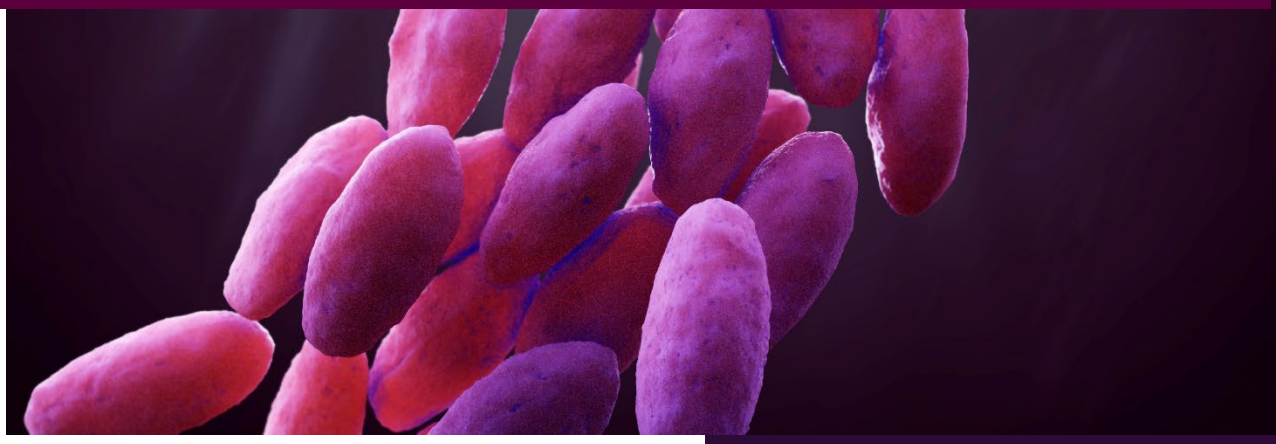
Carbapenem-Resistant Enterobacterales

Data Validation Toolkit for Hospitals



County of Los Angeles Public Health

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Background

The accuracy of data reported to public health authorities by healthcare professionals is vital to understand disease prevalence and transmission dynamics. In the case of carbapenem-resistant Enterobacterales (CRE) events reported to the National Healthcare Safety Network (NHSN) and shared with the Los Angeles County Department of Public Health (LAC DPH), these data are vital for healthcare facilities and public health professionals to understand the true rate and spread of CRE, as reflected by the consistency, completeness, and timeliness of reported CRE cases. Ensuring the precision of data instills confidence in users regarding the reliability of their facility's CRE data and countywide CRE trends. This toolkit is specifically tailored for infection preventionists, healthcare epidemiologists, and other data analysts in acute care hospitals, inpatient rehabilitation hospitals, and long-term acute care facilities engaged in reporting CRE data to NHSN. The toolkit outlines practices to ensure high-quality CRE surveillance data, ultimately enhancing patient safety and the effectiveness of infection prevention and control measures.

Data Validation Process Overview

The data validation process is not complicated but is expected to take several weeks as datasets are compiled, and individual events reviewed. A number of steps are required:

1. **Select a time period** of data that will be validated. Once the time frame is set, create an NHSN report that contains all submitted CRE cases.
2. **Generate two data sets.** One list is of all lab records of all positive CRE cases for the same time frame, which will be used as the "gold standard" And the other list will be your NHSN line list for reported CRE.
3. **Compare** the NHSN list to the lab line list and track correctly reported, missing, and incorrectly reported cases (see the methods section for more details on this process).
4. **Double check your results**. Have a second staff member repeat the comparison or have the same staff repeat the review if possible.
5. **Calculate accuracy**. In the validation form, calculate the number of correctly reported events and missed events. Use those numbers to determine the reporting sensitivity, or the proportion of true events that were reported correctly. Ideally the validation process would be conducted periodically and incorporated into broader infection prevention surveillance activities.

Now that we have discussed the conceptual framework, this toolkit will explain all of the validation steps in more detail in the guide below.

NHSN CRE definition:

> Any *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, or *Enterobacter* spp. demonstrating resistance to carbapenems by one or more of the following methods:
>
> > 1. Resistant to imipenem, meropenem, doripenem, or ertapenem by standard susceptibility testing methods (i.e., minimum inhibitory concentrations of ≥4 mcg/mL for doripenem, imipenem and meropenem or ≥2 mcg/mL for ertapenem); OR

2. Production of a carbapenemase (e.g., KPC, NDM, VIM, IMP, OXA-48) demonstrated using a recognized test (e.g., polymerase chain reaction (PCR), metallo-β-lactamase test, modified Hodge test, Carba-NP, Carbapenem Inhibition Method (CIM)).

Step-by-Step Instructions

1. **Select a Time Period**. To initiate the validation effort, establish a specific time frame. To account for variation in reporting and trends, a validation time frame of one year is ideal, but any length of time may be selected as long as it is after the start of routine reporting to NHSN which was mandated by LAC DPH in 2017.
2. **Generate two datasets:** 1) a line list of CRE instances as recorded in NHSN (please see *Appendix B* for step-by-step screen shots on this process), and 2) a comprehensive laboratory list encompassing all positive CRE cases (per the NHSN definition below) among inpatients at your facility collected within the validation timeframe. The latter is considered the gold standard, representing the correct cases for reference. The line list of all CRE cases will likely need to be compiled in coordination with your facility's microbiology laboratory. To note, to account for lag in reporting into NHSN, which is due to many factors (i.e., testing timelines), the reporting data should be at least two months prior to the current date.
    a. Utilizing the designated form found in *Appendix A*, enter each positive result from the CRE lab list onto separate lines.
3. **Compare** each individual case to the NHSN dataset once all lab cases are within the form.
    a. You will either determine if the lab case was reported to NHSN (Yes) or not reported into NHSN (No).
    b. If reported yes, you will have to determine if it was reported correctly or not. Although the focus is validating if a CRE case is reported correctly, it is highly recommended to review other variables such as date of specimen collection, organism name, patient location, race/ethnicity, and any relevant factors to your organization.
    c. If you select "no", determine if it was not reported due to "Did not meet NSHN definition or duplicate" or "MISSED -Should have been reported". Please review the NHSN definition of CRE above to ensure you are capturing the correct cases.
4. **Double check your results**. Following the comprehensive evaluation of all lab cases, ensure the validation project's integrity by either having another individual independently review the results or conducting a reevaluation with the same individual. This step is essential to ensuring inter-rater reliability throughout the validation process. If any errors or inaccuracies are identified, promptly submit missing cases to NHSN and rectify any erroneously reported cases.
5. **Calculate your reporting accuracy** by calculating the sensitivity, or the probability of a positive test result conditioned on the individual being truly positive.
    a. To calculate sensitivity, divide the number of true positive results (where both the hospital lab result and NHSN lab result agreed, labeled as "A" in the CRE validation form) by the sum of true positive and false negative cases (cases that should have been reported but were not, labeled as "B" in the CRE validation form).

        Sensitivity = A / (A + B)

    b. A high sensitivity indicates a low rate of false negatives, signifying accurate reporting to NHSN.

6. Upon completion of the validation process, effectuate necessary changes in NHSN. Add any missing cases and remove inaccurately reported cases to ensure the utmost accuracy and reliability in CRE reporting. Consider conducting a gap analysis to identify the root cause of reporting gaps.

Using Validation Results

Validation results can be shared with your facility's infection prevention committee, laboratory staff, and persons responsible for reporting in NHSN.

If the calculated sensitivity is below 90%, facilities should review their NHSN reporting process to identify root causes of poor reporting. Quality improvement tools are recommended to perform this review. This may lead to changes in how communication between the laboratory and infection prevention team is conducted, who is responsible for reporting in NHSN, and reporting protocol changes.

It is recommended that facilities conduct validation for CRE and other HAI reporting routinely, and detail validation plans in the infection prevention plan. Within this annual validation plan, thorough detailing is crucial. It should encompass the frequency and types of data quality checks, providing a clear roadmap for the ongoing assessment of data accuracy. Equally vital is the identification of individuals that should carry out validation. This ensures accountability and a streamlined approach to maintaining the integrity of CRE data throughout the year.

Contact

For questions about this validation toolkit, contact hai@ph.lacounty.gov.

Appendices

Appendix A: CRE Validation Form

CRE Validation Form

Instructions

1. From the lab line list, enter each positive CRE specimen onto a separate line, filling in the specimen collection date and hospital unit at time of specimen collection.

2. Generate a line list of CRE LabID Events in NHSN reported by your hospital from for the validation review period.

3. For each numbered specimen, answer Q1 by referring to your NHSN line list. For CRE cases reported to NHSN, record NHSN Event #.

4. For each specimen NOT reported to NHSN, indicate reason why in the appropriate column. If case should have been reported but was not, record as missed. Review the reason for the missed event.

5. For each specimen reported to NHSN, verify if case met the LabID reporting criteria. If no, review the reason why it was incorrectly reported. If yes, CRE LabID criteria met, compare specimen date, admission, and location as reported on NHSN line list to the same info in the medical record. Verify accuracy.

6. Sum the columns and calculate your percentage of CRE validation on the summary of findings table.

7. **When the review is complete, please make all necessary corrections to your data in NHSN.**

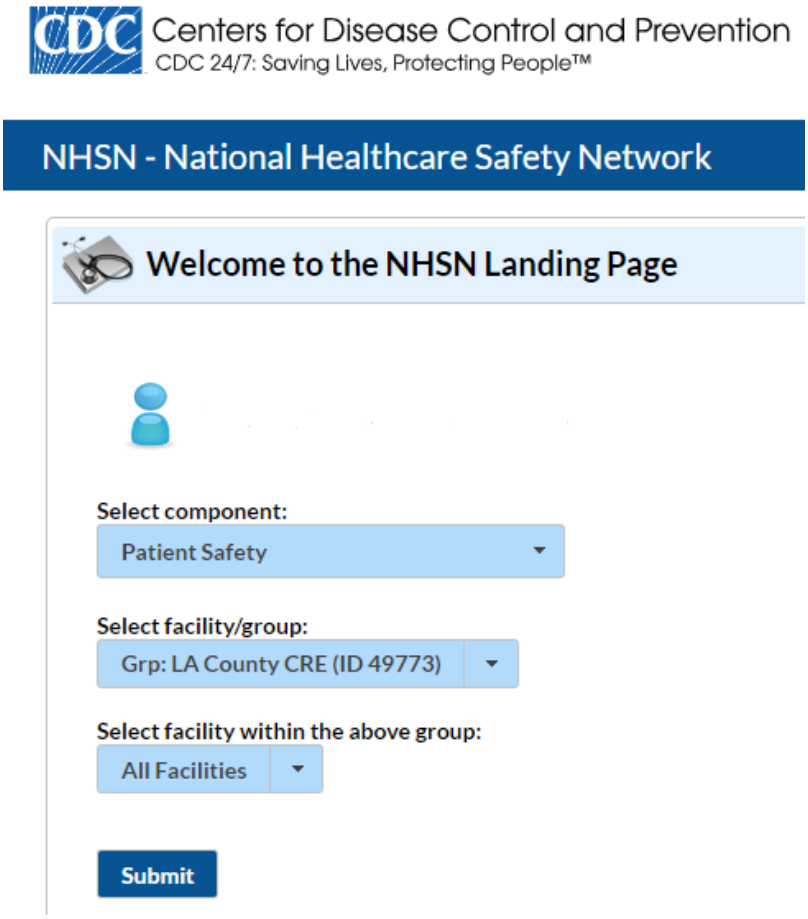
CRE Validation Form

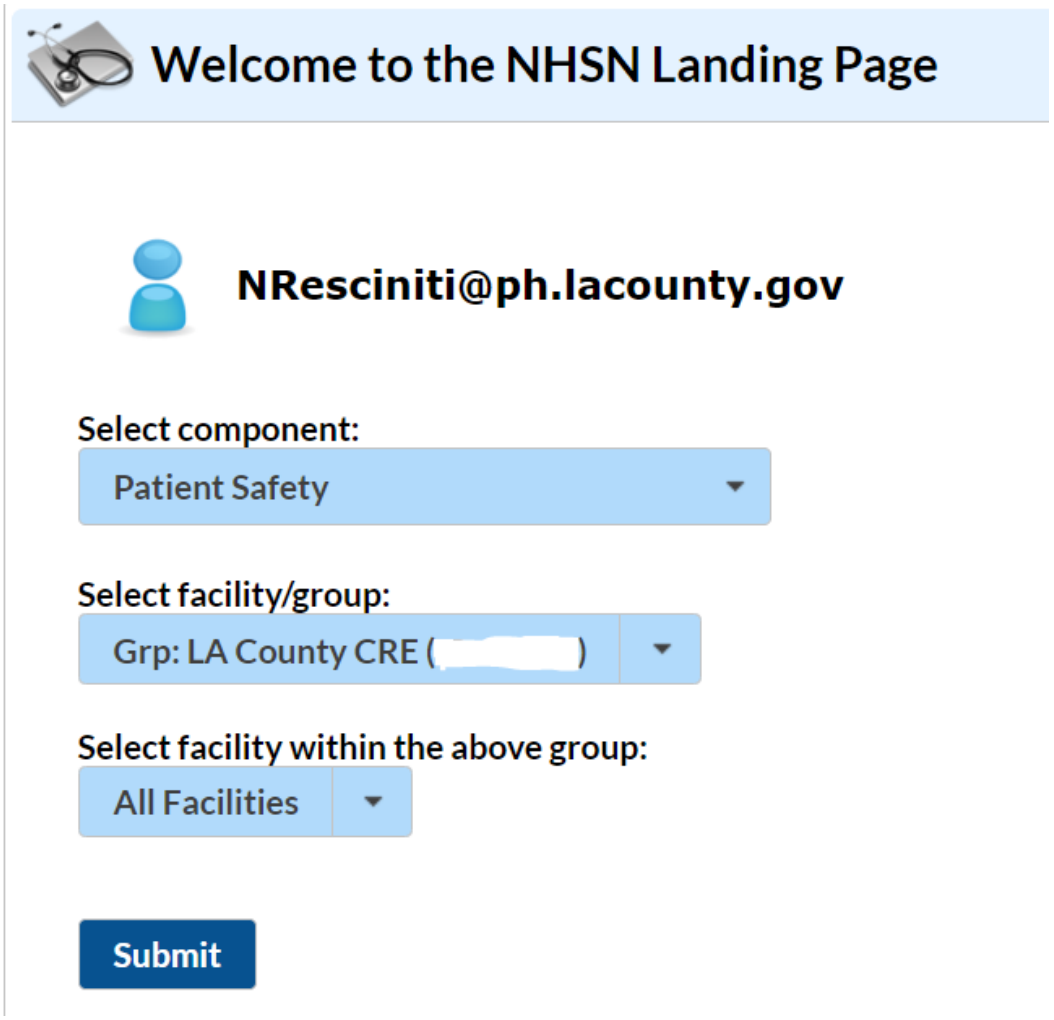
Lab List No.	CRE specimen collection date:	Admit date:	Unit at time of specimen collection:	Q1. Was the CRE Event reported to NHSN?			If Q1 answer is NO, complete this section		If Q1 answer is YES but event was reported in ERROR, complete this section: Does not meet inpatient Lab ID criteria:	If Q1 answer is YES and event was **Reported Correctly**, check box below:
				Yes	NHSN Event #	**No**	Did not meet NSHN definition or duplicate:	**MISSED** Should have been reported:		
C1				☐		☐	☐	☐	☐	☐
C2				☐		☐	☐	☐	☐	☐
C3				☐		☐	☐	☐	☐	☐
C4				☐		☐	☐	☐	☐	☐
C5				☐		☐	☐	☐	☐	☐
C6				☐		☐	☐	☐	☐	☐
C7				☐		☐	☐	☐	☐	☐
C8				☐		☐	☐	☐	☐	☐
C9				☐		☐	☐	☐	☐	☐
C10				☐		☐	☐	☐	☐	☐
C11				☐		☐	☐	☐	☐	☐
C12				☐		☐	☐	☐	☐	☐
C13				☐		☐	☐	☐	☐	☐
C14				☐		☐	☐	☐	☐	☐
C15				☐		☐	☐	☐	☐	☐
C16				☐		☐	☐	☐	☐	☐
C17				☐		☐	☐	☐	☐	☐
C18				☐		☐	☐	☐	☐	☐
C19				☐		☐	☐	☐	☐	☐
C20				☐		☐	☐	☐	☐	☐
							Total Missed	A:	Total Correct	B:

Appendix B: Instructions for Creating the NHSN CRE Line List

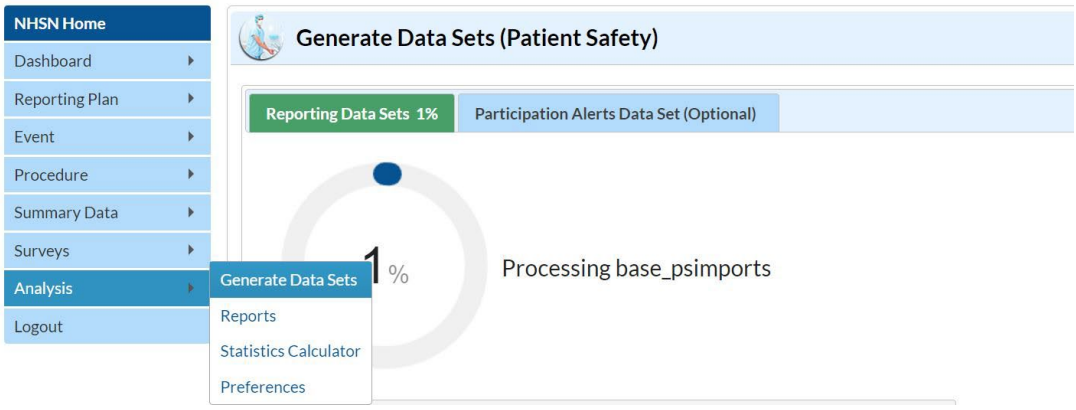
Instructions for Creating the NHSN CRE Line List

Step 1. Select the appropriate component and facility.





Step 2. Generate a new data set that at least includes your validation timeframe.



Step 3. Use the Analysis button on the Navigation bar and select "Reports" to export the data. For more information about how to make modifications to these output options, read "How to Modify a Report" found in the NHSN Analysis Quick Reference Guide library at: http://www.cdc.gov/nhsn/PS-Analysis-resources/reference-guides.html.

Select "HAI Detailed Reports (Line Lists, Rate Tables, etc.)" > "MDRO/CDI Module – LABID Events" > "All CRE LabID Events" > "List Listing for All CRE LabID Events" > "Modify Report".

Suggested Modifications:

- Change the output title to desired file name.
- Select Excel (.xls) or desired format.
- Select "Time Period" and use the drop-down box to set eventDate to validation time period.