

Letter to the Reader

The North Carolina Division of Public Health publishes hospital-specific healthcare-associated infections (HAI) data on a quarterly basis and state level data annually for healthcare providers and healthcare consumers. These data include statistical measures such as rates, ratios and 95% confidence intervals.

This document is provided to facilitate understanding of the statistical measures and to promote accurate interpretation of published results. It is an updated and refined reference document to the Healthcare-Associated Infections Report that was first published in October 2012. Also included in this document is a brief summary of HAI reporting and surveillance activities in North Carolina.

Visit the North Carolina Healthcare-Associated Infections website for more information: <u>http://epi.publichealth.nc.gov/cd/diseases/hai.html</u>.

The annual reports can be found at the following web address: <u>https://epi.publichealth.nc.gov/cd/hai/figures.html</u>

Table of Contents

Lett	ter to the Reader	i
I.	Reporting Requirements of Healthcare-Associated Infections in North Carolina	1
II.	Surveillance for HAI in North Carolina	1
А	A. HAI Surveillance before 2012	1
В	B. HAI Surveillance since 2012	2
С	C. Strengths and Limitations of HAI Data Reported through NHSN	2
III.	HAI - Measures of Disease Occurrence	4
A	A. Prevalence and Incidence	4
В	B. Incidence Rates	4
С	C. Crude Rates versus Adjusted Rates	5
D	 Standardized Infection Ratios 	6
E R	. Reading Guide: Explanation of Each Variable in the Tables and Figures in the NC Quarterly reports	8

I. Reporting Requirements of Healthcare-Associated Infections in North Carolina

On June 27, 2011, House Bill 809 was signed into law by Governor Perdue, requiring North Carolina hospitals to report specified healthcare-associated infections (HAI) to the NC Department of Health and Human Services (General Statute 130A-150). Since the passage of House Bill 809, the Commission for Public Health has adopted rules for implementation (10A North Carolina Administrative Code 41A .0106) which specify the use and reporting requirements of the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN), a web-based system for data collection and analysis.^{1,2} To mitigate the reporting burden on healthcare facilities, these rules align NC reporting requirements with the conditions required for reporting under the Centers for Medicare and Medicaid Services (CMS) Inpatient Prospective Payment System Rule (IPPS).

As of January 1, 2013, select healthcare facilities are required to report five healthcare-associated infections to the North Carolina Division of Public Health (NC DPH). Some requirements differ by facility type. These infections include:

- 1. Central line-associated bloodstream infections (CLABSI)
- 2. Catheter-associated urinary tract infections (CAUTI)
- 3. Surgical site infections (SSI) occurring after inpatient abdominal hysterectomies or colon surgeries
- 4. Laboratory-identified bloodstream infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA)
- 5. Laboratory-identified infections caused by *Clostridium difficile* (CDI)*

II. Surveillance for HAIs in North Carolina

Reporting of selected HAIs is mandated in North Carolina and is conducted via NHSN. NHSN is a secure, internetbased patient and healthcare personnel safety surveillance system that is managed by the Division of Healthcare Quality Promotion at CDC. Enrollment is free and open to all healthcare facilities including short-term acute care hospitals, long-term acute care hospitals, Ambulatory surgery centers, long-term care facilities, critical access hospitals, outpatient dialysis facilities, home dialysis facilities, psychiatric hospitals, and inpatient rehabilitation facilities (according to https://www.cdc.gov/nhsn/enrollment/index.html). Healthcare facilities use NHSN to fulfill the reporting requirements of CMS. For further information on NHSN, please visit www.cdc.gov/nhsn.

A. Surveillance before 2012

Beginning November 2010, the NC DPH's Surveillance for Healthcare-Associated and Resistant Pathogens Patient Safety (NC SHARPPS) Program began working with hospitals statewide to encourage voluntary reporting of CLABSIs in NHSN. This voluntary process allowed NC SHARPPS to track, evaluate and determine a baseline rate for CLABSIs in North Carolina and allowed healthcare facilities to become familiar with the process of reporting through NHSN. By the end of 2011, there were 72 hospitals submitting data on CLABSIs to the NC SHARPPS Program.

¹ North Carolina House Bill 809, An act to require the department of health and human services to establish a statewide surveillance and reporting system for health care-associated infections and to subject hospitals to the requirements of the statewide surveillance and reporting system. Session 2011 ed; 2011. Available at www.ncleg.net/Sessions/2011/Bills/House/PDF/H809v4.pdf.

² North Carolina Administrative Code 41A .0106. Reporting of Health-Care-Associated Infections. Permanent rule effective October 1, 2012. <u>http://reports.oah.state.nc.us/ncac/title%2010a%20-%20health%20and%20human%20services/chapter%2041%20-%20epidemiology%20health/subchapter%20a/10a%20ncac%2041a%20.0106.html</u>

^{*}in 2019, NHSN changed the nomenclature for *C. difficile* from *Clostridium* to *Clostridioides*. This report will use *Clostridium* as the data for this report was pulled in 2018. Moving forward, reports will use the *Clostridium* nomenclature.

NC Division of Public Health, NC Surveillance for Healthcare-Associated and Resistant Pathogens Patient Safety Program Quarterly and Annual Report Reference Document – Revised October 2019

B. Surveillance since 2012

Beginning on January 1, 2012, short-term acute care hospitals were required to report select HAIs to NC Division of Public Health via NHSN. In October 2012, this expanded to include long-term acute care hospitals and inpatient rehabilitation facilities. As of September 27, 2019, a total of 107 North Carolina hospitals reported HAIs to NC SHARPPS, including 93 short-term acute-care hospitals, seven long-term acute-care hospitals, seven inpatient rehabilitation facilities, and six specialty hospitals. Hospitals and rehabilitation facilities that have been licensed by the NC Department of Health and Human Services' Division of Health Service Regulation are classified as licensed facilities. Small, rural facilities designated by CMS as critical access hospitals are not required to report HAIs to NC DPH.

C. Strengths and Limitations of HAI Data Reported through NHSN

NHSN collects data from a range of healthcare facility types using standardized methods and definitions that permit comparison of HAIs between different facilities.³ Availability of these data allows facilities to monitor HAIs in their patient populations, look for trends, compare their infection rates to national data, and detect potential problems in a timely manner.⁴

These same benefits are applicable at the state level, where HAI data can be used to further our understanding of the burden of HAIs in North Carolina, monitor trends over time, identify priorities for HAI prevention, evaluate the effectiveness of control and prevention programs, and further inform HAI related policies in North Carolina.

Although there are numerous benefits to using NHSN for HAI surveillance, HAI data in NHSN are vulnerable to the same limitations that apply to most surveillance systems, including reliability, validity, and completeness of data.⁵ Reliability refers to the ability of a disease to be consistently classified in the same way (disease or not a disease) by different reporters. Validity refers to whether the reported disease is truly a disease.⁵ Completeness refers to whether all occurrences of disease and corresponding data elements have been reported.

Reliability

The use of standardized methods and definitions is one way to improve the reliability of data. To improve reliability across reporters, NHSN provides an extensive array of training opportunities for individuals including web-based online training courses, webinars, and in-person training events.⁶ These resources can be found at the NHSN website at <u>www.cdc.gov/nhsn/training</u>. The NC SHARPPS Program also works with individual facilities to ensure data have been reported correctly and within the required time frames.

Validity

Two questions are of interest when considering validity of the data: 1) Are HAIs and non-HAIs accurately classified during reporting? and 2) Do data entered in NHSN reflect the true number of infections in the facility?

³ CDC. CDC/NHSN Surveillance Definition of Healthcare-Associated Infection and Criteria for Specific Types of Infections in the Acute Care Setting. January 2012.

http://www.cdc.gov/nhsn/PDFs/pscManual/17pscNosInfDef_current.pdf. Accessed June 7, 2016.

⁴ CDC. National and State Healthcare-associated Infections Standardized Infection Ratio Report - Using Data Reported to the National Healthcare Safety Network, January – December 2010.

⁵ Teutsch SM, Churchill RE. *Principles and practice of public health surveillance*. 2nd ed. Oxford; New York: Oxford University Press; 2000.

⁶ CDC. National and State Healthcare-associated Infections Standardized Infection Ratio Report - Using Data Reported to the National Healthcare Safety Network, January – December 2010.

NC Division of Public Health, NC Surveillance for Healthcare-Associated and Resistant Pathogens Patient Safety Program Quarterly and Annual Report Reference Document – Revised October 2019

Sensitivity and specificity are measures of validity that can be used when assessing surveillance systems.⁷ Sensitivity refers to the proportion of individuals with an HAI who are correctly classified as having that HAI, whereas specificity refers to the proportion of individuals without an HAI who are correctly classified as not having that HAI.

$$Sensitivity = \frac{\text{Number of individuals correctly classified as having an HAI}}{\text{Total number of individuals who actually have that HAI}} \times 100\%$$

 $Specificity = \frac{\text{Number of individuals correctly classified as NOT having an HAI}}{\text{Total number of individuals who actually do not have that HAI}} \times 100\%$

In general, higher sensitivity and specificity are desired. If sensitivity is low, many HAIs are being missed, leading to an underestimation of the true number of HAIs. If the specificity is low, an overestimation of the number of HAIs will result as non-HAIs will be incorrectly labeled as HAIs. Both of these errors will give a false impression of the true number of HAIs at the facility and can have undesired consequences.

The second question with data validity is whether data in the system accurately reflect reality. Discrepancies may occur as the result of data entry errors, which reduce the validity of the data and can limit the ability to draw conclusions if not identified and corrected. NHSN includes a number of data entry check mechanisms to ensure data are entered correctly. In addition, facilities can generate data entry reports that allow them to review their entered data, including identification of potential duplicate reports.

Completeness

Completeness of data can refer to one of two concerns - completeness in reporting or completeness of records. An example of the former would be if an NHSN user entered the records of only four individuals who had colon surgery rather than the 10 individuals who had surgeries performed. As one could imagine, this type of completeness in reporting is difficult to assess from simply reviewing the data. Completeness in reporting is assessed by a review the records, for example, to see who had a colon surgery performed. On the other hand, completeness of records is easier to identify. By reviewing the data, missing information can be easily spotted, such as a patient's age. Although easy to spot, obtaining the missing information is often not as easy because it requires going back to the reporting source to obtain the information.

⁸ CDC. Updated Guidelines for Evaluating Public Health Surveillance Systems. NC Division of Public Health, NC Surveillance for Healthcare-Associated and Resistant Pathogens Patient Safety Program Quarterly and Annual Report Reference Document – Revised October 2019

III. HAI - Measures of Disease Occurrence

The NC DPH HAI reports that are published on a quarterly basis include a number of statistical measures. Prior to 2014, the primary measures were rates. Since 2014 data onward NC DPH has presented standardized infection ratios (SIRs) in these reports. Presenting SIRs is in accordance with the National Healthcare Associated Infections Data Analysis and Presentation Standards Workgroup recommendations. Although many people are familiar with rates and ratios, an overview of these statistics are provided to ensure common understanding among readers.

A. Prevalence and Incidence

Before discussing rates and ratios, it is important to clarify two types of measures often used to describe disease occurrence. The first is prevalence. Prevalence is a useful measure for estimating the burden of a disease in a population and simply asks what proportion of the population has the disease. Recall that a proportion is simply one number divided by another number, where the numerator is a subgroup of the denominator.

 $Prevalence Proportion = \frac{\text{Number of individuals in the population with the disease at a specified time}}{\text{Number of individuals in the population at a specified time}}$

An example is the prevalence of CLABSI reported by Facility A. On February 1, there were 80 patients hospitalized, two of whom had a CLABSI. The prevalence proportion of CLABSI in Facility A on February 1 is 2.5%.

Prevalence Proportion =
$$\frac{2}{80} \times 100\% = 2.5\%$$

B. Incidence Rates

For HAIs, generally the interest is in another measure of disease frequency - incidence. Unlike prevalence which quantifies all diseases – new and existing – incidence is the occurrence of new cases of disease. Although there are a number of ways to quantify incidence, the following discussion will focus on the incidence rate.

Rates describe the speed with which an event occurs; likewise an incidence rate describes the speed in which new cases of a disease occur. The incidence rate is the number of individuals in the population who develop the disease during a specified period of time divided by the total person-time among those at risk for developing the disease during a specific period of time. The formula for calculating the incidence rate is below.

Incidence Rate = $\frac{\text{# of individuals who develop the disease during a specified period of time}}{\text{Person} - \text{time at risk for developing the disease during the specified period of time}}$

In the denominator, note that "person-time" is the unit and not individuals. Recall that a rate includes a measure of time in its denominator, such as per-day or per-hour. Table 1 summarizes the person-time units used for each of the reportable HAIs.

Table I. Ferson-Time Units for TAI	Table	1.	Person-Time	Units	for	HAIs
------------------------------------	-------	----	-------------	-------	-----	------

HAI	Person-time Unit
CAUTI	Number of catheter-days
CLABSI	Number of central-line days
Clostridium difficile	Number of patient-days
MRSA bacteremia	Number of patient-days

Why is the measure of person-time different for each of the HAIs in Table 2 As noted in the incidence rate equation, the focus is on the person-time of individuals "at risk" for developing the HAI. In order for an individual to develop a CLABSI, the individual has to have a central line inserted. Without a central line, there is no risk of developing CLABSI. Similarly, an individual has to have a urinary catheter inserted to be at risk for a CAUTI and one must have an operative procedure to be at risk for a SSI. However, all hospitalized patients are at risk for developing *C. difficile* infection and MRSA bacteremia; therefore, the person-time is simply the number of patient days. The calculation of person-time only includes those "at risk" for developing the disease. The true incidence rate of HAIs would be underestimated if people never at risk for the disease were included in the denominator.

Going back to the previous example of two CLABSIs in Facility A, what is the incidence rate for CLABSI on February 1? One patient was diagnosed on January 31 and the other on February 1. The numerator for calculating the incidence rate for CLABSI would include the one CLABSI diagnosed on February 1. Of the 80 hospitalized patients, 50 people contributed one central line day on February 1 for a total of 50 central-line days (denominator). The incidence rate for CLABSI on February 1 is 1/50 = 0.02 per central-line day or 20 CLABSIs per 1,000 central-line days. What would have happened if the denominator was not restricted to the "at-risk population"- that is, patient-days were used instead of central-line days? The CLABSI incidence rate would have been 1/80 = 0.0125 per patient-days or 12.5 per 1,000 patient-days. This is an underestimation of the true CLABSI incidence rate.

SSIs are expressed as the number of SSIs per 100 operative procedures. Although this is a proportion and not a rate, it is often described as a rate due to accepted conventions.

C. Crude Rates versus Adjusted Rates

Rates are commonly used to describe disease occurrence. A crude rate is simply a rate that does not account for variations between populations; it assumes an equal distribution of risk factors. Crude rates are often used for overall populations. For instance, the incidence rate calculated for Facility A is an example of a crude incidence rate. The use of crude rates for comparisons is valid if the distribution of risk factors is similar between populations.

Healthcare consumers are often interested in comparing facilities when making decisions about healthcare needs. However, the patient population served by healthcare facilities can vary dramatically from one to another and are influenced by a number of factors including services offered, resources, and number of beds. These differences in patient populations can make it difficult to draw accurate conclusions when comparing crude HAI incidence rates between healthcare facilities.

For example, the crude incidence rate of CAUTI in Facility B was four per 1,000 catheter-days for January compared to Facility C where the incidence rate was five per 1,000 catheter-days. One may conclude that Facility B has a lower rate of CAUTI than Facility C; however, this summary measure may not accurately reflect differences between the facilities. Table 3 shows the hypothetical rates of CAUTIs by patient care locations at each facility.

	Facility B			Facility C		
Care Location	# of CAUTI	# of catheter- days	Rate per 1,000 catheter days	# of CAUTI	# of catheter- days	Rate per 1,000 catheter days
Burn Critical Care	-	-	-	3	87	34.5
Medical Critical Care	1	250	4	2	1171	1.7
Pediatric Medical Critical Care	-	-	-	2	116	17.2
Surgical Critical Care	-	-	-	0	26	0
Total	1	250	4	7	1400	5

 Table 2. Example Patient Care Location-Specific CAUTI Rates for Facilities B and C, January 1st -31st

There were differences between the two populations served by each facility. Facility B provided services to adults with medical critical care needs whereas Facility C served adults with burn and surgical critical care needs in addition to adults and children with critical care needs. Hence, the populations hospitalized at the facilities differed. Moreover, when the patient care location-specific rates were compared, the medical critical care-specific CAUTI rate in Facility B was more than twice the rate of Facility C.

Patient care location-specific incidence rates are an example of adjusted incidence rates. These can provide more meaningful comparisons (both within and between facilities) because patients in one unit may have different risk factors for CAUTI than patients in another unit. Patient care location-specific incidence rates allowed a more accurate conclusion to be drawn about the CAUTI incidence rates between the two facilities.

D. Standardized Infection Ratios

The CDC has provided an easy-to-understand guide on standardized infection ratio (SIRs) calculations and interpretations which has been modified and presented below.⁸

SIRs are measures used to summarize complex data to monitor HAIs at the national, state, and local level over time. The SIR is an adjusted ratio and is adjusted for risk factors associated with specific HAIs. SIRs are a comparison between the number of observed infections and the number of predicted infections.

SIR = <u>Observed HAIs</u> Predicted HAIs

The predicted number of infections was calculated using infection rates from a standard population during the 2015 baseline time period. Prior to 2015, each HAI used data from a different year or years to come up with this original predicted number of infections: CLABSIs and SSIs used data from 2006-2008; CAUTIs used data from 2009; MRSA and CDI LabID events used data from 2010-2011.

There are occasions when SIRs cannot be calculated. If the number of predicted HAIs is less than 1, there is not enough information to calculate a SIR that is precise and useful for comparison.

Interpretation of the SIR:

SIR = 1.0 Number of observed HAIs is not different from the predicted number of infections.

SIR > 1.0 Number of observed HAIs was more than the predicted number of infections.

SIR < 1.0 Number of observed HAIs was less than the predicted number of infections.

An advantage of the SIR over a rate is that it is a single summary measure that accounts for differences between populations. However, adjusted rates are still useful measures, especially for prevention measures in which monitoring trends over time is important.

More information on how the SIR is calculated can be found here: <u>https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf</u>.

Statistical Significance

Caution should be used when interpreting statistical significance or the lack thereof. In some cases, it might still be important to understand why infection rates were higher (or lower) than predicted even if those differences were not statistically significant.

⁹ CDC. The NHSN Standardized Infection Ratio (SIR): A Guide to the SIR.

95% Confidence Interval

The SIR is viewed as an estimate because there are factors that can influence the accuracy of the reported data. Presentation of estimates like the SIR are accompanied by the 95% confidence interval (CI) which quantifies the precision of the estimate; the narrower the 95% CI, the more precise the estimate.

The 95% CI can also be used for hypothesis testing. The 95% CI that accompanies the SIR is used to test the hypothesis that there were no statistically significant differences in the number of observed and predicted infections. If the 95% CI around an SIR includes the value of 1.0, then the difference between the number of observed and predicted HAIs was not statistically significant. However, if the 95% CI does not include the value of 1.0, then there was a statistically significant difference in the number of observed and predicted infections. This may have been a significantly lower number of observed infections than predicted (SIR < 1.0) or a significantly higher number of observed infections than predicted (SIR > 1.0).

Of note: When the number of observed HAIs is 0, the lower bound of the 95% CI is not calculated.



The figure above shows an example of the facility CLABSI SIR along with the CLABSI SIRs of similarly-sized facilities and all facilities in NC. The CLABSI SIR in the facility appears to be lower than expected (less than one). To test the hypothesis that there were fewer infections than predicted in the facility, the 95% CIs are examined. The 95% CI of the facility CLABSI SIR includes the value of 1.0. Therefore, although the facility CLABSI SIR was lower than predicted by the national baseline (that is, less than 1.0), the observed differences were not statistically significant different.

P-value

The p-value is also used to convey whether the observed number of HAIs was significantly different statistically from the predicted number of HAIs. A p-value less than 0.05 is generally used to indicate a statistically significant difference.

SIRs for Specific HAIs

NHSN uses a negative binomial regression model to calculate the number of predicted infections for CLABSI, CAUTI, VAE, LabID MRSA, and LabID CDI. A logistic regression model is used to calculate the number of predicted SSIs. Once the number of predicted infections is calculated, NHSN divides the number of observed infections by the number of NC Division of Public Health, NC Surveillance for Healthcare-Associated and Resistant Pathogens Patient Safety Program Quarterly and Annual Report Reference Document – Revised October 2019

predicted infections to calculate the SIR. A description of the models used for predicting the number of infections for CLABSI, CAUTI, VAE, LabID MRSA, LabID CDI, and SSI, including which variables are used for risk adjustment, is available in NHSN's SIR guide: <u>https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf</u>

There are a few points about SSI SIRs that are published by NC DPH that needs to be clarified. Recall that the HAI reporting requirements in N.C. are aligned with those of CMS.

- 1. SIRs are only calculated for inpatient abdominal hysterectomies and colon surgeries because these are the only operative procedures required to be reported to CMS as of September 2012.
- 2. SSI from deep incisional or organ/space and only from admission or readmission to the same hospital are included in the calculation of SIRs.
- 3. Procedures are excluded from SIR calculations due to data quality limitations if any of the following criteria are met:
 - a. Gender = "Other" or is missing
 - b. Present at time of surgery (PATOS) = "Yes"
 - c. The duration of the colon surgery was more than 697 minutes or the abdominal hysterectomy was greater than 547 minutes
 - d. The procedure duration is less than 5 minutes
 - e. The patient's age was > 109 years at the time of the procedure
 - f. The closure technique is missing
 - g. The ASA score is missing
 - h. If BMI is less than 12 or greater than 60

E. Reading Guide: Explanation of Each Variable in the Tables and Figures in the NC Quarterly Reports

Below is a list of all variables shown in the data tables and figures:

- **Title:** The title of the table gives you information about the infection type, time period, facility unit(s)/group(s) included in the table.
- **Procedure Type:** This is the specific type of surgery for which the surgical site infection (SSI) data are presented (e.g., abdominal hysterectomy, colon surgery).
- Unit/Unit Type: This is the specific unit/type of unit in the hospital from which the data was collected. Hospitals have distinct locations, or units, within the facility that are designated for certain types of patients. For example: "Med/Surg ICU" represents the intensive care unit (ICU) for very sick patients needing medical or surgical care.
- **Observed Infections (or Observed Events):** This is the number of infections (or events, for LabID measures) that was reported by the facility.
- **Predicted Infections (or Predicted Events):** This is a calculated value that reflects the number of infections (or events, for LabID measures) that we have "predicted" to occur in this facility, based on the national experience.
- **"How Does North Carolina Compare to the National Experience?"** Colors and symbols are used to help you quickly understand and interpret the hospital's data. This is the "take-home message" about healthcare-associated infections in this facility.

 \bigstar Indicates that North Carolina had fewer infections than were predicted (better than the national experience)

= Indicates that North Carolina had about the same number of infections as were predicted (same as the national experience)

X Indicates that North Carolina had more infections than were predicted (worse than the national experience)

No Conclusion: Indicates that North Carolina reported data, but there was not enough information to make a reliable comparison to the national experience (# of predicted infections was less than 1).

- Facility Group: Hospitals are grouped with similarly-sized facilities and inpatient rehabilitation facilities and long term acute care hospitals are grouped together. This allows readers to compare a facility's SIR to the SIR of similarly-sized facilities within North Carolina.
- Note: Footnotes are included in the report in order to bring important data caveats to the reader's attention.

