National Healthcare Safety Network (NHSN) External Validation Guidance and Toolkit 2018 for use in Long Term Care Facilities.

- *Clostridium difficile* Infection (CDI) LabID Event

Contents

About the 2018 External Validation Guidance and Toolkit

CDC NHSN External Validation Guidance and Toolkit for use in Long Term Care facilities (LTCFs) provides guidance for NHSN data validation. This guidance provides tools for validation of *Clostridium difficile* Infection (CDI) in all eligible settings such as nursing homes, skilled nursing facilities, chronic care facilities, and assisted living and residential care facilities. The purpose of validation is to assure high-quality surveillance data through accountability and by identifying, understanding, and correcting reporting problems. The focus of this document is external validation of facility-reported NHSN surveillance data conducted by state health departments or other oversight agencies. A separate guidance for performing data quality checks for groups https://www.cdc.gov/nhsn/pdfs/ltc/data-quality-check-guidance-508.pdf.

For 2018 data audits, the specified approach to facility and medical records sampling will be targeted external validation. This document proposes standard methods for state health departments and other oversight agencies to conduct external validation of reported 2018 event data. Developing a standard approach to HAI data validation is important to assure nationwide data quality. NHSN-specified external validation standards are intended to assure concordance of reported surveillance outcomes with those expected under NHSN surveillance definitions and methods, as determined and documented by trained auditors. Recommended sample sizes attempt to balance feasibility with adequate precision for HAI metrics at the facility level. Survey tools are provided to assess reporter knowledge and facility practices required to conduct adequate surveillance.

Comments and Feedback Welcome: NHSN validation approaches are a work-in-progress and will improve more quickly with the generous input and feedback of those implementing the methods. Please direct any comments or suggestions for improvement to the NHSN Helpdesk: *NHSN@cdc.gov*.

Acknowledgment and Thanks

Many aspects of this document were adapted from states conducting validation. In addition, many experts from state and local health departments and healthcare facilities collaborated to develop, review, and contribute to this document. The contributions of these individuals are gratefully acknowledged. However, the Guidance and Toolkit recommendations are the sole responsibility of the Centers for Disease Control and Prevention (CDC) and should not be regarded as having received the endorsement of any individuals or organizations outside of CDC.

Key Terms and Acronyms

ADT	Admissions/discharges/transfers (A core facility data system)
CDC	Centers for Disease Control and Prevention
CDI	*Clostridium difficile* infection. Also frequently referred to as C. diff or *C. difficile*
CEO	Chief executive officer
CMS	Centers for Medicare & Medicaid Services
EVENT Date	Date the specimen used to meet the LabID event criteria was collected
DOB	Date of birth
DOH	Department of health
ED	Emergency department
EMR	Electronic medical record
EXTERNAL VALIDATION	Survey and resident medical record review process by external agency to assure quality of NHSN surveillance and reporting
FACILITY LEADERSHIP	Director of nursing, medical director, NHSN facility administrator, etc.
FacWideIN*	(NHSN) Facility-Wide Inpatient, a type of surveillance used for LabID Event reporting
INTERNAL VALIDATION	Active efforts by a reporting facility to assure completeness and accuracy of NHSN data
IP	Infection Control and Prevention Officer https://www.cdc.gov/nhsn/pdfs/ltc/data-quality-check-guidance-508.pdf
IP or IPC	Infection Preventionist or Infection prevention and control
IT	Information technology
LabID Event*	(NHSN) A measure developed for infection surveillance using laboratory results data without the requirement for extensive clinical documentation and intended for easy electronic reporting
MEDICAL RECORD	A record systematically documenting a single patient's medical history and care across time within a healthcare provider's jurisdiction. For the purpose of sampling, a medical record (which over time could include many healthcare encounters) refers to a single facility inpatient admission.
MRN	Medical record number
NHSN	National Healthcare Safety Network
OrgID*	(NHSN) NSHN facility identifier
PROBABILITY SAMPLE	Sample based on randomization or chance that allows calculation of confidence intervals regarding how well the overall population is likely to be represented
Resident DAYS*	(NHSN) The number of residents housed in a facility during the designated counting time each day, and summed for a monthly denominator report for urinary tract infections (UTI) and for LabID Events.
RIN	Resident Identification Number
SIR*	(NHSN) Standardized infection ratio
TARGETED SAMPLE	In this document, a purposive sample taken to target facilities at higher risk for HAI or medical records at higher risk for misclassification of HAI status (See also, purposive sample)

*(NHSN) indicates a term used and defined by NHSN

Chapter 1: Overview and 2018 Validation Standards

Validation can be defined as confirming or assuring that data meet pre-determined specifications and quality attributes. NHSN validation should assure high quality of three domains in reporting healthcare-associated infections (HAIs): denominators, numerators, and risk adjustment variables.

Why validate?

NHSN was established as a voluntary, confidential HAI reporting system for hospitals conducting surveillance, benchmarking, and quality improvement for HAIs.

Since 2006, NHSN data have also been used by state and federal agencies for public reporting purposes and increasingly are used to incentivize quality improvement through payment mechanisms. In 2012 NHSN launched the long-term care facility component ideal for use by: nursing homes, skilled nursing facilities, chronic care facilities, and assisted living and residential care facilities. These new uses have heightened the importance of the completeness and accuracy of the data. Hospital and Long Term Care Facility boards, administrators, and clinical leadership need to trust their own facility's data to assess performance, manage change in their facilities, and to know that other facilities are held to the same high standards when reporting. Consumers seeking to make informed decisions about their healthcare expect that publicly reported data are valid. These requirements are challenging because NHSN definitions are complex and may involve tracking and linking information from multiple hospital and laboratory information systems (e.g., admissions, and clinical data); coordinated data collection, interpretation, and entry by multiple staff members; and sometimes require subjective interpretation, all of which introduce opportunities for variation. This complex landscape will continue to change over time as NHSN methods evolve, use of electronic medical records increases, and reporting requirements expand.

Validation is an important step toward assuring that reported NHSN data are actionable and motivate improved infection control efforts rather than strategies to avoid accounting for HAIs. Accurate, high quality NHSN data are important to infection prevention programs for setting priorities and measuring the impact of prevention efforts. Further, public health agencies at the local, state and federal levels need these data to identify HAI problems and to measure prevention program success. Each of these data users also has a role and a stake in assuring quality of NSHN data.

External Validation

External validation is a survey and audit process conducted by an agency outside the reporting facility (for example state health department), in which a facility's surveillance determinations and methods are investigated by one or more trained validators who work for the external agency, to evaluate surveillance program quality (for example knowledge and practices), and

completeness and accuracy of reporting. Findings from external validation can be used to correct reporter misconceptions about NHSN definitions, criteria, and data requirements. As a result, external validation can help assure adherence to NHSN's specifications for HAI reporting by identifying and correcting shortcomings that would be difficult to address through internal validation alone. Data correction and completion should be required of reporters, and helping reporters understand what led to the errors enhances the likelihood of better reporting in the future. Common errors and challenging cases should be documented to derive information for teaching and to improve future reporting.

Sampling of long term care facilities and medical records for review can be done in a variety of ways to meet different goals. It is typically not possible or necessary for validators to visit every facility or review every resident record in search of candidate HAIs. Sampling is a practical necessity, and sampling methods should strike a balance between resource availability and programmatic objectives.

Validation Guidance

For 2018 data validation, this guidance document specifies an algorithm for targeted sampling that provides for efficient investigation of potential surveillance and reporting problems in highly exposed facilities and medical records, where HAIs are most expected. Exposure risk derived from increased device days, surgical procedures, or specified positive laboratory test results, and targeting is driven by either high or low event reporting. In targeted samples, the ability to produce generalizable information about the population as a whole is constrained. A favorable outcome under targeted sampling suggests that success would be even more likely in a probability sample representing the entire population at risk. States should not be constrained by the algorithm, and should seek adequate reporter training and internal quality assurance of all reporting facilities in their jurisdiction, even those that are not audited.

Chapter 2: Guidance for Conducting 2018 NHSN Validation

A targeted validation approach is recommended to use resources as efficiently as possible to identify reporting errors, particularly errors caused by correctable systematic surveillance problems or misconceptions. Facilities are grouped within the state or jurisdiction by bed size. A percentage of each group is randomly selected for validation.

Facilities that will not be targeted for external validation audits using this suggested sampling method should still be held accountable for high quality surveillance and reporting programs and for conducting internal validation activities. Requesting evidence of up-to-date NHSN reporter training (such as a 2018 certificate of successful completion produced by each of NHSN's LTC multimedia training modules from all facilities) is one way to assure appropriate reporter training without a site visit. Some may wish to administer surveillance process surveys or request documentation of internal validation activities by facilities.

This external validation guidance and toolkit, recommends on-site medical record reviews by trained validators using a medical record abstraction tool that follows 2018 NHSN methods and definitions, with CDC serving as adjudicator of discordant outcomes when necessary. On-site validation provides optimal opportunity for validators to gain full access to any documented information used by reporters when conducting surveillance, and to strengthen relationships with reporting facilities through transparency. Use of electronic medical records systems that are made available at a distance to validators is a feasible, though perhaps a sub-optimal alternate way to audit medical records. This approach may require technical expertise and iterative work with facilities to assure validator access to all relevant documentation. In addition, without site visits the opportunities for interaction, education, and understanding of the overall HAI surveillance program are likely to be reduced. Remote review of copied medical records is discouraged for external validation program methodology, as potentially lacking complete data access and the interactivity that facilitates program capacity building. Ideally, validators will be either employed or contracted by agencies that have oversight responsibilities for patient/resident safety and public health in the audited healthcare facilities, and across the continuum of healthcare.

CDC Recommended Validation Elements and Preferred Approach

Validation Element	Off-site	On- or Off-site	On-site
Validator training and assessment	X		
NHSN Data analysis for completeness, timeliness, and quality	X		
Facility selection sampling frame development	X		
Medical Record Selection, NHSN data download, and arrangements for audit	X		
Facility surveillance practices survey		X	
Review of facility bed size			X
Medical Record Reviews			X
Post-review conference with IP re: surveillance practices and medical records audit discrepancies			X
Administration of additional denominator counting surveys, as needed		X	
Review of facility results, strengths, and weaknesses		X	
Follow-up corrections and report to IP and administration	X		

Chapter 3 Preparation for External Validation

Surveillance and validation require rigorous adherence to standard NHSN protocols, surveillance methods, and NSHN definitions as written. Persons conducting audits must be trained in NHSN component -specific (such as Long Term Care), definitions, remain up-to-date when changes are made, and commit to using appropriate NHSN methods and definitions to validate HAI data reported to the system. In addition to reporter training resources, validator training resources are available on the NHSN website and will be expanded in the future. The following trainings are available on the training website: Training | NHSN | CDC; or at the Long Term Care Webpage: https://www.cdc.gov/nhsn/ltc/index.html. They are listed in order of recommendation for validators:

Type of NHSN Training	Recommended Validator Standard	Symbol Key for Online NHSN Training Types (Examples as below)
Interactive Online Multimedia Instruction Modules	Assure that all 2018 validators successfully complete these courses for any NHSN component they will validate, and provide copies of the certificates of completion	 Self-paced, interactive trainings used to gain in-depth knowledge of NHSN HAI definitions
Slide sets	Highly recommended: Slide presentations include case-studies to help validators implement the basic content presented in HAI training webinars	 Presentations and case studies used to walk through difficult cases to learn to apply the NHSN HAI definitions accurately
Webinars & Podcasts	Basic prerequisite for prospective validators; Basic training in HAI and LabID event surveillance 	 Webinars and podcasts used to provide basic information on NHSN HAI and LabID event definitions and surveillance protocols

1. Assure validator expertise in 2018 definitions

Other opportunities for training include:

- CDC-sponsored trainings.
- NHSN blast emails, external partner calls, the quarterly NHSN newsletter, and the NHSN Manual, updated prior to each January with any changes to methods and definitions.

Even after training, willingness to seek help when needed from NHSN on definitions and criteria is important when cases are challenging. If facilities and auditors cannot agree on case-determination using documented information and the NHSN case-definition as a gold standard, the case should be referred to CDC for adjudication. Forms for tracking cases that result in discrepancies and that require adjudication are found in Appendix 1.

Finally, although it is not required, duplicate abstraction of medical records by another auditor (early in the process and periodically repeated) may be a useful adjunct to validator training, in order to identify areas of difficulty and to achieve improved inter-rater reliability.[3,4]

2. Select facilities

CDC recommends targeted validation in order to investigate and correct potential deficiencies in an efficient manner, given the assumption of limited resources for validation. This approach also provides maximum opportunity to work with reporters to improve reporting. See sample letter, Appendix 2.1, inviting facilities to participate in the validation process.

3. Establish a mechanism for secure data transfer between facilities and the state health department

To build a sampling frame for medical record selection, electronic files (spreadsheets) are required from laboratories that list CDI tests, with test dates, resident locations when collected, identified pathogens and resident information to identify medical records for review. In addition, assistance may be needed from LTC facility medical records departments to identify LTC re-admissions. Some agencies have established secure FTP sites for transfer of these sensitive data. Consider existing systems for secure data transfer and how to secure these data in both directions--to send line listings to characterize the sampling frame and to respond with the sample of medical records to be reviewed.

4. Develop and characterize the medical record sampling frame for each selected facility and each LabID event or HAI to be validated.

For LabID Event, sampling frames are derived from positive laboratory CDI specimen line-listings. LTC should be encouraged to develop capacity to generate these lists electronically, because recurring need for this capability is expected, and creation of manual line-listings would present an excessive burden.

Facilities should report positive laboratory tests according to date of specimen collection, not date of result reporting.

In order to assure completeness of the laboratory line-listings, it is generally recommended that laboratory data derive directly from the laboratory information management system and not from vendor software (such as data-mining programs). However, if convincing evidence exists that vendor software can provide complete laboratory data, vendor systems may provide convenient linkage to ADT data that would otherwise need to be created. This issue may need to be explored through individual discussions with facilities, and by facilities with their vendors.

Structure of laboratory line listings

Validators need to be able to identify NHSN-reported LabID events on laboratory line listings. Facilities should be reporting LabID events to NHSN using the resident identification number (RIN, and may also use resident name. In most cases, matching of reported LabID events will be based on MRN or Resident identification, gender, date of birth, and date of event. In some situations, more information may be needed from the IP about reported NHSN events to identify reported LabID events on

the laboratory line listing, for example, a request for additional personal identifiers of residents with NHSN-reported LabID events that can be linked to laboratory-reports.

The selected sample of positive laboratory tests also will need to be linked to resident medical records for review. The required resident MRN or Resident Identification and laboratory test date from the line listing will be the primary identifiers for this purpose, but knowing resident date of birth, admission date, and possibly resident name may facilitate the request to medical records for record audits. If the facility can provide these fields with the line listing they should be requested.

CDI LabID Event

To create a sampling sample, obtain from each selected facility, a complete list of final *Clostridium difficile* -positive laboratory results collected in 2018 for residents facility-wide plus ED/ 24 hour observation units with the same calendar day or the following calendar day return to facility. Laboratories may conduct one- two- or three-step testing for *C. difficile* on unformed stool specimens; regardless of the testing approach, any positive result indicating the presence of toxin producing *C. difficile* should be included.

A spreadsheet format is recommended for ease of use. These laboratory line lists should include resident location at the time of specimen collection.

Template positive *C. difficile* assay (* indicates required data) Printable template Appendix 6.

*RIN Resident ID	*Facility Current Admission Date	*Laboratory Stool Specimen Number	*Specimen Collection Date	*Result of CDI Test (assure test is positive for CDI)	* Specific NHSN Location, include ED/OP	Continued…

…continued	*Gender	*Date of Birth	First Name	Last Name

- For positive CDI LabID Event (facility-wide, inpatient /resident identification number, facility current admission date, stool specimen number, specimen collection date, result of CDI test, resident location, gender, and date of birth are required. Additional resident identifiers such as resident name may be helpful.
- This list should include ED/OP visits when the date of return to the facility is the same calendar day or the next calendar day (no change in current admission date).
- Validation time frame is entire year (review a minimum of 2 quarters).
- Using the line listing, sort by RIN and facility admission date (which together characterize unique eligible admissions/episodes of care with possible CDI LabID Event).

5. Notify facilities of the planned audit and request the required laboratory line listing

For chosen facilities, contact the IP or NHSN point of contact and discuss the audit process, including the likely scope of the audit and how the audit sample will be drawn from eligible medical records. Discuss the current request for *C. difficile* -positive line listings (with structures described above). Choose up to 30 specific medical records, and if less than 30, validate all applicable records. For LabID Event, validator will need access to either a) ADT data or complete resident records for up to 30 specified episodes of care CDI LabID Event auditing OR b) corresponding medical records that include these elements during on-site validation. Ask about the lead-time for the facility to generate the required line listings and how much lead-time the medical records department will need to arrange for medical record access. Ask how resident medical records can best be accessed onsite and how they are organized; this can affect the time required to abstract the records. Disorganized records on microfilm may be particularly difficult and time-consuming to abstract. Discuss the anticipated number of days and reviewers needed to complete the audit, based on experience or the guidance to follow. Request documentation that the facility's NHSN reporters have completed training on 2018 NHSN reporting methods and definitions.
Consider a mutually agreeable due date for the laboratory line listings, dates for the medical record request, and proposed date(s) for the onsite audit. For the audit, request arrangements for medical records access including e.g., workspace, computer systems, terminals and passwords, microfilm readers, and specific medical records.

The laboratory line listings should be provided by the facility through a secure file transfer (for example, encrypted email, secure FTP site, or encrypted file by courier, or snail mail) as a sortable and searchable (e.g., .csv, Excel) file, and should include facility information (identity and NHSN facID), facility contact name, facility contact phone, facility contact email, date of report, and timeframe of laboratory results.

Compose a letter notifying the Facility Administrator or other leadership, and copied to the IP or NHSN point of contact, that provides an overview of your authority to conduct validation (if applicable) or requesting voluntary access to medical records for the audit process, the purpose of the audit, proposed dates for the audit, and specific data and accommodations needed from facility staff (see Appendix 2.1 for an example letter). Explain the purpose of the audit (for example, to assure accountability of all long term facilities in complete and accurate reporting of HAIs according to NHSN methods and definitions) and how validation results will be used and/or reported.

6. Select medical records (to be discussed in the Chapter 4)

7. Download ("freeze") the facility's reported data from NHSN before disclosing which medical records were selected for the audit.

Do this after selecting the medical records sample to minimize downloads using NHSN analysis and the modifications described below for "freezing," essentially taking a snap shot of the data, and exporting the reported 2018 NHSN data.

NOTE: Use the **Analysis** button on the Navigation bar. Generate data sets. Once completed, select "Reports" to export the data. For more information about how to make modifications to these output options, read "How to Modify a Report for Long Term Care" found at in the Supportive Material at: https://www.cdc.gov/nhsn/ltc/cdiff-mrsa/index.html.

Select "MDRO/CDI Module – LABID Event Reporting" > "All C. difficile LabID Events" > "Line listing of all C. difficile LabID Events" > "Modify Report"

Suggested Modifications:

- Change the output title to "<Facility ID > Freeze Data <Freeze Date> **CDIF LabID Events, FacWideIN, 2018"**
- Select "Excel" (xls) or desired format.
- Select "Time Period" from the drop down box select **eventDateYr** 2018 to 2018
- Select "Sort Variables" (optional) "specimenDate"
- Select "Run"

8. Request selected medical records in advance of the facility site-visit

Submit the medical records request to the facility in a secure fashion so they can arrange for access to the information for your visit.

Chapter 4: Targeted Sampling of Facilities and Medical Records

Targeted Facility Sampling

Validators are encouraged to use the facility selection method described below. Additional analyses to evaluate data completeness, timeliness, and quality also are encouraged.

Ultimately, validation resources must be weighed and decisions made as to which LabID events will be validated based on past validation work, need for information on data quality and training needs, unrealized disease prevention, and perceived utility for prevention activities.

State Health Department or other external validator will determine the number of facilities in the state or jurisdiction and sort by bed size. Use the following break points: <50 beds; 50-99 beds; 100-199 beds; >199 beds.

- ≤ 20 facilities statewide: validate all facilities
- < 50 facilities: randomly select 20 facilities
- 50-99 facilities: randomly select 10% of facilities with > 100 beds
- 100-199 facilities: randomly select 5% of facilities with > 100 beds
- > 199 facilities: randomly select 2.5% of facilities with > 100 Beds

For example:

Bed Size – Number of Nursing Homes (Percent)						
	<50 beds	**50-99 beds**	**100-199 beds**	**>199 beds**	**All Facilities**	**>100 beds**
Alabama	5 (2.2)	86 (38.1)	122 (54.0)	13 (5.8)	**226**	**135**
Alaska	12 (66.7)	5 (27.8)	1 (5.6)	0 (0.0)	**18**	
Arizona	14 (9.7)	40 (27.6)	79 (54.5)	12 (8.3)	**145**	**91**
Arkansas	3 (1.3)	85 (37.1)	139 (60.7)	2 (0.9)	**229**	**141**
California	197 (16.2)	638 (52.3)	331 (27.2)	53 (4.3)	**1,219**	**1022**
Colorado	29 (13.6)	86 (40.2)	93 (43.5)	6 (2.8)	**214**	**185**
Connecticut	16 (7.0)	68 (29.7)	128 (55.9)	17 (7.4)	**229**	**145**
Delaware	7 (15.2)	11 (23.9)	28 (60.9)	0 (0.0)	**46**	
District of Columbia	3 (15.8)	5 (26.3)	6 (31.6)	5 (26.3)	**19**	
Florida	41 (6.0)	127 (18.4)	485 (70.4)	36 (5.2)	**689**	**521**
Georgia	17 (4.8)	118 (33.1)	197 (55.2)	25 (7.0)	**357**	**222**
Hawaii	16 (34.8)	13 (28.3)	14 (30.4)	3 (6.5)	**46**	

Source: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Downloads/nursinghomedatacompendium_508-2015.pdf

	All Facilities	Facilities > 100 beds	Proportion	Validation sample
Alaska	**18**			**18 facilities**
Delaware	**46**			**20 randomly selected**
Arkansas	**229**	**141**	**0.10 *141**	**14 randomly selected**
Georgia	**357**	**222**	**0.05 *222**	**11 randomly selected**
Florida	**689**	**521**	**0.025 *521**	**13 randomly selected**

If facilities refuse to participate, replace with additional facilities to meet the adequate sample size.

Retain the facility level information of those facilities, which refused to participate. This information is useful in addressing the potential bias of accuracy measures determined from the validation study.

Targeted Medical Record Sampling

For sampling, a medical record refers to the record of a single facility inpatient admission, also referred to as an episode of care. For each LabID Event to be validated, a sample size of 30 Medical Records/Episodes of Care per facility is recommended as a goal.

CDI validation

1. For each facility, request a line listing of all positive *C. difficile* stool specimens, for the validation timeframe (minimum 2 quarters/year) as describe in **Chapter 3**. This includes from facility (FacwideIN) residents and ED or OP office visits when the resident **returns the same calendar or the following calendar day (i.e., the current admission date does not change).** Request any additional variables used for medical record identification and possible matching to NHSN reports. Strongly encourage facilities to use an Excel format.
2. Assign a sequential number [1 to X] to each positive CDI result. Using a random number generator select 30 resident charts randomly for review. If multiple records are selected for same resident identification or medication record number, replace the duplicate records with additional random selections from the list.
3. If less than 30 episodes of care are available, review all the charts.

Surveillance guidance for laboratories recommends that *C. difficile* testing be performed only on unformed stool specimens, and formed stool should be rejected.

Prior to the site visit, extract the frozen facility data for the validation time frame
Use the frozen data file to tally the findings from chart review post site visit

Chapter 5: Activities During and After the Facility Site Visit

Preparing for the visit

Send a letter addressed to the facility leadership (for example, director of nursing, medical director, NHSN facility administrator, etc.) to explain the NHSN LTCF data evaluation project and solicit the facility's participation. This communication describes the importance and usefulness of HAI data validation.

After confirming the date of the site visit, send an additional letter (or email) describing the visit and the requested onsite needs:

- **Letter addressed to the facility leadership confirming the date of the site visit**
- **Description of the site visit**
- **Process is expected to be least disruptive to facility's routine activities**
- **Request the onsite needs:**
    - **Access to medical records charts for review**
    - **If electronic medical records: login for reviewers to be set up in advance**
    - **Interview time (Approximately an hour) with the one staff responsible for data entry and submission**
- **Request for specific lists of resident information that will be used to select residents' charts for review.**

Request documentation of current NHSN reporter training

NHSN reporters should have documentation of successful completion of the online, self-paced multimedia training modules for HAIs they oversee. This is an opportunity to establish or reinforce state expectations for this annual update. Consider recording the results in Appendix 3, *LTC CDI Survey*.

Bring a copy of the facility NHSN Annual Facility Survey, and review with the IP or NHSN point of contact.

Medical Record Review

The Medical Record Abstraction Tool (MRAT) is a tool for collecting data during the on-site review of the facility resident's medical record. The data is then used to determine whether CDI events were reported into NHSN correctly. The form follows the NHSN LTCF CDI LabID Event protocol definitions, methods, and algorithms.

Staff Surveillance Practices Survey

The second form is the on-site surveillance practices survey. (Appendix 3). The survey should be administered to the primary person or people responsible for all aspects of NHSN surveillance and reporting – CDI event determination, denominator collection, data entry into NHSN, and data analysis. If multiple people perform these roles, please include them in the survey. The survey will take about an hour.

The survey is designed to assess the facility's surveillance and reporting practices, and the staff understanding of the CDI LabID protocol. The questions are both open-ended and multiple choice. Some of the questions are scenario-based. Some have follow-up questions to elicit more information. Throughout the survey there are "Notes to Interviewer" – these notes provide information that can be shared with the interviewees for educational purposes during the survey. The survey contains 4 sections:

A. Facility Information and NHSN

This section gathers information on the staff involved in CDI reporting and how they use NHSN.

B. Admission Dates and Denominator Data Collection

The questions in this section assess staff understanding of CDI denominator definitions and the facility's denominator collection practices

C. CDI LabID Events

The questions in this section assess staff understanding of CDI LabID Event definitions and the facility's case surveillance practices

D. Additional Questions to Identify Areas of NHSN Improvement - opportunity for users to provide feedback to NHSN

- Survey is dual-purposed:
    - Assess user knowledge and facility practices
        - Understanding of definitions
        - Event surveillance practices
        - Denominator collection practices
        - Data reporting practices
    - Provide education to improve data quality going forward
        - Educate staff on protocol/definitions
        - Process improvement for data collection
- Survey is intended to be interactive and educational
- Educational feedback : essential component of validation project, valuable to the participating facility

Suggested Tools to bring along for validation site-visits

- Letter of introduction, state ID badge or other authorization
- 2018 NHSN LTCF Manual
    - Before visit: Tag/highlight case definitions
- Information about the facility:
    - Facility's most recent NHSN Annual Facility Survey
    - List of medical records requested for screening
    - Confidential list of LabID events reported by facility to NHSN (assure that validators are blinded until after review is completed).
- Blank audit discrepancies reports (Appendix 1)
- Copies of LTC CDI Survey (Appendix 3)
- Multiple copies of blank medical record abstraction tools (Appendix 4)
- Copies of 2018 NHSN checklists
- Miscellaneous tools: Straight edge (e.g.: ruler) for reading data printouts, stapler, binder clips, pens, highlighters, sticky notes, tape flags

Please note that some of the listed tools are templates that should be adapted to the facility and state before copies are made.

Review denominator methods and documentation

Electronically collected CDI facility-wide inpatient (FacWideIN) denominators

"FacWideIN" surveillance data includes all resident days counted at the same time each day for residents housed in a bedded location. This information is often collected electronically. Manual counts should be within 5% of the referent (usual) electronic counts, or an evaluation of why they differ should be conducted. Electronic ADT data often are found to be more accurate than electronic billing data in this regard. This internal validation process can be conducted by facilities when requested or required.

Structured Medical Records Review

Validator blinding and consultation at the facility site-visit

Validator blinding as to HAI status is required and is normally accomplished by mixing and reviewing the selected medical records before determining which have been reported to NHSN with HAIs.

Medical records should be reviewed in a blinded manner using 2018 Medical Records Abstraction Tool processes (Appendix 4). These tools include algorithms and logic designed to establish presence or absence of required criteria for case definitions and to provide support to avoid common errors.

If working on paper, bring enough copies of the medical records abstraction tools to complete a separate form for each medical record. After all medical records have been abstracted by validators, events reported to NHSN should be revealed and a meeting arranged with IPs / NHSN reporters to discuss any discrepancies between validator outcomes and reported outcomes, while medical records are readily available.

Discussion of audit results with IP

Whether or not reporting errors are identified, review the data with the IP to assure transparency and provide opportunity for discussion and feedback. If case-determinations are discordant, determine whether reporters or auditors missed any documented information that would affect the correct result (undocumented information should not be considered). Use NHSN criteria as the gold standard. For difficult cases, seek adjudication from CDC.

Look carefully for systematic reporting errors or misconceptions that could affect reporting beyond the reviewed medical records. If systematic errors are found, the facility should be asked to re-review and correct affected data, not just those records reviewed by auditors. These errors should be re-assessed during the next audit to evaluate improvement.

Use errors as learning opportunities for reporters and validators. These discussions may provide insight into the soundness of the facility's surveillance processes and competencies, and topics where additional training may be useful. Leave a copy of expected changes to NHSN data with the IP and agree to a deadline for changes to be made (see Appendix 1). An exit interview with a facility administrator may not be necessary unless a process improvement plan is indicated.

Post-visit

Document validation findings (for example, using Appendix 1) to create a facility summary report. Denominator data collection surveys (Appendix 5) may be completed after the visit.

A follow-up letter to the IP and facility leadership (e.g., director of nursing, medical director, NHSN facility administrator, etc.) will close the communication loop and provide valuable feedback. Send a letter thanking them, recognizing all participants in the audit, and documenting results, necessary corrections, and recommendations. When appropriate, identify systematic strengths as well as problems with resources and support for surveillance, data collection, and reporting (Appendix 2.3).

If the facility was required to change data in NHSN or to re-review information due to systematic errors, follow-up with the facility and assure corrections are made by the agreed upon deadline.

Suggested Time Line for Activities ~ 24 weeks

- ❑ **Preparation (estimated duration 4 weeks)**
  - ❑ Read project implementation materials
  - ❑ Determine the number of facilities that will be included in the project and select facilities
  - ❑ Customize Template Letters 1 and 2 for your organization and project parameters
  - ❑ Determine when the site visits will occur
  - ❑ Train project staff on NHSN LTCF Event Surveillance and evaluation tools
- ❑ **Solicit Facility Participation (estimated duration 2 weeks)**
  - ❑ Send Template Letter 1 to the facility leadership of the selected facilities
  - ❑ Follow-up with facility leadership to provide a brief description of the project
- ❑ **Schedule Site Visits (estimated duration 4 weeks)**
  - ❑ Schedule site visits and confirm details of each visit with facility leadership and request resident lists
  - ❑ Use resident lists to determine which resident charts will be selected for review
  - ❑ Inform facility leadership of which resident charts will be reviewed; ask for these resident charts to be available on the day of the site visit
- ❑ **Site Visits (estimated duration 6 - 12 weeks)**
  - ❑ Prepare for site visit: print sufficient number of all the data collection instruments
  - ❑ Conduct site visits
  - ❑ Upon completion of each site visit, summarize findings, customize Template Letter 3 and send to the facility leadership
- ❑ **Facility Follow-up and Data Summary and Dissemination (estimated duration 4 - 8 weeks)**
  - ❑ Follow-up 4 weeks post-site visit to ensure identified errors were corrected
  - ❑ Aggregate and summarize findings for all facilities that participated in the project
  - ❑ Share summary findings with CDC
  - ❑ Write a report, disseminate findings to facility leadership

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APPENDIX 1 Evaluation Summary

Summary Findings from Evaluation of NHSN CDI LabID Event Reporting between ___/___/_____ and ___/___/_____ (Page ___ of ____)

Facility Name: _____ # Resident Charts Reviewed:_____ Date of Site Visit: ___/___/_____

LabID Event = CDI LabID Event

Res ID	LabID Event identified				This LabID was determined to be			Comments/notes
	No	Yes	Identified during evaluation site visit	Reported to NHSN by facility staff	*Correctly reported*	*Under reported*	*Over* reported	

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

Appendix 2 Sample Letters

Appendix 2.1 Introduction/Invitation Letter

<<Insert Date >>

<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>

Dear *<<Name of Facility Manager>>*:
I am inviting you to help in a data quality evaluation of Long-term Care Facility *Clostridium* difficile Infection Laboratory Identified (CDI LabID) Event data that are reported to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). This evaluation is being conducted by *<<agency/group conducting evaluation>>* to learn how NHSN CDI LabID Event surveillance data collection procedures are understood and carried out in long-term care facilities (LTCFs), as well as to identify and address barriers to reporting complete and accurate data.

We are contacting you because your facility is among a subset of long-term care facilities within *<<Network/state/area>>* that are expected to have, on average, more data to review, or that are part of a random sample. To conduct the evaluation, staff from *<<agency/group conducting evaluation>>* will be visiting several long-term care facilities in *<<geographic area>>* during *<<time period month(s)/year of visits>>*. These site visits include three main activities:

1. A standardized interview with facility staff involved in NHSN CDI LabID Event data collection or reporting to evaluate surveillance practices within your facility.
2. A review of pre-selected resident medical records, including both paper charts and any electronic records, to assess the completeness and accuracy of the data reported to NHSN.
3. Education for facility staff about CDI LabID Event surveillance, use of the NHSN system, and common reporting omissions and errors and their causes.

It is anticipated the visit will be completed within one day, and that the staff interview will take no longer than one (1) hour. On the day of the visit, *<<agency/group conducting validation>>* staff will need a space to review resident charts and access the facility's electronic medical records systems.

Evaluation 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. Your participation is vital to these surveillance support and data quality improvement efforts.

This evaluation is not related to any regulatory surveys; no observations will be made of infection control practices or other aspects of patient care during the site visit. The identities of participating facilities will remain confidential, and all resident identifiable information will be maintained securely and remain confidential. All visits will be scheduled – no unannounced visits will occur.

In return for your facility's participation, you will have the following opportunities:

- obtain confidential feedback about your facility's NHSN reporting
- interact one-on-one with an CDI LabID Event surveillance expert who can address any questions you may have about reporting, and
- provide feedback about your experience with CDI LabID Event data collection and reporting that will be used to help inform changes that will improve future reporting efforts.

Please confirm your interest in participation by contacting me with available dates for a site visit during the months of *<<site visit time period>>*. Once you confirm your participation, we will schedule a mutually agreeable date for the site visit and ask you to prepare some information on the residents at your facility during *<<evaluation period>>*.

I am happy to answer any questions you have or provide further information. I can be reached at *<<phone>>* or via email at *<<email address>>*.

Thank you for your assistance to evaluate and improve the quality of NHSN CDI LabID Event Surveillance data and reporting.

Sincerely,

<<Primary Contact's Name>>
<<Primary Contact's Title>>
<<Agency/Group's Contact Information>>

Appendix 2.2 Confirm Site Visit Letter

<<Insert Date >>

<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>

Dear *<<Name of Facility Leader>>*:

Thank you again for agreeing to participate in our evaluation of NHSN *Clostridium difficile* Infection Laboratory Identification (CDI LabID) Event data and reporting. Without your participation, this valuable project would not be possible.

As discussed, we will be visiting your facility on *<<date of visit>>*. *<<Names of persons who will be conducting validation>>* from *<<name of agency>>* will arrive at approximately *<<time of arrival>>*.

Preparation before the site visit

In order to select the resident charts that will be undergoing review, we need you to provide the lists of residents outlined below. Each list should include a resident identification number, date of birth, first and last name. Please send these lists to the attention of *<<Name>>* via fax at *<<number>>* by *<<deadline date>> (or via secure upload/email)*.

1. All residents in your facility between *<<month year to month year – the evaluation timeframe>>*.
2. All residents who had any *C. difficile* positive laboratory assay results between *<<month year to month year – the evaluation timeframe>>*. This might require contacting the laboratory routinely used by your facility for C. difficile specimen testing.
3. List of residents that left the facility for an outpatient visit (Emergency Department visit/ clinic visit/ outpatient) *<<month year to month year – the evaluation timeframe>>*.

Facilities are strongly recommended to provide the resident lists in an Excel format. A template of the required information is provided in the table below. These lists will be maintained securely by us to protect the release of any resident identifiers. Using the lists provided, we will preselect resident charts for us to review during the site visit. The list of resident charts for review will be provided to you in advance of the site visit.

Template positive C. difficile assay line listing. See Appendix 6. (*indicates required data):

*Resident ID	*Date of current admission to the facility	*Laboratory Specimen Number	*Specimen Collection Date	*Result of CDI Toxin Test	*Location of resident at time of specimen collection	*Date of Birth	First Name	Last Name

What to expect during the site visit

When we arrive, we will need assistance to obtain the preselected resident charts. For the chart review, we will require a workspace and access to your electronic medical record system(s). You do not need to stay with us during our review, but we may need your assistance to answer intermittent questions throughout the day. When it is most convenient for you, we will interview the facility staff involved in NHSN data collection or entry, which takes about one (1) hour. The group interview is interactive and provides on-the-spot feedback about NHSN surveillance practices and is a valuable learning opportunity for staff. Before we conclude, we will summarize our findings and review them with you, as well as address any outstanding questions from you or your staff.

Please confirm your receipt of this information, and contact me if you have any questions about preparing the lists or the site visit itself.

Thank you,

<<Primary Contact's Name>>
<<Primary Contact's Title>>
<<Agency/Group's Contact Information>>

Appendix 2.3 Post Site Visit Letter

<<Insert Date >>

<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>
Date of site visit: _____/_____/_____

Dear *<<Name of Facility Manager>>*:

Thank you for participating in the evaluation of facility surveillance practices and the *Clostridium difficile* Infection Laboratory Identification (CDI LabID) Event data reported to the National Healthcare Safety Network (NHSN). We appreciate you taking time from your schedule to work with us. The valuable information you provided will enable us to improve the quality of the data reported to NHSN, and identify focus areas for education and training of NHSN users.

During our visit, *<<number>>* resident charts were reviewed. The documentation from these charts was used to identify CDI LabID Events that should have been reported to NHSN. Here is a summary of our findings:

- *<<Number>>* of CDI LabID Events found in charts by our staff
  - *<<Number>>* of these events found in charts that were reported to NHSN
  - *<<Number>>* of these events found in charts that were not reported to NHSN
  - *<<Number>>* of these events reported to NHSN, but were not found in charts

A summary of our findings can be found in the table below with additional details. **We would like you to perform the following steps to correct data discrepancies that were identified**:

1. Report to NHSN the events listed below as "under-reported." These are events that were not reported to NHSN by your facility staff, but should have been.
2. Delete or edit the NHSN records of the events listed below as "over-reported." These are events that were reported to NHSN by your facility staff, but should not have been.

Please make these corrections by *<<deadline>>*. Please contact us with any questions or concerns you have about making these changes.

<u>Denominators for LTCF Form</u>
From the information obtained during the interview, it appears the monthly denominator data/patient census data *<<is/is not>>* being reported correctly on the Denominators for LTCF form. Please *<<begin/continue>>* to report using the NHSN LabID Event Protocol for LTCF "Denominator" instructions and the "Instructions for Completion of the MDRO and CDI Monthly Monitoring for Long-term Care Facility" form.

In addition, it is recommended that you and your staff involved in reporting review the NHSN LabID Event Protocol for LTCF, noting the following common reporting issues found at your facility:

- *<<Highlight up to 3 main issues that were discovered during the validation process. Include excerpt(s) of the NHSN LabID Event Protocol for LTCF that pertain to those issues. If data validation (quality checks) is not being performed, please highlight this as an issue and provide guidance on the importance of performing data quality checks on a routine basis (at least quarterly prior to CMS submission deadlines).>>*
- *<<Issue 2>>*
- *<<Issue 3>>*

Thank you for work with regards to improving the quality of NHSN LTCF CDI LabID Event surveillance data. We recognize the time and effort that you have committed. We also appreciate your willingness to participate in these important quality improvement activities. We hope the experience was also helpful to you. Please do not hesitate to contact us with any remaining questions or concerns you may have.

Sincerely,

<<Primary Contact's Name>>
<<Primary Contact's Title>>
<<Agency/Group's Contact Information>>

Appendix 3 Long Term Care CDI Survey

NHSN Long-term Care Facilities (LTCFs) 2018 CDI LabID Event Surveillance Practices

Survey

INTERVIEWER INSTRUCTIONS

Prior to interview:
Identify the primary person who does NHSN *Clostridium difficile* Infection Laboratory Identification (CDI LabID)Event data collection and reporting at the facility to interview. If other staff perform NHSN activities such as data entry or analysis, it is ideal for them also to be included.

During Interview:
This interview is a tool to evaluate and improve NHSN CDI LabID Event data collection and reporting. If data collection or reporting errors are identified through this evaluation of practices, the interviewer should provide education and information to help correct errors and ensure that staff report data correctly to NHSN. Refer to the "*Note to Interviewer*" boxes for reference information.

Note to Interviewer –

If there is a correct answer to a question, the correct answer is **bolded**.

SECTION A: FACILITY INFORMATION AND NHSN

Facility Name: _____ NHSN Org ID: _____

Interviewer Name: _____ Interview Date: _____

1. Are any NHSN CDI LabID Event data collected or reported by persons that do not work directly within this facility (for example, IP consultant, quality improvement partner, hospital/corporate partner) Yes No
   a. If yes, specify who and what data:_____
      _____

2. Please list all staff involved in NHSN CDI LabID Event Surveillance and their involvement:

	Interviewee 1	Interviewee 2	Interviewee 3
Name(s)			
Job Title(s)			
Background/Degree(s)			
Collects NHSN CDI LabID Event data?	Yes No	Yes No	Yes No
Collects NHSN CDI LabID denominator data?	Yes No	Yes No	Yes No
Has access to NHSN?	Yes No	Yes No	Yes No
Does NHSN data entry?	Yes No	Yes No	Yes No
Creates reports/uses NHSN analysis?	Yes No	Yes No	Yes No
Has read the NHSN CDI LabID Event Protocol?	Yes No	Yes No	Yes No
Has completed NHSN CDI LabID Event Surveillance reporting training?	Yes No	Yes No	Yes No

3. For staff that completed NHSN CDI LabID Event Reporting Training, what kind of training did they do?

(Check all that apply)

- ☐ Online NHSN CDI LabID Event Surveillance Protocol training
- ☐ In person, presented by a CDC trainer
- ☐ Webinar, presented by a CDC trainer
- ☐ In person, by a non-CDC trainer (for example, State Health Department or Quality Innovation Network-Quality Improvement Organization (QIN-QIO))
- ☐ Webinar, by a non-CDC trainer (for example, State Health Department or QIN-QIO)
- ☐ Other, specify: _____

4. What have you done if you had a question about how or what to report to NHSN?

(Check all that apply)

- ☐ Read the NHSN CDI LabID Event Protocol
- ☐ Visit the NHSN CDI LabID Event website (https://www.cdc.gov/nhsn/ltc/cdiff-mrsa/index.html)
- ☐ Send an e-mail to the NHSN Helpdesk (nhsn@cdc.gov)
- ☐ Contact Hospital/Corporate Partner
- ☐ Contact QIN-QIO
- ☐ Contact IP Consultant
- ☐ Contact State Health Department
- ☐ Other, specify: _____
- ☐ Never had a question
- ☐ Never sought an answer

5. Once data are reported to NHSN, does anyone from your facility go back and review the reported data to make sure it is correct? Yes No
   a. If yes, specify who: _____
   b. If yes, specify how often: _____

6. Does anyone from your facility use the NHSN analysis reports (also called "output options")? Yes No
   a. If yes, which ones?

   (Check all that apply)

   - ☐ Line Listing – All CDI LabID Events
   - ☐ Rate Tables for CDI LabID Event Data
   - ☐ Line Listing – All Events
   - ☐ Line Listing – All Summary Data
   - ☐ Line Listing – Monthly Reporting Plan
   - ☐ Other, specify: _____

   b. If yes, for what are the reports used?

   (Check all that apply)

   - ☐ Checking that reported data are correct (data quality checks)
   - ☐ Shared at quality improvement meetings
   - ☐ Communicating to leadership about event rates
   - ☐ Communicating to frontline staff about event rates
   - ☐ Performing root cause analysis of infections

- ☐ Informing prevention activities
- ☐ Other, specify: _____

SECTION B: ADMISSION DATES AND DENOMINATOR DATA COLLECTION

7. The date of first admission to the facility is the date the resident first entered the facility.
   a. If a resident transfers from your facility to a hospital on June 1 and returns to your facility on June 4, does the first admission date change? Yes **No**
   b. If a resident transfers from your facility to a hospital on June 1, then goes to an inpatient rehab facility, and finally returns to your facility on July 10, does the first admission date change? **Yes** No
   c. If yes, what is the new date of first admission? _____ (answer: July 10)

8. The date of current admission is the most recent date the resident entered the facility.
   a. If a resident transfers from your facility to a hospital on June 1 and returns June 4, does the current admission date change? **Yes** No
   b. If yes, what is the new current admission date? _____ (answer: June 4)
   c. If the same resident goes to the ED for an evaluation on June 12 and returns on June 13, does the current admission date change? Yes **No**

9. In your facility, how do you count residents to obtain the monthly denominator data for number of residents?

   _____
   _____

10. In your facility, how do you count the number of admissions for the month?

    _____
    _____

11. In your facility, how do you count the number of admissions on *C. difficile* treatment for the month?

    _____
    _____

Note to Interviewer – Protocol instructions for admission dates and denominator data collection:

- Date of first admission to facility: If the resident leaves the facility for < 30 consecutive days, the date remains the same. If the resident leaves the facility for > 30 consecutive days, the date of first admission should be updated to the date of return to the facility.
- Date of current admission to facility: If the resident leaves the facility for > 2 calendar days (the day the resident left the facility = day 1) and returns, the date of current admission should be updated to the date of return to the facility. If the resident has not left for > 2 calendar days, then the date of current admission should not be changed.
- Number of residents: For each day of the month, record the number of residents present in the facility at the same time each day. The aggregate count for the calendar month should be entered as the total Resident Days. Do not include residents for whom a bed is being held but who are not actually in the facility.
- Number of admissions: For each day of the month, count and record the number of residents admitted to the facility. The aggregate count for the calendar month should be entered as the total Resident Admissions. Include both new admissions and re-admissions when a resident was out of the facility for >2 calendar days (that is, change to the Current Admission Date).
- Number of admissions on *C. difficile* treatment: For each day of the month, count and record the number of residents who are receiving antibiotic therapy for *C. difficile* infection at the time of admission. The aggregate count for the calendar month should be entered as the total Number of Admissions on *C. difficile* Treatment. Include both new admissions and re-admissions when a resident was out of the facility for > 2 calendar days (that is, change to the Current Admission Date).

12. What sources are used to determine your denominator data (number of residents, number of admissions, and number of admissions on *C. difficile* treatment) for the "Denominators for LTCF" form? (*Check all that apply*)
    - ☐ From a computer generated report (specify types of reports)
      _____
      _____
    - ☐ By performing resident chart reviews
    - ☐ By observation and counting residents
    - ☐ Other methods used, specify: _____

13. Has anyone at your facility checked the accuracy of the denominator data or reviewed the denominator data method to identify errors?
    Yes No
14. If not using NHSN denominator criteria, summarize below how denominator data is determined at this facility:

_____

_____

_____

SECTION C: CDI LABID EVENTS

The following questions are designed to assess the interviewee's ability to correctly identify CDI LabID Events.

15. Only results from unformed/loose stool specimens that conform to the shape of the container should be included in CDI LabID Event reporting. **True** False

16. Mr. A is a long-term resident in your facility. On December 31, he developed diarrhea and abdominal pain. On January 1, a loose stool specimen was collected and tested positive for *C. difficile* toxin. This is the first time Mr. A. has tested positive for *C. difficile* in your facility. Is this event reportable? **Yes** No
If yes, what is the date of the event? _____ (answer: January 1, the date of specimen collection)

17. Mr. A was started on treatment for *C. difficile*, and over the next few days his symptoms resolved. On January 13, he had several more episodes of diarrhea, and another loose stool specimen was collected that tested positive for *C. difficile*. Is this event reportable? Yes **No**
(since this is a duplicate specimen, collected < 15 days from the first specimen, it is not reportable to NHSN)

18. On January 20, Mr. A had another positive *C. difficile* toxin result. Is this event reportable? Yes **No**
(while it has been more than 14 calendar days since the most recent CDI LabID Event was entered into the NHSN on January 1, it has not been more than 14 calendar days since his most recent *C. difficile* positive laboratory assay on January 13; therefore, this is considered a duplicate event)

19. On February 10, Mr. A had another positive *C. difficile* toxin result. Is this event reportable? **Yes** No
(since it has been more than 14 calendar days since his most recent *C. difficile* positive laboratory assay on January 20, this specimen is entered into NHSN as a CDI LabID Event)

20. Mrs. X is a resident in your facility. She does not have a history of *C. difficile*. On March 1, she was transferred to the local emergency department (ED) for evaluation of diarrhea. While in the ED, a loose stool specimen was collected and tested positive for *C. difficile*. She given IV fluids in the ED, and transferred back to your facility on March 2. Is this event reportable into NHSN by your facility? **Yes** No
(when a specimen is collected from an outpatient setting, such as an emergency department or clinic and the resident returns back to the LTCF on the same calendar day of the outpatient visit or the very next calendar day, the specimen collected from the outpatient location should be reported by the LTCF as if the resident never left the LTCF)

21. Mrs. X continues to have diarrhea and is transferred back to the ED on March 4. She is admitted to the acute care facility where she has a positive *C. difficile* toxin result on March 5. She returns to your facility on March 10 and is receiving antibiotic treatment for *C. difficile*.
    a. Is the positive *C. difficile* toxin result on March 5 reportable by your facility? Yes **No**
    (laboratory results obtained during an admission in another facility are excluded from the LTCF LabID Event reporting)
    b. Is Mrs. X counted as an admission on *C. difficile* treatment for denominator data? **Yes** No
    (since she left the facility for > 2 days, her current admission date changes, and she is considered a re-admission for denominator data counting)

22. On March 13, Mrs. X has another positive *C. difficile* toxin result at your facility. Is this reportable? Yes **No** (since it has been < 15 calendar days since her most recent positive *C. difficile* positive laboratory assay reported for this facility on March 1, it is not reportable to NHSN; the 14 calendar days between specimens crosses current admissions)

23. On April 1, Mr. C. a long-term care resident in your facility, is admitted to the local hospital for treatment of acute diarrhea. During his hospital admission, a stool specimen was collected on April 1 and tested positive for *C. difficile* toxin. After receiving care in the acute care facility for several days, he returned to your facility on April 5. His diarrhea returned on April 7 and a loose stool specimen was collected and tested positive for *C. difficile* toxin. Is the April 7 event reportable by your facility? **Yes** No (since he had not had a *C. difficile* positive laboratory assay while receiving care in your facility; specimens collected during an admission to another healthcare facility are not reported by the LTCF nor are they counted when considering duplicate events)

Note to Interviewer – Protocol definitions for CDI LabID Events:

- Date of event: The date of specimen collection.
- *C. difficile* positive laboratory assay: An unformed/loose stool that tests positive for *C. difficile* toxin A and/or B (includes molecular assays [PCR] and/or toxin assays)

  OR
  A toxin-producing *C. difficile* organism detected in an unformed/loose stool sample by culture or other laboratory means.
- Duplicate *C. difficile* positive laboratory assay: Any *C. difficile* positive laboratory assay from the same resident following a previous *C. difficile* positive assay within the past 2 weeks (< 15 days). Duplicate assays should not be reported into NHSN. There should be 14 calendar days with no *C. difficile* positive assay for the resident before another CDI LabID Event is entered into NHSN for the resident (date of specimen collection = Day 1 of count).

24. When a resident has been transferred from an acute care facility, how do you determine if he/she was receiving treatment for *C. difficile*?
    - ☐ Review hospital discharge summary
    - ☐ Review admission/transfer medication list
    - ☐ Review hospital medication administration record
    - ☐ Ask the resident's physician
    - ☐ Other, specify: _____

Note to interviewer: Residents admitted from an acute care facility always have an admission/transfer medication list (which is verified by an RN/clinician) upon arrival to the facility. The most common medications used to treat Clostridium difficile are oral (PO) vancomycin and/or oral (PO) metronidazole (Flagyl); Fidaxomicin may also be use, although much less frequently. In the absence of CDI documentation, users are encouraged to consult with the physician or nurse to verify treatment for *C. difficile* since these medications could be prescribed for other conditions.

25.

a. What data sources do you use to help you find CDI LabID Events?	
Daily direct observation of residents	☐
Resident chart reviews	☐
Review computer generated reports	☐
If used computer reports, specify the type(s):	

Staff discussion	☐
Pharmacy records	☐
Positive laboratory reports	☐
Hospitalization records	☐
Administrative (billing or discharge) codes	☐
Other data sources, specify:	
How frequently is case finding performed (for example, daily, weekly, monthly, quarterly)?	
b. Once you have identified a resident with a CDI LabID Event, what process do you use to keep track of them before they are entered into NHSN?	
Keep a line listing (for example, a log) of events	☐
Fill out a paper NHSN CDI LabID Event form	☐
Flag events in Electronic Medical Record	☐
Other, specify:	

26. Does your facility keep track of all resident hospitalizations and outpatient visits? Yes No

27. After residents return to your facility following a hospitalization or outpatient visit, does your facility request a copy of your residents' medical records? Yes No

a. Are records requested for <u>every</u> hospitalization and outpatient visit? Yes No

b. Is there a standard process to request records (for example, a request form)? Yes No

c. Does your facility have a follow-up system in place to ensure all requested records are received? Yes No

If yes, please describe the process:

_____

_____

_____

d. Please specify the type of records requested for all resident hospitalizations or outpatient visits:

(Check all that apply)

- ☐ Admission history and physical
- ☐ Microbiology laboratory reports
- ☐ Pharmacy/drug administration records/logs
- ☐ Discharge summary
- ☐ The complete record
- ☐ Other, specify: _____

28. If a resident develops diarrhea that is concerning for *C. difficile*, when does your facility usually start treatment with antibiotics? (*Check all that apply*)

- ☐ Treatment is started **without** sending a stool specimen for *C. difficile* testing for residents who have any history of *C. difficile* anytime in the past
- ☐ Treatment is started **without** sending a stool specimen for *C. difficile* testing only for residents who have a recent history of *C. difficile* (within the past 4 weeks)
- ☐ For all residents with or without a history of *C. difficile*, treatment is started immediately and a specimen is sent for *C. difficile* testing; if the test results are negative then treatment is discontinued
- ☐ For all residents with or without a history of *C. difficile*, a specimen is always sent for *C. difficile* testing, and treatment is only started if the result is positive
- ☐ Other (please specify): _____

SECTION D: ADDITIONAL QUESTIONS TO IDENTIFY AREAS OF NHSN IMPROVEMENT

29. What two things would be most helpful to improve NHSN data collection and/or reporting?

_____

_____

30. What are the two main challenges to NHSN reporting?

_____

_____

31. Do you have any other questions or comments about NHSN?

_____

Appendix 4 Medical Record Abstraction Tool

NHSN Long-term Care Facilities (LTCFs): 2018 LTCF CDI LabID Event Surveillance Chart Review Form

Instructions: This form is a tool to review a long-term care facility resident chart and collect NHSN LTCF CDI LabID Event Surveillance information to determine whether data were correctly reported. Chart reviewers must be familiar with the NHSN LTCF CDI LabID Events Protocol instructions and definitions prior to chart review. First complete sections A and B. For section C, note all *C.difficile* positive laboratory assay results identified for this resident, as defined by the NHSN LTCF CDI LabID Event Surveillance Protocol. Arrange the positive results chronologically. Include all specimens obtained while the resident is receiving care from the LTCF, including specimens collected from an emergency department (ED) or outpatient (OP) setting during a resident's current admission. Use a calendar to help you to determine which events are duplicate events (< 15 days since the last positive specimen).

Section A: Facility and Resident Information			
Facility name		Resident/Med Record Number	
NHSN Org ID		Date of birth	
NHSN Resident ID Number		Gender	
Resident Name		Date of First Admission to Facility	
Section B: Chart Review Information			
Reviewer name		Review Start Time	
Review date		Review End Time	
Time Period Reviewed (Month/Year to Month/Year)	From: To:	Total Review Time (in minutes)	

Section C: CDI LabID Events

☐ Chart review for this resident completed and no CDI LabID Events were found during the evaluation time period.

Current Admission Date	Date of Specimen Collection	Location of Specimen Collection	Number of days since last *C. difficile* positive laboratory assay result	Was this a "duplicate specimen" (collected < 15 days since the last positive specimen)?*	Should this event be reported to NHSN?†	Was this event reported to NHSN by the facility?
		LTCF ED OP	_____ days ☐ no prior	Yes No	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No	Yes No
		LTCF ED OP	_____ days	Yes No	Yes No	Yes No

*Note: The LabID Event algorithm for determining duplicate events (<15 calendar days between positive specimens) applies across current admissions.

†Event is reportable to NHSN if

- No prior *C. difficile* positive laboratory assay for the resident while receiving care from this LTCF
- More than 14 calendar days since the last *C. difficile* positive laboratory assay for the resident

Appendix 5 LabID Event Facility-Wide Inpatient (FacWideIN) Denominator Validation Template

Please feel free to adapt this template to meet your state's needs

Electronically collected CDI FacWideIN denominators

"FacWideIN" surveillance data includes all admissions (new and re-admissions) and resident days counted at the same time each day for residents housed in a bedded location. This information may be collected electronically. Manual counts should be within 5% of the referent (usual) electronic counts, or an evaluation of why they differ should be conducted. Electronic ADT data often are found to be more accurate than electronic billing data in this regard. This internal validation process can be conducted by facilities when requested or required.

Number of Admission on C. difficile treatment

For each day of the month, count and record the number of residents who are receiving antibiotic therapy for *C.difficile* infection at the time of admission to the facility. Include both new admissions and re-admissions when a resident was out of the facility more than 2 calendar days (specifically, change to the Current Admission Date). **NOTE**: A resident admitted on CDI treatment should be included in this count even if he/she does not have a CDI LabID event for the LTCF.

CDI LabID Event Denominator Validation									
	Month of Validation *(specify)*	Admissions			Resident Days			Number of Admissions on C. diff Treatment:	
		Usual Count	5% Tolerance interval†	Manual Count	Usual Count	5% Tolerance interval†	Manual Count	Reported by facility	Identified during validation
†Equation for 5% tolerance interval is: Usual Count ± (Usual Count * 0.05). Example calculations where Usual Count = 164 and Manual Count = 178: Eligible 5% tolerance interval = [164±(164*0.05)]=155.8 to 172.2 Manual Count 178 falls outside the tolerance interval, suggesting that Usual Count is inaccurate and should be investigated.								The most common medications used to treat CDI are oral (PO) vancomycin, oral (PO) metronidazole (Flagyl); and Fidaxomicin	

Appendix 6 Line List Template (Optional)

*Required data

*Resident ID	*Date of Current Admission to the Facility	*Laboratory Specimen number	*Specimen Collection Date	*Results of CD Toxin Test	* Specific NHSN Location at the time of collection, include ED/OP	*Date of birth	First Name	Last Name	++Transferred directly from ACF

++Has resident recently transferred directly from ACF in previous 4-weeks of current admission to facility and on treatment for CDI?