AU Validation Plan
Overview

- **Purpose and Scope**
- **Acronym and Definition**
- **Verification vs Validation**
- **Prerequisites**
- **Overall Report Validation**
  - Denominator Validation
  - Numerator Validation
- **CDA and NHSN Validation Steps**
- **Reviewing an NHSN CDA Document**
- **Estimated Level of Effort**
- **Reference**
Purpose and Scope

• This document helps validate and verify data before submission for NHSN AU reporting. It focuses on verifying the calculation algorithms used for counting Days Present and Days of Therapy and validating the format of the report.
• The plan targets the primary points where most data errors occur. It is not a comprehensive validation of all data.
• For a comprehensive validation, refer to the NHSN AU Validation Plan document.
• Intended audience: Staff responsible for reporting AU data to NHSN
Timeline Estimate

**Prerequisites**
- Variable (est. 4 hr.)
  - **Goal:** Acquire raw data access and sample CDA outputs to perform verification.

**Denominator**
- 2 hr.
  - **Goal:** Review patients’ location data.

**Numerator**
- 2 hr.
  - **Goal:** Review antimicrobial administrations. Ensure the therapy day counts add up.

**CDA and NHSN**
- 1 – 5 hr.
  - **Goal:** Obtain zero CDA and NHSN upload errors on submission.
Acronyms and Definitions

• **CDA** – Clinical Document Architecture, an XML-based file format required for AU reports
• **FacWideIn** – Facility Wide Inpatient, a single, all-encompassing location that represents the entire inpatient setting of an AU report
• **Days of Therapy** – Total days of exposure for a specific antimicrobial agent
• **Days Present** – The number of patients present in an inpatient location within the facility for any portion of each day of a calendar month
• **Admission Count** – Aggregate number of patients admitted to an inpatient location within the facility
Validation vs. Verification

The terms “validation” and “verification” are often used interchangeably. This document distinguishes these words as follows.

Validation:
Ensure the report format and structure is correct.

Verification:
Ensure the information found within the report is accurate.
Manual Verification Prerequisites

- NHSN AU reports contain:
  - Days of Therapy count
  - Days Present count

- Reviewer gets exports from:
  - eMAR/BCMA, which contain:
    - Administration time and date
    - Antimicrobial administered
    - Route of Administration
    - Location of Administration
    - Patient information
  - ADT, which contain:
    - Patient Information
    - Location of admission, transfer or discharge
    - Time and Date of A/D/T
Sanity Checks

- Raw data extract is from the same reporting period as the report being verified
Overall Report Validation

One CDA file per location

AU Reporting requires one CDA file per location.

CDA file contains both the Days Present Count and the Days of Therapy Counts

A valid AU report contains both counts for inpatient locations.

(Instruction to review an NHSN CDA File)

AU Report must be a valid CDA File

CDA File must validate against the NHSN formatting rules.
Denominator Verification

Denominator Section must contain Days Present (and Admission Count if FacWideIn report)

Confirm **Days Present and Admission Count** are present in the denominator.

Validate accuracy of the Days Present count for Inpatient Locations

Manually verify the accuracy of the days present count with data from specific locations (**see next slide**).

Validate accuracy of the Days Present count for FacWideIn Locations

Manually verify the accuracy of the days present count using data from the entire facility.*

*Verifying the days present count using data from the entire facility will require separate queries.
Days Present Verification – Inpatient Location Report

1. Select a location that has a low Days Present Count (i.e., ~50-100).

2. Extract admissions, discharge, and transfer one month of data from ADT system for this location.

3. For each unique patient, count the number of days the patient was present in the location.

4. Aggregate the count of days present for each patient. This count represents the days present for the location.

5. Compare the count from step 4 and the count in the AU report for the month.
Numerator Verification

All 90 Antimicrobials are reported in the AU report

The AU report contains data for 90 Antimicrobials, regardless of whether it appeared that month.

(Instruction to review an NHSN CDA File)

Antimicrobial Days of Therapy are stratified by route

Confirm that Days of Therapy are aggregated by four routes: Intravascular, Intramuscular, Digestive, and Respiratory.

(Instruction to review an NHSN CDA File)

Antimicrobial Days of Therapy aggregate count

The AU report includes a count of aggregate days in therapy for each antimicrobial listed.
Days of Therapy Verification – Inpatient Location Report

1. Select a combination of an antimicrobial and a location so the Days of Therapy count patient flow are low.
2. Count the number of unique days of administration of the antimicrobial for each patient, regardless of route. This is the aggregate days of therapy for the chosen antimicrobial.
3. Compare the count in step 2 and the aggregate Days of therapy count for this antimicrobial in the AU report.
4. Repeat Steps 2 and 3 for each valid route of administration for the drug.
5. Check for unusual routes of administration (e.g., Vancomycin digestive includes rectal administration in rare cases when used at your facility).
6. Confirm appropriate use of N/A vs. 0 in therapy day counts:
   - “zero” should be reported when no aggregate usage occurred during a given reporting period for a specific antimicrobial agent/route.
   - “NA” (Not Applicable) should be reported when data are not available for a specific antimicrobial agent/route at a facility (i.e., the agent can’t be electronically captured at that facility).
   - A value (i.e., “zero”, a specific number, or “NA”) must be reported for every antimicrobial agent and route of administration.
Days of Therapy Verification – FacWideIn Report

1. Select an antimicrobial with a low Days of Therapy count for facility wide inpatient locations.

2. For each patient, count the unique days the facility administered the antimicrobial, regardless of location. The total count of unique days of administration is the aggregate days of therapy count for that antimicrobial.

3. Compare the count from step 2 and the FacWideIn Days of Therapy count in the AU Report.

4. Repeat Steps 2 and 3 for each valid route of administration for the antimicrobial.
FacWideIn Common Errors

• The FacWideIn count is not the sum of the individual location counts of days present and days of therapy.

• If the FacWideIn Counts are equal to the sum of the individual location counts, you may find a bug—especially for patient transfers within the hospital in that month.

• FacWideIn counts can never exceed the sum of all inpatient location counts.
Validation Quick Checks

• The Days Present Count for any location cannot be less than the Days of Therapy count.

• The days present count in an AU report is almost always higher than the patient days count in other HAI reports. If they are equal, review the calculation algorithm.
Fallback: No eMAR/BCMA Report

• For those who can’t create a hospital based eMAR report, manually confirm eMAR/BCMA through the EMR of individual patients.

• Use ten patients per patient care location in three separate patient care locations.

• When comparing the AU report and the eMAR/BCMA report, manually verify whether the antimicrobials administered and routes of administration are identical for each location per calendar day during the specified validation time period (source).
Reviewing an NHSN CDA Document

• Review NHSN CDA files in a browser using “hai-display.xsl”.
• Associate .XSL File within the CDA document.
Reviewing an NHSN CDA Document

• Right-Click the XML file associated with the stylesheet.
• Select “Open With” and select a web browser.
# Reviewing an NHSN CDA Document

## Antimicrobial Use, Pharmacy Option (AUP) Summary Report

<table>
<thead>
<tr>
<th>Document Id</th>
<th>20202201 (2.16.840.1.113883.3.117.1.1.5.2.1.1.2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document Created</td>
<td>July 1, 2008</td>
</tr>
<tr>
<td>Case</td>
<td>Summary data reporting antimicrobial usage from June 1, 2008 to June 30, 2008</td>
</tr>
<tr>
<td>Author</td>
<td>aSoftwareID (2.16.840.1.113883.3.117.1.1.5.2.1.1)</td>
</tr>
<tr>
<td>Document maintained by</td>
<td>2.16.840.1.114222.4.3.2.11</td>
</tr>
<tr>
<td>Encounter Location</td>
<td>2.16.840.1.113883.3.117.1.1.5.1.1</td>
</tr>
<tr>
<td>Legal authenticator</td>
<td>aLegalAuthenticatorID (2.16.840.1.113883.3.117.1.1.5.1.1.2)</td>
</tr>
<tr>
<td>Signed date/time:</td>
<td>July 1, 2008</td>
</tr>
</tbody>
</table>

## Summary Data

<table>
<thead>
<tr>
<th>Location</th>
<th>Antimicrobial Ingredient</th>
<th>Route</th>
<th>Number of therapy days</th>
</tr>
</thead>
<tbody>
<tr>
<td>9W Medical/Surgical critical care unit</td>
<td>Penicillin G</td>
<td>Aggregate - n/a</td>
<td>6 d</td>
</tr>
<tr>
<td>9W Medical/Surgical critical care unit</td>
<td>Penicillin G</td>
<td>Respiratory tract route</td>
<td>0 d</td>
</tr>
<tr>
<td>9W Medical/Surgical critical care unit</td>
<td>Penicillin G</td>
<td>Digestive tract route</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>9W Medical/Surgical critical care unit</td>
<td>Penicillin G</td>
<td>Intravenous route [An intravascular route that begins with a vein.]</td>
<td>3 d</td>
</tr>
<tr>
<td>9W Medical/Surgical critical care unit</td>
<td>Penicillin G</td>
<td>Intramuscular route [A route that begins within a muscle.]</td>
<td>3 d</td>
</tr>
<tr>
<td>9W Medical/Surgical critical care unit</td>
<td>Amikacin</td>
<td>Aggregate - n/a</td>
<td>6 d</td>
</tr>
<tr>
<td>9W Medical/Surgical critical care unit</td>
<td>Amikacin</td>
<td>Respiratory tract route</td>
<td>0 d</td>
</tr>
<tr>
<td>9W Medical/Surgical critical care unit</td>
<td>Amikacin</td>
<td>Digestive tract route</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>
Validate CDA Files

• Use the Lantana Group online validator: http://lantanagroup.com/validator/

• Ensure no PHI:

Choose the CDA file you wish to validate

Select the HAI/Normative R1 option

Click to Validate

Validate this file
Uploading to NHSN: Common Errors

• NHSN will not allow multiple files from the same location in the same reporting period.
  Remove files from NHSN when performing multiple test uploads within the same reporting period.

• NHSN does not recognize Facility identifier
  Ensure the Facility OID is submitting CDA documents to NHSN. NHSN assigns Facility OIDs, which are different than FacilityIDs.
Reference
Additional Resources

- **NHSN Video Explaining AUR Option**
  - Explains data elements
  - Describes available analysis reports
  - Reviews requirements for participation in NHSN AUR

- **Antimicrobial Use ToolKit**
  - Contains all supporting information for AU implementation

- **NHSN HAI CDA Implementation Guide**
  - Contains technical guidance on the structure of an CDA-based AU report

- **Comprehensive Verification Plan**
  - Detailed checklist that records issues and resolutions
## Key Data Elements

<table>
<thead>
<tr>
<th>Data Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility OID</td>
<td>Identifier assigned to facility, included in the importation file prior to submission. Visit the <a href="https://cda-submit.orscalifornia.gov/">CDA Submission Support Portal</a> for more information on how to obtain an OID for your facility.</td>
</tr>
<tr>
<td>Month/Year</td>
<td>2-digit month / 4-digit year representing the data collection period</td>
</tr>
<tr>
<td>Location</td>
<td>Patient care location</td>
</tr>
<tr>
<td>Numerator: Antimicrobial days/month per location</td>
<td>Total sum of the days of exposure for a specific antimicrobial agent. These are required from the electronic medication administration record (eMAR) and/or bar coding medication record (BCMA). Measures antimicrobial days for select agents, stratified by route of administration.</td>
</tr>
</tbody>
</table>
# Key Data Elements – Denominator

<table>
<thead>
<tr>
<th>Data Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days Present</td>
<td>Risk for antimicrobial exposure per time unit of analysis stratified by location. For patient care location-specific analyses, the days present count represents the number of patients present for any portion of each day of a calendar month for a patient care location. For facility-wide inpatient analyses, the days present count is the number of patients present in an inpatient location within the facility for any portion of each day of a calendar month.</td>
</tr>
<tr>
<td>Admissions</td>
<td>Aggregate number of patients admitted to an inpatient location within the facility (i.e., facility-wide inpatient) starting on first day of each calendar month through the last day of the calendar month. In the AU Option, admissions only cover facility-wide inpatient.</td>
</tr>
</tbody>
</table>