

TECHNICAL NOTES *Clostridium difficile* Infections in California Hospitals, 2012

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]. Morbidity and mortality rates due to *Clostridium difficile* 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 [2-4]. Infection control precautions including hand hygiene and environmental cleaning are essential in prevention transmission. Virtually all patients with CDI received antibiotics between two weeks and three months prior to the infection; therefore, judicious use of antibiotics is also important in decreasing and preventing CDI [2-5].

Health and Safety Code section 1288.55(a)(1) requires general acute care hospitals to 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 the CDPH data release on CDI. The reporting period for this release is January through December 2012 and the data were submitted by California hospitals to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).

The distribution of information on the health of the community is a core function and essential service of public health. CDPH strongly supports the goals of public reporting on HAIs including the production and distribution of quality data that are valid, fair to hospitals, and useful to the public. Bearing in mind important limitations, the public can use these data as a starting point to discuss patient safety and quality of care with their healthcare providers and to make more informed healthcare decisions. Hospitals and health care providers can also use these data to examine their patient safety practices and improve quality of care, as appropriate.

Materials and Methods

Reporting hospitals

As indicated in the table below, we identified 388 licensed general acute care hospitals representing 429 physical campuses with active acute care beds that operated continuously (for the full 12 months) during the reporting period. Of these, 46 licensed hospitals had more than one campus associated with its license. We defined a multi-campus reporting facility as a licensee that reported HAI data combined for two or more jointly operated general acute care campuses (38 licenses comprising 79 campuses). We defined a single-campus reporting facility as an individual general acute care campus whose license included: (a) only one general acute care campus (331 licenses comprising 331 acute care campuses) or (b) more than one jointly-operated general acute care campus, at least one of which reported infection information separately (8 licenses representing 19 campuses). In total, there were 388 reporting entities,

hereafter referred to as hospitals. We referred to multi-campus hospitals by the business name of the licensee in CDPH Licensing and Certification (L&C) records except for the licenses involving University of California hospitals, which are described as such.

General Acute Care Hospitals (GACHs)	Number of Licenses	Number of Campuses
With active beds (total)	377	429
Consolidated license, <i>reported together</i>	38	79
Consolidated license, <i>reported separately</i>	8	19
<i>Single license, reporting separately</i>	331	331
Reporting entities	38 + 19 + 331 = 388	

Data sources

California hospitals submitted CDI data into NHSN using the surveillance and reporting protocols described in the Multidrug Resistant Organism (MDRO) Laboratory-Identified (LabID) Event Module [6]. Hospitals provided CDPH with electronic permission to access these data. On May 16, 2012, we accessed the NHSN CDI data for the reporting period January 1, 2012 through December 31, 2012. The data included NHSN-produced files listing all CDI LabID events (event file) and number of inpatient days and CDI predicted and standardized infection ratio and rate (SIR and rate files).

Missing data

In some cases, hospitals did not report CDI LabID events and the corresponding monthly counts for inpatient days for 12 months. We excluded from this analysis hospitals that reported CDI LabID events and inpatient days for less than 12 months.

Definitions

CDPH required hospitals to comply with NHSN surveillance and reporting protocols, including NHSN standardized definitions. Key definitions are defined here.

- A **C. difficile LabID Event** is a positive result for a laboratory assay for *C. difficile* toxin A and/or B or a toxin-producing *C. difficile* organism detected in stool sample. This included laboratory tests positive for *C. difficile* from all available inpatient locations, excluding neonatal intensive care units (NICUs) and well-baby nurseries.
- **Community-Onset (CO)** is 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)** is a LabID Event that occurs more than three days after admission to the facility (i.e., on or after day four), excluding NICUs and well-baby nurseries.
- **Community Onset Hospital Associated (CO-HA)** is a LabID Event from a patient within the first three days of admission who was discharged from the same facility within four weeks prior to the current date of stool specimen collection, excluding NICUs and well-baby nurseries.
- **Hospital Associated (HA)** is the sum of HO LabID Events and CO-HA LabID Events, excluding NICUs and well-baby nurseries.
- **Inpatient Days** are the cumulative numbers of patients hospitalized each day during the reporting period, excluding NICUs and well-baby nurseries.
- **Polymerase Chain Reaction (PCR)** is a type of nucleic acid amplification test that detects *C. difficile* toxin gene(s); 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 [4].
- **Long-Term Acute Care** is a hospital 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 [7].
- **Rehabilitation Hospitals** are 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. These hospitals were self-identified through NHSN.
- **Reporting Period** was January 1, 2012 through December 31, 2012.

Quality assurance and control

Hospital personnel were solely responsible for the quality and completeness of their CDI data. In July and November 2012 and April 2013, CDPH distributed quality assurance and control reports that identified missing, incomplete, or potentially aberrant data for the reporting period. CDPH made available to hospitals the assistance of data managers, epidemiologists, and regional infection prevention staff to help resolve NHSN enrollment or reporting issues. Additionally, in March and/or April 2013 we emailed hospitals with fewer than 12 months of data or with missing or incomplete Annual Hospital Survey to notify them of missing or incomplete data in NHSN. We encouraged hospitals to conduct a final review of their data and complete all corrections and changes before the final data download on May 16, 2013.

Data presentation, organization, and statistical analyses

New in this report, we present hospital specific CDI SIRs and 95% confidence interval (CI) for general acute care hospitals other than long-term and rehabilitation acute care hospitals. 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 [8]. Adjusting for these factors provides for a more fair comparison of hospitals' infections to the predicted. For more precise comparisons, NHSN provides an SIR only when at least one infection is predicted. Baseline data and the time period are defined as the CDI data reported from facilities as in-plan data in each month's Patient Safety Monthly Reporting Plan during 2010-2011. If an SIR was generated for a hospital, the calculated 95% CI determines if the observed number of infections was significantly different from predicted. Based on the 95% CI, we labeled each SIR as indicating either: N (no difference in number of observed and predicted infections), high (H, more infections than predicted), or low (L, fewer infections than predicted). The 95% CI is a range of values that includes the true SIR, knowing that the reported SIR in Table 1 is the most likely value. If the CI includes the value of one, then the SIR is not significant.

As in the prior report, we report the following primary CDI measures: number of HO CDI LabID events, number of HA CDI LabID events, inpatient days, unadjusted HO and HA CDI rates per 10,000 inpatient days, and 95% confidence intervals assuming an exact Poisson distribution [9] for LTAC and rehabilitation hospitals. Confidence intervals provide a measure of the precision of each CDI rate. We also report whether a hospital uses PCR to detect CDI, as these hospitals may have higher rates resulting from use of a more sensitive laboratory test. In this report, we do not group or stratify the LTAC and rehabilitation hospitals by PCR use. Some hospitals use different testing algorithms in addition to PCR; it would be difficult to calculate rates by testing methodology. Additionally, grouping hospitals by PCR use does not indicate that rates from those hospitals would be comparable, as the rates are unadjusted for other risk factors associated with CDI. Additionally, hospital comparisons within each group might be misleading due to differences in laboratory testing methodology between individual hospitals.

We performed the following calculations on data submitted to NHSN during the reporting period for LTAC and rehabilitation hospitals. The numerators for the rates were all LabID Events categorized as HO or HA. The denominators for the rates were total inpatient days for all available inpatient locations, excluding NICUs and well-baby nurseries. For each hospital we calculated the HO Incidence Rate and HA Incidence Rate. The equations for the rate calculations are:

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

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

We used 10,000 as the multiplier to yield whole numbers or large fractions because CDI rates generally are low. Also, total inpatient days are most commonly in the tens of thousands. Hospitals summed and entered into NHSN all denominator data (inpatient days). We calculated HO and HA incidence rates for each LTAC and rehabilitation hospital that reported data into NHSN for 12 months of the reporting period.

For each incidence rate, we calculated exact 95 percent confidence intervals using the Poisson distribution [9]. We calculated the statewide pooled mean (average) rate for LTAC and rehabilitation hospitals by dividing the sum of all CDI LabID Events by the sum of all inpatient days and multiplying 10,000.

A 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.

Limitations and context

Differences in rates for LTAC and rehabilitation hospitals can result from differences in laboratory testing methodology, patient populations, infection and transmission prevention practices, antibiotic utilization, and/or community onset rates of CDI. Rates from LTAC and rehabilitation hospitals using different types of laboratory tests are not comparable, as there can be as much as a two-fold difference in test sensitivity. Additionally, some facilities may have changed laboratory testing methodology during the reporting period. Laboratory-based reporting depends on appropriate clinician test ordering and laboratory processing. Hospital CDI rates also may 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 for CDI, such as patients from skilled nursing facilities. Facilities may have falsely lower rates if patient days from NICUs and well-baby nurseries were not excluded from denominator data. Therefore, the LTAC and rehabilitation hospital-specific rates presented here have not been risk adjusted and are not comparable. To account for the differences in laboratory method and other significant risk factors, with the implementation of CMS reporting requirements for CDI beginning January 2013, an NHSN risk-adjustment method was available for the 2012 data in general acute care hospitals other than long-term and rehabilitation acute care hospitals [8]. Because few LTAC and rehabilitation hospitals reported CDI data during the baseline period (2010-2011), they were excluded from all SIR analyses.

There are no national reports of CDI incidence rates from NHSN data for comparison with this report; therefore, it is not possible to compare these SIRs and rates from California hospitals with national data. We cannot compare the risk-adjusted SIRs to rates from the previous report for general acute care hospitals other than long-term and

rehabilitation acute care hospitals because of using different measures of risk and adjustment factors in this report.

References

1. McDonald LC, Coignard B, Dubberke E, Song S, Horan T, Kuty PK. Recommendations for surveillance of *Clostridium difficile*-associated disease. *Infect Control Hosp Epidemiol* 2007;28:140-5.
2. Cohen SH, Gerdin DN, Johnson S, Kelly CP, Loo VG, McDonald LC, Pepin J, Wilcox MH. Clinical practice guidelines for *Clostridium difficile* infection in adults: 2010 update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA). *Infect Control Hosp Epidemiol* 2010;31:431-55.
3. Kachrimanidou M, Malisiovas N. *Clostridium difficile* infection: a comprehensive review. *Crit Rev Microbiol* 2011;37(3):178-87.
4. Lessa FC, Gould CV, McDonald LC. Current status of *Clostridium difficile* infection epidemiology. *Clin Infect Dis* 2012;55 Suppl 2:S65-70.
5. Olsen MM, Shanholtzer CJ, Lee JT Jr et al. Ten years of prospective *Clostridium difficile*-associated disease surveillance and treatment at the Minneapolis VA Medical Center, 1982-1991. *Infect Control Hosp Epidemiol* 1994;15:371-81.
6. Centers for Disease Control and Prevention. National Healthcare Safety Network Multidrug-Resistant Organism and *Clostridium difficile* Infection (MDRO/CDI) Module. Available at http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf Accessed 29 July 2013.
7. Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy. Chapter 10 Long-term care hospital services. 2012. Available at http://www.medpac.gov/documents/Mar12_EntireReport.pdf. Accessed 29 July 2013.
8. Centers for Disease Control and Prevention. Risk Adjustment for Healthcare Facility-Onset *C. difficile* and MRSA Bacteremia Laboratory-Identified Event Reporting in NHSN. Available at: <http://www.cdc.gov/nhsn/PDFs/mrsa-cdi/RiskAdjustment-MRSA-CDI.pdf>. Accessed 29 July 2013.
9. Daly L. Simple SAS macros for the calculation of exact binomial and Poisson confidence limits (1992). *Comput Biol Med*;22(5):351-61.