وزارة الصحة
Ministry of Health

الإدارة العامة لمكافحة عدوى المنشآت الصحية

General Directorate of Infection Prevention and Control in Healthcare Facilities

(GDIPC)

Healthcare-Associated Infection Surveillance Data Validation Guidelines

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In the Name of ALLAH, Most Gracious, Most Merciful

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A. Introduction

Healthcare-associated infection (HAI) surveillance validation guidelines are a set of standards and procedures that can be used to assess the accuracy and completeness of HAI surveillance data. These guidelines are important because they ensure that the infection prevention priorities are set correctly and progress is accurately measured.

Validation means checking that data meets pre-determined specifications and quality standards. It assures high-quality data across three healthcare-associated infections (HAI) reporting domains: denominators, numerators, and risk adjustment variables.

The GDIPC Surveillance Program is offering HAI Surveillance Validation Guidelines to help assess the completeness of HAI case findings for different healthcare-associated infections such as CLABSI, CAUTI, VAE, SSIs, Dialysis Events, and MDRO.

Hospitals can benefit from the validation process in multiple ways. By assessing HAI case findings, hospital infection prevention program staff can review and refine their surveillance practices and correct reporting errors discovered during validation.

B. Purpose

HAI Surveillance Validation aims to ensure a systemic validation process to ensure accurate and reliable collected data for monitoring and preventing healthcare-associated infections.

C. Scope

These guidelines apply to all healthcare facilities and organizations involved in HAI surveillance activities.

D. Responsibilities

GDIPC Surveillance Coordinators, Regional, Cluster, and Hospital Surveillance Coordinators in all healthcare sectors.

E. General Principles for HAI Surveillance Validation

1. Validation should be conducted regularly. This will help to ensure that HAI surveillance data is consistently accurate and reliable.
2. Validation should be conducted by trained and expert personnel. This will help to ensure that validation activities are conducted effectively.
3. Validation should be focused on the surveillance process. This will help to avoid bias in the validation results.

F. Key Components of HAI Surveillance Validation

1. Visit: On-site visit to the targeted hospital/s for validation.
2. Data review: This involves reviewing medical files, records, laboratory results, and interviewing staff from other departments to ensure accurate identification and classification of HAI cases.
3. Feedback and recommendation: This involves providing feedback to healthcare staff on the results of surveillance validation activities.
4. Follow-up: Arrange a meeting or discussion with the relevant stakeholders to discuss the validation results and the action plan. This will allow for further clarification, collaboration, and agreement on the next steps.
5. Conduct post-follow-up evaluation: Once the follow-up actions have been completed, evaluate the effectiveness of the measures taken. Assess whether the issues have been resolved satisfactorily and if any further steps are required.

G. Categories by type of Validation

1. Internal Validation are active effort by a reporting facility to assure completeness and accuracy of data.
2. External Validation are survey and audit process by an external coordinator to ensure the quality of surveillance data and reporting.

H. Benefits of Internal and External Validation

1. Improved accuracy and completeness of HAI data: It can help to identify and correct errors in HAI data. This can lead to more accurate and complete data, which can be used to make better decisions about IPC practices.

2. Enhanced quality of IPC programs: It can help healthcare facilities identify areas where their IPC programs need improvement. This can lead to more effective IPC programs and improved patient outcomes.
3. Increased transparency and accountability: It can help to increase transparency and accountability in HAI surveillance. This can help to build trust with the public and stakeholders.
4. Impact on HAI rate reduction and provide recommendations for improvement.

I. Validation Process (GDIPC)

i. Roles of Coordinators in HESN Plus Data Entry

a. Hospital Surveillance Coordinator

1. Review the actual number of patients in ICU ***daily (at regular time).***
2. Enter the data of all ICU admitted patients in HESN (devices, events, bundles)
3. If not possible to enter patients in HESN on time, data entry of ICU patients must be done before the end of the shift.

b. Cluster Surveillance Coordinator

1. Monitor the Hospital HAI Surveillance Data entry in the HESN Plus ***daily.***
2. Review the data entry and compare (the actual number of patients in the ICU and the total number of patients entered in HESN Plus).
3. Share with the Regional Surveillance Coordinator the data validated per hospital in your region and the actions taken.
4. Follow up with the hospital coordinator/s for improvement in data entry.

c. Regional Surveillance Coordinator

1. Monitor the Hospital HAI Surveillance Data in the HESN dashboard ***daily.***
2. Review the validated data submitted by the Cluster Coordinator.
3. Compare (the actual number of patients in the ICU and the total number of patients entered in HESN Plus).
4. If the data entry in HESN Plus does not match the actual number, contact the Cluster Surveillance Coordinator and ask for action.
5. Share with GDIPC Surveillance the data validated per hospital in the region.
6. Follow up with the Cluster coordinator/s for improvement in data entry.

ii. When to validate Surveillance data based on HAI rates

a. Conditional Validation for High HAI Rates

1. For hospitals with High HAI rate/s for ***one month***, the ***Cluster Coordinator*** will investigate the issue by:
   - 1.1 Reviewing the submitted data including the previous months
   - 1.2 Calling the Hospital Surveillance Coordinator/s and asking the reasons behind the High HAI rates
   - 1.3 Giving recommendations to do an action plan to lower the HAI rates.
   - 1.4 Advising the hospital surveillance coordinator/s on
     - 1.4.1 The proper implementation of Prevention Tools Compliance to CLABSI, CAUTI, or other HAI.
     - 1.4.2 Provide re-education and training sessions as needed.
   - 1.5 Following up on the Implementation of the corrective action plan.

2. For hospitals with High HAI rates for ***two consecutive months***, the ***Regional and Cluster Coordinator*** will:
   - 2.1 Visit the healthcare facility
   - 2.2 Conduct root cause analysis
   - 2.3 Request for a corrective action plan
   - 2.4 Check for the Implementation of Prevention Tools Compliance to CLABSI, CAUTI, or other HAI.
   - 2.5 Conduct on-site (ICU) short education and training sessions if needed
   - 2.6 Submit a summary report to GDIPC
   - 2.7 Follow up on the implementation of the plan

3. For hospitals with High HAI Rates for ***three consecutive months***, ***GDIPC Surveillance Coordinators will:***
   - 3.1 Contact the Regional Coordinator
   - 3.2 Arrange a visit to the healthcare facility if required and do the following:
     - 3.2.1 Check and review the Line List of patients
     - 3.2.2 Check the Compliance with HAI Prevention Bundles
     - 3.2.3 Check the implementation of Prevention Tools Compliance to CLABSI, CAUTI, or other HAI.
     - 3.2.4 Conduct a meeting with the IPC department, regional coordinator, cluster coordinator, and healthcare facility leaders
     - 3.2.5 Prepare a summary report on the findings
     - 3.2.6 Share feedback to the concerned region
     - 3.2.7 Follow up on the implementation of the plan

b. Conditional Validation for Zero Reporting

1. For hospitals that report Zero HAI rates for ***one, two, or three consecutive months***, the ***Regional Coordinator*** will investigate the issue by:
   1.1 Contacting the ***cluster coordinator*** and the facility to conduct a thorough review of the data.
   1.2 Investigating the reasons behind the zero reporting such as problems in the system or inability to identify cases.
   1.3 Visiting hospitals with zero reporting for 2 months or more.
   1.4 Following the ***On-site visit validation process.***
   1.5 Preparing a corrective action plan to improve the data reporting process.
   1.6 Conducting short education and training sessions if necessary.
   1.7 Monitoring the implementation of the corrective action plan.

c. Routine Validation

1. Regional coordinators must have a scheduled routine validation visit in their Surveillance Program Plan.
   1.1 Regional Coordinator will do a routine validation visit to the hospital/s **Quarterly.**
   1.2 Review the hospital data entry in HESN Plus
   1.3 Compare the HESN Plus data with their manual data
   1.4 Compare denominator data (patient days, device days, number of surgeries, patient months in DE)
   1.5 Compare numerator data (numbers of CLABSI, CAUTI, VAE, SSI, DE, etc.)
   1.6 If there is more than a 5% difference between manual and HESN Plus data, ***contact the Cluster or Hospital IC Director*** and ask to Identify issues related to HAI Surveillance data entry and reporting in HESN Plus:
      1.6.1 Surveillance process check-up
      1.6.2 Availability of updated manual and educational materials
      1.6.3 Any need for training and HESN Plus
      1.6.4 Identify any technical challenges
      1.6.5 Identify any causes of low compliance in data entry
      1.6.6 Ask for a corrective action plan
      1.6.7 Monitor the improvement
      1.6.8 Submit a summary report of all validation done every 25th of the month after the quarter to the GDIPC Surveillance Program (ex. 1st quarter (Jan-March), submit on the 25th of April)
      1.6.9 Regular follow-up with hospitals to improve data entry

iii. Instructions for On-site Validation (HAI and Compliance Rates)

a. HAIs: CLABSI, CAUTI, VAE, MDRO

1. Prepare for validation
2. The hospital surveillance coordinator/s should prepare in advance the following:
   2.1 A Line list of all patients under surveillance with detailed positive cultures from the ICU during the requested period. This line list should include but not limited to:
   - 2.1.1 Month
   - 2.1.2 Bed no.
   - 2.1.3 ID/Medical Record Number (MRN)
   - 2.1.4 Patient name
   - 2.1.5 Gender/ Age
   - 2.1.6 Type of ICU
   - 2.1.7 ICU admission date
   - 2.1.8 Admission diagnosis
   - 2.1.9 Specify Signs and symptoms
   - 2.1.10 Date of symptoms
   - 2.1.11 Antibiotic use
   - 2.1.12 Worsening oxygenation
   - 2.1.13 Date of first worsening
   - 2.1.14 Purulent respiratory secretions
   - 2.1.15 Number of devices
   - 2.1.16 Types of devices inserted
   - 2.1.17 Date of insertion
   - 2.1.18 Date of removal
   - 2.1.19 Types of specimens
   - 2.1.20 Reason for specimens (screening or clinical decision)
   - 2.1.21 Date of specimen collection
   - 2.1.22 Organisms detected (***specify***) MDRO or others
   - 2.1.23 Current status (Discharged, transferred, referred, or death)
   - 2.1.24 Date of discharge, transfer, referral, death
   - 2.1.25 HAI (yes or no)
   - 2.1.26 Types of HAI
   - 2.1.27 Device-related HAI
   - 2.1.28 Date of event
   - 2.1.29 HAI by Criteria
   - 2.1.30 Reporting as HAI surveillance
   - 2.1.31 Comments
3. Randomly select 20 patients (from the line lists) to review including the identified events
4. Do a thorough data review of the selected 20 patients

5. Evaluate if HAI or event is identified or missed according to CDC/NHSN Definitions and Criteria
6. Complete the Surveillance Validation Reporting Form for 20 randomly selected patients including those with identified events (*Refer to the shared form*)
7. Prepare a summary report of the findings.
8. Submit a summary report with recommendations as feedback to the concerned region or hospital.
9. Request for an action plan for improvement if needed.
10. Schedule meetings with the concerned region/hospital to discuss the follow-up implementation of the plan

b. Surgical Site Infection (SSI)

1. Prepare for validation
2. Request the hospital surveillance coordinator/s to prepare in advance the following:
   - 2.1 Line lists of chosen surgical procedure/s reported in surveillance for the period requested from the Surgical Ward, ICU, Maternity Ward, and outpatient. This line list should include but not limited to:
     - 2.1.1 Month
     - 2.1.2 Ward/Unit
     - 2.1.3 Medical Record Number (MRN)
     - 2.1.4 Patient Name
     - 2.1.5 Gender/ Age
     - 2.1.6 Admission Diagnosis
     - 2.1.7 Date of operative procedure
     - 2.1.8 Name of Operative Procedure
     - 2.1.9 Type of Surgery
     - 2.1.10 Signs and symptoms
     - 2.1.11 Is it present at the time of surgery (PATOS)
     - 2.1.12 Date of specimen collection if taken
     - 2.1.13 Positive culture
     - 2.1.14 Name of microorganism
     - 2.1.15 Was it an SSI or not
     - 2.1.16 Date of Event
     - 2.1.17 Current status (discharge, transfer, referral, or death)
     - 2.1.18 Date of discharge, transfer, referral or death
     - 2.1.19 Comments
3. Identify the total number of patients who had the selected operative procedures in the period requested like quarter reports etc.
4. Randomly select 20 patients to review including the identified SSI events.
5. Do a retrospective data review of the selected 20 patients (***ask for medical records file***).

6. Evaluate if HAI was identified on or within 30 or 90 days post-operative procedure and according to CDC/NHSN Definitions and Criteria.
7. Check for the SSI Post Discharge Surveillance Process: how the facility follows the patients after discharge to detect SSI.
8. Complete the Surveillance Validation Reporting Form.
9. Submit a summary report with recommendations and feedback to the concerned hospital/s.

c. Dialysis Event (DE)

1. Prepare for validation.
2. Request a line list from the DE surveillance coordinator in the dialysis center to prepare in advance the following:
   2.1 A line listing of all dialysis patients who came into the center during the 1st and 2nd working days for the period requested. This line list should include but not limited to:
      2.1.1 Patient name and/or Medical Record Number (MRN)
      2.1.2 Gender/ Age
      2.1.3 Diagnosis
      2.1.4 Date of Dialysis procedure (***1st or 2nd working day of the month/s)***
      2.1.5 Type of vascular access
      2.1.6 Dialysis event identified or not
      2.1.7 Signs and symptoms
      2.1.8 Comments
3. Identify the total number of patients who came for dialysis during the 1st and 2nd working days of the months
4. Randomly select 20 patients to review including the identified events
5. Evaluate if DE was identified correctly according to CDC/NHSN Definitions and Criteria.
6. Complete the DE Surveillance Validation Reporting Form for the patients who had an event.
7. Submit a summary report with recommendations and feedback to the concerned center.

d. Compliance with HAI Prevention Tools

1. Prepare for validation
2. All HAI Prevention Tools Compliance Rates must be prepared in a file for review and separated for each type of HAI (CLABSI, CAUTI, VAE, SSI, MDRO, DE).
3. Review the compliance rates accordingly per type of HAI
4. Correlate the compliance rates with the corresponding HAI rates
   4.1 To identify any correlations or discrepancies.
   4.2 To determine the impact of compliance on infection rates.
   4.3 To identify areas that require improvement.
   4.4 Address gaps and barriers

5. If there are gaps or barriers to compliance, such as lack of resources or staff resistance, address them promptly. Provide additional training, resources, or support to overcome these challenges and improve compliance rates.

J. Conclusion

The validation guidelines of HAI Surveillance provide a comprehensive framework for ensuring the accuracy and reliability of surveillance systems in monitoring healthcare-associated infections (HAIs). These guidelines emphasize the importance of intensive validation processes, including data collection, analysis, and reporting, to ensure that surveillance systems effectively identify and track HAIs. By adhering to these guidelines, healthcare facilities can enhance patient safety, improve infection control practices, and ultimately reduce the incidence of HAIs.

Regularly review and update the HAI prevention tools and guidelines based on new research and emerging best practices. Continuously strive for improvement in both compliance rates and HAI rates. By coordinating compliance rates to HAI prevention tools and monitoring HAI rates, healthcare facilities can effectively identify areas for improvement, implement targeted interventions, and ultimately reduce the incidence of healthcare-associated infections.

K. References

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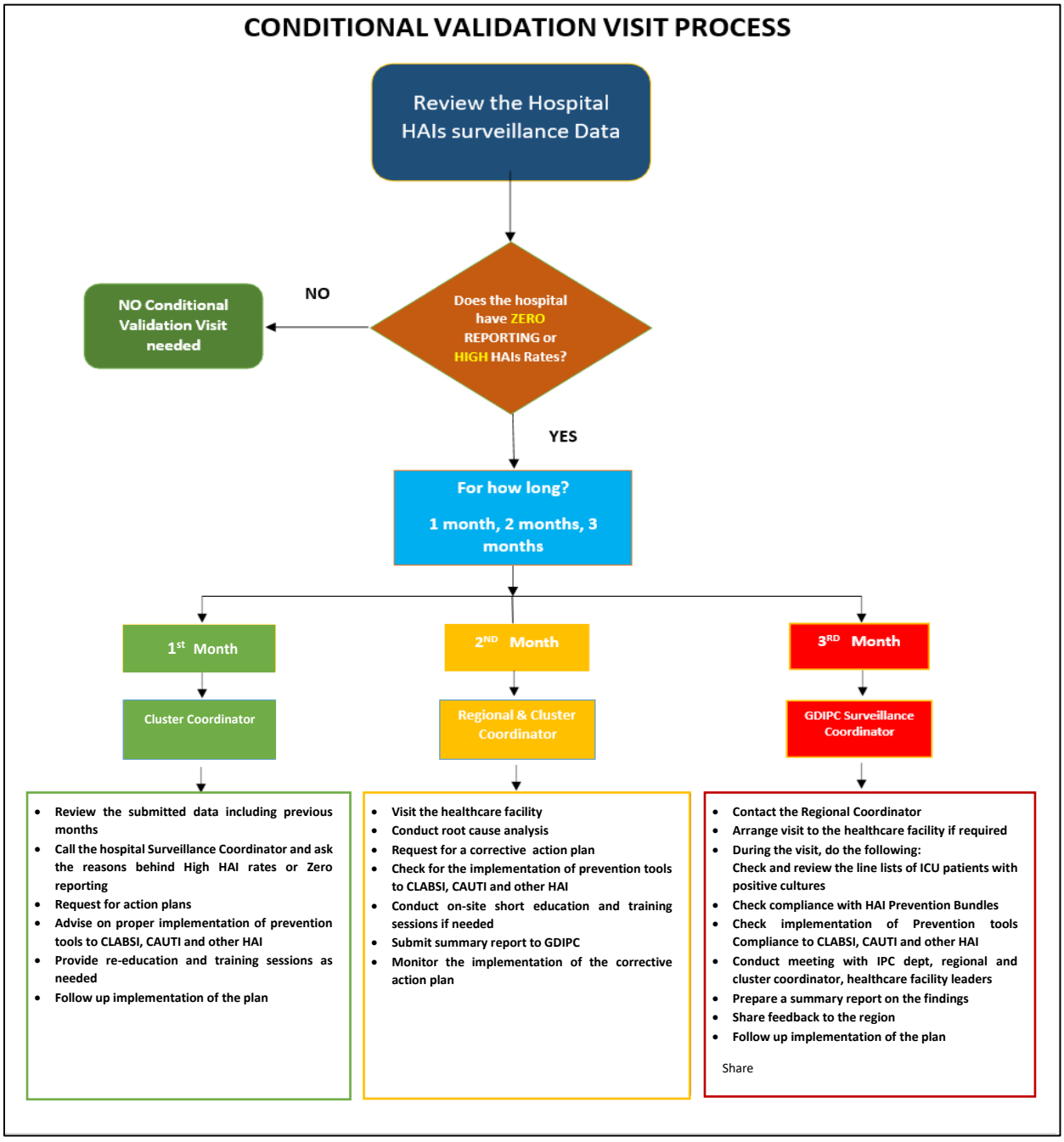
2. HAI Data Validation for Acute Care Hospitals August 2022, Healthcare-Associated Infections Program Center for Health Care Quality California Department of Public Health https://public.staging.cdph.ca.gov/Programs/CHCQ/HAI/CDPH%20Document%20Library/DataValidationACHWebinarAug2022.pdf
3. Australian Commission on Safety and Quality in Health Care (ACSQHC). Surveillance Validation Guide for healthcare-associated Staphylococcus aureus Bloodstream Infection. 2014.
4. World Health Organization (WHO). Guidelines for the Prevention and Control of Healthcare-Associated Infections. 2011.
5. Association for Professionals in Infection Control and Epidemiology (APIC). Guidelines for Infection Control Practice. 2023

L. Attachments

5.1.1 Flowchart of Conditional Validation Visit Process



5.1.2 Flowchart of Routine Validation Visit Process