

## Statewide Validation of Laboratory-identified *Clostridium difficile* Infections in New Mexico, 2013

Healthcare-associated infections (HAIs) are recognized as a complication of modern medicine and a source of significant morbidity and mortality among hospitalized individuals.<sup>1,2</sup> Among the HAIs, *Clostridium difficile* infection (CDI) incidence has increased markedly in the past decade and now has become the most common HAI pathogen.<sup>3</sup> Furthermore, CDI contributes to health care costs with a recent source estimated the attributable cost of CDI to be \$3427 to \$9960 per episode for acute care hospitals. [3] In anticipation of Centers for Medicare and Medicaid Services (CMS) federal reporting requirements, the New Mexico (NM) HAI Advisory Committee recommended adding CDI reporting to the New Mexico Department of Health (NMDOH) notifiable conditions list. Beginning in February 2012, laboratory-identified (LabID) CDI acute care hospital-wide data became reportable to NMDOH under NM Administrative Code, Notifiable Diseases or Conditions in New Mexico, via the National Healthcare Safety Network (NHSN). Facility-wide laboratory-identified data submission was required of acute care hospitals for CMS reporting as of January 2013.

NMDOH not only recognizes the importance of obtaining surveillance data, but also the importance of validating surveillance data. Data validation is a process to assure high quality, accurate, and reliable surveillance data and to identify and correct reporting errors. NMDOH was funded in 2014-2015 via the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) cooperative agreement to conduct CDI validation using the Centers for Disease Control and Prevention (CDC) 2013 External Validation of NHSN Patient Safety Component Data Toolkit (2013 Toolkit). The 2013 Toolkit provides a standardized process and data collection instruments to ensure meaningful validation across and within states.

### Methods

**Sampling Framework.** Facilities were selected based on the “Targeted top tertile plus 5 percent plan” in ac-

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cordance with the 2013 Toolkit. NM had 32 facilities sorted in tertiles based on the expected/predicted number of CDI events. Targeted facility selection was conducted per the 2013 Toolkit algorithm, which resulted in 11 top tertile facilities being selected. This selection algorithm was then applied to second tertile that resulted in seven facilities being selected. A five percent random sample from the remaining facilities resulted in one facility being randomly selected.

Medical records were selected per the 2013 Toolkit. A complete linelist of 2013 final *Clostridium difficile* (*C. difficile*) toxin-positive laboratory results on unformed stool specimens was obtained securely from each chosen facility. Sorting strategy was then applied to determine first and non-first inpatient positive test results during an episode of care dividing the original list into two lists. From list A, first reportable positive tests results during an episode of care, random samples of 20 specimens were drawn. Using list B, non-first inpatient specimens, a random sample of up to 40 positive tests results were to be selected. For both list A and B, the selected positive test results were then evaluated to determine whether the events were reportable to NHSN.

**Review of Medical Records.** Medical record reviews were completed both onsite and remotely. Most of the facilities granted access to the electronic medical records (EMR); however, some facilities with EMR provided paper charts (Figure). The 2013 Toolkit Medical Record Abstraction tools (MRATs) were utilized to review the records. The MRAT required information such as: inpatient admission date, first inpatient bed location, inpatient CDI toxin-positive specimen collection dates, as well as transfer locations and dates. Medical record reviewers included the HAI Epidemiologist, infection preventionist (IP) contractor, and HAI intern.

Reviewers were blinded to whether the hospitals had reported particular CDI events in NHSN.

*Case Discrepancy Resolution.* The HAI Epidemiologist reviewed CDI events that were discordant between events reported to NHSN by facilities and event determinations made by reviewers during the validation process. On some occasions, event determinations made by NMDOH staffs were modified based on additional review by the HAI Program Manager. Remaining discrepant cases were reconciled through teleconference between NMDOH and facility IP's. There were no instances where further adjudication by NHSN was required in determining reportable events.

*Surveillance Methods Survey.* Facility IPs were surveyed on denominator and numerator data collection procedures for CDI surveillance and laboratory policy regarding unformed stool testing for *C. difficile*. NMDOH also collected information about hospital-specific application of NHSN definitions and rules, as well as surveillance and laboratory software systems.

*Analysis.* Summary data from medical record reviews, NMDOH CDI event determinations, CDI events in NHSN, and reasons for CDI event discrepancies were entered into an Excel spreadsheet. The mean and median times for medical record reviews were calculated. Sensitivity and specificity were calculated in aggregate for 2013 CDI validation. Positive and negative predictive values were also calculated in aggregate.

## Results

A total of 19 facilities were selected for validation in NM. The mean bed size of facilities participating in validation was 141 (median 186, range 26-723). The mean time for medical record review was 11 minutes (median 9 minutes, range 4-60 minutes). Among the 379 medical records NMDOH reviewed, there were 321 first positive CDI events and 58 non-first positive CDI events.

Final event reconciliation was determined in conjunction with facility IPs and 58 discrepant cases were confirmed. Of the 379 medical records validators reviewed, 275 events were 'true positives' that both facilities and DOH agreed to be reportable and 46 events were 'true negatives', as agreed to be non-reportable by facilities and DOH. Discrepancies were categorized into under-reported (53) and over-reported (5) events

(Table). Under-reported events were those DOH determined to be reportable but facilities had not entered in NHSN. Reasons for under-reported CDI events for 2013 included: hospital system issues that resulted in the IP not being properly alerted to a positive *C. difficile* toxin test, and improper assessment of reportable LabID events by IPs that led to not reporting an event in NHSN (i.e., IPs ruled out an event as duplicate but it had been more than 14 days since the last CDI toxin-positive specimen from the patient in same location).

For the majority of under-reported cases a reason for underreporting could not be determined. Over-reported events were events entered in NHSN by facilities but DOH determined them to be non-reportable. These events were duplicate (positive CDI toxin-positive specimen collected from the same patient in same location within 14 days of prior specimen collection in an episode of care) and emergency department (ED) events not from the same calendar day as admission. Facilities were instructed to enter all newly identified events in NHSN and to remove previously reported events that were determined not to be cases. Final determinations resulted in sensitivity of 84%, specificity of 90%, positive predictive value of 98%, and negative predictive value of 46% for *C. difficile* surveillance.

*IP Interviews.* Results from the IP interviews revealed that despite NHSN's recommendation to obtain line-lists directly from the laboratory information management system (LIMS), only five facilities (29%) obtained their lists solely from LIMS. Four facilities (23%) retrieved line-lists from surveillance software and six lists (35%) came from a combination of LIMS and surveillance software. Two facility lists (12%) came from the quality department and one (1%) from the IP log. Among the 19 facilities, 15 facilities (79%) granted access to EMR for chart reviews; three facilities (16%) with EMR did not provide direct access but printed out necessary entries; one facility (5%) provided paper charts (Figure). Denominator data were obtained electronically by 12 facilities (63%) and manually by four facilities. Three facility IPs could not identify the source of their denominator data (n=3, 16%). Consistent with the CDC recommendations, all facility laboratories reported having a policy to perform CDI toxin stool tests only on unformed stool.

## Discussion

External validation of NHSN HAI events provides the opportunity to ensure accurate and reliable findings. The validation project provided mutual learning opportunities for the NM HAI Program and facility staffs while improving NHSN data quality for the time period examined and for future reporting. Surveying hospital IPs in one-on-one conversations permitted the reviewers to maximize educational opportunities about surveillance methods and hospital-specific practices. Summary letters were provided to each hospital which included facility-specific system issues that could be addressed to improve the accuracy and ease of data collection for reporting and validation.

Major challenges encountered during the 2013 CDI validation project were lack of a common method for secure transmission of spreadsheet data between healthcare facilities and NMDOH, failure to obtain a searchable excel file of toxin-positive stool test results from each facility's LIMS, and discrepancies in MRNs, admission dates, and specimen collection locations. Also, there is still need for facilities to grant remote access to EMR as well as access to the full record, not just an audit view. Additional challenges noted were time constraints and distance and travel time to facility locations for onsite medical record reviews.

Validation of laboratory-identified CDI NHSN events improves accuracy of hospital-based CDI infection surveillance. Discussing the discrepant cases with hospital IPs promotes acceptability, reliability, and transparency of the review process. The experience and knowledge gained from this CDI Data Validation Project well-positions the NM HAI Program to conduct ongoing CDI data validation work and improve the quality of public health surveillance data.

## References

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Table. Comparison of final CDI LabID Event Determinations and Original Facility Determination

Original facility determination	Final Determinations by NMDOH and IPs		
	CDI LabID Events	Not an Event	Total
CDI LabID Events	275	5	280
Not an Event	53	46	99
Total	328	51	379

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Figure. Access to Electronic Medical Records (EMR) for Chart Reviews

