Committee: Infectious Disease

Subcommittees: CSTE HAI Subcommittee, CSTE HAI Standards Subcommittee

Title: Placing Clostridium difficile (C. difficile) Infection (CDI) Under Surveillance through the National Healthcare Safety Network (NHSN), Laboratory-Identified Event (LabID Event) Module

I. Statement of the Problem:
C. difficile is an important cause of serious healthcare-associated infections (HAIs), with adverse consequences for patients that include increased length of stay, costs, and mortality. Clostridium difficile infection is readily transmitted in and across healthcare settings, as well as in the community. Optimal prevention and control of spread requires surveillance to identify potential reservoirs of infection and to focus prevention efforts. A plan for establishing and expanding surveillance for C. difficile in a variety of healthcare settings is needed.

II. Background and Justification:
C. difficile may cause severe diarrhea estimated to be linked to 14,000 deaths and at least $1 billion in extra health care costs annually in the United States. Healthcare Infection Control Practices Advisory Committee (HICPAC) Guidelines recommend that focused C. difficile surveillance be conducted to determine infection control approaches to reduce the impact of this pathogen. Prevention collaboratives in New York, Massachusetts and Illinois demonstrated a decrease of 20% in C. difficile infections in less than two years with infection prevention and control measures. The importance of this issue to public health and quality medical care led the Department of Health and Human Services (DHHS) to include these measures as targets for the National HAI Action Plan.

Generating actionable, standardized surveillance data for C. difficile requires use of a common reporting platform such as that provided by the NHSN. Beginning January 2013, the Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Quality Reporting (IQR) Program began requiring participating acute care hospitals nationwide to report C. difficile LabID Events (with facility-wide inpatient denominators) through NHSN, thus establishing a standard for reporting from many of the over 3,300 hospitals that receive funds from Medicare. Facilities that do not participate in the hospital IQR Program include Maryland hospitals, critical access hospitals, Department of Defense and Veterans' Administration Hospitals, inpatient rehabilitation facilities, long-term acute care hospitals (termed "long-term care hospitals" by CMS), selected oncology hospitals, and some pediatric hospitals. However, it could be expected that the patient populations in these facilities may also develop CDI. In addition to the nationwide CMS reporting standard, several states have established mandates for reporting of C. difficile (CA, CT, GA, HI, IL, ME, NM, NY, OR, TN, UT), the majority of which require use of NHSN’s LabID Event reporting option.

NHSN is a secure, internet-based surveillance system that collects HAI process and outcome data directly from reporting facilities. NHSN also provides public health departments and facilities an array of high quality support services, such as online training, surveillance definitions, data analysis features, and monthly conference calls that provide technical assistance and opportunities for user input. As of December 2012, over 11,300 healthcare facilities were enrolled. NHSN data are used to improve patient safety at the facility, local, and national levels. Facilities retain real-time access to reported data and structured analytic tools. Group administrators, such as state health departments, can analyze NHSN data in their jurisdictions and support local facilities accordingly. CDC uses NHSN data to establish benchmarks for disease control and to focus prevention activities at the national level. CDC publishes NHSN surveillance data to characterize the national burden of HAIs; local users and facilities can compare their experience to these benchmarks.
NHSN data complements other C. difficile surveillance systems (e.g., the Emerging Infections Program Healthcare Associated Infections Community Interface projects) used to assess the national burden and distribution of CDI over time. While the Emerging Infections Program and other surveillance systems can provide more in-depth data through focused surveillance, NHSN has the potential of providing real time and nearly universal facility data, because nearly all eligible facilities participate in the CMS hospital IQR or other similar CMS quality programs (for other facility types), and non-IQR participating facilities can readily join NHSN.

III. Statement of the desired action(s) to be taken:

1. CSTE recommends use of National Healthcare Safety Network (NHSN) surveillance definitions, case identification and classification, and denominator collection methods for Clostridium difficile infection and recommends that any State or Territory conducting surveillance for this condition use these standard methods. This entails sharing of case information with CDC through NHSN, using established procedures for such reporting.

2. CSTE recommends that CDC publish aggregate data on Clostridium difficile Infection (CDI) as appropriate in MMWR and other venues.

3. CSTE recommends that States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction, under circumstances defined in Section VII, but not to add the condition to the Nationally Notifiable Condition List. (Jurisdictions may also elect to go beyond these circumstances). Doing so will assure the jurisdiction access to reported data, with full functionality of NHSN tools and analysis through the NHSN group function.

4. CSTE recognizes Clostridium difficile Infection (CDI) as important to public health, anticipates a need to periodically review and revise surveillance and prevention plans as resources and priorities permit. The current vision and proposed strategies to reduce disease burden are discussed in Section VIII.

Additional detail on desired actions:

1. CSTE recommends that a proxy measure be used for Clostridium difficile infection (C. difficile LabID Event). In states where CDI is reportable, these data should be reported and be placed under standardized surveillance using the LabID Event option of the NHSN CDI Module under circumstances defined in Section VII. Jurisdictions may elect to go beyond these circumstances, for example, by conducting surveillance in additional facility types, accelerating the timeline, or using the more labor-intensive Infection Surveillance option of the NHSN CDI Module under circumstances where proxy measure surveillance is not recommended.

2. CSTE recommends that reported C. difficile LabID Event data be validated to ensure the completeness and consistency of data across facilities and jurisdictions, and that validation methods be described in national or local reports of the data.

3. CSTE recommends that other venues for publication of C. difficile LabID Event data include the National and State Healthcare-associated Infections Standardized Infection Ratio Report published by CDC annually. Local health departments and state health departments are recommended to publish their jurisdiction-specific data.

4. CDC and CMS should coordinate to assure that adequate resources are available to train facilities to use NHSN and validate data.

IV. Goals of Surveillance:

1. To provide facility- and jurisdiction-specific risk-adjusted information and analytic tools imbedded in NHSN to facilities and public health jurisdictions for transparent situational awareness, trend analysis, and planning and prevention activities.

2. To provide data for public reporting, as required by law or regulation in some jurisdictions.
3. To provide facility-specific, jurisdiction-specific, and national risk-adjusted information to federal agencies on the temporal, geographic, and demographic occurrence of *C. difficile* proxy measures over time to facilitate national standards and programmatic support for infection prevention and control.

**V. Methods for Surveillance:**
The dynamics of *C. difficile* colonization and infection are complex, involving reservoirs in both community and healthcare settings, and accelerated transmission and progression to infection in healthcare settings. Proxy measures for surveillance available in NHSN can provide an opportunity to efficiently monitor pathogens, to follow trends longitudinally and identify disease reservoirs, and to focus interventions with the intent of reducing disease burden. Use of proxy measures may be facilitated as capacity for electronic reporting by facilities becomes more widespread.


The LabID Event option provides a proxy measure of clinical *C. difficile* infections, relying on laboratory and limited data elements collected by the facilities at patient admission without the need to gather clinical detail. Facilities that report *C. difficile* LabID Events to NHSN are able to calculate a variety of incidence and prevalence statistics that are useful in tracking exposure burden and healthcare acquisition. NHSN requires facilities conducting surveillance through LabID Events to indicate this in their monthly reporting plan and to perform LabID Event surveillance for at least three consecutive months each year to provide meaningful data, though facilities reporting LabID Events to comply with the CMS hospital IQR Program must report data 12 months each year beginning January 2013. NHSN permits collection and reporting of LabID events and denominator data at the individual unit level within the facility for internal quality improvement if the facilities prefer, although only facility-wide level reporting is required by CMS. The NHSN surveillance protocol also defines parameters to categorize LabID Events for *C. difficile* as reportable (incident or recurrent) or non-reportable (duplicate). Incident and recurrent *C. difficile* LabID Events are further categorized as community-onset (CO), or healthcare facility-onset (HO), or as community-onset healthcare facility-associated (CO-HCFA) for reporting. This classification scheme can guide the location and type of prevention interventions.

**VI. Case and Denominator Definitions, and Risk-adjustment for *C. difficile* LabID Event:**
Current and regularly updated NHSN surveillance definitions for *C. difficile* LabID Event are located at the same website as methods: [http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf](http://www.cdc.gov/nhsn/PDFs/pscManual/12pscMDRO_CDADcurrent.pdf). No modifications are recommended.

*C. difficile* LabID Event cases are a positive laboratory test result for *C. difficile* toxin A and/or B, (molecular assays [PCR] and/or toxin assays) or a toxin-producing *C. difficile* organism detected by culture or other laboratory methods performed on unformed (i.e., conforming to the shape of the container) stool samples. Admissions and patient days, either facility-wide or by location, can be used as denominators to permit stratification by location if needed for assessment and prevention planning, though facility-wide surveillance overall is recommended.

Initial work on risk adjustment of the *C. difficile* measures has been completed and implemented in the NHSN data analysis tool available to users on the NHSN web server. The measure is risk-adjusted based on facility bed size and teaching status (e.g., training center for medical students and residents), as well as a facility’s *C. difficile* prevalence rate. The *C. difficile* measure is also risk-adjusted by the type of microbiological test used to identify *C. difficile*, as various test methods have different levels of sensitivity. Additional analysis and refinement of the risk adjustment for *C. difficile* will be done by CDC as the volume of LabID Event data reported to NHSN continues to increase.

**VII. Proposed Circumstances for Surveillance and Reporting of *C. difficile* LabID Event:**
A. Narrative and Justification

Acute care hospitals are an epidemiologically important facility type for CDI surveillance, and for prevention interventions. *C. difficile* was the most common HAI pathogen in the Emerging Infections Program (EIP) HAI point prevalence survey conducted in 2011. The Healthcare Cost and Utilization Project (H-CUP) tracking of *C. difficile* ICD-9 coded discharges (primary or secondary) from acute care hospitalizations, demonstrates an increase in CDI from 5.6 per 1,000 non-maternity discharges in 2001 to 11.5 per 1,000 in 2010.

Beginning January 1, 2013, acute care hospitals participating in the nationwide CMS hospital IQR program have been reporting *C. difficile* LabID Events from all inpatients as required to receive the CMS funding. Nearly all acute care hospitals that are eligible for the IQR incentive funds submitted HAI data in 2012. As these facilities are already reporting to CMS through the NHSN, widespread surveillance with public health reporting is achievable in 2013.

This reporting should also expand beyond CMS hospital IQR Program participants to include other relevant non-IQR participating facilities, according to the timeline in Table VII-B.

Though most of the epidemiological literature on CDI addresses acute care hospitals and patient factors, there is some literature addressing infection burden by facilities other than acute care hospitals. Long term acute care hospitals (LTACH), a growing segment of the healthcare system, care for medically complicated patients with significant long term morbidities requiring more intensive services than those commonly available in nursing homes, such as mechanical ventilation, complex wound care, intravenous antibiotics, etc. LTACH patients have risk factors for CDI, including advanced age (mean 77 years), and high utilization of antibiotics. The literature on CDI in long term acute care hospitals is limited, but in a brief study at one facility, 13% of patients were either colonized or symptomatic with *C. difficile* on admission, and 13% developed CDI within three months of admission. Critical access hospitals (CAH) are CMS-designated short-stay facilities, generally in rural areas, far from other hospitals, and which have no more than 25 beds. One study of CDI predictors in hospitals found that 15% of “high *C. difficile* disease” hospitals were critical access facilities. Inpatient rehabilitation facilities (IRFs) are either freestanding facilities or units within acute care hospitals that offer rehabilitation services (such as physical and occupational therapy), more intensively than in long term care, upon acute care hospital discharge, to patients with certain conditions that affect their capacity to function. Data on IRF *C. difficile* infection burden is lacking, but it can be expected that it would approximate that of long term care facilities, summarized below. “Other” hospitals that also should be included in CDI surveillance are acute care hospitals in the State of Maryland, Department of Defense and Veteran’s Administration Hospitals, and oncology hospitals. These “other” acute care facilities deliver medical and surgical care that is similar to IQR participating acute care hospitals. Though these facilities are not required to participate in the CMS IQR program, there is no evidence they are less likely than IQR-participating facilities to be affected by CDI. A review of the epidemiological literature in the 2002 Society for Healthcare Epidemiology of America (SHEA) guideline on prevention of *C. difficile* in long term care indicates 4-20% patients are colonized at the time of admission to long term care facilities (LTCF), and that an additional 10-20% may acquire *C. difficile* during their stay in LTCF. Moreover, development of CDI in patients often occurs across healthcare settings. According to 2010 Emerging Infections Program data, 20% of hospital-onset CDIs occurred in patients who had recently been in a nursing home, and 67% of nursing home–onset CDI cases occurred in patients recently discharged from acute care hospital.

The time frame for initiating surveillance in these non-acute care hospital settings is based on an estimate of the time required for facilities to gain the capacity to use NHSN for *C. difficile* surveillance and to begin to use these data to guide prevention activities. LTACH and IRF facilities are already required to use NHSN to report data to CMS (CLABSI and Catheter Associated Urinary Tract Infections (CAUTI) for LTACHs, CAUTI for IRFs) to receive annual payment updates. Several states with large rural areas have already trained CAHs on NHSN (e.g., GA, NH, Region VIII). Therefore these facility types could be ready to participate in *C. difficile* surveillance beginning in 2014. Because the “other” facilities are not required by CMS to use NHSN for reporting of *Clostridium difficile*, additional time will be required to ensure they have developed the capacity to
participate in NHSN and use the LabID Event module, they would start in 2015. LTCF will take longer still, until 2016, because they are not yet required to use NHSN for CMS reporting, the NHSN module for these facilities has just launched recently, and they are under-resourced for information technology and infection prevention staffing.

The NHSN protocol excludes Neonatal Intensive Care Units (NICUs) and well-baby locations from C. difficile LabID Event data collection.7

B. Tables of Circumstances where Surveillance through NHSN of C. difficile Infection Should Be Conducted and Reported to Public Health in all Jurisdictions

Table VII-B.

<table>
<thead>
<tr>
<th>Organism/specimen</th>
<th>Type of facility</th>
<th>Type of location</th>
<th>Time frame</th>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. difficile</td>
<td>Acute Care Hospitals Participating in CMS hospital IQR</td>
<td>All inpatient</td>
<td>X</td>
<td>Neonatal Intensive Care Units (NICUs), well-baby nurseries</td>
</tr>
<tr>
<td></td>
<td>Healthcare Facilities not participating in hospital IQR, including:</td>
<td>Long-term acute care hospitals</td>
<td>x</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Critical access hospitals</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inpatient rehabilitation facilities</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. difficile</td>
<td>Residential Long Term Care Facilities*</td>
<td>Skilled nursing and extended care facilities</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

* Inclusion of long term care facilities (e.g., skilled nursing and extended care facilities) for surveillance of C. difficile LabID Event reporting through the NHSN Long Term Care module will require that a sufficient number of facilities develop the infrastructure and skills necessary to effectively use NHSN.

VIII. Narrative: Public Health Surveillance Vision, Proposed Priorities, and Strategy for Future Expansion or Decrease in Surveillance for CDI

A key aim of adopting C. difficile LabID Event reporting is to accomplish the targets for reduction of these conditions specified in the National HAI Action Plan. The national target is to reduce CDI Lab Events by 30% in 2015 from the 2010 NHSN baseline.4 Achievement of this target would prevent approximately 3,710 CDI in 2015.

Readily implementable prevention guidelines have been developed by expert consensus and are widely disseminated and are available on the CDC website in a toolkit.16,19 These prevention strategies include widely implementable “core” prevention strategies (antimicrobial stewardship, contact precautions, hand hygiene, cleaning and disinfection of equipment and environment, laboratory-based positive test alerts, and education). They also include “supplemental” strategies including extended duration of contact precautions, presumptive isolation for symptomatic patients, optimized CDI testing, enhanced hand hygiene and glove use, and use of sodium hypochlorite for environmental cleaning. Statewide CDI prevention collaboratives based on such practices have achieved success as noted earlier.3 C. difficile LabID Event data can be useful as standardized outcome measures for prevention collaboratives and other healthcare-based prevention programs within and across states. The C. difficile prevention recommendations developed for acute care hospitals or long term care facilities can be adapted to any of the proposed healthcare facility locations, ensuring that the surveillance data can be used to guide effective action to improve care and benefit patients.
C. difficile is expected to remain a public health priority over the long-term, largely because of emerging strains with increased pathogenicity and its environmental persistence and transmissibility. Therefore, it is expected that surveillance for these conditions will be on-going. There is potential that the burden of data collection can be reduced if disease burden and positive laboratory findings can be reduced, and especially as reliable electronic medical records-based surveillance becomes available.

IX. Data Sharing/Release and Print Criteria

NHSN maintains confidentiality of individuals and reporting facilities. Facilities reporting to NHSN are required to sign an Agreement to Participate and Consent that allow CDC to share aggregate de-identified data with CMS. CDC has developed templates for annual national and state-specific Standardized Infection Ratio (SIR) reports, in which data are not publicly repomatized if the volume of reporting is inadequate. These reports are shared with states for preview and comment prior to publication. Moreover, local and state health departments and others (e.g., hospital associations, Quality Improvement Organizations, Partnership for Patients Hospital Engagement Networks, and facility corporations) can have access to data if the reporting facility confers rights to the data, which they do for surveillance and prevention purposes or if required by state law/regulation.

X. References


5. CDC. Personal communication, 3/18/13.


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