Table of Contents

1. Overview 1
2. Description of Synthetic Data Sets 2
3. Synthetic BCMA data 4
   3.1. BCMA Data Table 4
   3.2. Route of Administration Mapping Table 4
   3.3. BCMA to NHSN Drug Ingredient Mapping Tables 5
4. Synthetic ADT data 5
   4.1. ADT Format 1 – ADT Movement Table 5
   4.2. ADT Format 2 – Transfer In-Out Table 6
   4.3. ADT Location Type Mapping Tables 6
5. Monthly Aggregate Data to be generated by the Participant 6
   5.1. Negative Test Cases 9
   5.2. Numerator Data 9
   5.3. FACWIDEIN 9
   5.4. Denominator Data 9
   5.5. Representation of NULL values in Output Data 10
6. Validation Methods 10
7. Questions from Vendors 11
8. Change Log 12

1. Overview

The goal of this AU validation project using synthetic data is to ensure vendor software are correctly aggregating ADT and Medication Administration data according to the NHSN AUR Module Protocol - AU Option[1]. Software must aggregate data in a semi-additive way, necessitating close attention to detail for the medication, route-of-administration, and location.

Note that mapping local codes to standard terminologies described in the protocol is not part of this exercise. These are already done and provided in various mapping tables for drug ingredients, routes of administration and location types. To preclude vendors from doing their own mappings, simulated local drugs are given sequential numbers (for example, drug 1, drug 2, etc.) instead of real drug ingredient names.

[1] NHSN AUR Module Protocol - AU Option: https://www.cdc.gov/nhsn/pdfs/pscmanual/11pscaurcurrent.pdf

Numerator data consist of Antimicrobial Days stratified by four different routes of administration, as well as aggregated together for all four routes. Denominator data consist of the number of admissions reported at the facility-wide inpatient level, and patient Days Present reported at both the facility-wide inpatient and unit location levels.

To assist the vendors in this process, the VA Informatics, Decision-Enhancement and Analytic Sciences (IDEAS 2.0) Center created a synthetic data set using a mathematical simulation. The synthetic data set is comprised of antimicrobial administrations in a simulated facility's units for 12 complete months in 2019. Some patient admissions may cross over into the previous or following years and we expect vendor software to exclude these from the final SDS file submission. We provide the source data set for this validation project in two different formats – comma-separated text files (CSV format) and MySQL database export.

After obtaining the synthetic data set, the vendors should load it into their database and process it just as they would their own real data, generating monthly summary data for the facility-wide inpatient (FACWIDEIN) and eligible locations for each month in tabular file format. Vendors can upload their monthly summary data in Microsoft Excel (2007 or later, .xlsx) format to the NHSN SDS Validation Web Service. The web application developed by the CDC NHSN Team for validation, will return the validation results which will consist of feedback on incorrect rows with descriptions and possible reasons for the errors. The NHSN SDS Validation Web Service URL is: https://nhsnpilot.ng.philab.cdc.gov/AUValidation-Production/home.html.

2. Description of Synthetic Data Sets

The synthetic data set consists of structured data from a simulated facility. Synthetic ADT and BCMA tables contain data using the local terminology of the simulated facility. Vendors do not need to map entries to standard terminologies as per NHSN; they will only need to implement the included mapping tables. All timestamps are in the local time zone of the test facility and time zone conversions are not required. We provide an Entity Relationship Diagram in Figure 1.

For convenience of the vendors, an empty table (`monthlysummaryauoutputdata`) demonstrating the data structure used for submission to the NHSN SDS Validation Web Service is included. Vendors will need to generate aggregated data following this structure in Excel (.xlsx) format to submit to the web application.

A full list of fields, their data types, whether they are required or optional (required fields denoted by 'NN', meaning 'NOT NULL'), primary keys, and foreign key relationships are shown in Figure 1 as well as the MySQL database export. Vendors are provided with all tables in Figure 1 but they will need to generate the content of `monthlysummaryauoutputdata`

Figure 1 Entity relationship diagram of AU synthetic data set

3. Synthetic BCMA data

The BCMA records provide both the timestamp and the corresponding unit identifier for each medication administration record. We have simplified the data sets to provide only the pertinent data necessary for the AU Option. The synthetic BCMA data tables contain the local drug codes and drug names. The mapping tables provide mapping between the local drug codes and the standard RxNorm or cdcNHSN drug codes. These mappings illustrate how a single drug ingredient may be represented in multiple ways in the local terminologies of homegrown or vendor systems. Vendors will need to join the medication administration table with the drug ingredient and medication route mapping tables to generate monthly summary output data.

3.1. BCMA Data Table

The synthetic BCMA data (`medicationadministration`) table includes the following fields.

Field	Description
FacilityID	Inpatient Facility (Hospital) identifier
PatientID	Unique patient identifier
LocalDrugIngredientCode	Drug ingredient code from the local homegrown or vendor system. This field contains duplicate codes from the same drug ingredient to illustrate data encountered in various systems.
AdministrationDateTime	The date and timestamp of drug administration. This table only includes administered drugs.
MedicationFormCode	Code indicating the form of the medication – tablet, capsule, injection, etc.
MedicationRouteCode	Indicates the route of administration – oral, intramuscular, inhalation, etc.
WardID	Unit location of the patient when the drug was administered
AdministrationStatusCode	Status of drug administration – GIVEN, NOT GIVEN or WITHHELD

3.2. Route of Administration Mapping Table

The `routeofadministrationmapping` table maps the local medication form and route to one of the four routes of administration used in the NHSN AU Option reporting (specifically, digestive, respiratory, intramuscular and intravenous).

Field	Description
MedicationFormCode	Code indicating the form of the medication – tablet, capsule, injection, etc.
MedicationRouteCode	Code indicating the route of administration – oral, intramuscular, inhalation, etc.
NHSNMedicationRouteCode	Medication administration route code required by NHSN.
NHSNMedicationRouteCodeSystem	Terminology to which the NHSN medication administration route code belongs – either SNOMED CT or CDCNHSN.
NHSNMedicationRouteName	Medication administration route name required by NHSN (i.e., digestive, respiratory, intramuscular or intravenous)

3.3. BCMA to NHSN Drug Ingredient Mapping Tables

Two tables – `drugIngredientMapping` and `dim_nhsndrugingredientcode` provide mapping from local drug ingredient codes to the NHSN drug ingredient codes. The columns in these tables are:

Field	Description
LocalDrugIngredientCode	Drug ingredient code from the local homegrown or vendor system. This field contains duplicate codes from the same drug ingredient to illustrate data encountered in various systems.
NHSNDrugIngredientCode	Drug ingredient code from the standard terminology.
NHSNDrugIngredientCodeSystem	A field with the values 'RXNORM' or 'CDCNHSN', indicating whether the StandardDrugIngredientCode and StandardDrugIngredientName are from RxNorm or cdcNHSN terminologies
NHSNDrugIngredientName	Human readable description of the drug ingredient from the standard terminology.

4. Synthetic ADT data

The synthetic ADT data consist of the following tables (4.1-4.3) in this section. The patient may be transferred multiple times in a given day, and should be included for the calculation of patient present days (specifically, days present) for all the AU reporting units.

The same ADT data are provided in two different formats (ADT Movement and Transfer In-Out) that reflect the most prevalent data structures for ADT data. ADT Movement format provides a list of transactions that corresponds to the HL7 v2.x ADT message format. Transfer In-Out format accommodates admission and paired discharge from each unit location on a single row. Vendors may use either format based on their preferences.

4.1. ADT Format 1 – ADT Movement Table

The `adtmovement` table contains one patient movement record per row, and has keys to link a given ADT row to the previous and next ADT rows. The data rows have a foreign key to the previous movement row to sequentially trace patient movements.

Field	Description
FacilityID	Inpatient Facility (Hospital) identifier
PatientID	Unique patient identifier
AdmissionID	Unique identifier of an inpatient admission
MovementID	Unique identifier for the patient movement (admission, discharge or transfer)
MovementDateTime	Date and timestamp of the patient movement
PreviousMovementID	Previous movement. NULL for a patient admission record.
MovementTypeCode	Movement type, chosen from a lookup list of movement types
DischargeDisposition	Code indicating the discharge disposition – type of facility, home, or whether patient died in the hospital.
BedSection	Bed section to which patient was moved
WardID	Unique ID for the ward or unit (location)
RoomBedID	Unique ID for the room or bed

4.2. ADT Format 2 – Transfer In-Out Table

The `transferinout` table consists of the admission (or 'transfer in') and discharge (or 'transfer out') timestamps of a patient into/from a given unit location. The data rows have a foreign key to the previous movement row to sequentially trace patient movements.

Field	Description
FacilityID	Inpatient Facility (Hospital) identifier
PatientID	Unique patient identifier
AdmissionID	Unique identifier of an inpatient admission
MovementID	Unique identifier for the patient movement (admission, discharge or transfer)
PreviousMovementID	MovementID of the previous row. NULL for admission row.
MovementTypeCode	Movement type, chosen from a lookup list of movement types
DischargeDisposition	Code indicating the discharge disposition – type of facility, home, or whether patient died in the hospital.
BedSectionID	Bed section to which patient was moved
WardID	Unique ID for the ward or unit (location)
RoomBedID	Unique ID for the room or bed
InDateTime	Admission or transfer-in date and timestamp for this unit location
OutDateTime	Discharge or transfer-out date and timestamp for this unit location

4.3. ADT Location Type Mapping Tables

We provide the ADT Location Type Mapping using the `dim_wardtype`, `adtwardmapping` and `dim_nhsnlocationtypecode` tables. These tables provide the mapping between the local units/locations and the NHSN-defined location types. In addition to the units in the hospital, we use a special 'FACWIDEIN' location type in these tables to denote all the inpatient locations in the facility as a single entity to report facility-wide inpatient antimicrobial use. Vendors will use these location types for including or excluding individual medication administration records.

Field	Description
FacilityID	Inpatient Facility (Hospital) identifier
WardTypeCode	Code that denotes the ward type (medicine, surgery, etc.)
WardTypeName	Ward type (medicine, surgery, MICU, etc.)
WardID	Unique ID for the ward
WardName	Ward name to which patient was moved (for example, 2 WEST, Adult observation room, etc.)
NHSNLocationTypeCode	NHSN Location Type Code.
NHSNLocationTypeName	Text Name for the NHSN Location Type

5. Monthly Aggregate Data to be generated by the Participant

We include the blank `monthlysummaryauoutputdata` table in the test data. This table provides the structure for the monthly summary output data. Vendors are not required to use this name within their databases; however, they will need to use this same structure when submitting the output to NHSN SDS Validation Web Service. It is highly recommended that vendors import this simulated data set into their own AU reporting systems – either a production or a test system, and produce the aggregate output data

so that their AU reporting systems can be validated. If vendors use a separate ad-hoc system created for this test, then the validation will not be applicable to the AU reporting system, and therefore limiting the benefits of this test. Figure 2 shows a screenshot of the output with example output values for illustration only. Please refer to the NHSN AUR Module Protocol - AU Option for specific definitions and examples for calculating the numerator and denominator values.

Figure 2 Screenshot of output file for validation

monthlysummaryauoutputdata-r1.xlsx - Excel

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	A	B	C	D	E	F	G	H	I	J	K	L
1	FacilityID	WardID	NHSNLocationTypeCode	SummaryYYYYMM	AdmissionsForMonth	NumberOfDaysPresentForMonth	NHSNDrugIngredientCode	AUDaysAllRoute	AUDaysIMRoute	AUDaysIVRoute	AUDaysDigestiveRoute	AUDaysRespiratoryRoute
2	1	1	1072-8	201601	NULL	276	1009148	0	0	0	0	0
3	1	1	1072-8	201601	NULL	276	10207	0	0	0	0	0
4	1	1	1072-8	201601	NULL	276	10395	0	0	0	0	0
5	1	1	1072-8	201601	NULL	276	1040005	0	0	0	0	0
6	1	1	1072-8	201601	NULL	276	10612	5	2	1	2	2
7	1	1	1072-8	201601	NULL	276	10627	0	0	0	0	0
8	1	1	1072-8	201601	NULL	276	10831	0	0	0	0	0
9	1	1	1072-8	201601	NULL	276	11124	0	0	0	0	0
10	1	1	1072-8	201601	NULL	276	113588	0	0	0	0	0
11	1	1	1072-8	201601	NULL	276	113931	0	0	0	0	0
12	1	1	1072-8	201601	NULL	276	119771	0	0	0	0	0
13	1	1	1072-8	201601	NULL	276	121243	0	0	0	0	0
14	1	1	1072-8	201601	NULL	276	1272	3	0	3	0	0
15	1	1	1072-8	201601	NULL	276	135098	1	0	1	0	0
16	1	1	1072-8	201601	NULL	276	138099	0	0	0	0	0
17	1	1	1072-8	201601	NULL	276	139462	0	0	0	0	0
18	1	1	1072-8	201601	NULL	276	140108	4	1	1	1	2
19	1	1	1072-8	201601	NULL	276	142438	NULL	NULL	NULL	NULL	NULL
20	1	1	1072-8	201601	NULL	276	1814-3	0	0	0	0	0
21	1	1	1072-8	201601	NULL	276	1815-0	0	0	0	0	0
22	1	1	1072-8	201601	NULL	276	1816-8	0	0	0	0	0
23	1	1	1072-8	201601	NULL	276	1817-6	1	0	0	1	0
24	1	1	1072-8	201601	NULL	276	1818-4	0	0	0	0	0
25	1	1	1072-8	201601	NULL	276	1819-2	2	0	0	2	0
26	1	1	1072-8	201601	NULL	276	1820-0	0	0	0	0	0
27	1	1	1072-8	201601	NULL	276	18631	0	0	0	0	0
28	1	1	1072-8	201601	NULL	276	190376	0	0	0	0	0
29	1	1	1072-8	201601	NULL	276	19552	0	0	0	0	0
30	1	1	1072-8	201601	NULL	276	19711	0	0	0	0	0
31	1	1	1072-8	201601	NULL	276	20481	10	2	2	4	4
32	1	1	1072-8	201601	NULL	276	20489	7	1	3	1	4
33	1	1	1072-8	201601	NULL	276	20492	0	0	0	0	0
34	1	1	1072-8	201601	NULL	276	21212	0	0	0	0	0
35	1	1	1072-8	201601	NULL	276	2176	5	2	2	0	2
36	1	1	1072-8	201601	NULL	276	2177	0	0	0	0	0
37	1	1	1072-8	201601	NULL	276	2180	13	3	5	4	3
38	1	1	1072-8	201601	NULL	276	2186	5	3	2	0	0
39	1	1	1072-8	201601	NULL	276	2187	0	0	0	0	0
40	1	1	1072-8	201601	NULL	276	2189	0	0	0	0	0
41	1	1	1072-8	201601	NULL	276	2191	0	0	0	0	0
42	1	1	1072-8	201601	NULL	276	2192	0	0	0	0	0

monthlysummaryauoutputdata-r1

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5.1. Negative Test Cases

We provide various negative test cases (specifically, ineligible drug ingredients, routes of administration and location types) in the data set. Vendors should exclude these from the monthly summary data set that their software generates for both numerator and denominator calculation.

5.2. Numerator Data

Antimicrobial Days (Days of Therapy): Defined as the aggregate sum of days for which any amount of a specific antimicrobial agent was administered to individual patients as documented in the eMAR and/or BCMA.

Aggregate antimicrobial days are reported monthly for inpatient locations, facility-wide inpatient (FacWideIN), and three select outpatient acute care settings (specifically, outpatient emergency department, pediatric emergency department, and 24-hour observation area) for select antimicrobial agents and stratified by route of administration (specifically, intravenous, intramuscular, digestive, and respiratory) as well as an aggregate of the four routes. The aggregate of all four routes is not a simple total of the data stratified by the four routes of administration; if a patient receives a single antimicrobial through multiple routes on a given day, the patient should be counted only once for that day to calculate the *total* number of antimicrobial days for the specific antimicrobial.

The vendor software should report the number 0 (*zero)* when no aggregate use of the antimicrobial occurred during the specific month in a facility that can accurately electronically capture that antimicrobial agent. If vendor software cannot electronically capture data for the antimicrobial for the specific route during the specific month at the facility, then the software should report blank (NULL), as described in section 5.4.

For this evaluation, the vendors should assume that administration of Penicillin V, Dicloxacillin and Gentamicin are not captured electronically for all four eligible routes in the simulated hospital and must be reported as blank values (NULL). Any other drugs not administered by any eligible route in the simulated data should be assumed as not used in the test facility during those months and must be reported as zero antimicrobial days.

5.3. FACWIDEIN

Facility-wide Inpatient (FACWIDEIN) denotes all the NHSN-defined inpatient locations in the hospital that are included for the NHSN AUR Module Protocol - AU Option (refer to the Location codes sheet in the IDM spreadsheet where CDC location type starts with 'IN:' and AUR column equals 'Y'). Vendor software should not include select NHSN-defined outpatient locations for AU reporting, namely adult emergency department, pediatric emergency department and 24-hour observation units in FACWIDEIN. However, if observation patients are physically located in inpatient locations, then vendor software should those patients under the respective inpatient locations and hence, in FACWIDEIN.

5.4. Denominator Data

The denominator data reportable to NHSN consist of the number of admissions and the number of patient present days (specifically, *Days Present*). If a patient is present in a location for any part of a calendar day, then the vendor software should count the patient in the location's Days Present for that calendar day. If a patient is transferred out of a unit and then back to the same unit on a calendar day, then the vendor software should count the patient only once for that day in that unit. The vendor software should then sum the daily denominator data for the entire month to find the Days Present and Number of Admissions for the calendar month.

The denominator data for facility-wide inpatient (FACWIDEIN) output rows are the number of admissions and Days Present. The denominator data for location-specific output rows are the number of Days Present only.

Vendor software should report number of admissions only for FACWIDEIN; software should not report admissions at the unit level and these cells must be left blank (NULL). Number of admissions for a given month should only include patients who were admitted during that month. Patients who were admitted during the previous month and stayed in the hospital through the beginning of the current month should not be counted for number of admissions for the current month. If a patient is first admitted to an outpatient location or an ineligible inpatient location for FACWIDEIN (see section 5.3) and subsequently transferred to an eligible inpatient location, the transfer record should be counted as an admission for FACWIDEIN as of the transfer date.

5.5. Representation of NULL values in Output Data

In the output Excel file, NULL values may be left blank or be denoted by the string NULL – they are both recognized by the NHSN SDS Validation Web Service during validation. Note that during real world implementation, the CDA specification requires the nullflavor of 'NA' for antimicrobial days, which is outside the scope of this validation project.

For the numerator data, if the data for all four stratified routes of administration are NULL, then the AUDaysAllRoute should also be NULL. If the data for any of the four stratified routes is not NULL, then the AUDaysAllRoute should not be NULL, and it should have the aggregate data following the NHSN AUR Module Protocol - AU Option.

6. Validation Methods

To validate the aggregated results, the output summary data populated with records generated by your system must be submitted in Excel (.xlsx) format to the NHSN SDS Validation Web Service by uploading this file to: https://nhsnpilot.ng.philab.cdc.gov/AUValidation-Production/home.html. The Excel file must contain only one worksheet. The first row of the worksheet must contain the **case-sensitive column names in the correct order.** Null values must be represented as NULL or be left blank. Vendors may use the included monthlyausummaryoutputdata table to obtain the correct structure (columns, column order, column names, data types and whether the column is nullable) of the output file.

The NHSN SDS Validation Web Service hosts the answer key to provide the validation results, but it will not save your uploaded data or the validation results. Vendors are welcome to resubmit updated output data until they pass validation.

After comparing the submitted file against the answer key table, the NHSN SDS Validation Web Service will render a webpage which summarizes the results of validation. Figure 3 shows an example with illustrative values. There are two categories of errors: the 'Record Level Errors' section indicates if your result table misses any records or has any unwanted records; the 'Value Level Errors' section documents the error of a particular attribute. In general, vendors should fix all record level errors first before looking into value level errors. Otherwise overlooked or unwanted records may disrupt the validation at value level.

Because ('FacilityID' + 'WardID' + 'SummaryYYYYMM' + 'NHSHDrugIngredientCode') is the composite primary key of the monthly summary table, the participant may use these values to locate a certain entry. 'AttributeName' in the 'Value Level Errors' section indicates the column which has an incorrect value, and

'AttributeValue' shows the value generated by your system. The 'Comments' column in this table provides potential causes of these errors and guidance on how to fix them.

Figure 3 Screenshot of validation results

Record Level Errors:

The result set should have the following missing records:

Index	FacilityID	WardID	SummaryYYYYMM	NHSNDrugIngredientCode
1	1	1	201601	10627

The result set should not have the following unwanted records:

Index	FacilityID	WardID	SummaryYYYYMM	NHSNDrugIngredientCode
1	1	1	201601	10625

Value Level Errors:

Index	FacilityID	WardID	SummaryYYYYMM	NHSNDrugIngredientCode	AttributeName	AttributeValue	Comments
1	1	1	201601	4053	AUDaysIVRoute	5	1. An incorrect large value may result if the same drug is counted twice on days when it is administered through different routes
2	1	1	201601	2708	AUDaysAllRoute	0	1. An incorrect small value may result if all eligible drug administration days or patients are not counted

7. Questions from Vendors

Vendors who implement the NHSN AUR Module Protocol - AU Option using this test data set may send questions via email to NHSNCDA@cdc.gov. We will update the test data set and the instructions based on questions from users.

8. Change Log

Production version 4.4. April 12, 2021

Fixes: WardID discrepancies between the ADT tables and MedicationAdministration table have been resolved.
Enhancements: Three drugs – Penicillin V, Dicloxacillin and Gentamicin are assumed to be not captured electronically for all four routes of administration. This change meant there is no need for two separate URLs based on the ability of the vendors to capture null values for some or all routes of administration. Therefore, instructions were updated to include only one NHSN SDS Validation Web Service URL.

Production version 4.3. July 17, 2020

Fixes: Resolved issue caused by two consecutive patient movements with exact same timestamp.
Enhancements: Rehab facility location types changed to Inpatient rehab location type. Operating room location types removed.

Production version 4.2. April 20, 2020

Instructions updated to include an alternative NHSN SDS Validation Web Service URL to meet the needs of vendors with varying capabilities of reporting null for specific routes of administration. Instructions updated in section 5.2 of this document.

Production version 4.2. December 6, 2019
Fixes: Data error in three rows in transferinout table resolved.
Enhancements: Instructions updated in sections 5.3 and 5.4 of this document for consistent implementation of admissions count for FACWIDEIN.

Production version 4.1. October 22, 2019

Fixes: Data error with trailing space in drug code '1815-0' resolved.
Enhancements: Referential integrity added between data and lookup tables. Ineligible drug and location codes used for negative tests instead of NULL values, and these columns were made NOT NULL to enforce referential integrity. Instructions updated in sections 5.3 and 5.4 of this document.

Production version 4. May 6, 2019

Added two new drugs – Delafloxacin and Meropenem/Vaborbactam.

Production version 3. February 9, 2018

Fixed ADTMovement and TransferInOut tables where the PreviousMovementID of some rows was larger than MovementID to make them more 'natural' even though this doesn't affect the validity of data. Fixed an issue with the TransferInOut table where the OutDateTime field was NULL for some Admit and Transfer rows.

Production version 2. December 18, 2017

Negative test cases were mapped to real NHSN drug ingredients, routes of administration and location types instead of NULL values. Updated instructions to state that the Number of Admissions should only include true admissions for a given month, i.e. patients who were admitted in the previous month and were present in the facility since should not be counted for Number for Admissions for the current month.

Updated instructions to describe that the select outpatient locations should not be included for FACWIDEIN numerator and denominator calculation.

Production version 1. November 9, 2017

Negative test cases included, which are shown by NULL mappings for drug ingredients, routes of administration and location types. The size of data set is larger than previous versions. Local drug ingredient names are populated with sequential numbers (e.g. drug 1, drug 2, etc.) to preclude vendors from performing their own mappings, since the mappings are provided in the data set.

Pilot version 2. June 5, 2017

LocalDrugIngredientName values in the dim_localdrugingredientcode table were not consistent with the mapped NHSNDrugIngredientName values in the dim_nhsndrugingredientcode table. Values of the LocalDrugIngredientName column in dim_localdrugingredientcode table have been updated to resolve this issue. No other changes. Vendors using version 1 may either import the entire version 2 data set, or replace only the data of the dim_localdrugingredientcode table and rerun their algorithms.

Pilot version 1. April 6, 2017

Initial version.