National Healthcare Safety Network

2016 Patient Safety Data Quality Guidance and Toolkit for Reporting Facilities

The NHSN Patient Safety Data Quality Guidance and Toolkit is purposed to inform internal validation of Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI) in validation locations, Surgical Site Infection (SSI) following Abdominal Hysterectomy (HYST) and Colon (COLO) procedures, Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia and Clostridium difficile infection (CDI) LabID events.

The Guidance and Toolkit recommendations are the sole responsibility of the Centers for Disease Control and Prevention (CDC) and should not be regarded as having received the endorsement of any individuals or organizations outside of CDC. For questions, contact NHSN Support: <a href="https://www.nhsn.gov/nhs

Contents

NHSN Data Quality Guidance and Toolkit2	
Who Needs the Data Quality Toolkit	2
How the Toolkit Works	2
Data Quality Tools	2
Data Quality Validation Guidance	
Surveillance Program Competencies	3
CLABSI and CAUTI	
SSI	4
LabID Event	4
Facility Self-Validation Guidance	6
Appendix : Data Quality Tools	
Appendix 1.1: CLABSI/CAUTI Surveillance Coordinator Survey	14
Appendix 1.2: Documentation of Electronic CLABSI/CAUTI Denominator Validation	18
Appendix 1.3: CLABSI and CAUTI Denominator Counting Survey (with Key)	20
Appendix 1.4: Surgical Procedure and SSI Surveillance Methods Survey (with Key)	27
Appendix 1.5: LabID Event Surveillance Methods Survey (with Key)	32
Appendix 1.6: Template for Internal Validation of LabID Event Denominator (FacWideIN)	33



NHSN Data Quality Guidance and Toolkit

Facilities report to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for several purposes:

- Monitor healthcare-associated infections (HAIs) and the impact of their own prevention efforts
- Benchmark facility performance against risk-adjusted national data
- Fulfill state-mandated reporting requirements, and/or to comply with the Centers for Medicare and Medicaid Services' (CMS) Quality Reporting
 Program requirements

Regardless of the reasons for participation, facilities that report to NHSN are required to follow NHSN methods and to use NHSN definitions and criteria. The principal source of information on NHSN methods, definitions, and criteria for reporters is the NHSN Manual. This data quality toolkit describes implementation practices by reporting facilities that support good quality surveillance data when reporting to NHSN.

Who Needs the Data Quality Toolkit

The intended audience of the data quality toolkit is nurses, infection preventionists, or quality of care professionals at facilities, including acute care hospitals, inpatient rehabilitation hospitals, and long-term acute care facilities, reporting selected data to NHSN.

How the Toolkit Works

The toolkit outlines the data quality validation components and processes necessary to validate NHSN reported data using tools designed for internal data validation. The data quality components and tools are specific to six HAI metrics: Central Line-Associated Bloodstream Infections (CLABSI), Catheter-Associated Urinary Tract Infections (CAUTI), selected Surgical Site Infections (following colon (COLO) and abdominal hysterectomy (HYST) procedures), Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia LabID Event and *Clostridium difficile* infection (CDI) LabID Event. A complete catalog of the tools is listed in the next section.

Data Quality Tools

Tools provided in this internal validation toolkit (Appendix 1.1 – Appendix 1.6) are intended for facility use to assess current HAI data collection knowledge and practices. Facilities are strongly recommended to implement the survey tools annually, to assess readiness of staff for NHSN reporting, identify gaps and need for further training.



Data Quality Validation Guidance

Surveillance Program Competencies

Quality validation HAI surveillance require rigorous adherence to standard NHSN protocols, surveillance methods, and NSHN definitions as written. Facilities assuring data quality must be trained in NHSN specifications; remain up-to-date when changes are made; and commit to using appropriate NHSN methods and definitions to validate HAI data reported to the system. The infection prevention program should assure the following facility-level competencies for NHSN CLABSI, CAUTI, SSI and LabID events surveillance and validation activities.

CLABSI and CAUTI

- Risk-Adjustment:
 - Assurance of appropriate risk-adjustment elements (bed size, mapping, and teaching hospital affiliation)
- Denominators: Ability to generate correct denominator data (CLABSI: central line days and patient days, CAUTI: indwelling urinary catheter days and patient days). Use CLABSI/CAUTI surveillance coordinator checklist (Appendix 1.1) to determine current denominator counting facility practices and training needs for staff.
 - Assurance that persons counting patient days, central line days, and/or indwelling urinary catheter days have good knowledge of NHSN methods and definitions pertaining to denominators
 - For manual denominator counting, oversight and maintenance of daily records for inspection during external validation audits
 - This includes the manual, sampled method (once/week) for locations other than specialty care areas/oncology (SCA/ONC) and NICUs (e.g., ICUs, step-down units, wards). Additional details are available in the NHSN Manual Chapter 4 and Chapter 7 (available at https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual 2016.pdf)
 - Before reporting electronically-counted denominator data, document validation of accuracy (within 5% of manual counts for at least 3 months). Use Appendix 1.2, Documentation of electronic CLABSI/CAUTI denominator validation template to document validation of accuracy prior to reporting electronic data.
- Numerators (CLABSI): Ability to correctly and completely identify CLABSI events in real time
 - o Awareness and investigation of all positive blood cultures among patients with central lines
 - Capacity to reproduce a complete list of positive blood cultures collected from patients assigned to facility surveillance location(s) to facilitate internal or external audits
 - o Documentation of candidate CLABSI events and relevant decisions leading to reporting outcomes
 - Ability to correctly apply CLABSI case-definitions, including ability to differentiate between primary and secondary bloodstream infections in accordance with NHSN protocols
 - Of note, NHSN definitions for alternative primary infection sites must be met to assign bloodstream infections as secondary. Up-to-date alternative primary site definitions are available in the NHSN Manual Chapter 17 (available at https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual 2016.pdf)

- Dated versions of the NHSN Chapter 17 HAI definitions have been transposed into checklist format by the Tennessee (TN) Department of Health, and are available at (https://tn.gov/health/topic/hai)
- Current rules for assigning a bloodstream isolate to an alternative primary site are detailed in the NHSN Manual, Chapter 4 (CLABSI), (https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual 2016.pdf)
- Numerators (CAUTI): Ability to correctly and completely identify CAUTI events in real time
 - Awareness and investigation of all positive urine cultures among patients with indwelling urinary catheters
 - Capacity to reproduce a complete list of positive urine cultures collected from patients assigned to facility surveillance location(s), to facilitate internal or external audits
 - o Documentation of candidate CAUTI events and relevant decisions leading to reporting outcomes
 - o Ability to correctly apply CAUTI case-definitions following NHSN protocols.

SSI

- Risk-Adjustment: Ability to correctly report SSI risk-adjustment variables for all surgical procedures entered in NHSN SSI procedure denominator
- Denominators: Ability to generate and report monthly procedure denominators completely and correctly for procedures under surveillance
- Numerators: Evaluation of all potential admission and readmission infections in real time during the
 prescribed surveillance window (30- or 90-days, based on the procedure); post-discharge surveillance
 tracking outpatient SSI events and reports of re-admissions to other facilities during the SSI surveillance
 window
 - Ability to identify all readmissions among patients undergoing surveillance procedures during the SSI surveillance window (30- or 90- days, based on the procedure; for COLO and HYST the window is 30 days)
 - Ability to correctly classify SSI cases using NHSN definitions as either Superficial Incisional, Deep Incisional, or Organ/Space infections (NHSN Manual Chapter 9 (SSI) available at https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual_2016.pdf)
 - Ability to correctly use the NHSN Principal Operative Procedure Category Selection List when attributing Organ/Space Infections in the context of multiple concurrent NHSN procedures

LabID Event

- Risk-adjustment: Assurance of accurate risk-adjustment elements
- Denominators: Internally validated ability to generate correct monthly summary denominator data (FacWideIN patient days, admissions to inpatient locations and surveillance from the emergency department and 24-hour observation units)
- Numerators: Ability to comprehensively identify and correctly assign positive laboratory tests as reportable vs. duplicate and number of patient encounters
 - Understanding of and ability to correctly apply LabID Event following NHSN protocols (available at https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual 2016.pdf)



- Awareness of MRSA-positive blood cultures and toxin-positive CDI test results among inpatient, emergency department and 24-hour observation patients
- Ability to identify MRSA-positive blood cultures and toxin-positive CDI test results obtained in facility-affiliated outpatient clinics on the day of admission
- o Tracking relevant decisions for positive laboratory tests leading to reporting outcomes
- Capacity to produce a complete list of MRSA-positive blood cultures and/or toxin-positive CDI test results from stool specimens by location for all NHSN inpatient, emergency department and 24-hour observation units to facilitate internal (or external) audits

The next sections of the toolkit provides guidance to ensure accurate collection of risk-adjusted variables, denominator data, screening of all potential HAI events as it relates to case status and case classification.



Facility Self-Validation Guidance

Validation		Items to review	Suggested method
component			
Annual surveillance and validation plan	 a T S p a S p L s h A a (// IT 	ratient care locations where CLABSI and CAUTI surveillance is planned types of surgical procedures collowed for SSI surveillance ources of information for surgical procedures, surgical readmissions, and post-discharge surveillance ource of inpatient admissions and ratient days as defined for LabID event aboratory capacity to produce pecified line listings by location or rouse-wide ability to link laboratory and dmissions/discharges/transfer ADT) data T support, especially if electronic eporting will be introduced training needs: Staff training for denominator counting: CLABSI, CAUTI Staff training for NHSN surgical procedure reporting NHSN training updates and case-studies for NHSN reporters	 On an annual basis consider plans for internal validation/quality assurance as you plan surveillance activities including: a. Staffing and training needed for quality data collection b. Plan for staff training and assessment c. Consider whether burden of manual data collection justifies establishing and validating manual daily or weekly sampled or electronic denominator reporting for any HAIs d. Assess adequacy of facility infrastructure, EMR or vendor systems, and practices for documenting device use, placement, and removal e. Evaluate access to IT and other support services for planned data checks; line listings from laboratory information system, linkage to ADT data for surgical readmissions, and counting of inpatient days and admissions f. Determine which facility information systems include patient days and admissions with and without observation patients, to assure that LabID Event denominators are being counted correctly and encounters from the emergency department and 24-hour observation units



Validation component	Items to review	Suggested method	
Facility and location information reported to NHSN	Facility level information reported to NHSN Teaching hospital status Number of facility beds	 The NHSN Patient Safety Component includes separate annual surveys for hospitals (Patient Safety Component – Annual Hospital Survey, 57.103), Long-term Acute Care Facilities (Patient Safety Component – Annual Facility Survey for LTAC, 57.150), and Inpatient Rehabilitation Facilities (Patient Safety component _ Annual Facility Survey for IRF, 57.151). On an annual basis, review and confirm that teaching status and number of beds (ICU vs. all other inpatient location beds) is accurate (see below). 	
	Patient location level mapping information reported to NHSN • Facility location label and CDC location description • The number of beds reported for ICU and non-ICU location types	On an annual basis, review data for each patient care location entered into NHSN using up-to-date information on patient demographics by location (objective data may be available from bed-control or a chief nursing officer) to confirm the following; 1. The CDC location label assigned meets the CDC 80% rule for the assigned CDC location description (See NHSN Manual, Chapter 15, https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual_2016.pdf). Note: NHSN mapping guidance was updated and detailed instructions were created to assist with facility-wide mapping, in recognition of CMS Inpatient Quality Reporting requirements for LabID Event surveillance. 2. The combined number of ICU beds and non-ICU beds is correct. 3. Physically separate acute care IRF/IPF/SNF units are enrolled and mapped according to NHSN guidance	
CLABSI and CAUTI denominator data	Patient days, central line days, and indwelling (Foley) catheter days. Use Appendix 1.3, CLABSI and CAUTI Denominator Counting Survey with Key to assess the current knowledge of denominator data collection methodology and to identify further training needs.	 Regardless of type of denominator data collection (manual or electronic); a. For CLABSI and CAUTI denominator data assure that each month is correctly listed as inplan b. For each in-plan month assure that denominator data (patient days, central line days, and catheter days) have been entered into NHSN If manual daily or weekly sampled denominator data collection is used; a. Assure that staff members collecting denominator data know correct NHSN procedures and definitions for this task and are following the chapter 4 and 7 of NHSN protocols https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual_2016.pdf	



Validation component	Items to review	Suggested method	
Component		either concurrent dual assessment of denominator data and/or by concurrent independent patient-level data collection (e.g. room number, room occupied, patient name/MRN, central line present or absent). The IP should review the corresponding data to determine if standard data collection is correct and compliant with NHSN protocols for the patient location (e.g., NICUs, specialty care areas, other). Results should be shared with staff for recognition of good work or to modify practices for collecting data if necessary. If problems are found manual validation should be repeated. State Health Department validators may ask to see results of internal validation, or may assess staff knowledge and practices. c. Periodically assess completeness and reliability of denominator data collected/reported to NHSN. Using denominator logs calculate % of days per year that: i. patient days were not collected iii. central line days were not collected iii. indwelling (Foley) catheter days were not collected iii. indwelling (Foley) catheter days were not collected iv. Be prepared to share your data logs and analysis with reviewers during external validation 3. If electronic data capture is used; a. The NHSN CLABSI and CAUTI protocols states "when denominator data are available from electronic databases these sources may be used as long as the counts are not substantially different (+/- 5%) from manually-collected counts." (https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual_2016.pdf). This guideline is important because unexamined electronic counts may be seriously flawed and can be difficult to align with NHSN reporting definitions. For each location where electronic databases are used to obtain counts of patients days and/or device days, determine if initial data validation was performed according to this guidance. If electronic counts were not validated or not within 5% of manual counts resume manual counting and continue working with IT staff to improve design of electronic denominator data extraction (while reporting m	



Validation .	Items to review	Suggested method	
component			
		b. Because electronic systems are subject to change and can result in disrupted or	
		inaccurate data streams, best practices for use of electronic data capture also require:	
		 i. Vigilance for aberrant data that could result from changes to electronic medical records or related systems 	
		ii. Periodic spot checks of electronic data to assure continued good performance	
		c. A report of successful alignment of electronic denominator counting at two related	
		facilities has recently been published (Tejedor SC, et al. Infect Control Hosp Epidemiol	
		2013; 34:900-907).	
CLABSI and	Complete ascertainment of candidate	Assure that the microbiology laboratory tracks and reports patient care location at the time of	
CAUTI	CLABSIs and candidate CAUTIs in	specimen collection and not at the time of final report for surveillance purposes.	
numerator	surveillance locations	2. Consider documentation of surveillance decisions, e.g.:	
data		a. Keep a record/line-listing of positive blood cultures and decisions with regard to CLABSI	
		particularly in surveillance locations. Patients without a recent central line can quickly be	
		eliminated from consideration for CLABSI. For any positive blood cultures that meet the	
		definition of laboratory-confirmed bloodstream infection (LCBI types 1, 2, or 3) in a	
		surveillance location, document the LCBI, presence or absence of a central line, why you	
		consider the blood culture to be either healthcare-associated (HA) or non-HA, primary or	
		secondary, and whether or not the event was reported as a CLABSI to NHSN.	
		b. Keep a record/line listing of positive urine cultures and decision making with regard to	
		CAUTI, particularly in surveillance locations. Patients without a recent or current	
		indwelling urinary catheter can quickly be eliminated from consideration for CAUTI. For	
		any positive urine cultures that meet the definition of asymptomatic bacteremic urinary	
		tract infection (ABUTI) or specific symptomatic urinary tract infection types (SUTI1a,	
		SUTI1b or SUTI2), document the urinary tract infection (UTI), presence or absence of an	
		indwelling urinary catheter, why you consider the culture HA or non-HA, and whether or	
		not the event was reported as CAUTI to NHSN.	
		3. Periodically assure that all positive blood and urine cultures have been reviewed by requesting	
		surveillance location line list for comparison to the record.	



Validation	Items to review	Suggested method	
SSI denominator data	Surgical procedures under NHSN surveillance for SSI. Use Appendix 1.4, Surgical Procedure and SSI Surveillance Methods Survey with Key to determine current knowledge and practices of SSI reporting and to identify training needs.	 Regardless of type of denominator data collection (manual or electronic); As part of annual surveillance and validation planning determine which surgical procedures will be reported to NHSN, whether inpatient or outpatient or both, and note the assigned surveillance period (30 or 90 days) for each procedure. Identify all primary sources of information about procedures for which you will conduct surveillance. For many facilities this will be the OR records system. It may be useful to identify one or more secondary data sources (e.g. ICD-10-PCS hospital discharge procedure codes) that can be used to cross-link to or validate the magnitude of data deriving from the OR system data stream. It is prudent to scrutinize the list of ICD-10-PCS procedure codes (and/or CPT codes) used by the OR system to identify procedures of interest for completeness. Failure to include one or more specified codes for designated procedures in the denominator can lead to the appearance of falsely higher SSI rates. Assure that all persons screening surgical procedures prior to data entry are familiar with the 2016 definition for primary closure (https://www.cdc.gov/nhsn/pdfs/validation/2016/pcsmanual_2016.pdf). If either manual or electronic denominator data entry is used; Manual data entry is subject to keystroke errors, omissions, and duplications during data entry, and thus data validation may include double checking of multiple data elements by two persons (one reading the OR record, and one reading the NHSN record) Both manual and electronic denominator data quality are subject to error at the source of information and to systematic error. In either case, data quality may be monitored by one of several internal validation methods	



Validation	Items to review	Suggested method	
component			
SSI Event numerator data	Sources of information for surgical infection events and surgical readmissions	 iii. Cross checking a second data source to identify discordant records that may had been missed or reported in error and to identify errors leading to large errors (such as omitting a required ICD-10-PCS procedure code) iv. Periodic (at least annual) download from the OR system to confirm that procedure data for individual days or weeks were not missed during the interval. 1. Identify information sources to identify infections among post-operative surgical inpatients, e.g. pharmacy, laboratory, and/or microbiology data. 2. Assure identification of surgical readmissions during the post-operative surveillance window an screen for infection as a cause of re-admission. 3. Optimize post-discharge surveillance methods Cooperate with other facilities to notify one another of SSIs following procedures at another. 	
		facility	
	Complete ascertainment of candidate SSIs post-op, whether in hospital or after discharge	 Assure a mechanism to routinely identify surgical readmissions and complete post-discharge surveillance during the 30-day SSI surveillance window following COLO and HYST procedures. Investigate options for optimal post-discharge SSI surveillance, including cross-facility communications and reporting of SSIs identified by other facilities. Multiple networked surveillance modalities (e.g., readmissions, surgical nursing contacts, surgical rounds, surgeon inquiry, chart review, patient survey) typically provide more complete information. Consult with other hospital IPs to consider best practices for inter-facility communication of SSIs (reports that you provide to other facilities that performed a procedure and for SSIs that are reported by other facilities to your facility). For example, the referring IP may be asked to complete the NHSN SSI report form and provide it to the facility responsible for filing the report in NHSN. 	
LabID Event denominator data	NHSN inpatient admissions and patient days must include observation patients who are located in inpatient locations	1. LabID Event denominators: facility-wide admissions and inpatient days (as defined by NHSN to include observation patients located in inpatient locations) normally are derived electronically. Determine how to assure inclusion of observation patients that are located in inpatient locations in denominator data counts.	



Validation	ion Items to review Suggested method			
component				
		2. Some systems (typically vendor and ADT systems) can be adjusted to count observation patients in inpatient locations but facilities relying on billing data must be careful to include observation patients from inpatient locations, who may be billed separately. Denominator validation can be accomplished using manual counting of patient days and admissions in three specified location types for one month each: one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location (if available), and one or more wards where observation patients are frequently located. Validated counts should be within 5% of the referent (usual) electronic counts or an evaluation of why they differ should be conducted. This internal validation process may be requested or required by state health departments. Use Appendix 1.6, LabID Event Facility-Wide Inpatient (FacWideIN) Denominator Validation Template to determine accuracy of validation using electronic counts.		
LabID Event numerator data	Assure that any reporter(s) overseeing LabID Event reporting understand rules for duplicate reporting and include laboratory reports from affiliated outpatient locations on admission date. Appendix 1.5, LabID Event Surveillance Methods Survey with Key to determine current knowledge and practices of LabID reporting and to identify training needs.	 Assure that the microbiology laboratory tracks and reports patient care location at the time of specimen collection and not at the time of final report to infection control. a. NOTE: For LabID Event, laboratory tests taken on the day of admission in affiliated facility-associated outpatient locations (e.g., clinics) should be included for accurate tracking of CO LabID Events. Consider periodic internal auditing e.g. duplicate auditor abstraction of candidate events 		



Appendix: Data Quality Tools

Appendix 1.1: CLABSI/CAUTI Surveillance Coordinator Survey

rgiD / Na	me of Hospital	_ Date of Survey		
Instruction	ns: Administer this survey to the person who oversees NSHN surveillar	nce and denominator counting		
1. Which	n best describes your facility's training for CLABSI and CAUTI Denomir	for CLABSI and CAUTI Denominator counters? (select all that apply)		
	No specific training is provided or required			
	Peer training (person who previously counted) trains new staff			
	Training is provided by IP			
	Training by NHSN (e.g. online training) is required			
	Annual training updates are required / provided			
	Other (describe):			
2. Do yo	_ u conduct periodic spot-checks or otherwise validate CLABSI and CAL)	JTI denominator counts? (select all that		
-1-1-77	Not at this time			
	Yes, when we have a new denominator counter			
	Yes, when I have concerns			
	Yes, routinely			



3.	3. Which best describes your own training for 2016 NHSN surveillance? (select all that apply)					
		No specific training for 2016	Select Training Modules Taken			
		CDC-sponsored 2016 training webinar (live or on-line)	□CLABSI □ CAUTI			
			□SSI □LabID Event			
		CDC-sponsored 2016 on-line case-studies	□CLABSI □ CAUTI			
			□SSI □LabID Event			
		CDC-sponsored 2016 online self-paced interactive multimedia	□CLABSI □ CAUTI			
		instruction trainings	□SSI □LabID Event			
		State-sponsored 2016 NHSN training event(s)	□CLABSI □ CAUTI			
			□SSI □LabID Event			
		Other (describe):				
4.		staff member(s) is/are responsible for entering CLABSI (numerator	☐ IP			
	events	data into NHSN?	Clerical support			
			Other			
5.		staff member(s) is/are responsible for entering CAUTI (numerator	☐ IP			
	events	data into NHSN?	Clerical support			
			Other			
6.	Is ente	red data checked for errors or validated by analysis?	Yes			
			□No			



		Unk
	a. If yes, describe what is done:	
7.	How many persons typically review a medical record before an event is reported to NHSN?	 □ One reviewer typically decides, with internal (e.g. second reviewer) adjudication when needed □ Two or more persons typically review and agree before reporting □ One reviewer typically decides, with external (e.g. CDC) adjudication when needed □ Approval is required (e.g. from physician or administrator) before events are reported □ Other (explain):
8.	Is there ever pressure (e.g.; from administrators or physicians) to not report a CLABSI, CAUTI (or other NHSN) event?	☐ Yes ☐ No ☐ Unsure Comment:
9.	In cases of ambiguity, who makes the final decision regarding the	



determination of whether an infection should be reported?



Appendix 1.2: Documentation of Electronic CLABSI/CAUTI Denominator Validation

OrgID/ Name of Hos	rgID/ Name of Hospital: Date of Survey: Date of Survey:				
Instructions: NHSN	Instructions: NHSN requires that the monthly electronic denominator count falls within a 5% tolerance interval				
of the monthly ma	nual denominator coun	t for 3 months befor	re reporting electronic de	enominator counts for	
CLABSI/CAUTI. If t	here is no electronic dei	nominator counting	at this facility, skip this s	urvey.	
•		_		,	
If electronic device	denominator counting	is used for reporting	at this facility, documen	t the NHSN-required	
validation results b	pelow:				
luitial alastuania d		/b.a.a.alaatwa.wia.ala	nominator reporting be	1.	
initial electronic d	enominator validation	(when electronic de	enominator reporting be	gan):	
Location name:		Manual count	*Calculated 5%	Electronic count	
			tolerance interval		
Month/year:	Patient days				
Wioriting year.	Central line days				
	Central line days				
	Indwelling urinary				
	catheter days				
Location name:	Location name:				
	Patient days				
	ratient days				
Month/year:	Central line days				
	Indwelling urinary				
	catheter days				
Location name:					



	Patient days			
Month/year:	Central line days			
	Indwelling urinary			
	catheter days			
If available, pleas	 e document additional	information for any	more recent electronic	denominator validation:
Location name:		Manual count	*Calculated 5%	Electronic count
			tolerance interval	
Month/year	Patient days			
	Central line days			
	Indwelling urinary			
	catheter days			
Location name:				
	Patient days			
Month/year	Central line days			
	Indwelling urinary			
	catheter days			
Location name:			1	
	Patient days			
Month/year:	Central line days			



Indwelling urinary		
catheter days		

^{*}Equation for calculating 5% tolerance interval is: manual count ± (manual count * 0.05).

Example calculations where manual count = 164 and electronic count = 178:

Eligible 5% tolerance interval = $[164\pm(164*0.05)]=155.8$ to 172.2

Electronic count 178 falls outside the tolerance interval.



Appendix 1.3: CLABSI and CAUTI Denominator Counting Survey (with Key)

Instru	ctions: Administer in person o	r by telephone, d	irectly to individuals responsible for der	nominator counting. This form is a	color-coded so that it can be	
divide	d into a CLABSI denominator	collection form (p	oink and orange) and a CAUTI denomind	ntor collection form (yellow and o	range) in facilities where these	
tasks (are performed by different pe	rsons. Orange in	dicates questions applicable to both CL	ABSI and CAUTI denominator coll	lection.	
Facility OrgID:	I Name/II)	Position IP Cleri Nurs Othe	cal	Interviewer initials:	Date of survey:	
(circle): CLABSI, CAUTI, BOTH NHSN location(s) covered:						
PATIEN	NT DAYS (for both CLABSI and CA	NUTI denominator o	counters)	Answer Key:		
1. Ho	ow are patient days usually colle					
	Electronically (document the so					
	system utilized and skip to Q8):					
	Manually (daily/weekly)					
	Some units electronic and som	e units manual				
	Comment:					
	there a specified time when the unt is taken?	denominator	☐ Yes ☐ No	The answer should be Yes		
3. When is it done?		Counts should be done at a specific time daily, preferably at nearly the same time throughout the facility to avoid errors when patients transfer				
4. Describe the method used to count patient days :		(from NHSN) "To calculate patient days, for each day of the month at				
Count the number of <u>patients</u> assigned to a unit bed <u>at the time counts are conducted</u>		the same time each day, record the number of patients. At the end of				
Other (specify)		the month, sum the daily counts and enter the total into NHSN. "				



	5. When reporting monthly patient day total, what is done if there are missing patient day data? (choose one)		NHSN issued specific guidance on imputing values for missing data in September 2013		
- 0	Report sum of available daily counts with no adjustment for missing data		(http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_S		
			, ,,,	,,,g <u>-</u> ,,,	
	Estimate or re-create missing data from existing information using our own meth	nods			
	Impute missing values using recent CDC/NHSN guidance				
	Other (specify):				
6. V	Which best describes your training for denominator (patient days and central line or	r catheter day	s) counting? (sele	ct all that apply)	
	No specific training was provided			Formal training by NHSN or NHSN-trained IP is recommended due to technical aspects of definitions	
	Peer training (person who previously counted explained their approach to new staff)			(e.g., central line, permanent line, temporary line) and	
	Formal training by IP			methods (e.g., when to count lines, how many to count).	
	Formal training by NHSN (e.g., online training)			county.	
	Annual training updates				
	Other (describe):				
	Which staff member counts patient days and central line or catheter days when	□ IP □	Another trained	counter Nobody Other (specify)	
	he "regular" data collector(s) is/are not working?	-2 /6-1+	.1.		
8. C	loes your facility have a mechanism in place for quality control of denominator data				
	(Electronic data) Yes, data submitted electronically is periodically checked using	_			
	(Manual data) Yes, manually collected data are periodically counted by more the	han one staff	member		
	Yes, other (explain)				
	No formal quality control process				
	Which staff member(s) is/are responsible for entering validation locations patient	☐ IP	☐ Counter ☐	Clerical Other (specify)	
d	ays and central line or catheter day data into NHSN?				



CENTRA	CENTRAL LINE DAYS (for CLABSI denominator counters only)				
10. How	are central line days collected for the unit(s) y				
	Electronically (specify software system				
	utilized and skip to Q13):				
	Manually (daily/weekly)				
	Some units electronic and some units manua				
	Comment:				

11. Ide	entify the method used to count central line days: (choose one)	A daily count of the number of patients with a central			
	Count the number of patients with at least one central line at the time surveillance round	line in the patient care location during a time period, which is summed for the monthly total			
	Count the number of central lines that are in place at the time surveillance rounds are con	nducted	which is summed for the monthly total		
	Count the number of central lines that are in use at the time surveillance rounds are cond	ucted			
	Other (specify):				
	hen reporting monthly patient day total, what is done if there are missing central line day ta? (choose one)	NHSN issued spec September 2013	ific guidance on imputing values for missing data in		
	Report sum of available daily counts with no adjustment for missing data (http://w		dc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf)		
	Estimate or re-create missing data using existing information (e.g.: medical records), then sum				
	Impute missing values using recent CDC/NHSN guidance for missing denominator data				
-	oatient has a radial arterial line and a peripheral IV. How many central line days are unted for this patient on this day?	Zero. The radial o	arterial line and peripheral IV are not central lines.		
us	14. A patient has a temporary central line and a permanent central line that have both been used during this hospitalization. How many central line days are counted for this patient on this day?		e patient has two central lines, a device day is defined as tients who have the device, not the number of devices.		
on	15. The patient above with the temporary central line and the permanent central line is on an oncology ward. Should you report one temporary line day, one permanent line day, or both a temporary and a permanent line day?		an oncology location has both temporary and the line day is reported as a temporary line day. This tailed in the NHSN Manual, Instructions for Form 57.117I)		
an	patient has a long-term port-a-cath that has not been accessed during this hospital stay, d a peripheral IV that is in use. How many central line days are counted for this patient on s day?	-	cath was not inserted during this visit and thus is not essed. The peripheral IV is not a central line. If the port-		



		,
		a-cath was inserted during this admission it would be counted each day thereafter, whether in use or not
17. A port-a-cath was inserted during this admission for pla How many central line days are counted for this patien		One. If a central line was inserted during this admission it would be counted each day that it remains in place, whether in use or not
18. A patient has a long-term central line that was accessed yesterday but is not currently in use, and a peripheral I line days are counted for this patient on this day?	One. The port-a-cath was accessed during this stay and subsequently the line will be counted for each daily count until discharge, unless removed.	
19. A patient has a long-term central line that was accessed during evaluation leading to admission, but the line is recentral line days are counted for this patient on this days	Zero. Brief access in an outpatient location does not count toward line- days during an admission. If the line had been accessed after admission or remained in use after admission following first access in the ED, it would be considered accessed for the purpose of counting line-days.	
20. If a central line is removed at 2PM and replaced at 8PM. The central line day count is done at 5PM, should the line be counted?		No. Central line must be in place at time of count
NICU-Specific Central Line Questions (Optional: Check here	e and skip section if NICU questions do i	not apply to your job) 🔲)
21. When reporting central line (CL) days, in neonates, which neonatal weight is used for reporting? (select one)	☐ Birth weight ☐ Current weight	Birth weight
22. Neonates with both a CL and an umbilical catheter (UC) are included in the daily count as: (select one)	UC only CL only	CL only. No separate reporting of UCs; UCs are considered CLs, and reporting is for one or more CL, stratified by birth weight.



Indw	elling Urinary Catheter Days (for indwelling urinary catheter counters only)	
23. H	low are indwelling urinary catheter-days collected for the units you oversee? (choose one)	
	Electronically (specify software system utilized and skip to Q26):	
	Manually (daily/weekly)	
	Some units electronic and some units manual	
	Comment:	
24. I	dentify the method used to count indwelling urinary catheter days: (choose one)	7-2: Indwelling urinary catheter (AKA Foley catheter): A drainage tube
	Count the number of patients on the unit with a urine collection bag	that is inserted into the bladder through the urethra, left in place, and connected to a drainage bag, including urinary catheters that are used
	Count the number of patients on the unit with a Foley catheter or condom catheter	for intermittent or continuous irrigation, but excluding suprapubic,
	Count the number of patients on the unit with a Foley catheter, condom catheter, or suprapubic catheter	condom, or straight in-and-out catheters.
	Count the number of patients on the unit with a Foley catheter or indwelling urethral three-way (infusion) catheter used for bladder washes	
	Other (specify):	
	When reporting monthly patient day total, what is done if there are missing catheter day lata? (choose one)	NHSN issued specific guidance on imputing values for missing data in September 2013
	Report the sum of available daily counts with no adjustment for missing data	(http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf)
	Estimate or re-create missing data using patient information (e.g.: medical record), then sum	
	Impute missing values using recent CDC/NHSN guidance for missing denominator data	
	patient has a draining ureteral stent and a Foley catheter; each one connected to a ollection bag. How many urinary catheter days are counted for this patient on this day?	One. Ureteral stents are not counted because they are not urethral catheters
þ	revent blood in the bladder from clotting, and to provide for irrigation after surgery to brevent blood in the bladder from clotting, and to provide for urinary drainage. How many brinary catheter days are counted for this patient on this day?	One. Catheters to be counted include indwelling urethral catheters used for intermittent or continuous irrigation, as well as those used for drainage.
	patient on the unit has a supra-pubic urinary catheter. How many urinary catheter days re counted for this patient on this day?	Zero. Supra-pubic catheters are not urethral catheters because they enter the bladder through the abdominal wall.
i	patient's indwelling urinary catheter is removed at noon and replaced at 5PM. Daily ndwelling urinary catheter counts take place at 2PM. How many urinary catheter days are eported for this patient on this day?	None. There was no indwelling urinary catheter at the time of the daily denominator count. NOTE: However, If this patient develops a bloodstream infection attributable to a urinary tract infection, this day will count as one of two required catheter days to establish CLABSI



criteria, because the catheter need only be in place for part of the two days to meet this criterion.



Appendix 1.4: Surgical Procedure and SSI Surveillance Methods Survey (with Key)

Instruct	nstructions: Administer this survey to the person who oversees NSHN SSI surveillance and reporting of surgical denominator (surgical procedure) data						
Facility o	Facility org ID: Name / ID of individual Position: interviewed: □IP □Other (explain)):	Interviewer initials:		Date of survey:	
Proced	ure (Denominato	r) Data	-				
2)	data electronic entered manu If manual, who	lity normally upload surgically to NHSN, or is procedually? (choose one): has primary responsibility a entry to NHSN? (choose o	for surgical	□ Electronic (skip to Q3) □ Manual □ Other (comment): □ IP □ Clerical/support staff		and un	responsible for entering denominator data nable to fully meet other responsibilities,
	·			☐ Clerical/support staff with IP oversight please		please	recommend clerical support for this task
3)	NORMALLY us) of information does your e to identify COLO and/or H choose all that apply):		☐ The complete OR records/reports ☐ Selected flagged/filtered OR records ☐ CPT codes assigned by surgeor ☐ ICD-10-PCS procedure codes a discharge ☐ Vendor system using OR record ☐ Vendor system using ICD-10-P after discharge (specify) ☐ Vendor system using both OR procedure codes assigned after or ☐ Other ☐ Other ☐ Other	ecords/reports as assigned by coders after ds (specify) CS procedure codes assigned and ICD-10PCS	ned	Discussion for Q 3 and 4: Medical records coder opinion is regarded as technical gold standard for identifying NHSN procedures, but may be questioned if other sources are inconsistent, and is often not as timely as OR systems. Presence of designated ICD-10-PCS procedure code is considered a requirement of NHSN procedure. Planned OR schedules are often inaccurate due to inability to predict procedures. OR records systems may be imprecise (e.g., may record XLAP rather than specifying that XLAP led to COLO, APPY, or SB). OR notes may be coded inaccurately; e.g.; surgeon may call procedure VHYS based on route of extraction whereas coder may classify as HYST based on route of detachment.
4)	How do you as reporting is co	sure COLO and/or HYST promplete?	ocedure	 □ No systematic way □ Extra scrutiny to XLAPs □ Cross-reference data sources (explain): □ Other 			Cross-referencing of sources (e.g.: OR records plus ICD-10-PCS procedure codes assigned after discharge) is probably the best way to assure complete denominator.



	In general, XLAPs should be scrutinized by
	IPs conducting surveillance for COLO and
	HYST.



5)	Under what circumstances do you remove COLO and/or HYST procedures from NHSN? (choose all that apply):	□ COLO or HYST ICD-10-PCS procedure code was not assigned for the procedure □ COLO or HYST ICD-10-PCS procedure code was assigned, but IP believes coder assigned COLO or HYST code in error □ Incision not primarily closed in OR □ Patient did not stay overnight □ Infection was present at the time of surgery (wound class = CO or D) □ ASA score was high □ Other	Although questioning of ICD-10-PCS procedure codes is acceptable, removal of procedures with designated ICD-10-PCS procedure code is only acceptable if procedure does not meet other aspects of NHSN procedure definition. Therefore it would be appropriate to remove procedure if there is 1) no appropriate ICD-10-PCS procedure code, 2) no primary closure (note: new definition of primary closure for 2016), 3) not an inpatient (no overnight stay), 4) no incision/scope (Correct answers 1,3,4)
6)	If the OR record does not match the listed ICD-10-PCS procedure codes, what should you do?		For validation purposes, NHSN recommends that IPs should bring coding mismatches to coders for review, and should not over-ride coders' decisions.
7)	Which of the following are consistent with the definition of primary closure for 2016? (check ALL that apply)	 □ Complete closure of skin with suture □ Partial closure of skin with staples □ Closure of skin except for wick/drain through incision □ Closed fascia with incision loosely closed at the skin level □ Closed fascia, with skin layer left open 	All but the last option are considered primary closure in 2016.
8)	Does your facility conduct NHSN analysis to look at longitudinal trends for COLO or HYST SSIs and procedures?		This is recommended practice for facility use of NHSN data
9)	What would you do if your procedure denominator this month was dramatically higher from one month to the next?		Recommended: investigate this aggregate data by exploring the data at a patient/procedure level to identify the



Surgical site Infection (Numerator) Data Collecti	on Questions			
Instructions: Interview individual(s) directly respo	ng SSI data	Date of survey:		
Name/ID of individual interviewed:	Position		(circle): COLO, HYST, BOTH	
Numerator (SSI Event) Data:				
10) If a patient with an SSI is admitted to your facility but the surgical procedure was performed in another hospital ("hospital A"), what do you do? (choose all that apply)		☐ Report the SSI to NHSN ☐ Report the SSI to "hospital A" ☐ Report the SSI to the health department ☐ No external reporting Comment:		Best practice is to report to "hospital A" and (if required by the state) to health department. Hospital A should report to NHSN.
11) If you do not report the SSI to "hospital A", why not? (choose all that apply)		☐ HIPAA concerns ☐ Not a priority for IP program ☐ Logistically difficult (which hospital, who to contact) ☐ Not required Comments:		If facility cites HIPAA concerns, consider sharing Appendix 7, or CSTE position statement 13-ID-09, which contains information from the Office of Civil Rights assuring that sharing SSI information with the originating facility does not violate HIPAA.
12) If you are contacted by the IP from another hospital regarding a patient with an SSI who underwent a procedure in your facility, what do you do? (choose all that apply)		☐ Ask the IP for help completing the NHSN report ☐ Document in your tracking records ☐ Report the SSI to NHSN ☐ Ask the IP to report the SSI to NHSN ☐ No internal reporting or documentation Comment:		The other IP can best document the depth of infection, but cannot report the event to NHSN because it has to be linked. Suggest asking the other IP to help complete the NHSN report form, include a note or a copy in the patient record, and report to NHSN.



13) What methods are routinely and systematically used to identify possible	Reports/Rounds:				
SSI? (Check all that apply)	☐ Emergency department line lists with diagn	oses			
	☐ Admissions line lists with diagnoses				
	☐ Surgical ward rounds				
	☐ Positive laboratory cultures from inpatients	3			
	☐ Positive laboratory cultures from ED				
	☐ Pharmacy reports (antibiotic starts or conti	nuations)			
	□ Other				
	Surgical service information:				
	☐ Inpatient returns to surgery				
	□ Surgical service readmissions				
	ADT/Medical Records Data Mining:				
	☐ Readmissions within one month of discharge	7A			
	☐ Extended LOS	50			
	☐ Discharge diagnostic coding				
	☐ Other				
14) How does your facility conduct post-discharge surveillance for SSIs?	☐ IP does not have a formal post-disc	- charge surveillance nlan			
(check all that apply)	☐ IP conducts patient survey by mail	and ge our vemance plan			
(encontain and apply)	□ IP conducts patient survey by telep	hone			
	☐ IP provides line list of patients to su				
	☐ Surgeon indicates SSIs identified at	•			
	☐ Surgeon surveys patient by mail	ě ,			
	☐ Surgeon surveys patient by telepho	ne			
	☐ IP reviews surgical clinic / wound cl				
	☐ IP reviews surgical patient records 3				
	Other/ Comment:				
15) During one trip to the operating room, both a COLO procedure and a	□ COLO	Two answers are correct (a and d): The			
HYST procedure are performed. A deep-incisional SSI develops. To	☐ HYST	procedure which is higher on the 2016			
which procedure should you attribute the SSI?	□ Both□ Whichever is higher on the procedure	procedure hierarchy (this would be COLO), because you cannot determine which			
	hierarchy	procedure led to the SSI			
	□ Neither				



16) During one trip to the operating room, both a COLO procedure and a HYST procedure are performed. The patient later meets criteria for a GIIAB with peritonitis (an organ-space SSI). To which procedure should you attribute the SSI?	COLO HYST Both Whichever is higher on the procedure hierarchy Neither	Two answers are correct(a and d): The procedure which is higher on the 2016 procedure hierarchy (this would be COLO) because you cannot determine which procedure led to the SSI
17) During one trip to the operating room, both a COLO procedure and a HYST procedure are performed. An abscess of the vaginal cuff (organspace SSI) develops. To which procedure should you attribute the SSI?	COLO HYST Both Whichever is higher on the procedure hierarchy Neither	The vaginal cuff is the operative site of the HYST, and the hierarchy is not needed; this SSI is attributable to the HYST (answer b).
18) During one trip to the operating room, both a SB procedure and a HYST procedure are performed. An abscess of the small-bowel anastomosis site (organ-space SSI) develops. To which procedure should you attribute the SSI?	SB HYST Both Whichever is higher on the procedure hierarchy Neither	The SSI is localized to the operative site of the SB, and the hierarchy is not needed; this SSI is attributable to the SB (answer a). SB is higher on the hierarchy, but the hierarchy is only used when attribution cannot be determined by localized infection.



Appendix 1.5: LabID Event Surveillance Methods Survey (with Key)

OrgID / Name of Hospital

6	/ Hame of Hospital								
	D Event Surveillance Methods Su ructions: Administer this survey to	•	s NHS	SN LabID Event reporting					
Denominator Data Collection Questions									
Name of individual interviewed: Position: FacWideIN MRSA bacteremia FacWideIN CDI						Interviewer Date initials:		e of survey:	
1)	For FacWideIN reporting, denom facility-wide level	inator data are entered	into I	NHSN once a month at the		True False		Т	
2)	For CDI reporting, the denominat	or should include all cor	mplet	ed CDI toxin tests				F (denominator = admissions and patient days)	
3)	Patient days include only admitte located on inpatient wards are ex		ward	s; observation patients				F (all patients housed in inpatient locations)	
4)	For CDI reporting pediatric location	ons should be excluded	from	FacWideIN reporting		True False		F (NICU and well- baby locations and babies on LDRP are excluded for CDI)	
5)	For MRSA bacteremia reporting be excluded from the denominator	paby locations (NICU, ne	wbor	n nursery, etc.) should be		True False		F (no location exclusions for MRSA)	
Nun	nerator Data Collection Questions	3							
Nan	ne of individual interviewed:	Position:		FacWideIN MRSA bacteremia FacWideIN CDI		erviewer ials:	Date	of survey:	
6)	For FacWideIN reporting, one mo	onthly numerator for Eve	ents is	s reported at the facility-		True F (events are False reported by loc		F (events are reported by location)	
7)	For CDI reporting, the numerator formed stool specimens	should include toxin-po	sitive	e CDI results conducted on		True False		F (laboratories should only process and report results for unformed stools)	
8)	A second event is always reporte MRSA bacteremia or toxin-positiv		d fro	m the most recent positive		True False		Т	
9) A second event is only reported if >14 days have passed from the most recently reported labID event Second event Properties Properties						True False		F (If the patient changes location, a second event is reported even within 14 days of prior event)	
10)	A second event is only reported in since the most recent positive Millocation			True False		Т			
11)	11) Only reportable CDI LabID Events should be entered into NHSN							Т	
Policy Question									
12)	Does your facility laboratory limit only, or does the laboratory proc			Unformed s specimens All stool specimens		Recommended policy is to only process unformed stool specimens for CDI			

Appendix 1.6: Template for Internal Validation of LabID Event Denominator (FacWideIN)

Please feel free to adapt this template to meet your state's needs

Electronically collected MRSA bacteremia and CDI FacWideIN denominators

"FacWideIN" includes all patient days counted at the same time each day for all inpatient locations, including any patients located for the day in inpatient locations, whether or not the facility considers them admitted patients or observation patients, but excluding any patients located for the day in outpatient observation locations. This information is typically collected electronically. Because the task of validating electronic patient days and admissions facility-wide is daunting, denominator validation can be accomplished using manual counting of patient days and admissions in three specified location types for three months each: one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location (if available), and one or more inpatient wards where observation patients are frequently located. Electronic counts should be within 5% of manual counts or an evaluation of why they differ should be conducted.

MRSA Bacteremia LabID Event Denominator Validation								
Location of Validation*	Month of Validation	Admissions			Patient Days			
Valladion	(specify)	Usual Count	5% Tolerance interval†	Manual Count	Usual Count	5% Tolerance interval†	Manual Count	
	1							
	2							
	3							
	1							
	2							
	3							

MRSA Bacteremia LabID Event Denominator Validation									
	2								
	3								

*Select one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location if available, and one or more inpatient ward location where observation patients are frequently located and conduct manual (patient level) validation of admissions and patients days for three months, according to NHSN definitions

(http://www.cdc.gov/nhsn/PDFs/pscManual/validation/pcsManual-2016-valid.pdf, and http://www.cdc.gov/nhsn/forms/instr/57 127.pdf).

Remember that for MRSA bacteremia both mothers and babies are counted in LDRP locations.

†Equation for 5% tolerance interval is: Usual Count ± (Usual Count * 0.05).

Example calculations where Usual Count = 164 and Manual Count = 178:

Eligible 5% tolerance interval = $[164\pm(164*0.05)]=155.8$ to 172.2

Manual Count 178 falls outside the tolerance interval, suggesting that Usual Count is inaccurate and should be investigated.



CDI LabID Event Denominator Validation									
Location of Validation*	Month of Validation		Admissions		Patient Days				
vandation	(specify)	Usual Count	5% Tolerance interval†	Manual Count	Usual Count	5% Tolerance interval†	Manual Count		
	1								
	2								
	3								
	1								
	2								
	3								
	1								
	2								
	3								

^{*}Select one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location if available, and one or more inpatient ward location where observation patients are frequently located and conduct manual (patient level) validation of admissions and patients days for three months, according to NHSN definitions

(http://www.cdc.gov/nhsn/PDFs/pscManual/validation/pcsManual-2016-valid.pdf, and http://www.cdc.gov/nhsn/forms/instr/57 127.pdf).



CDI LabID Event Denominator Validation

Remember that for CDI, only mothers (and not babies) are counted in LDRP locations.

†Equation for 5% tolerance interval is: Usual Count ± (Usual Count * 0.05).

Example calculations where Usual Count = 164 and Manual Count = 178:

Eligible 5% tolerance interval = $[164\pm(164*0.05)]=155.8$ to 172.2

Manual Count 178 falls outside the tolerance interval, suggesting that Usual Count is inaccurate and should be investigated.

