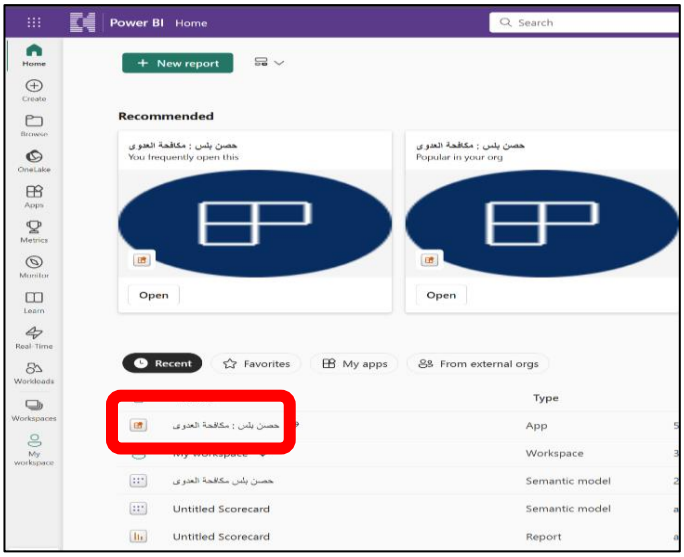
| Items | Method I<br>Prioritizing Facilities with Highest Likelihood of Event Occurrence | Method II<br>Prioritizing Facilities with Highest Likelihood of Event Occurrence but with few or None reported events | Method III<br>Stratified Random Sample |
|---|---|---|---|
| Target criteria | This method prioritizes facility selection based on highest likelihood of event occurrence. It is more likely to select facilities with higher patient volume, and thus a higher predicted/expected number of events. | These facilities reported zero or very few events and have a high predicted number of events. | Applicable to Healthcare Facilities with bed size 200 or less with small ICU size and low device Utilization ratio) |
| What type of facilities are selected? | Focuses on larger healthcare facilities with high exposure volume, and thus high predicted/expected events. | Focuses on potential under reporters: facilities that reported very few events yet have a high predicted number of events. | Focuses on reviewing a **representative sample** in each PHA branch with hospital size 200 **& less beds** |
| Ranking algorithm | Facilities are arranged in descending order according to high HAI rate reported in specific time frame chosen for validation | Facilities with high bed capacity & risk of HAI exposure but reported ZERO or few HAIs. | a. Facilities are stratified by bed size.<br>– *Bed size of 1-100*<br>– *Bed size of 101-200* |
| Number of facilities | a) **20 or fewer facilities:** validate them all<br>b) **21 to 149 facilities:** at least 18 targeted facilities plus a 5% random sample of remaining facilities<br>c) **150 or more facilities:** select at least 21 targeted facilities plus a 5% random sample of remaining facilities. | a) **Fewer than 30 facilities:** validate them all<br>b) **30 or more facilities:** 30 facilities, distributed between Stratum I and II<br>***Stratum 1: Facilities who have reported ZERO events***<br>***Stratum II: Facilities who reported few events*** | a) **Fewer than 15 facilities:** validate them all<br>b) **15 or more facilities:** choose 15 facilities distributed between Stratum 1 and 2 as described above. |

# 3) Methodology for Generating Data for Validation:

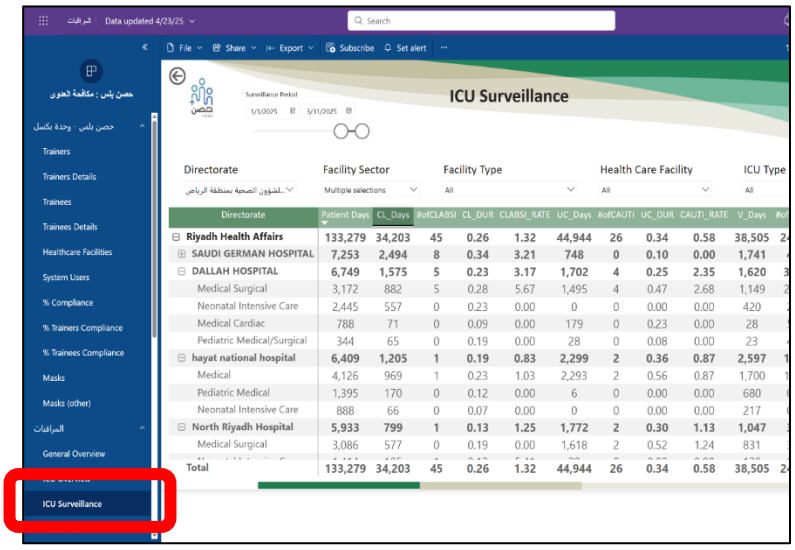
## STEPS:

- Access Power BI Dashboard & generate data sets
- Choose ICU Surveillance from list in left navigation panel.
- Use filter to select time frame for validation Period
- Choose export data from dropdown list.
- Choose summarized data & and export an excel spreadsheet
- Open excel sheet & assign bed capacity for each facility.
- Sort the healthcare facilities based on type of methods chosen for facility selection e.g. Method 1: sort facilities in descending order (highest to smallest HAI rate) according to type of KPI chosen for validation e.g. CLABSI rate in facilities from Ist Jan – 31st March 2025 (Quarter-I)
- Usual trend in your region will guide you in selecting specific methodology e.g. if a region has high number of facilities with zero or underreporting issues choose method-2.

### STEP 1: Access Power BI Dashboard

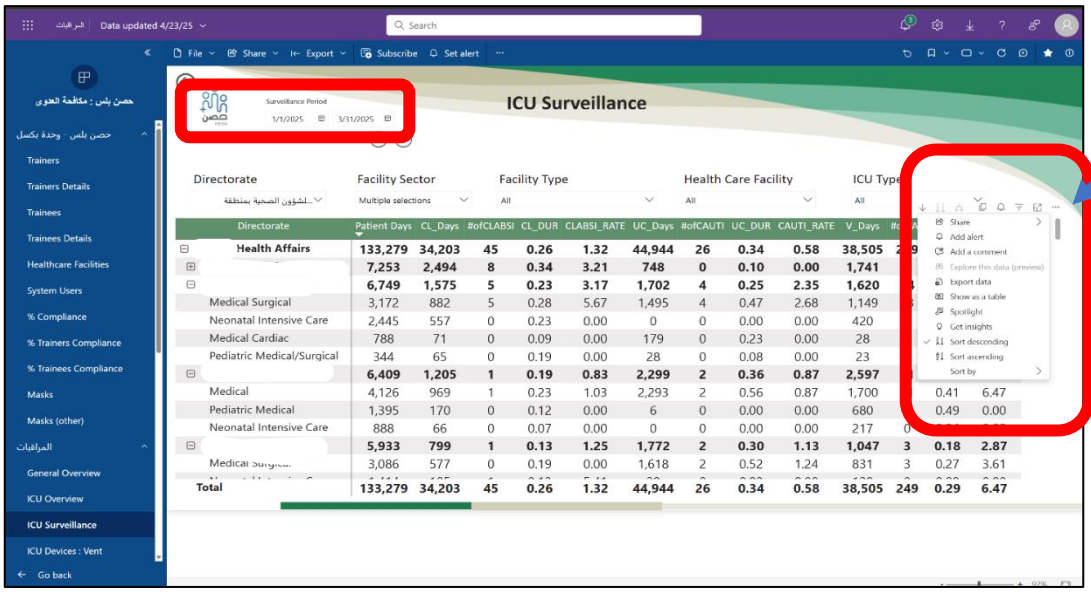



### STEP 2: Choose ICU Surveillance from left navigation panel

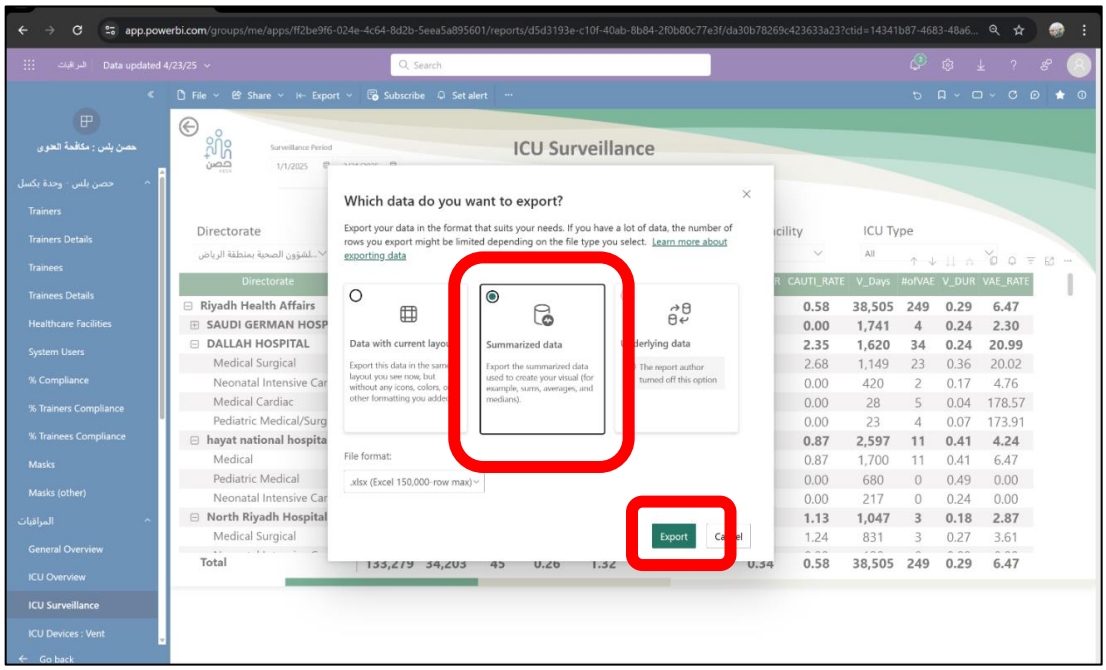


## STEP 3: Use filter to select time frame for validation Period

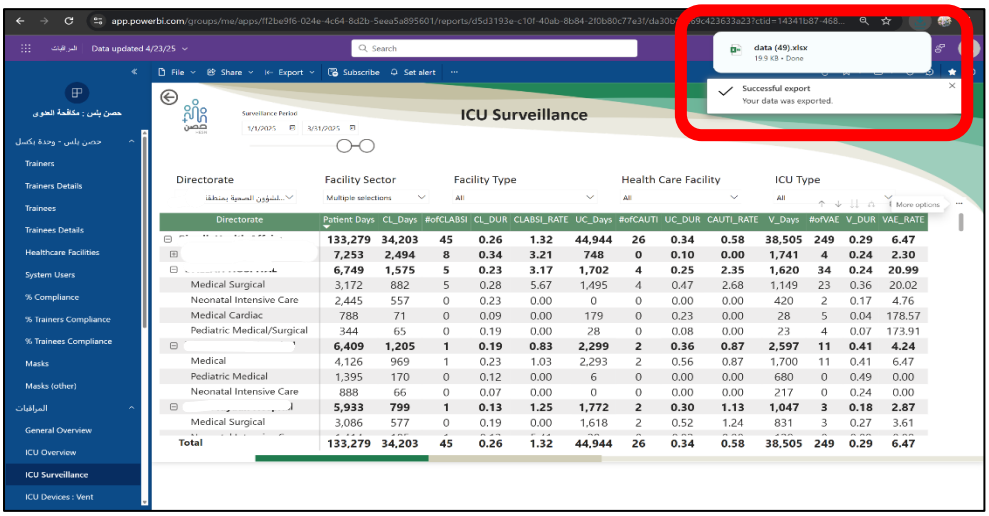
## STEP 4: Choose export data and extract excel worksheet




## STEP 5: Choose Summarized Data



## STEP 6: Export excel worksheet




## STEP 7 : Sort the healthcare facilities based on type of methods chosen for facility selection using extracted excel spreadsheet

| Branch | Name of Facility | Bed Capacity | ICU Type | patient Days for ICU | CL DAYS | # of CLABSI | CLABSI_RATE | CL DUR |
|---|---|---|---|---|---|---|---|---|
| Health Affairs | MM | 200 | Medical Surgical | 538 | 174 | 2 | 11.49425287 | 0.323420074 |
| Health Affairs | TT | 450 | Medical | 2,122 | 470 | 3 | 6.382978723 | 0.221489161 |
| Health Affairs | XX | 550 | Medical Surgical | 3,172 | 882 | 5 | 5.66893424 | 0.278058008 |
| Health Affairs | AA | 950 | Medical Surgical | 2,826 | 1,511 | 7 | 4.63269358 | 0.53467799 |
| Health Affairs | BB | 130 | Medical | 3,089 | 309 | 1 | 3.236245955 | 0.100032373 |
| Health Affairs | CC | 150 | Medical Surgical | 1,167 | 331 | 1 | 3.021148036 | 0.283633248 |
| Health Affairs | DD | 220 | Medical Surgical | 3,174 | 864 | 2 | 2.314814815 | 0.27221172 |
| Health Affairs | EE | 330 | Medical | 3,079 | 876 | 2 | 2.283105023 | 0.284507957 |
| Health Affairs | FF | 240 | Medical | 1,926 | 470 | 1 | 2.127659574 | 0.244029076 |
| Health Affairs | GG | 490 | Medical | 4,126 | 969 | 1 | 1.031991744 | 0.234852157 |
| Health Affairs | HH | 750 | Medical Surgical | 2,557 | 1,202 | 1 | 0.831946755 | 0.470082127 |
| Health Affairs | JJ | 120 | Medical Surgical | 3,086 | 577 | 0 | | 0.186973428 |
| Health Affairs | KK | 140 | Medical Surgical | 2,932 | 668 | 0 | 0 | 0.227830832 |
| Health Affairs | QQ | 330 | Medical Surgical | 2,668 | 2,004 | 0 | 0 | 0.751124438 |
| Health Affairs | RR | 400 | Medical Surgical | 2,311 | 748 | 0 | 0 | 0.323669407 |
| Health Affairs | SS | 200 | Medical Surgical | 2,245 | 381 | 0 | 0 | 0.169710468 |
| Health Affairs | TT | 150 | Medical Surgical | 2,007 | 1,288 | 0 | 0 | 0.641753861 |
| Health Affairs | UU | 350 | Medical | 1,842 | 290 | 0 | 0 | 0.157437568 |
| Health Affairs | VV | 400 | Medical Surgical | 1,757 | 234 | 0 | 0 | 0.133181559 |
| Health Affairs | WW | 650 | Medical Surgical | 1,562 | 363 | 0 | 0 | 0.232394366 |
| Health Affairs | XX | 1200 | Medical | 1,559 | 226 | 0 | 0 | 0.144964721 |
| Health Affairs | ZZ | 875 | Medical | 1,549 | 706 | 0 | 0 | 0.455777921 |

*Method 1: Sort facilities in descending order (highest to smallest HAI rate) according to type of KPI chosen for validation e.g. CLABSI rate in facilities from Ist Jan - 31st March 2025 (Quarter-I)*

### STEP 8 : Choose hospitals based on selection criteria in each method and proceed with further validation steps *(Refer to table 1)*

### Examples of facility selection calculation:

**PHA Branch - A:** HAI coordinator has chosen to validate VAE data for Quarter I 2025.
Total number of facilities in the region are 17. Based on validation guidelines all 17 facilities will be contacted to participate in the external validation.

**PHA Branch - B :** HAI coordinator has chosen to validate CLABSI data for Quarter I 2025.
There are 85 facilities in the Region. Based on the validation guidelines the coordinator will need to select 18 targeted facilities and an additional 5% sample of randomly selected facilities.
18 + [(85-18) x 5/100] = 67 x 5/100= 3.35 (rounding to the nearest whole number)

**18 + 3 = (21 facilities selected for validation in region B)**

## 4) Notify facilities of the planned validation visit & onsite activities:

- **Use the official letter template & inform healthcare facilities:**

1) Evaluation of surveillance practices within your facility & to assess if HAI Event surveillance & outbreak protocols are well understood and carried out in hospitals.
2) Data quality evaluation of hospital data that are reported via official electronic Platforms.
3) A review of pre-selected patient clinical derived from line lists, including both paper charts and any electronic records, to assess the completeness and accuracy of the data.
4) Validation rounds to AICUs, PICUs, NICUs, Inpatient Medical/Surgical ward & HDU etc.
5) Education for facility staff about HAI surveillance & outbreak, use of the electronic platforms, and common reporting errors and their causes.

- **Request the following data prior to validation Visit :**

### a) Request the required laboratory line listings -:

- To ensure that facilities are accurately identifying and reporting HAIs via official electronic Platforms
- Submit the following line lists required before the tentative date of visit.

| HAI Event to be Validated | Request to Facility for Line Listing |
|---|---|
| CLABSI | Line listing of positive blood cultures from HESN-reporting surveillance locations, where organism(s) was identified with patient MRN and admission dates, specimen details etc. |
| CAUTI | Line listing of positive urine cultures from HESN -reporting surveillance locations (non-NICU) with patient MRN and admission dates, specimen details etc. |
| VAE | Line listing of Positive Cultures from respiratory specimens e.g. Endotracheal aspirate, Bronchoalveolar lavage (BAL), lung tissue, sputum etc. |
| MDROs | Inpatient specimens positive for Targeted MDROs (ESCKAPE-C) from HESN-reporting surveillance locations. |
| SSI | Line list of positive cultures e.g. wound swab etc. & Surgical Procedures line list |
| Dialysis Events | Line listing of Positive blood cultures (PBC), IV antimicrobial Start & Local Site Infection |

## Structure of Laboratory line listing

### Template positive culture line listing

| Facility Admission Date | MRN | Age | Location | Date of unit Admission | Diagnosis | Date of Device insertion (If applicable) | Date of Device removal (If applicable) | Signs & Symptoms | Specimen type | Date of Sample collection | Organism name *MDRO?* | Decision HAI/CAI |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | CL:<br>FC:<br>Vent: | CL:<br>FC:<br>Vent: | | | | | |
| | | | | | | CL:<br>FC:<br>Vent: | CL:<br>FC:<br>Vent: | | | | | |

### Example: CLABSI Validation

- Include all positive laboratory (blood culture) in line listing from all surveillance locations (SLs). (AICU, PICU & NICUs)
- Obtain a complete list of positive blood cultures (PBCs) collected from all surveillance locations (SLs).
- Includes all PBCs taken:
  - ***During surveillance location/s (SLs) stay***
  - ***Day of transfer from the surveillance location/s (SLs)***
  - ***Day following transfer or discharge from the surveillance location/s (SLs)***

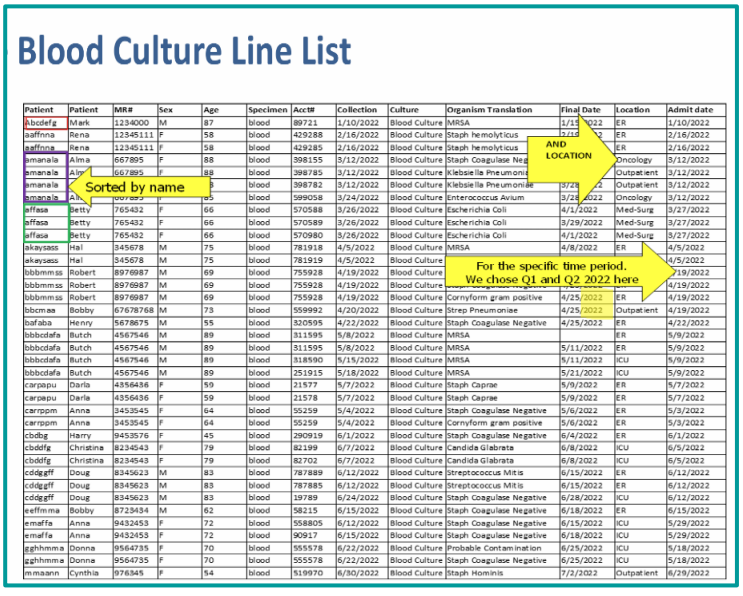
## b) Review line lists & select patients /cases for further validation:

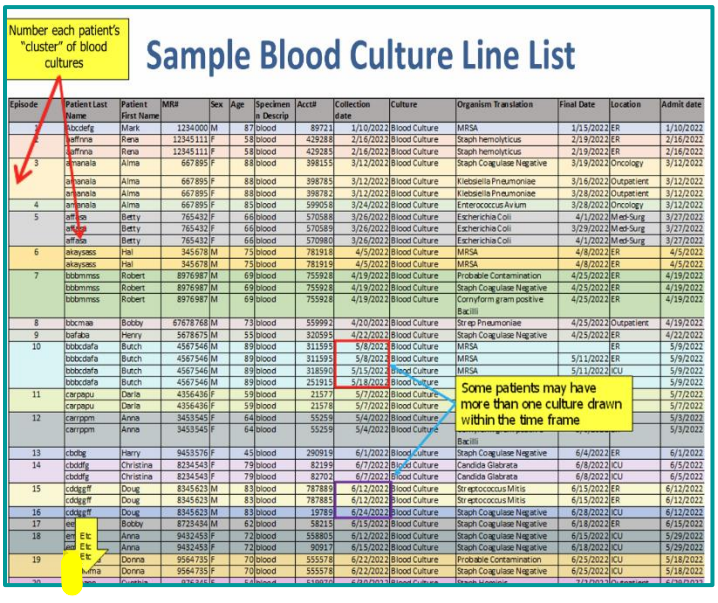
- Review the line list in detail and ensure all data is complete.
- Select the specific patients / cases from list after reviewing laboratory line listings that need further validation. *e.g. patient/s likely meeting specific CDC-NHSN criteria as per line list missed by ICP but needs further review of patients clinical information.*
- Choose clinical patient information corresponding with the HAI(s) being validated VAE, CLABSI,SSI etc

## c) Request pre - selected patients clinical data in advance for onsite-visit.

- Request pre - selected patients clinical data in advance of the facility site-visit after reviewing the line lists submitted by hospital.
- Inform the ICP of the selected clinical records to be arranged for access on day of visit.
- Specific **clinical records** should be requested for each HAI reviewed: for example for VAE: RT notes for ventilation parameters PEEP-FiO2,ABX,WBC count & relevant clinical information as per criteria for each HAI etc.
- Specific **clinical records** for patient who underwent chosen surgical procedure/s with any subsequent readmissions within 30/90 days following the procedure, procedure information & relevant clinical information as per criteria for each SSI category. *(Superficial, Deep, Organ/Space)*---to be arranged for on site validation
- For LabID Events, access and review all laboratory results in the specified validation period.
- Patients can be selected for further validation from line list of patients under SSI surveillance or ICU Surveillance already entered in electronic platform in addition to line lists provided by hospitals for chosen validation time frame.

**EXAMPLE:**




- *From each selected facility, obtain a complete list of positive blood cultures (PBCs) collected from all surveillance locations:*
  - *Include all PBCs taken during surveillance location stay*
  - *Day of transfer from the surveillance location*
  - *Day following transfer or discharge from surveillance location*
- *Sort each positive blood culture by patient.*
- *If these cultures are taken multiple days in a row and would be reported as same infection, that is one "event".(Apply RIT)*
- *Highlight each suspected event and request clinical records to verify if matching criteria.*
- *Focus if there are any undetected, misidentified/misclassified events in order to ensure accuracy of events reporting.*
- *Derive / select patients from line list for clinical records request availability during visit.*

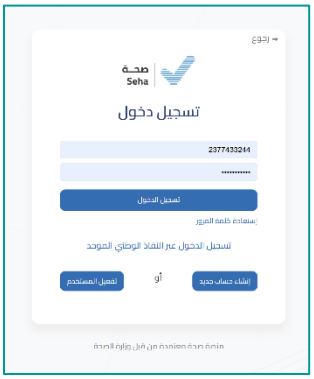
# Template of Targeted Surgical Procedures data

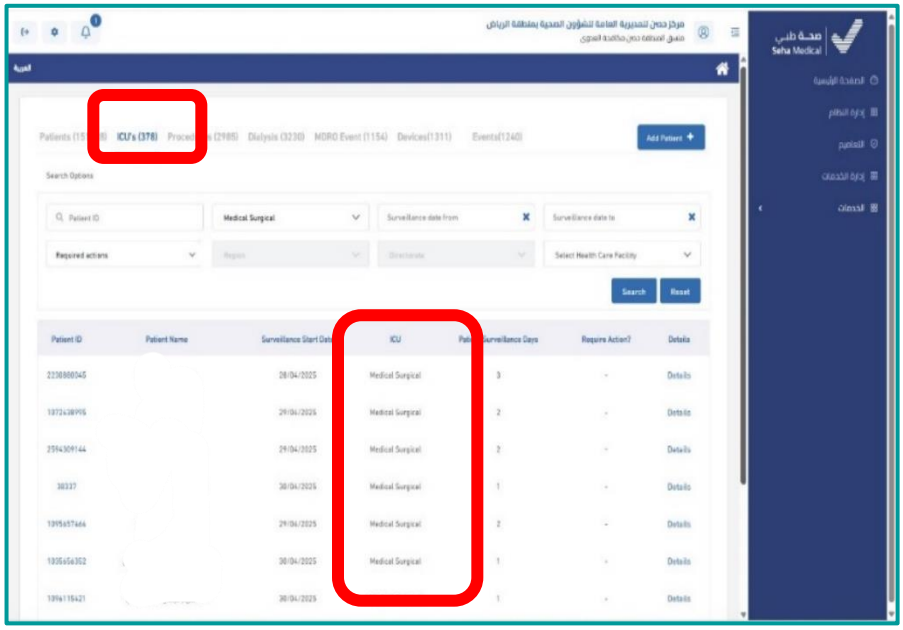
## Monthly breakdown of selected Surgical Procedures & Surgical Site Infections (SSIs)

| Year | Type of Procedure/s | Number of Procedure/s | Number of SSI/s |
|---|---|---|---|
| January | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| February | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| March | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| April | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| May | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| June | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| July | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| August | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| September | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| October | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| November | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |
| December | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: | Procedure 1:<br>Procedure 2:<br>Procedure 3: |

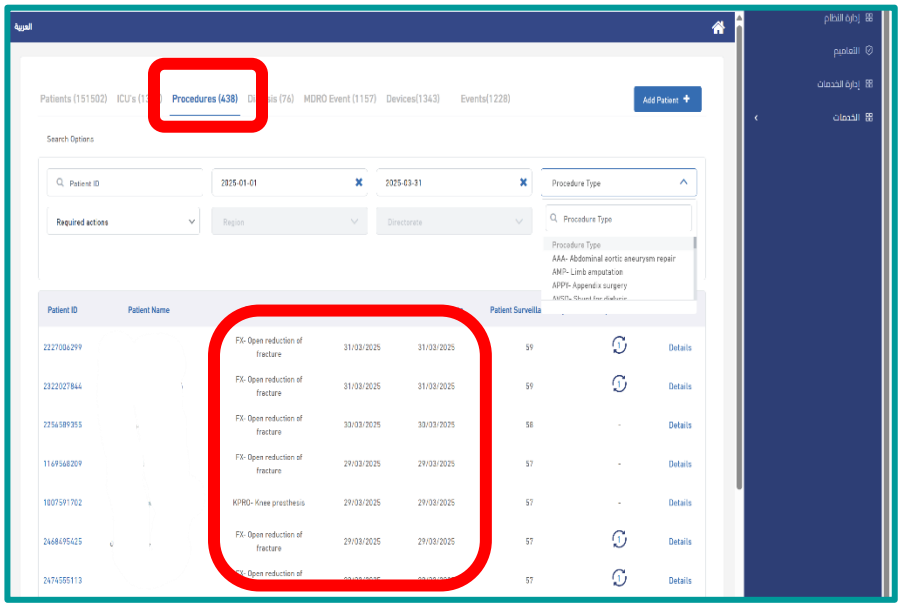
# 5: Review Electronic Data reported via official electronic platforms before on site visit for Manual Data Comparison:

- Access the electronic platform and check if all domains are complete before the planned visit.
- Check the Numerator & denominator data reported via official electronic platforms.
- Compare with manual data during on site visit.




1) Verify if number of currently admitted patients in all surveillance locations adult, pediatric & Neonatal ICUs is matching with patients under surveillance in HESN Plus.
2) Ensure completeness and accuracy of data entry by checking the date when last patient was registered.
3) Ensure End of Surveillance (EOS) is done for all patients who are discharged/ transferred from ICUs.
4) Randomly check at least 10-20 patients from each location to ensure all relevant forms are filled. e.g. device information, bundle review, event information & microbiology information etc.
5) Verify if number of patients under SSI surveillance in HESN Plus is matching with current patients under SSI surveillance according to type of chosen procedure.
6) Randomly check at least 10-20 patients for each chosen procedure to ensure all relevant forms are filled. e.g. procedure information, surgical bundle review, SSI event information etc.

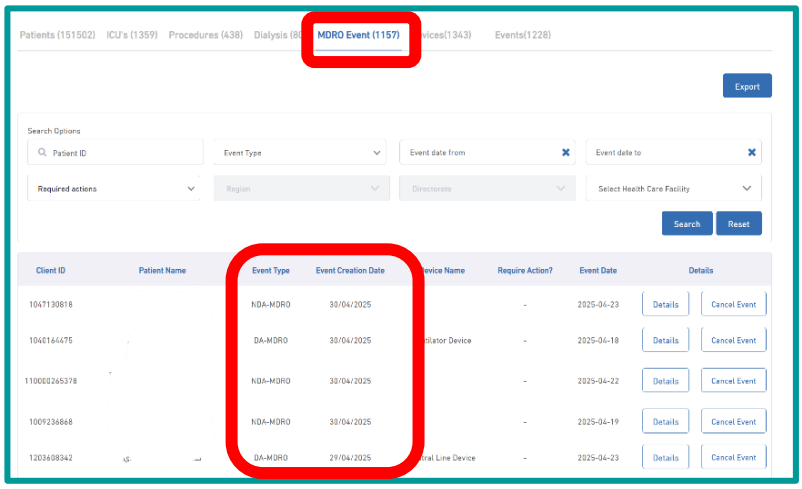


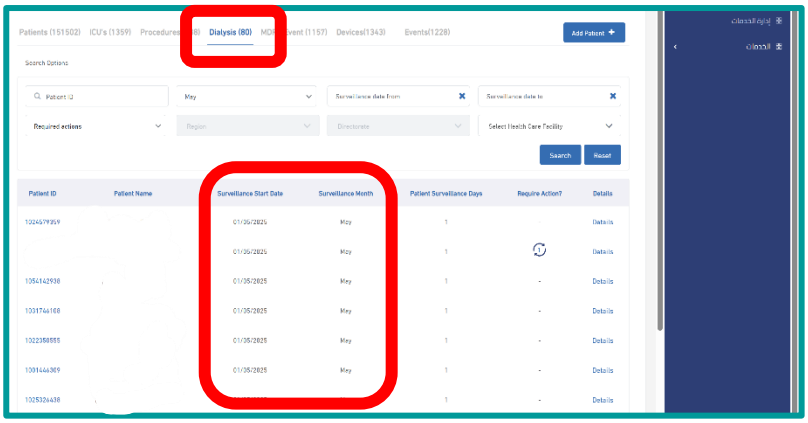
1) Check the MDRO Events data and ensure all Lab ID Events (Hospital Onset & Community onset are reported via HESN Plus. Notice if same HO-MDROs are reported from same location within same time frame - contact facility to verify.

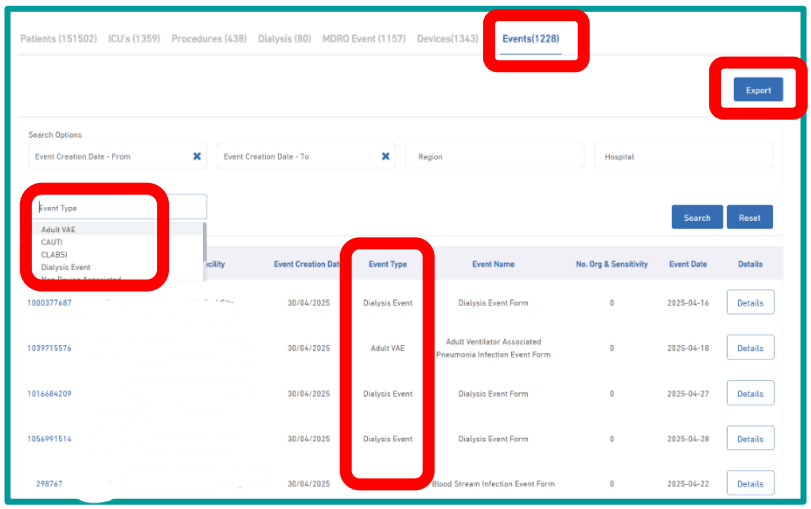
2) Check the dialysis denominator data and verify if all HDU patients are registered in HESN plus on Ist & 2nd working days of each month & Dialysis Events reported during the month including the transient patients.

3) Click on Events Tab and export events line list for the chosen surveillance period.

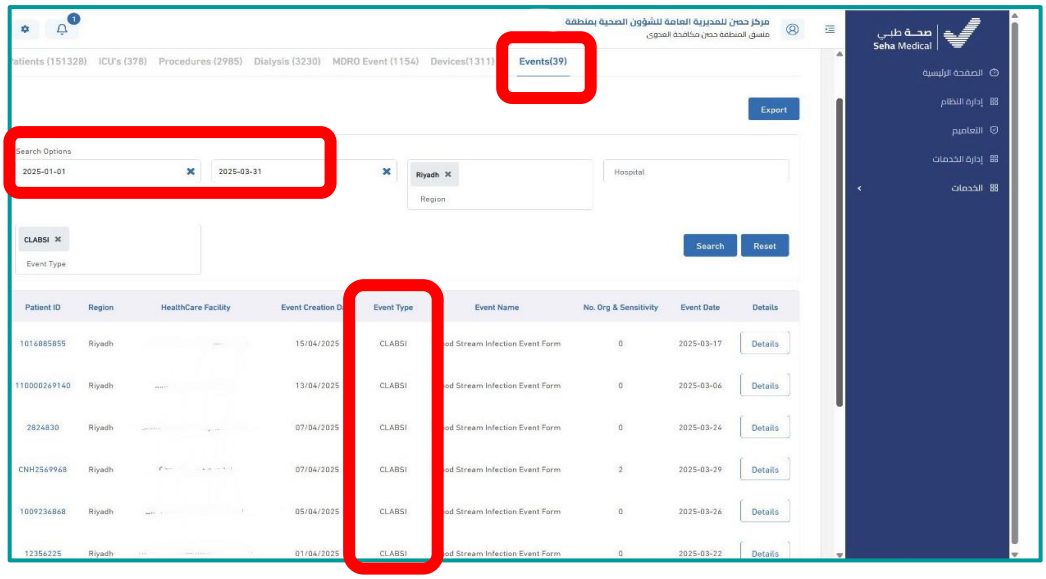
I. CLABSI
II. CAUTI
III. Adult VAE
IV. Ped VAE
V. SSI
VI. Dialysis Event
VII. Non Device Associated Event



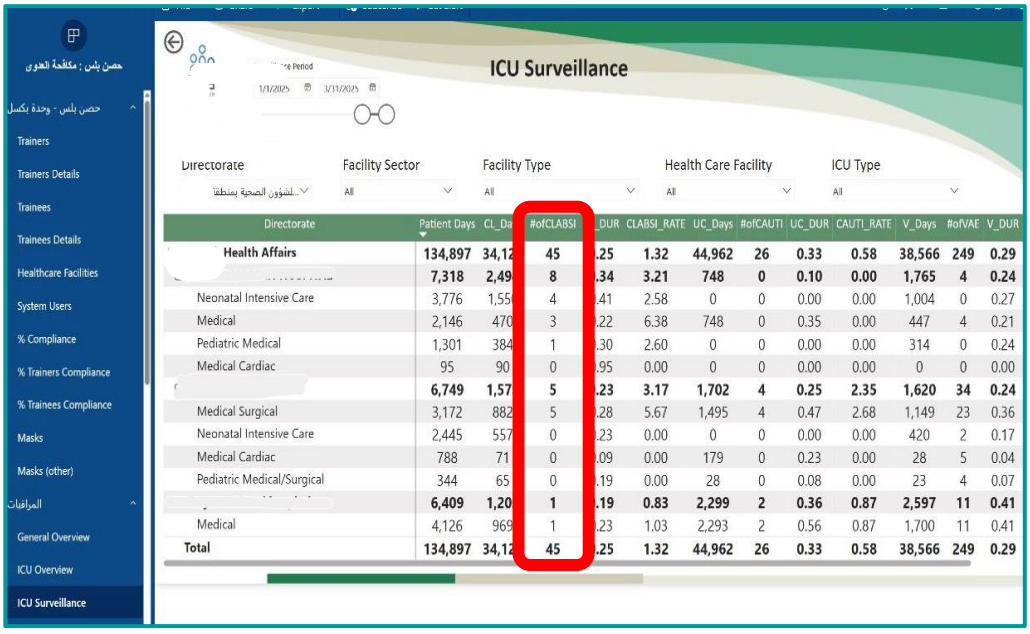



## Example: Compare number of CLABSI Events reported Via official electronic platforms during chosen surveillance period & notice any discrepancy.




**Vs**



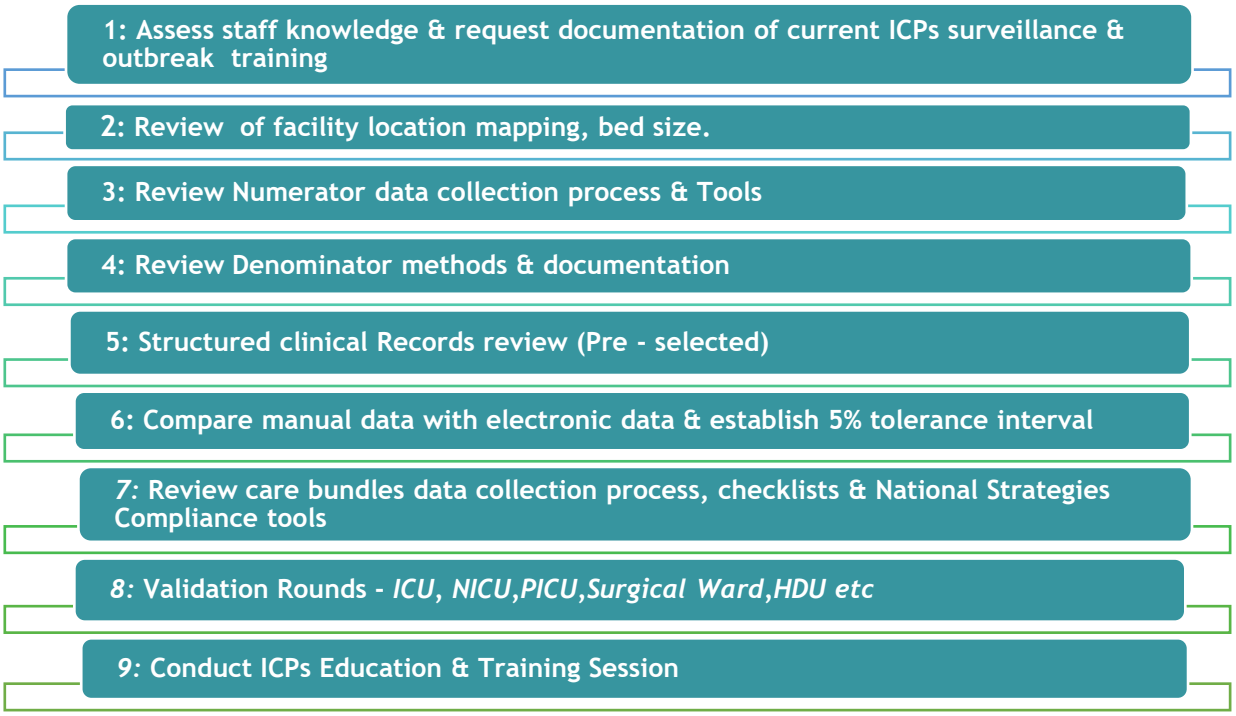

| Directorate | Patient Days | CL_Da | #ofCLABSI | _DUR | CLABSI_RATE | UC_Days | #ofCAUTI | UC_DUR | CAUTI_RATE | V_Days | #ofVAE | V_DUR |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Health Affairs** | **134,897** | **34,12** | **45** | **.25** | **1.32** | **44,962** | **26** | **0.33** | **0.58** | **38,566** | **249** | **0.29** |
| **[redacted]** | **7,318** | **2,49** | **8** | **.34** | **3.21** | **748** | **0** | **0.10** | **0.00** | **1,765** | **4** | **0.24** |
| Neonatal Intensive Care | 3,776 | 1,55 | 4 | .41 | 2.58 | 0 | 0 | 0.00 | 0.00 | 1,004 | 0 | 0.27 |
| Medical | 2,146 | 470 | 3 | .22 | 6.38 | 748 | 0 | 0.35 | 0.00 | 447 | 4 | 0.21 |
| Pediatric Medical | 1,301 | 384 | 1 | .30 | 2.60 | 0 | 0 | 0.00 | 0.00 | 314 | 0 | 0.24 |
| Medical Cardiac | 95 | 90 | 0 | .95 | 0.00 | 0 | 0 | 0.00 | 0.00 | 0 | 0 | 0.00 |
| **[redacted]** | **6,749** | **1,57** | **5** | **.23** | **3.17** | **1,702** | **4** | **0.25** | **2.35** | **1,620** | **34** | **0.24** |
| Medical Surgical | 3,172 | 882 | 5 | .28 | 5.67 | 1,495 | 4 | 0.47 | 2.68 | 1,149 | 23 | 0.36 |
| Neonatal Intensive Care | 2,445 | 557 | 0 | .23 | 0.00 | 0 | 0 | 0.00 | 0.00 | 420 | 2 | 0.17 |
| Medical Cardiac | 788 | 71 | 0 | .09 | 0.00 | 179 | 0 | 0.23 | 0.00 | 28 | 5 | 0.04 |
| Pediatric Medical/Surgical | 344 | 65 | 0 | .19 | 0.00 | 28 | 0 | 0.08 | 0.00 | 23 | 4 | 0.07 |
| **[redacted]** | **6,409** | **1,20** | **1** | **.19** | **0.83** | **2,299** | **2** | **0.36** | **0.87** | **2,597** | **11** | **0.41** |
| Medical | 4,126 | 969 | 1 | .23 | 1.03 | 2,293 | 2 | 0.56 | 0.87 | 1,700 | 11 | 0.41 |
| **Total** | **134,897** | **34,12** | **45** | **.25** | **1.32** | **44,962** | **26** | **0.33** | **0.58** | **38,566** | **249** | **0.29** |

***Conclusion:*** *Number of CLASBI events reflected in Power BI Dashboard are (45) in comparison with Seha Platform (39)*

# CHAPTER II

## ON SITE VISIT ACTIVITIES

*(To be carried out by PHA branches surveillance team members during on site visit)*




### *1*: Assess staff knowledge & request documentation of recent Surveillance & outbreak training:

- Assess staff knowledge and understanding of surveillance process and protocols as per specific HAI external validation tool.
- Review Surveillance coordinators training documentation, such as a certificate of successful completion of the most recent on site / online self-paced training modules for HAIs & Outbreak management.
- Annual training is mandatory for all hospital surveillance coordinators.
- Refer to page # 8 for training resources & links

## 2: Review of facility location mapping, bed size:

- Review facility location mapping & bed size for each critical care unit.
- Check if the surveillance locations are accurately identified and matching with official electronic platforms.
- Correct Location Mapping is important because like populations are believed to have similar risks for healthcare-associated infections (HAIs)
    - *Similar medical devices*
    - *Similar invasive procedures*
    - *Similar host factors affecting susceptibility*

- 80% rule should be applied. If ≥ 80% of patients are of a certain type, then that area is designated as that type of location.
  **Example:**
- If ≥ 80% of patients in an ICU are adult patients with medical problems, the area would be mapped as an **"Adult Medical ICU"** *(100% of the patients in this unit would be included for surveillance)*
- If there is mix of patients in a location serving both medical & surgical patients. The mix of patients should then be a **50/50 to 60/40** mix of medical and surgical patients to label this location to be **Medical / Surgical ICU.**

***Example 1: An ICU that is 85% Burn patients, 15% Trauma***
***Location: Burn Critical Care Unit***

***Example 2: An ICU that is 55% medical and 45% surgical***
***Location: Medical/Surgical Critical Care Unit***

## 3: Review Numerator data collection process & Tools:

- Check surveillance data collection tools / Process (Manual/electronic)
- Ask about surveillance locations, targeted patients for each type of HAI etc.
- Numerator data collection methods & source of data

***(Refer to specific External Validation Tools (EVTs) for details***
***(CLABSI, VAE, CAUTI, SSI, MDROs, DEs)***

## 4: Review Denominator methods & documentation:

- Request original records of denominator data collection paperwork, which can provide insight into the frequency, reliability, and consistency of this task.
- Denominator data collection method (Manual/electronic) for patient days & device days.
- Denominator data i.e. number of surgical procedures for targeted procedure/s.
- Review the manual denominator data collection sheets for specific validation period.
- Electronic denominator counts should fall within 5% of manual counts for **three consecutive months** before electronic counts can be used.

## 5: Manual Vs Electronic Data comparison & calculating 5% tolerance interval:

- Compare manual data with electronic data & establish 5% tolerance interval.

**EXAMPLE:**

**Equation for calculating 5% tolerance interval :**

- **Manual Central Line Days count = 164**
- **Electronic Central Line Days count = 178**
- ***Eligible 5% tolerance interval = [164±(164 X 5/100)] = 164 ± 8.2)***
- ***5% tolerance interval =155.8 to 172.2***

***Conclusion: Electronic count 178 falls outside the tolerance interval.***

## 6: Structured Clinical Patient Record Review:

- Review of pre-selected patient medical records, including paper charts and any electronic records to assess the completeness and accuracy of the data reported via HESN
- Review previously selected clinical records: microbiology results, clinical diagnosis, treatment (ABX), Clinical information, readmissions etc.
- Rule out the possibility of any misclassification or misidentification as per criteria.

## Example: VAE Data Validation:

- Choose at least 20 ventilated patients in specific quarter from each location and request ICPs to arrange required data.
- Request VAE monitoring forms for all identified VAEs (VAC-IVAC,PVAP) & VAEs not meeting criteria as per ICPs to be reviewed during on site visit.
- Review medical files (Electronic/manual) to verify VAE parameters i.e. PEEP, Fi02, fever, WBC count, Antibiotics (ABX) & lab results for respiratory specimens in addition to VAE monitoring forms.

**Match with CDC -NHSN VAE Criteria**

## Figure 1: Ventilator-Associated Events (VAE) Surveillance Algorithm

Patient has a baseline period of stability or improvement on the ventilator, defined by ≥ 2 calendar days of stable or decreasing daily minimum* $FiO_2$ or PEEP values. The baseline period is defined as the 2 calendar days immediately preceding the first day of increased daily minimum PEEP or $FiO_2$.

*Daily minimum defined by lowest value of $FiO_2$ or PEEP during a calendar day that is maintained for > 1 hour.

After a period of stability or improvement on the ventilator, the patient has at least one of the following indicators of worsening oxygenation:

1) Increase in daily minimum* $FiO_2$ of ≥ 0.20 (20 points) over the daily minimum $FiO_2$ of the first day in the baseline period, sustained for ≥ 2 calendar days.
2) Increase in daily minimum* PEEP values of ≥ 3 $cmH_2O$ over the daily minimum PEEP of the first day in the baseline period†, sustained for ≥ 2 calendar days.

*Daily minimum defined by lowest value of $FiO_2$ or PEEP during a calendar day that is maintained for > 1 hour.
†Daily minimum PEEP values of 0-5 $cmH_2O$ are considered equivalent for the purposes of VAE surveillance.

**Ventilator-Associated Condition (VAC)**

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, the patient meets both of the following criteria:

1) Temperature > 38 °C or < 36°C, **OR** white blood cell count ≥ 12,000 cells/$mm^3$ or ≤ 4,000 cells/$mm^3$.

**AND**

2) A new antimicrobial agent(s) (see Appendix for eligible antimicrobial agents) is started and is continued for ≥ 4 qualifying antimicrobial days (QAD).

**Infection-related Ventilator-Associated Complication (IVAC)**

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, ONE of the following criteria is met (**taking into account organism exclusions specified in the protocol**):

1) Criterion 1: Positive culture of one of the following specimens, meeting quantitative or semi-quantitative thresholds† as outlined in protocol, without requirement for purulent respiratory secretions:
   - Endotracheal aspirate, ≥ $10^5$ CFU/ml or corresponding semi-quantitative result
   - Bronchoalveolar lavage, ≥ $10^4$ CFU/ml or corresponding semi-quantitative result
   - Lung tissue, ≥ $10^4$ CFU/g or corresponding semi-quantitative result
   - Protected specimen brush, ≥ $10^3$ CFU/ml or corresponding semi-quantitative result
2) Criterion 2: Purulent respiratory secretions (defined as secretions from the lungs, bronchi, or trachea that contain ≥ 25 neutrophils and ≤ 10 squamous epithelial cells per low power field [lpf, x100])† **PLUS** organism identified from one of the following specimens (to include qualitative culture, or quantitative/semi-quantitative culture without sufficient growth to meet Criterion #1):
   - Sputum
   - Endotracheal aspirate
   - Bronchoalveolar lavage
   - Lung tissue
   - Protected specimen brush
3) Criterion 3: One of the following positive tests:
   - Organism identified from pleural fluid (where specimen was obtained during thoracentesis or within 24 hours of chest tube placement; pleural fluid specimens collected after a chest tube is repositioned or from a chest tube in place > 24 hours are not eligible for PVAP)
   - Lung histopathology, defined as: 1) abscess formation or foci of consolidation with intense neutrophil accumulation in bronchioles and alveoli; 2) evidence of lung parenchyma invasion by fungi (hyphae, pseudohyphae, or yeast forms); 3) evidence of infection with the viral pathogens listed below based on results of immunohistochemical assays, cytology, or microscopy performed on lung tissue
   - Diagnostic test for *Legionella* species
   - Diagnostic test on respiratory secretions for influenza virus, respiratory syncytial virus, adenovirus, parainfluenza virus, rhinovirus, human metapneumovirus, coronavirus

† If the laboratory reports semi-quantitative results, those results must correspond to the quantitative thresholds. Refer to Table 2 and 3.

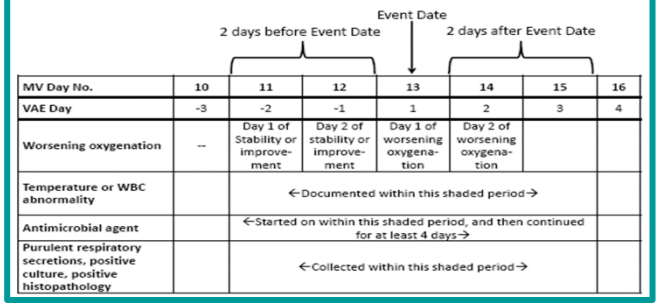
**Possible Ventilator-Associated Pneumonia (PVAP)**

وقاية
هيئة الصحة العامة
PUBLIC HEALTH AUTHORITY

| Date | PEEP (min) | FiO2 (min) | T min | T | WBC | WBC max | Antibiotic | Antibiotic |
|---|---|---|---|---|---|---|---|---|
| Jan 1 | 10 | 100 | | | | | | |
| Jan 2 | 5 | 50 | | | | | | |
| Jan 3 | 5 | 40 | | | | | | |
| Jan 4 | 5 | 40 | | | | | | |
| Jan 5 | 8 | 60 | | | | | | |
| Jan 6 | 8 | 50 | | | | | | |
| Jan 7 | 8 | 40 | | | | | | |
| Jan 8 | 5 | 40 | | | | | | |
| Jan 9 | 5 | 40 | | | | | | |

VAE window

## VAE Window Period




| Date | PEEP (min) | FiO2 (min) | T min | T max | WBC min | WBC max | Antibiotic | Antibiotic |
|---|---|---|---|---|---|---|---|---|
| Jan 1 | 10 | 100 | | | | | | |
| Jan 2 | 5 | 50 | | | | | | |
| Jan 3 | 5 | 40 | | | | | | |
| Jan 4 | 5 | 40 | | | | | | |
| Jan 5 | 8 | 60 | | | | | | |
| Jan 6 | 8 | 50 | | | | | | |
| Jan 7 | 8 | 40 | | | | | | |
| Jan 8 | 5 | 40 | | | | | | |
| Jan 9 | 5 | 40 | | | | | | |

VAC

| Date | PEEP (min) | FiO2 (min) | T min | T max | WBC min | WBC max | Antibiotic | Antibiotic |
|---|---|---|---|---|---|---|---|---|
| Jan 1 | 10 | 100 | | | | | | |
| Jan 2 | | | | | | | | |
| Jan 3 | | | 99.1 | 99.9 | 8.4 | 10.1 | | |
| Jan 4 | 5 | 40 | 99.0 | 101.9 | 9.9 | 11.2 | Linezolid | Cefepime |
| Jan 5 | 8 | 60 | 98.6 | 102.2 | 12.1 | 15.3 | Linezolid | Cefepime |
| Jan 6 | 8 | 50 | 98.8 | 100.3 | 14.1 | 17.4 | | Cefepime |
| Jan 7 | 8 | 40 | 96.8 | 99.1 | 15.0 | 16.1 | | Cefepime |
| Jan 8 | 5 | 40 | | | | | | Cefepime |
| Jan 9 | 5 | 40 | | | | | | Cefepime |

IVAC

| Date | PEEP | FiO2 | Gram Stain Polys | Gram Stain Epis | Culture |
|---|---|---|---|---|---|
| Jan 1 | | | | | |
| Jan 2 | | | | | |
| Jan 3 | | 40 | | | |
| Jan 4 | 5 | 40 | 3+ | 0 | Klebsiella pneumoniae |
| Jan 5 | 8 | 60 | | | |
| Jan 6 | 8 | | | | |
| Jan 7 | | | | | |
| Jan 8 | | | | | |
| Jan 9 | 5 | 40 | | | |

Possible VAP

Provided that IVAC was met

Semi-quantitative

**VAC**
Ventilator-Associated Condition

**IVAC**
Infection-related
Ventilator-Associated Complication

**PVAP**
Possible Ventilator
Associated Pneumonia

Figure 1: Pediatric Ventilator-Associated Events (PedVAE) Surveillance Algorithm

Patient has a baseline period of stability or improvement on the ventilator, defined by ≥ 2 calendar days of stable or decreasing daily minimum* $FiO_2$ or MAP values. The baseline period is defined as the 2 calendar days immediately preceding the first day of increased daily minimum $FiO_2$ or MAP.

*Daily minimum $FiO_2$ is defined as the lowest value of $FiO_2$ documented during a calendar day that is maintained for > 1 hour.
Daily minimum MAP is the lowest value documented during the calendar day.
For patients < 30 days old, daily minimum MAP values 0-8 cm $H_2O$ are considered equal to 8 $cmH_2O$ for the purposes of surveillance.
For patients ≥ 30 days old, daily minimum MAP values 0-10 $cmH_2O$ are considered equal to 10 $cmH_2O$ for the purposes of surveillance.

⇩

After a period of stability or improvement on the ventilator, the patient has at least one of the following indicators of worsening oxygenation:

1) Increase in daily minimum $FiO_2$ of ≥ 0.25 (25 points) over the daily minimum $FiO_2$ of the first day in the baseline period, sustained for ≥ 2 calendar days.
2) Increase in daily minimum MAP values of ≥ 4 $cmH_2O$ over the daily minimum MAP of the first day in the baseline period, sustained for ≥ 2 calendar days.

⇩

**Pediatric Ventilator-Associated Event (PedVAE)**

*Example 1: Daily minimum MAP is ≥ 4 cmH2O greater than the daily minimum MAP during the baseline period increase in the daily minimum MAP to at least 12 cmH2O, sustained for at least 2 calendar days, would be needed to meet the PedVAE definition).*

| MV Day | Daily minimum MAP ($cmH_2O$) | Daily minimum $FiO_2$ (oxygen concentration, %) | PedVAE |
|---|---|---|---|
| 1 | 7 (8) | 1.00 (100%) | |
| 2 | 7 (8) | 0.50 (50%) | |
| 3 | **8** | 0.50 (50%) | |
| 4 | **8** | 0.50 (50%) | |
| 5 | **12** | 0.50 (50%) | ✓ |
| 6 | **12** | 0.50 (50%) | |

*Example 2: Daily minimum FiO2 is ≥ 0.25 (25 points) over the daily minimum FiO2 during the baseline period*

| MV Day | Daily minimum MAP ($cmH_2O$) | Daily minimum $FiO_2$ (oxygen concentration, %) | PedVAE |
|---|---|---|---|
| 1 | 12 | 1.00 (100%) | |
| 2 | 11 | 0.50 (50%) | |
| 3 | 9 | **0.40 (40%)** | |
| 4 | 9 | **0.40 (40%)** | |
| 5 | 11 | **0.70 (70%)** | ✓ |
| 6 | 11 | **0.70 (70%)** | |

# Sample VAE Data Validation Results

## Hospital - A

| Numerator Validation Number of VAEs YY//MM//DD | | | | |
|---|---|---|---|---|
| Type of Event | Total # VAEs reported via SEHA platform *(before validation)* | Number of VAE/s correctly Identified & reported via HESN-Plus | Missed, Undetected VAE/s that were meeting criteria. | Over identification / wrong identification of VAE/s not matching criteria |
| Adult VAEs (AICUs) | 6 | 6 | 0 | 0 |
| Ped VAE (PICU) | 3 | 3 | 0 | 0 |
| Ped VAE (NICU) | 2 | 2 | 0 | 0 |
| Grand Total | 11 | 11 | 0 | 0 |

*Conclusion: No discrepancies observed*

## Hospital - B

| Numerator Validation Number of VAEs YY//MM//DD | | | | |
|---|---|---|---|---|
| Type of Event | Total # VAEs reported via SEHA platform *(before validation)* | Number of VAE/s correctly Identified | Missed, Undetected VAE/s that were meeting criteria. | Wrong identification of VAE/s not matching criteria |
| Adult VAEs (AICUs) | 2 | 2 | 2 | 0 |
| Pediatric VAE (PICU) | 3 | 2 | 0 | 1 |
| Pediatric VAE (NICU) | 1 | 1 | 2 | 0 |
| Grand Total | 06 | 05 | 04 missed | 1 |

*Conclusion:* *Some discrepancies observed*
*4 missed cases & 1 misidentified reported case*

# Denominator Data Collection Forms

## Denominator Days Form (Adult & Pediatrics)

Surveillance Month: Location:

Date of Surveillance:

| Date | No. of Patients | No. of Patients on Central Line | No. of Patients on Urinary Catheters | No. of Patients on Ventilator |
|---|---|---|---|---|
| 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 | | | | |
| | Patient days | Central line Days | Urinary Catheter Days | Ventilator days |

## Denominator Days Form (Neonates - NICU)

Surveillance Month: Location:

Date of Surveillance:

| Date | Birth Weight Categories | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | <750 gm | | | 751-1000 gm | | | 1001-1500 gm | | | 1501-2500 gm | | | >2500 gm | | |
| | PTS | CL | VENT | PTS | CL | VENT | PTS | CL | VENT | PTS | CL | VENT | PTS | CL | VENT |
| 1. | | | | | | | | | | | | | | | |
| 2. | | | | | | | | | | | | | | | |
| 3. | | | | | | | | | | | | | | | |
| 4. | | | | | | | | | | | | | | | |
| 5. | | | | | | | | | | | | | | | |
| 6. | | | | | | | | | | | | | | | |
| 7. | | | | | | | | | | | | | | | |
| 8. | | | | | | | | | | | | | | | |
| 9. | | | | | | | | | | | | | | | |
| 10. | | | | | | | | | | | | | | | |
| 11. | | | | | | | | | | | | | | | |
| 12. | | | | | | | | | | | | | | | |
| 13. | | | | | | | | | | | | | | | |
| 14. | | | | | | | | | | | | | | | |
| 15. | | | | | | | | | | | | | | | |
| 16. | | | | | | | | | | | | | | | |
| 17. | | | | | | | | | | | | | | | |
| 18. | | | | | | | | | | | | | | | |
| 19. | | | | | | | | | | | | | | | |
| 20. | | | | | | | | | | | | | | | |
| 21. | | | | | | | | | | | | | | | |
| 22. | | | | | | | | | | | | | | | |
| 23. | | | | | | | | | | | | | | | |
| 24. | | | | | | | | | | | | | | | |
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| 26. | | | | | | | | | | | | | | | |
| 27. | | | | | | | | | | | | | | | |
| 28. | | | | | | | | | | | | | | | |
| 29. | | | | | | | | | | | | | | | |
| 30. | | | | | | | | | | | | | | | |
| 31. | | | | | | | | | | | | | | | |
| Total | | | | | | | | | | | | | | | |

## 7: Review care bundles data collection & internal validation process, checklists & National Strategies Compliance tools:

- Ask about the care bundles internal validation process & compliance rates.
- Ask about the data related to National Strategies Compliance tools compliance.

***(Refer to specific External Validation Tools (EVTs) for details***
***(CLABSI, VAE, CAUTI, SSI, MDROs, DEs)***

## 8: Validation Rounds - ICU, NICU, PICU, Surgical Ward, HDU etc.

- Conduct on site unit visits to assess clinical staff knowledge about the relevant devices insertion & maintenance bundles, SSI, MDRO & DE bundles.
- Assess if staff are aware about specific National Strategies tools with implementation.

## 9: Conducting ICPs Education & Training Session:

- Conduct brief training & education session for ICP according to type of HAI event selected for Validation e.g. VAE, CLABSI, SSI.
- Conduct brief training & education session for ICPs about outbreak detection & reporting.
- Brief training about the electronic platforms & specific national strategies overview.

# CHAPTER III

## POST VISIT ACTIVITIES

*(To be carried out by PHA branches surveillance team members after on site visit)*

1: Creation of Validation visit report.

2: Sharing findings with hospital & key stakeholders

4: Request for necessary corrections and other recommendations via an action plan

5: Follow up with hospital to ensure corrective interventions are completed as per agreed timeline.

### 1: Creation of validation visit report :

- Prepare the validation visit report for each specific HAI validated using the excel version of HAI external validation tool/s. ***(Excel template)***
- Prepare validation summary report for each domain. ***(see templates)***

### 2: Sharing findings with hospital & key stakeholders:

- Submit validation feedback report to hospital.
- PHA branch head and other key personnel.

### 4: Follow - up for corrective Interventions:

- Request for corrective action plan based on recommendations
- Follow up with hospitals to ensure corrective interventions are completed as per agreed timeline.

# Appendices:

## *Appendix 1: Letter Templates:*

*Appendix 1.1: Sample Letter Requesting on site hospital visit, Line Listings & Clinical records for External Validation*

## *Appendix 2: Validation Templates:*

### *A: External Validation Tools (EVTs):*

1. *CLABSI Surveillance External Validation Tool*
2. *VAE Surveillance External Validation Tool*
3. *CAUTI Surveillance External Validation Tool*
4. *SSI Surveillance External Validation Tool*
5. *MDRO Surveillance External Validation Tool*
6. *DE Surveillance External Validation Tool*

### *B: Validation Summary Reports:*

1. *CLABSI Validation Summary Report*
2. *VAE Validation Summary Report*
3. *CAUTI Validation Summary Report*
4. *SSI Validation Summary Report*
5. *MDRO Validation Summary Report*
6. *DE Validation Summary Report*

## *Appendix 1.1: Sample Letter Requesting Site Visit, Line Listing & Clinical Records for External Validation*

*Name of Hospital/Facility:*
*Subject: XYZ*
*Date:*

*Dear IC Team:*

*We are contacting you to inform you that an site visit will be conducted in your facility on DD/MM/YY in order to conduct data quality evaluation of hospital data reported via official electronic platforms. We hereby request your availability & facilitation during the visit.*

*This evaluation will be conducted to know how HAI Event surveillance data collection procedures are understood and carried out in hospital, as well as to identify and address barriers to reporting complete and accurate data.*

*There will be three main activities during these site visits include:*

1. *A standardized survey to evaluate surveillance practices within your facility.*
2. *A review of pre-selected patient medical records, including both paper charts and any electronic records, to assess the completeness and accuracy of the data reported via electronic platforms.*
3. *Education for facility staff about Event surveillance, use of the electronic system, and common reporting omissions and errors and their causes.*

*It is anticipated the visit will be completed within one day. On the day(s) of the visit, <> staff will need a space to review patient charts and access the facility's electronic clinical records systems. Validation of the data is critical to ensure they are complete and accurate. The findings from this evaluation will be used to identify, correct, and prevent common reporting errors and confidentiality of data will be maintained.*
*During the visit following healthcare-associated infections domains will be evaluated:*

1) *Central line-associated bloodstream infections (CLABSI)*
2) *Catheter-associated urinary tract infections (CAUTI)*
3) *Adult & Pediatric Ventilator Associated Events (VAE)*
4) *Surgical site infections (SSI)*
5) *MDRO Lab ID Event*
6) *Dialysis Events*

*Kindly provide us following before & during onsite visit:*

- *Microbiology laboratory based line listing for positive cultures*
- *Monthly count of selected inpatient surgical procedures performed in your facility*
- *Availability of pre-selected clinical Records derived from line list for onsite Validation*
- *Review of diagnostic/laboratory results, clinical documentation etc. when needed*

*We look forward to visiting your facility and working with you.*
*Thank you in advance for your assistance to evaluate and improve the quality of HAI Surveillance & outbreak data and reporting.*

***Sincerely,***

***HAI Surveillance Coordinator,***
***Public Health Authority – Branch***

*External Validation Tools (EVTs)*
*CLABSI Surveillance External Validation Tool*

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## CLABSI Surveillance Data Validation Tool

### PART I : CLABSI Surveillance Process
(Catheter Associated Blood Stream Infection)

| # | Items | A: Staff Knowledge | Score | Comments |
|---|---|---|---|---|
| WHAT? *(ICPs responsible for CLABSI Surveillance must be well trained about CLABSI Surveillance Protocols* | CDC - NHSN CLABSI Criteria (Numerator) | **Assess if ICPs assigned for CLABSI surveillance are well familarized with case definitions as per CDC-NHSN criertia & fullly understand CLABSI surveilance process.**<br><br>Numerator: Laboratory Confirmed Bloodstream Infection (LCBIs) Hierarchy<br>LCBI-1: **Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common commensal list.**<br>A) Identified from one or more blood specimens obtained by a culture non-culture based microbiologic testing &<br>B) Organism(s) identified in blood is not related to an infection at another site.<br><br>LCBI-2: A) **Patient of any age** has at least one of the following signs or symptoms: fever (>38.0oC), chills,or hypotension **AND**<br>B) Organism(s) identified in blood is not related to an infection at another site. **AND**<br>C) Same NHSN common commensal is identified by culture from two or more blood specimens collected on separate occasions | | |
| | | LCBI-3: A) Patient ≤ 1 year of age has at least one of the following signs or symptoms: fever (>38.0oC), hypothermia (<36.), apnea OR bradycardia<br>B) Organism(s) identified in blood is not related to an infection at another site. AND<br>C) Same NHSN common commensal is identified by culture from two or more blood specimens collected on separate occasions | | |
| | Denominator Data Collection Denominator data | Ask about denomintaor data colllection methodology??<br>Denominator/s:<br>**Patinet Days: Number of patients housed in a facility inpatient location during the designated counting time each day and summed for a monthly denominator report.**<br>**Central Line days: The number of days a central line is accessed to determine if an LCBI is a CLABSI.**<br><br>NICU Denomintaor data collection: *(Collect the denominator data as per birth weight categories because the risk of BSI varies by birth weight)*<br><750 gm 751-1000 gm<br>1001-1500 gm 1501-2500 gm >2500 gm<br><br>*NOTE: (patient days and device days) should be collected at the same time, every day, for each location performing surveillance to ensure that differing collection methods don't inadvertently result in device days being greater than patient days.* | | |
| WHERE? | CLABSI Surveillance Location | ***Ask where CLABSI surveillance should be conducted ??***<br>***CLABSI Surveillance is conducted in all Adult Critical Care Units where denominator data can be collected - Patient days & Central Line days***<br><br>*1: Adult Critical Care Units*<br>*2: Pediatric ICU (PICU)*<br>*3: Neonatal ICU (NICU)*<br><br>*(NOTE: Currently only critcal care units are included in HAI surveillance data reporting via electronic platforms)* | | |

| | | | | |
|---|---|---|---|---|
| WHO? | Targeted Patients | **1: Ask about targeted patients for CLABSI surveilalnce??**<br>Any patient admitted in Adult ICU. PICU, NICU who is on Central Line is cadidate for CLABSI Surveillance.<br>**2: What is CLABSI??**<br>Central line-associated BSI (CLABSI): A laboratory confirmed bloodstream infection where an eligible BSIorganism is identified, and an eligible central line is present on the LCBI DOE or the day before.<br>**3: What is eligible central line??**<br>A CL that has been in place for more than two consecutive calendar days (on or after CL Day 3), following the first access of the central line, in an inpatient location, during the current admission.<br>**4: What is an eligible organism??**<br>Any organism that is eligible for use to meet LCBI 1,2 or 3 criteria. In other words, an organism that is not an excluded pathogen for use in meeting LCBI criteria.<br>A common commensal identified in a single blood specimen is considered a contaminant. A single common commensal organism is not used to meet LCBI 2 or 3 criteria or secondary BSI attribution. | | |
| HOW? | CLABSI Surveillance Data Collection | **1: Ask how CLABSI Surveillance data is collected?**<br>ICPs must conduct active CLABSI surveillance from all surveillance locations included in Seha Platform.<br>***(Collect data as per criteria using manual data collection sheet or electronic data source)***<br><br>**2: Ask about Blood Specimen Collection protocols?"Two or more blood specimens drawn on separate occasions" criterion is met if there is blood collected from at least two separate blood draws on the same or consecutive calendar days.**<br>***2 sets must be collected -1 set for Aerobic Organisms & 1 set for anaerobic organisms (4 Bottles)***<br><br>NOTE: Important points for Blood Specimen Collection :<br>a: 1 Central Line & 1 Peripheral Line specimens are Acceptable for CLABSI determintaions<br>b: 2 Peripheral Line specimens are Acceptable CLABSI determintaions<br>c: Cather Tip Cultures are NOT Acceptable for CLABSI determintaions<br>*Blood specimens drawn through central lines can have a higher rate of contamination than blood specimens collected through peripheral venipuncture.However, all positive blood specimens, regardless of the site from which they are drawn or the purpose for which they arecollected, must be included when conducting in-plan CLABSI surveillance* | | |
| | Data Source for CLABSI | LCBI Criteria 1 :<br>**1: Microbiology lab results for recognized pathogens (Refer to CDC list of pathogens)**<br>***https://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx***<br>***2: Patient medical records to rule out possibility of infection at other site e.g UTI***<br><br>*LCBI Criteria 2:*<br>**1: Microbiology lab results for common commensals (2 matching organisms)**<br>**2: Patient medical records / patient charts for Signs & Symptoms -- fever (>38.0°C), chills, or hypotension**<br><br>LCBI Criteria 3 : **Patient ≤ 1 year of age**<br>**1: Microbiology lab results for common commensals (2 matching organisms)**<br>**2: Patient medical records / patient charts for Signs & Symptoms -- fever (>38.0oC), hypothermia (<36.0oC), apnea, or bradycardia** | | |

| | | | | |
|---|---|---|---|---|
| **B: Positive Culture Linelist & Internal Validation** | | | | |
| WHAT? | Line list Review | Is there any effective notification system between the IPC department, laboratory, and all departments in the hospital for any critical values (i.e MDROs, positive cultures & high-alert microorganisms). | | |
| | | Is there any updated linelist/logbook of all positive microbiological cultures that includes Patient information,Date of admission to hospital & unit, date of device insertion date of device removal , date of specimen collection, type of organism, sings & symptoms etc | | |
| | | Internal validation done to review data for candidate CLABSI in Adult, pediatric & Neonatal Locations. | | |
| | | Internal validation done to review denominator data - 3 consecutive months | | |
| | | Possiblity of Outbreak ruled out - No epidemiological link between cases reported from same location in same time frame. | | |
| **C: CLABSI Events Idetification & Reporting** | | | | |
| WHAT? | Data Analysis & Event reporting | Number of CLABSI Events correctly identified as per CDC-NHSN Criteria | | |
| | | Number of CLABSI events matching CDC criteria that were missied by ICP and were detected during visit. | | |
| | | Number of correctly idetified CLABSI Events reported Via seha platform in a timely mannner. | | |
| | | Number of CLABSI events as per manual sheet are 100% matching with *Seha Platform & Power BI dashboard* | | |

| D: CLABSI Surveillance Data Entry Via Seha Platform | | | | |
|---|---|---|---|---|
| WHAT? | Electronic Platforms | All patients admitted in critical care units are registered in Seha Platform with or without devices. | | |
| | | Central Line Device information is entered accurately for all patients on central Line and required central Line bundle form is filled. | | |
| | | Number of patients currently admitted in Adult ICUs, PICUs & NICUs is 100% matching with Seha platform on day of visit. | | |
| **E: HAI Outbreak Detection & Reporting (ESCKAPE-C)** | | | | |
| WHAT? | Outbreak Detetction Reporting | Outbreak was detected correctly as per latest GDIPC updates (version 7.2 Jan 2025) | | |
| | | Outbreak was reported in a timely manner via electronic Platform | | |
| | | An outbreak was missed which was detetced during visit as per linelist *(Device associated (Central Line) or non device associated)* | | |
| **F: Neonatal CLABSI Reduction Strategy Implementation (NCRS)** | | | | |
| WHAT? | NCRS Tools (Knowledge & Practices) | Assess staff knowledge about Natioanal VAE Reduction Strategy. (NVRS) | | |
| | | Ask about the NVRS prevention tools & their implementation (Adult & Ped VAE Location) | | |
| | | Compare the actual complaince data Vs data submitted each month - observe any discrepency. | | |
| **PART II : On Site Visit - Validation Rounds (Adult ICU, PICU, NICU)** | | | | |
| WHAT? | IC Rounds | Conduct rounds in adult ICU, PICU & NICU & ensure care bundles & prevention tools are applied. | | |
| | | Assess staff knowledge about central Line insertion & maintenance bundles. | | |
| | | Assess staff knowledge and awareness about NCRS prevention tools. (NICU) | | |
| **PART III (Education & Training Session)** | | | | |
| WHAT? | CLABSI Surveillance Education & Training | External Validator conducted short concluding training & education session ?? | | |
| | | CLABSI Surveillance Protocols based on CDC-NHSN<br>Central Line Insertion Bundle<br>Central Line Maintenance Bundle<br>NCRS Tools overview | | |
| WHO? | | Targeted Audience:<br>Infection Control Team<br>Nursing representatives /Staff from Adult ICUs, PICUs, NICUs | | |

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# HAI Surveillance & Outbreak Validation
## CLABSI Validation Summary Report

| Facility Validation Overview | | | | |
|---|---|---|---|---|
| Facility Name: | | | | |
| Facility Type: | Governmental (MOH) ☐ | | Private ☐ | |
| Facility Selection Method (Reason) | | | | |
| Date of Visit: | | | | |
| Time of Visit: | Start Time: | | End Time: | |
| Name of Validator | | | | |

| Numerator Validation<br>Number of CLABSI/s | | | | |
|---|---|---|---|---|
| Elements reviewed for validation | – Positive Blood Culture (PBC) line list<br>– Specific medical records | | | |
| Type of Event | Total # CLABSI/s reported via SEHA platform *(before validation)* | Number of CLABSI/s correctly Identified & reported via HESN-Plus | Missed, Undetected CLABSI/s that were meeting criteria. | Over identification / wrong identification of CLABSI/s not matching criteria |
| CLABSI (AICUs) | | | | |
| CLABSI (PICU) | | | | |
| CLABSI (NICU) | | | | |
| Grand Total | | | | |

| Denominator Validation:<br>Central Line and Patient days for CLABSI | | | | |
|---|---|---|---|---|
| Denominator data collection method<br>(CL days & Patient days in all surveillance locations) | ☐ Manual counting:<br>☐ Electronic counting<br>☐ Both manual and electronic counting | | | |
| **Has this facility completed an internal validation of CLABSI in surveillance locations denominator data for this year? | ☐ Yes ☐ No | | | |
| Denominator Data Comparison | | | | |
| Surveillance Location | Manual Data | | Electronic Data (Power BI) | |
| Adult ICU | Patient Days : | | Patient Days : | |
| | Central Line Days: | | Central Line Days: | |
| Neonatal ICU (NICU) | Patient Days : | | Patient Days : | |
| | Central Line Days: | | Central Line Days: | |
| Pediatric ICU (PICU) | Patient Days : | | Patient Days : | |
| | Central Line Days: | | Central Line Days: | |

## Conclusion:

| Validation Outcome | | | | |
|---|---|---|---|---|
| Numerator Validation | Numerator manual data matching with electronic platforms - No further action neeeder.<br>All events correctly identified and reported. | Yes ☐<br>No ☐<br>N/A ☐ | Numerator manual data not matching with electronic platforms - Further action needed<br>CLABSI events were missed / unidentified. | Yes ☐<br>No ☐<br>N/A ☐ |
| Denominator Validation | Denominator manual data matching with electronic platforms<br>(within +-5% Tolerance interval)<br>No further action needed | Yes ☐<br>No ☐<br>N/A ☐ | Denominator manual data **NOT** matching with electronic platforms<br>(> +-5% Tolerance interval)<br>Further action needed | Yes ☐<br>No ☐<br>N/A ☐ |
| Outbreak Validation | Outbreak timely detected and Reported via electronic platforms. No further action needed. | Yes ☐<br>No ☐<br>N/A ☐ | An Outbreak was **missed / undetected** as per line list - Further action needed | Yes ☐<br>No ☐<br>N/A ☐ |

**Equation for calculating 5% tolerance interval is:**
**Manual Central Line Days count = 164**
**Electronic Central Line Days count = 178**
***Eligible 5% tolerance interval = [164±(164 X 5/100)] = 164 ± 8.2)***
***5% tolerance interval =155.8 to 172.2***
***Conclusion: Electronic count 178 falls outside the tolerance interval***

## References:


1) *2023NHSN Patient Safety External Validation Toolkit 2023 Data Validation Resources | NHSN | CDC https://www.cdc.gov/nhsn/pdfs/validation/2023/patient-safety-external-validation-toolkit-508.pdf*
2) *National Healthcare Safety Network (NHSN) Patient Safety Component Manual https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf*
3) *MOH HAI Surveillance Manual 2023 (2nd Edition) https://ipcksa.com/Surveillance-Department.html*
4) *https://www.cdc.gov/nhsn/pdfs/pscmanual/15locationsdescriptions_current.pdf*


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