TECHNICAL NOTES: *Clostridium difficile* Infections in California Hospitals, 2015

Introduction

Clostridium difficile (*C. difficile*) is a common cause of diarrhea in health care settings, resulting in longer hospital stays and higher hospital costs [1-4]. Morbidity and mortality rates due to *C.* infection (CDI) have increased over the past several years as a result of the emergence of *C. difficile* strains that are more infectious and more virulent [5-10]. Infection control precautions including strict adherence to hand hygiene and thorough environmental cleaning are essential in preventing transmission. Most patients with CDI received antibiotics between two weeks and three months prior to the infection. Judicious and appropriate use of antibiotics is also important to prevent CDI [5-10].

California Health and Safety Code section 1288.55(a)(1) requires general acute care hospitals to perform surveillance and report to the California Department of Public Health (CDPH) all cases of CDI identified in their facilities. These *Technical Notes* describe the definitions, methods, and limitations associated with CDI data for the reporting period January 1, 2015 to December 31, 2015. California hospitals reported data via the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN). CDPH accessed the NHSN data to produce this report.

NHSN is using HAI data reported by all U.S. hospitals in 2015 to establish new risk adjustment models and new national baselines against which future HAI prevention progress will be measured. Next year's annual report will show how California hospitals compare with the new 2015 national baselines and demonstrate if HAI prevention progress was made in 2016.

Methods

Reporting hospitals

In 2015, CDPH received data from 393 licensed general acute care hospitals representing 416 physical campuses that operated for the full 12 months of the reporting period. Of these, 21 hospitals reported combined CDI data for multiple hospital campuses under a single hospital license, and 372 hospitals reported data separately for each campus (Table A).

Table A. Reporting by General Acute Care Hospitals, 2015

	Reporting Hospitals	**Number of Campuses**
Hospitals that reported separately for each campus	372	372
Hospitals that reported multiple campuses together	21	44
Total	**393**	**416**

Data sources

California hospitals entered CDI data into the NHSN online reporting system using the surveillance and reporting protocols described in the Multidrug Resistant Organism (MDRO) Laboratory-Identified (LabID) Event Module [11]. Hospitals reported CDI LabID events and the number of inpatient days (excluding NICU and well-baby nursery patient days). Hospitals reported the type of CDI test being used each quarter (March, June, September, and December). Hospitals were responsible for providing permission to CDPH to access NHSN data from hospital inpatient units/wards where CDI surveillance was conducted. On March 1, 2016, we downloaded the NHSN data sets used to produce this 2015 report.

Missing data

CDPH excluded from this analysis hospitals that reported less than 12 months of required CDI data. Hospitals excluded from our CDI analysis are shown in CDI Table 4.

Definitions

CDPH requires hospitals to comply with NHSN surveillance and reporting protocols, including NHSN standardized definitions [12]. Key definitions related to CDI reporting are:

- A ***C. difficile* LabID event** is a positive result of a laboratory assay for *C. difficile* toxin A, *C. difficile* toxin B, or detection of a toxin-producing *C. difficile* organism in a stool sample. This report included all positive *C. difficile* laboratory tests from all inpatient locations, excluding neonatal intensive care units (NICU) and well-baby nurseries.

- **Community-onset (CO)** describes a LabID event specimen collected as an outpatient or an inpatient less than or equal to 3 days after admission to the facility (i.e., days 1, 2, or 3 of admission).

- **Hospital onset (HO)** describes a LabID event that occurs more than three days after admission to the facility (i.e., on or after day four).

- **Inpatient days** are the cumulative numbers of patients hospitalized each day during the reporting period. Patient days from NICU and well-baby nurseries are excluded when reporting CDI inpatient days.

- **Polymerase chain reaction (PCR)** is a type of nucleic acid amplification test that detects *C. difficile* toxin genes. It is commonly referred to as a molecular test method. Advantages for this laboratory test method are the high sensitivity (the ability of the test to detect *C. difficile* when present) and short turn-around time compared to other methods [7].

- A **long-term acute care (LTAC)** hospital is defined by the Centers for Medicare & Medicaid Services (CMS) as a licensed general acute care hospital providing care for patients with medically complex conditions requiring an average length of stay for all patients of greater than 25 days [13].

- A **rehabilitation hospital** is a hospital with inpatient wards for evaluation and restoration of function to patients who have lost function due to acute or chronic pain, musculoskeletal problems, stroke, or catastrophic events resulting in complete or partial paralysis.

Quality assurance and control

Hospital personnel were responsible for the quality and completeness of their CDI data. CDPH assisted hospitals to identify systematic data errors by reviewing hospital-specific NHSN data and notifying hospitals of discrepancies. In September, October, November, and December 2015, and February and March 2016, CDPH distributed quality assurance and control reports that identified missing, incomplete, or potentially aberrant data for the reporting period. In February 2016, we also notified hospitals with fewer than 12 months of data or missing a complete Annual Hospital Survey. We encouraged hospitals to conduct a final data review and complete all corrections and changes before the final data download on March 1, 2016. Hospitals were responsible for making data corrections in NHSN.

Validation

In 2014, CDPH validation efforts helped hospitals assess and improve case-finding and evaluate completeness in identifying and reporting CDI. Hospitals identified gaps in their routine CDI surveillance practices that resulted in missing reportable CDI. Hospitals found to have low case-finding during this 2014 validation process were targeted for more assistance. CDPH staff conducted 38 onsite re-validations in 2015 to hospitals that had been found in 2014 to be missing three or more CDI, MRSA BSI, or VRE BSI cases and having less than 85% sensitivity. Of the 38 hospitals re-validated in 2015, eight were still missing three or more cases and had less than 85% sensitivity. In 2015, CDPH is continuing to follow up with these eight hospitals and their leadership representatives to review their case finding processes and related reporting issues.

Data presentation and statistical analyses

A. General acute care hospitals (other than LTAC and rehabilitation hospitals):

We presented hospital-specific CDI standardized infection ratios (SIR) and 95% confidence intervals (CI) for general acute care hospitals other than LTAC and rehabilitation acute care hospitals (CDI Table 1). The NHSN SIR compares the reported number of HO incident cases with the predicted (expected) number based on the national baseline data, adjusting for the significant risk factors such as CDI test type, CO admission prevalence rate, facility bed size, and medical school affiliation [14]. Quarterly reports of CDI test type are used in the SIR risk adjustment beginning with 2014 data [15]. Adjusting for these factors provides for a more fair comparison of hospitals' infections with the predicted. The NHSN system calculates an SIR only when the predicted number of CDI is greater than 1.0. In 2015, CDPH also calculated and reported an SIR when the predicted number of infections was less than 1.0, but greater than or equal to 0.2. This change allowed more hospitals (e.g., small and rural hospitals) to compare their infection incidence to the national baselines. CDPH was able to report SSI results (i.e. incidence higher, lower, or the same as predicted) for more California hospitals. In the past, these hospital results would have been missing, with an indication that there were "too few data to calculate." National CDI baselines for general acute care hospitals are calculated from data reported to NHSN in 2010-2011.

If an SIR was generated for a hospital, the calculated 95% confidence interval determined if the observed number of infections was significantly different from predicted. If the confidence interval included the value of 1.0, the SIR indicated that the observed number of infections was not considered different from the predicted number of infections. Based on the 95% confidence interval, we labeled each SIR as indicating: "no difference" between the number of observed and predicted infections, "higher" because more infections were observed than predicted, or "lower" because fewer infections were observed than predicted.

B. LTAC and rehabilitation hospitals:

NHSN excludes LTAC and rehabilitation hospitals from the CDI SIR risk model. CDPH reported key CDI measures for LTAC (CDI Table 2), and free-standing rehabilitation acute care hospitals and rehabilitation units with their own CMS certification number (CCN) (CDI Table 3). Measures included the numbers of HO CDI LabID events and inpatient days, unadjusted HO CDI rates per 10,000 inpatient days, and 95% confidence intervals assuming an exact Poisson distribution [16].

We also reported hospitals using a PCR method to detect CDI, as reported in their annual NHSN survey. Hospitals using PCR may have higher CDI rates as a result of using of a more sensitive laboratory test. We did not group or stratify LTAC and rehabilitation hospitals/units based on CDI test type. CDPH recommends caution when comparing hospital CDI rates because they may be misleading due to differences in laboratory testing methodology.

We performed the following calculations on 2015 CDI data submitted to NHSN by LTAC and rehabilitation hospitals/units. The numerators for the CDI rates were all LabID events categorized as HO. The denominators for the rates were total inpatient days for all available inpatient locations, excluding NICU and well-baby nurseries. We calculated the HO incidence rate for each hospital using the following equation:

$$HO\ Rate\ per\ 10{,}000\ inpatient\ days\ = \frac{Number\ of\ HO\ Cases}{Total\ Inpatient\ Days} \times 10{,}000$$

We used 10,000 as the multiplier to yield whole numbers or large fractions because CDI rates are generally low, and current clinical practice guidelines for CDI surveillance recommend that CDI rates should be expressed as the number of cases per 10,000 patient days [5]. Hospitals summed and entered into NHSN all denominator data (inpatient days). We calculated the HO incidence rate for each LTAC and rehabilitation hospital that reported data into NHSN for all 12 months of the reporting period.

We also calculated the statewide pooled mean (average) rate for LTAC and rehabilitation hospitals/units by dividing the sum of all HO CDI LabID Events by the sum of all inpatient days and multiplying by 10,000.

A 95% confidence interval is a range of values that quantifies the random variation of a rate; it does not provide information about systematic errors or bias. The wider the interval, the greater the uncertainty associated with the rate. The width of the confidence interval is in part related to

the reported number of inpatient days. Smaller facilities with fewer inpatient days have the least precision associated with their rates and the widest confidence intervals. If a 95% confidence interval includes 1.0, the CDI rate is not statistically significant.

Limitations and Context

To account for the differences in laboratory method and other significant risk factors, an NHSN risk-adjustment method was available beginning with 2012 CDI data in general acute care hospitals [14]. LTAC and rehabilitation hospitals/units were excluded from CDI SIR analyses because too few of these hospital types reported CDI data during the 2010-2011 baseline period. The LTAC and rehabilitation hospital-specific rates presented here have not been risk adjusted and may not be comparable.

The SIR adjusts for significant risk factors that influence CDI rates in hospitals, specifically, CDI laboratory testing methodology, CO admission prevalence rate, facility bed size, and medical school affiliation. Hospital CDI incidence may also differ due to other factors not included in the NHSN risk adjustment model, such as different patient populations with different risks for infection.

The CDI rates for LTAC and rehabilitation hospitals/units are not risk-adjusted. Differences in rates for LTAC and rehabilitation hospitals/units may have resulted from differences in laboratory testing methodology, patient populations, infection and transmission prevention practices, antibiotic utilization, and/or CDI CO rates. CDI rates from LTAC and rehabilitation hospitals/units using different types of laboratory tests are not comparable, as there can be as much as a two-fold difference in test sensitivity. Hospital CDI rates may also differ due to patient populations with different risks for infection such as age. The rate of community onset cases has also been shown to affect the rate of HO infections, perhaps reflecting higher admission rates of patients already at increased risk, such as patients from skilled nursing facilities.

Laboratory-based surveillance and reporting depend rely on appropriate clinician test ordering and laboratory processing. Some hospitals may have changed laboratory testing methodology during the reporting period. Hospitals may have falsely lower rates if patient days from NICU and well-baby nurseries were not excluded from denominator data.

CDPH recommends caution if comparing these 2015 HAI data to previous California hospital HAI annual reports and to national baselines. NHSN implemented several data classification and reporting changes that affected these 2015 HAI data. The differences observed in 2015 CDI data were the result of the following improvements and changes:

- NHSN changed how hospitals reported infections identified in the emergency department and 24-hour hold units. In past years, a positive CDI lab test result from a patient in the hospital emergency department or 24-hour hold location was attributed as an inpatient community-onset infection if the patient was admitted to the hospital on the same day that the test was ordered. In 2015, CDI test results from these locations were no longer included in the hospital's inpatient community-onset prevalence, even if the

patient was admitted to the hospital. Community-onset prevalence is an important risk adjustment factor used to report CDI data. Hospitals that reported fewer inpatient community-onset cases in 2015 had fewer hospital-onset infections predicted. This could have resulted in higher CDI incidence when the number of infections that occurred in 2015 was compared to the number of infections predicted by the national baseline data.

- CDI are less common in inpatient rehabilitation and psychiatric facilities. In 2015, NHSN required hospitals with inpatient rehabilitation and psychiatric units to report data separately from other general acute care hospital data. Rehabilitation and psychiatric patient days were no longer included in the overall hospital-wide patient days reported for 2015. This resulted in calculations of higher CDI incidence than in past years for some hospitals.

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