Late-Onset Sepsis/Meningitis Event

LaTasha R. Boswell RN, BSN, MPH, CIC

Infection Prevention Consultant

CACI, Subcontractor to Leidos | Contractor for the National Healthcare Safety Network (NHSN)

NCEZID, Division of Healthcare Quality Promotion (DHQP)

Centers for Disease Control and Prevention (CDC)

nhsn@cdc.gov

Objectives

- Locate LOS/MEN resources for reporting and education
- Define the National Healthcare Safety Network (NHSN) criteria for LOS/MEN
- Identify the data requirements for electronic detection and reporting of LOS/MEN numerator and denominator data

Neonatal Component Website Live!!!

Neonatal Component

Use the Neonatal Component to track healthcare-associated infections and events in very low birth[illegible]ght and extremely premature neonates housed in acute care hospital facilities.

Facilities Reporting in Neonatal Component

Acute Care Hospitals

New Users

Enroll New Facility

Neonatal Training

Neonatal Modules & Events

Access relevant training, protocols, data collection forms and supporting materials for each module.

LOS/MEN Events

https://www.cdc.gov/nhsn/neonatal/index.html

Late-Onset Sepsis/Meningitis Protocol

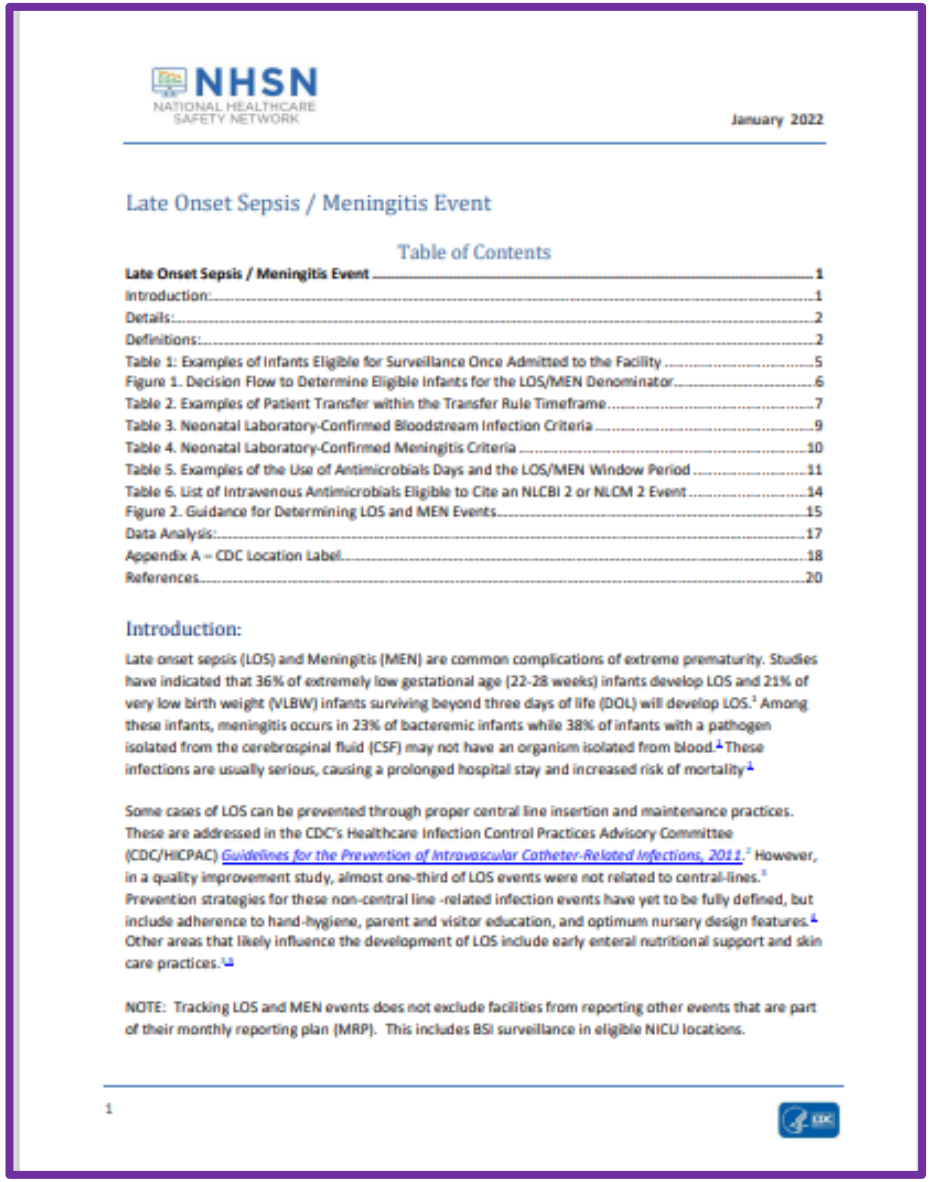
Protocols

Late-Onset Sepsis/Meningitis (LOS/MEN) Event – January 2022 [PDF – 1 MB]

Supporting Chapters

NHSN Overview – January 2022 [PDF – 350 KB]

CDC Location Labels and Location Descriptions – January 2022 [PDF – 1 MB]



NHSN
NATIONAL HEALTHCARE SAFETY NETWORK

January 2022

Late Onset Sepsis / Meningitis Event

Table of Contents

Introduction:

Late onset sepsis (LOS) and Meningitis (MEN) are common complications of extreme prematurity. Studies have indicated that 36% of extremely low gestational age (22-28 weeks) infants develop LOS and 21% of very low birth weight (VLBW) infants surviving beyond three days of life (DOL) will develop LOS.[3] Among these infants, meningitis occurs in 23% of bacteremic infants while 38% of infants with a pathogen isolated from the cerebrospinal fluid (CSF) may not have an organism isolated from blood.[4] These infections are usually serious, causing a prolonged hospital stay and increased risk of mortality.[4]

Some cases of LOS can be prevented through proper central line insertion and maintenance practices. These are addressed in the CDC's Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) *Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011*.[2] However, in a quality improvement study, almost one-third of LOS events were not related to central-lines.[5] Prevention strategies for these non-central line -related infection events have yet to be fully defined, but include adherence to hand-hygiene, parent and visitor education, and optimum nursery design features.[4] Other areas that likely influence the development of LOS include early enteral nutritional support and skin care practices.[4,6]

NOTE: Tracking LOS and MEN events does not exclude facilities from reporting other events that are part of their monthly reporting plan (MRP). This includes BSI surveillance in eligible NICU locations.

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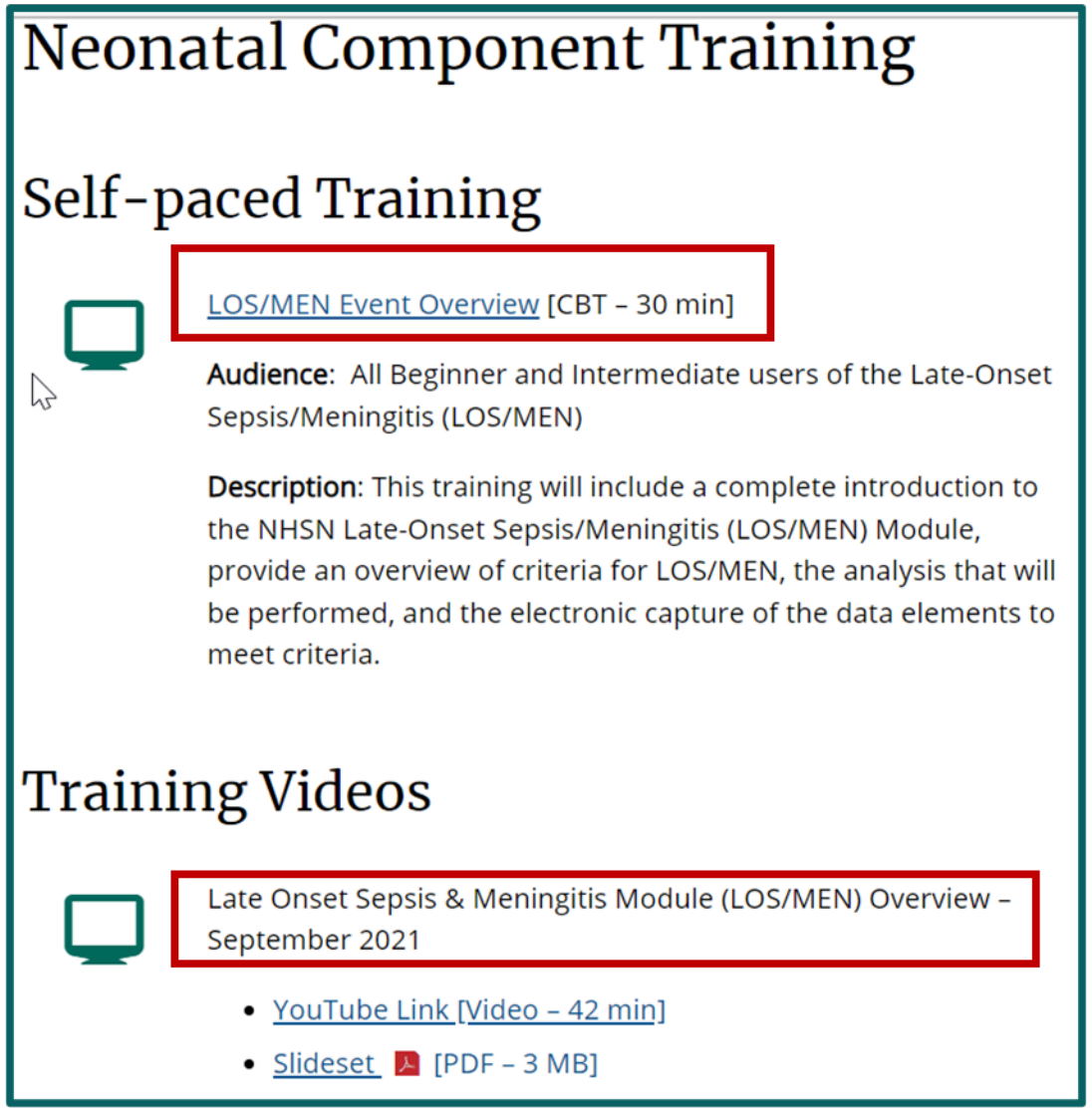
https://www.cdc.gov/nhsn/neonatal/los-men/index.html

Neonatal Component Training



Neonatal Component Training

Self-paced Training

LOS/MEN Event Overview [CBT – 30 min]

Audience: All Beginner and Intermediate users of the Late-Onset Sepsis/Meningitis (LOS/MEN)

Description: This training will include a complete introduction to the NHSN Late-Onset Sepsis/Meningitis (LOS/MEN) Module, provide an overview of criteria for LOS/MEN, the analysis that will be performed, and the electronic capture of the data elements to meet criteria.

Training Videos

Late Onset Sepsis & Meningitis Module (LOS/MEN) Overview – September 2021

- YouTube Link [Video – 42 min]
- Slideset [PDF – 3 MB]

https://www.cdc.gov/nhsn/training/neonatal/index.html

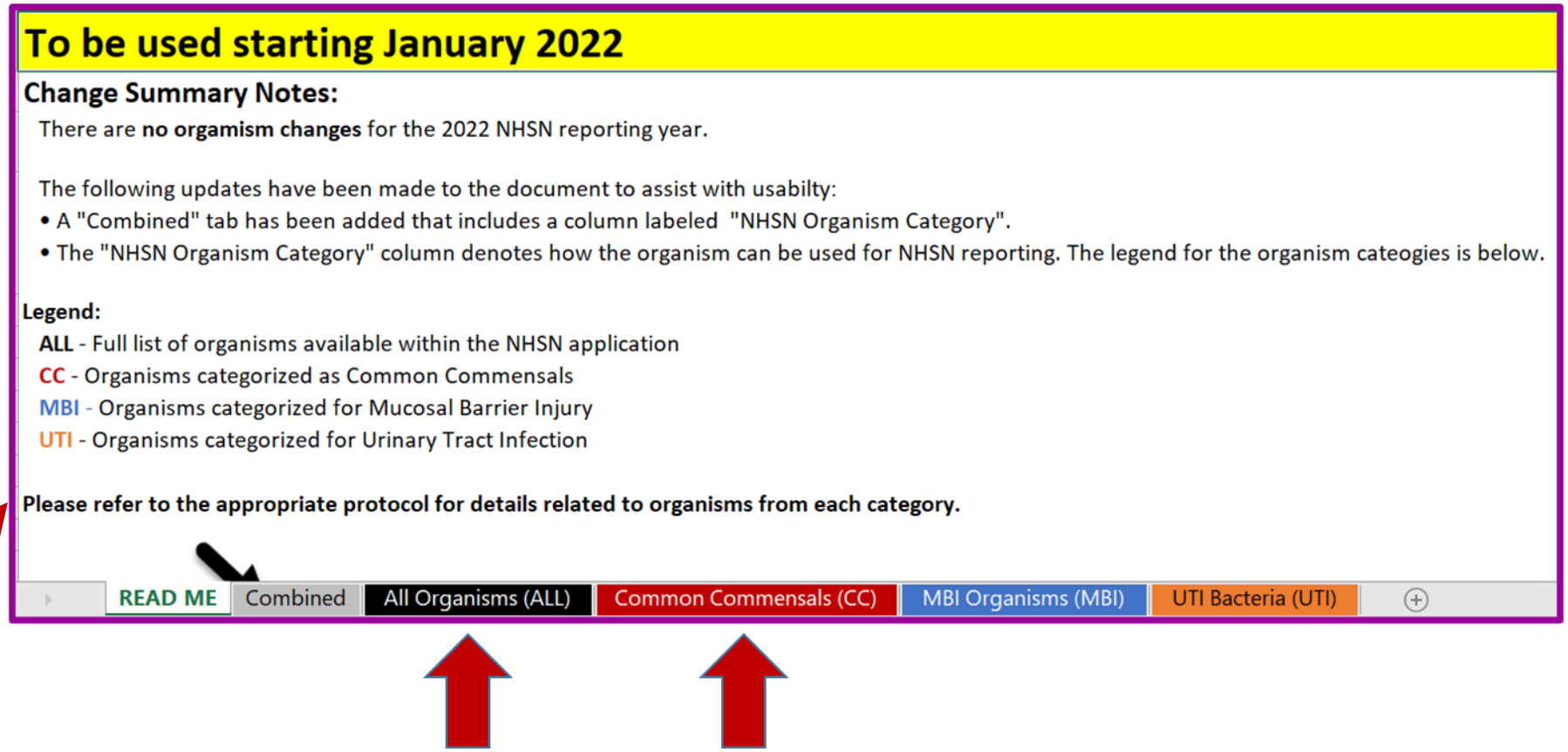
NHSN Organism List

Supporting Materials

NHSN Patient Safety Component Alerts [PDF – 1 MB]

Unusual Susceptibility Profiles Alert – January 2022 [PDF – 500 KB]

NHSN Organism List (All Organisms, Common Commensals, MBI Organisms, and UTI Bacteria) – January 2022 [XLS – 257 KB]



What Facilities Need to Know about this Module

- No manual data entry available for this module: You will need an electronic process/system to upload your data
  - Software vendor
  - Electronic Health Record System
  - Homegrown System

- If BSI **and** LOS/MEN are part of your monthly reporting plan, ***you must report both events.*** A BSI cannot be deemed secondary to an LOS/MEN event.

LOS/MEN Module

Eligible Surveillance Locations

Level II/III Nursery

- Mixed acuity nursery housing both Level II and level III neonates
- Level II special care nursery
  - Level I capabilities plus: Provide care for infants born ≥32 wks. gestation and weighing ≥1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis
  - Provide care for infants convalescing after intensive care
  - Provide mechanical ventilation for brief duration (<24 h) or continuous positive airway pressure or both
  - Stabilize infants born before 32 wks. gestation and weighing less than 1500 g until transfer to a neonatal intensive care facility
- Level III
  - Level II capabilities plus: Provide sustained life support
  - Provide comprehensive care for infants born < 32 wks. gestation and weighing <1500 g and infants born at all gestational ages and birth weights with critical illness
  - Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists
  - Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide
  - Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography

Level III Nursery

- Level II capabilities plus: Provide sustained life support
- Provide comprehensive care for infants born < 32 wks. gestation and weighing <1500 g and infants born at all gestational ages and birth weights with critical illness
- Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists
- Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide
- Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography

Level IV Nursery

- Regional NICUs
- Level III capabilities plus:
  - Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions
  - Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric subspecialists at the site
  - Facilitate transport and provide outreach education

LOS/MEN Module

Key Terms

Key Terms

- **Inborn Infant:**

  Any infant delivered at your facility

- **Outborn Infant:**

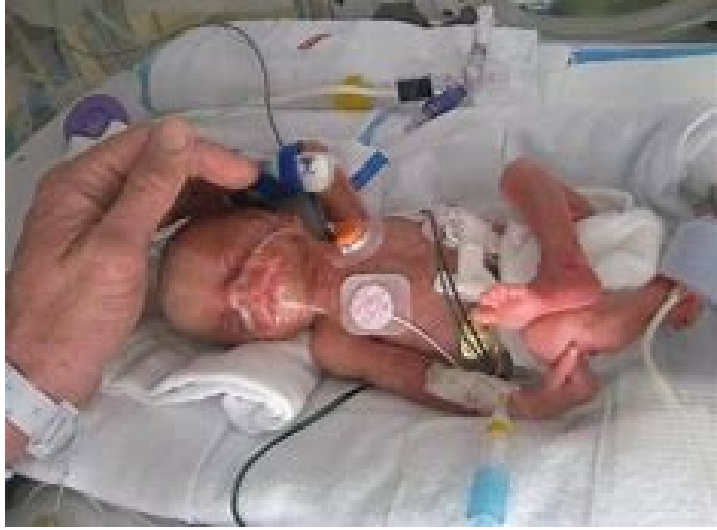
  An infant born outside your facility

  - Any infant that arrives at your facility in an ambulance is outborn

- **Date of Event:**

  Collection date of the blood or CSF specimen from which an organism is identified by culture or non-culture based microbiologic testing, performed for purposes of clinical diagnosis or treatment.

Eligible Infant



- Inpatient > 2 days,
- Housed on a Level II/III, Level III, or Level IV nursery
- Birth Weight 401 to 1500 grams
- Older than Day of Life (DOL) 3 but younger than DOL 121
  - Birth Date = DOL 1, regardless of the time of birth

LOS/MEN Module

Key Concepts

Repeat Infection Timeframe (RIT)

- 14-day timeframe during which no new infections of the same type, specifically, LOS or Meningitis, are reported for the same patient.

- Infant may have more than 1 episode of LOS/MEN during a single hospitalization

  BUT there is a 14-day RIT during which no new infection of the same type can be reported

- An infant may have an LOS and MEN event during a RIT period since these are two different infections

Transfer Rule

- If the date of the event occurs on the day of transfer to a receiving facility or the next day, the infection event will be identified by the receiving facility as present on admission (POA)

*Note: Facilities will not be able to capture post discharge events

Transfer Rule Example

Day of Life (DOL)	Event/Location Description
DOL 5	Infant in Facility A, NICU 1
DOL 6	Infant transferred from Facility A NICU 1 to Facility B NICU 1
DOL 7	LOS is present on admission (POA) to Facility B and no infection event will be attributed to Facility B or Facility A since electronic capture of laboratory results is not possible for the transferring facility.

LOS/MEN Module

Event Details

Neonatal Laboratory-Confirmed Bloodstream Infection 1 (NLCBI 1)

An eligible infant has a recognized pathogen (specifically a bacterial or fungal organism which is not on the Common Commensals tab of the NHSN Organisms List) identified from one or more blood specimens by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing).

LOS/MEN Protocol, page 9

Table 3. Neonatal Laboratory-Confirmed Bloodstream Infection Criteria

Criterion	Neonatal Laboratory-Confirmed Bloodstream Infection (NLCBI) *Comments and reporting instructions that follow the site-specific criteria provide further explanation and are integral to the correct application of the criteria.* Must meet one of the following criteria:
NLCBI 1	An eligible infant has a recognized pathogen (specifically a bacterial or fungal organism which is not on the Common Commensals tab of the NHSN Organisms List) identified from one or more blood specimens by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing).
	OR
NLCBI 2	A Common Commensal (specifically, a bacterial organism which is on the Common Commensal tab of the NHSN Organisms List) is identified from one or more blood specimens by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing). ***AND*** Treatment is initiated during the LOS/MEN Window Period, on or after DOL 4 with one or more **new** intravenous (IV) antimicrobial agent*(s) from the Table 6 LOS/MEN antimicrobial list and continued for 5 or more calendar days (referred to as 5 "qualifying antimicrobial days" or "QADs"). Days on which a new antimicrobial agent is administered count as QADs. Days between administrations of a new antimicrobial agent also count as QADs as long as there is a gap of no more than 1 calendar day between administrations. * New IV antimicrobial agent: Defined as any agent for which all 4 of the following are true: 1. Is listed in Table 6. 2. The antimicrobial "start date", which is the date of antimicrobial initiation, must occur sometime within the LOS/MEN Window Period, which is 2 calendar days before, the day of, or within 2 calendar days after the specimen collection date. 3. Antimicrobial start date must occur on or after DOL 4 with one or more new intravenous (IV) antimicrobial agent*(s) and continued for 5 or more qualifying antimicrobial days (QADs). Days between administrations of a new antimicrobial agent also count as QADs provided there is a gap of no more than 1 calendar day between administrations. 4. Was NOT given to the patient on either of the 2 days preceding the first antimicrobial initiated in the LOS/MEN Window Period current start date. (See **Table 5: *Examples of the Use of Antimicrobials Days and the LOS/MEN Window Period***.) Substitution of a different antimicrobial agent from Table 6 within the LOS/MEN Window Period due to therapy/organism sensitivity factors will continue to meet the requirements for QADs.

Neonatal Laboratory-Confirmed Bloodstream Infection 2 (NLCBI 2)

A Common Commensal (specifically, a bacterial organism which is on the NHSN Common Commensal list) is identified from one or more blood specimens by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing).

AND

Treatment is initiated during the LOS/MEN Window Period, on or after DOL 4 with one or more **new** intravenous (IV) antimicrobial agent*(s) from the Table 6 LOS/MEN antimicrobial list and continued for 5 or more calendar days (referred to as 5 "qualifying antimicrobial days" or "QADs").

LOS/MEN Protocol, page 9

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	OR
NLCBI 2	A Common Commensal (specifically, a bacterial organism which is on the Common Commensal tab of the NHSN Organisms List) is identified from one or more blood specimens by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing). ***AND*** Treatment is initiated during the LOS/MEN Window Period, on or after DOL 4 with one or more **new** intravenous (IV) antimicrobial agent*(s) from the Table 6 LOS/MEN antimicrobial list and continued for 5 or more calendar days (referred to as 5 "qualifying antimicrobial days" or "QADs"). Days on which a new antimicrobial agent is administered count as QADs. Days between administrations of a new antimicrobial agent also count as QADs as long as there is a gap of no more than 1 calendar day between administrations.
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LOS/MEN Window Period

- The 5-day period around the common commensal positive blood or CSF specimen that includes the 2 days before, the day of, and the 2 days after the LOS/MEN event date. Exception: LOS/MEN period may be shortened in cases when the LOS/MEN date of event occurs on DOL 4 or 5. Example cases are as follows:

  - *Example:* LOS/MEN date of event, DOL 4: LOS/MEN Window Period = 3 days, the day of the LOS/MEN date of event and the 2 days after. Rationale: The 2 days before LOS/MEN event date are before DOL 4 and the infant is not eligible for surveillance on those days.

  - *Example:* LOS/MEN date of event, DOL 5: LOS/MEN Window Period = 4 days, the 1 day before the LOS/MEN date of event (DOL 4), LOS/MEN event date and 2 days after.

Eligible Antimicrobials for NLCBI 2 and NLCM 2 Events (Table 6)

Table 6. List of Intravenous Antimicrobials Eligible to Cite an NLCBI 2 or NLCM 2 Event

Ampicillin
Ampicillin-Sulbactam
Cefazolin
Cefepime
Cefotaxime
Ceftazidime
Ceftriaxone
Clindamycin
Gentamicin
Imipenem
Linezolid
Meropenem
Metronidazole
Nafcillin
Oxacillin
Penicillin G
Piperacillin-Tazobactam
Vancomycin

LOS/MEN Protocol, page 14

New Antimicrobial Agent

Must meet all **four** criteria

1. Listed in **Table 6** of the LOS/MEN protocol
2. The agent must be administered intravenously (IV)
3. The antimicrobial agent must be started on or after DOL 4 AND within 2 days before or 2 days after the collection date of the positive blood or CSF specimen
4. Was NOT given to the patient on either of the 2 days preceding the first antimicrobial initiated in the LOS/MEN Window Period

What Are Qualifying Antimicrobial Days (QADs)?

- QADs are days on which a new antimicrobial agent is administered
- One or more new antimicrobial agents must be continued for at least 5 calendar days
  - Days between administrations of a new antimicrobial agent also count as long as there is no more than 1 calendar day gap between administration
  - The 5-calendar day requirement can be met with multiple antimicrobial agents, as long as each antimicrobial agent was determined to be new

Determining QADs – Example

Date	DOL	Antimicrobial Administered	Positive Specimen Collection
Infant E			
June 12	11		
June 13	12		
June 14	13	Ampicillin	
June 15	14	Ampicillin	(+) Blood culture for *Staphylococcus capitis*
June 16	15	Ampicillin	
June 17	16	Vancomycin	
June 18	17	Vancomycin	

QADs

Explanation: Since Ampicillin was not given in the 2 days preceding the first antimicrobial initiated during the LOS/MEN Window Period (denoted by the shaded area) and was started within the LOS/MEN Window Period, Ampicillin is a new antimicrobial agent. The change to Vancomycin within the LOS/MEN window can be used to meet the ≥ 5-day QAD requirement and an NLCBI 2 event is identified.

Note: LOS/MEN Window Period in grey.

Neonatal Laboratory-Confirmed Meningitis 1 (NLCM 1)

An NHSN recognized pathogen, which is not an NHSN common commensal, identified from a cerebrospinal fluid (CSF) specimen obtained from an infant and tested by a culture or non-culture based microbiological testing method, performed for purposes of clinical diagnosis or treatment (not for purposes of active surveillance)

LOS/MEN Protocol, page 10

Table 4. Neonatal Laboratory-Confirmed Meningitis Criteria

Criterion	Neonatal Laboratory-Confirmed Meningitis (NLCM)
	Comments and reporting instructions that follow the site-specific criteria provide further explanation and are integral to the correct application of the criteria.
	Must meet one of the following criteria:
NLCM 1	An eligible infant has a recognized pathogen (specifically, a bacterial or fungal organism which is not on the Common Commensal tab of the NHSN Organisms List) identified from a CSF specimen by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing).
	OR
NLCM 2	A Common Commensal is identified from a CSF specimen (specifically, a bacterial organism which is on the Common Commensal tab of the NHSN Organisms List) from one or more CSF specimens by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing). ***AND*** Treatment is initiated during the LOS/MEN Window Period, on or after DOL 4 with one or more **new** intravenous (IV) antimicrobial agent*(s) from Table 6 LOS/MEN antimicrobial list that are continued for 5 or more calendar days (referred to as 5 "qualifying antimicrobial days" or "QADs"). Days on which a new antimicrobial agent is administered count as QADs. Days between administrations of a new antimicrobial agent also count as QADs as long as there is a gap of no more than 1 calendar day between administrations. * New IV antimicrobial agent: Defined as any agent for which all 4 of the following are true: 1. Is listed in Table 6. 2. The antimicrobial "start date", which is the date of antimicrobial initiation, must occur sometime within the LOS/MEN Window Period which includes 2 calendar days before, the day of, or within 2 calendar days after the specimen collection date. 3. Antimicrobial start date must occur on or after DOL 4 with one or more new intravenous (IV) antimicrobial agent*(s) and continued for 5 or more qualifying antimicrobial days (QADs). Days between administrations of a new antimicrobial agent also count as QADs provided there is a gap of no more than 1 calendar day between administrations. 4. Was NOT given to the patient on either of the 2 days preceding the first antimicrobial initiated in the LOS/MEN Window Period. (See **Table 5: *Examples of the Use of Antimicrobials Days and the LOS/MEN Window Period***.) Substitution of a different antimicrobial agent from **Table 6** within the LOS/MEN Window Period due to therapy/organism sensitivity factors will continue to meet the requirements for QADs.

Neonatal Laboratory-Confirmed Meningitis 2 (NLCM 2)

An NHSN Common Commensal is identified from a CSF obtained from an infant and tested by a culture or specimen non-culture based microbiological testing method, performed for purposes of clinical diagnosis or treatment

AND

Treatment is initiated during the LOS/MEN Window Period, on or after DOL 4 with one or more new intravenous (IV) antimicrobial agent*(s) from Table 6 LOS/MEN antimicrobial list that are continued for 5 or more calendar days (referred to as 5 "qualifying antimicrobial days" or "QADs").

LOS/MEN Protocol, page 10

Table 4. Neonatal Laboratory-Confirmed Meningitis Criteria

Criterion	Neonatal Laboratory-Confirmed Meningitis (NLCM) *Comments and reporting instructions that follow the site-specific criteria provide further explanation and are integral to the correct application of the criteria.* Must meet one of the following criteria:
NLCM 1	An eligible infant has a recognized pathogen (specifically, a bacterial or fungal organism which is not on the Common Commensal tab of the NHSN Organisms List) identified from a CSF specimen by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing).
	OR
NLCM 2	A Common Commensal is identified from a CSF specimen (specifically, a bacterial organism which is on the Common Commensal tab of the NHSN Organisms List) from one or more CSF specimens by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing). ***AND*** Treatment is initiated during the LOS/MEN Window Period, on or after DOL 4 with one or more **new** intravenous (IV) antimicrobial agent*(s) from Table 6 LOS/MEN antimicrobial list that are continued for 5 or more calendar days (referred to as 5 "qualifying antimicrobial days" or "QADs"). Days on which a new antimicrobial agent is administered count as QADs. Days between administrations of a new antimicrobial agent also count as QADs as long as there is a gap of no more than 1 calendar day between administrations.
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Reporting Instructions

- If both NLCBI and NLCM are met, both should be reported with the event date reported as the date(s) of specimen collection
- If an NLCBI 1 and NLCBI 2 are identified from a specimen, the event should be reported as NLCBI 1 with the “recognized pathogen” reported as pathogen 1 and the common commensal as pathogen 2
- An NLCM 1 shall be reported if both NLCM 1 and NLCM 2 events are both identified from the same specimen
- Active surveillance cultures are not eligible for NLCBI or NLCM criteria

Data Collection and Reporting

The LOS/MEN Calculator

- Uses computer algorithms to identify Late-Onset Sepsis and Meningitis Events and denominator eligible infants (numerator and denominator, respectively)
- Software library that can be integrated into your system
- On-premise deployment: can be invoked locally

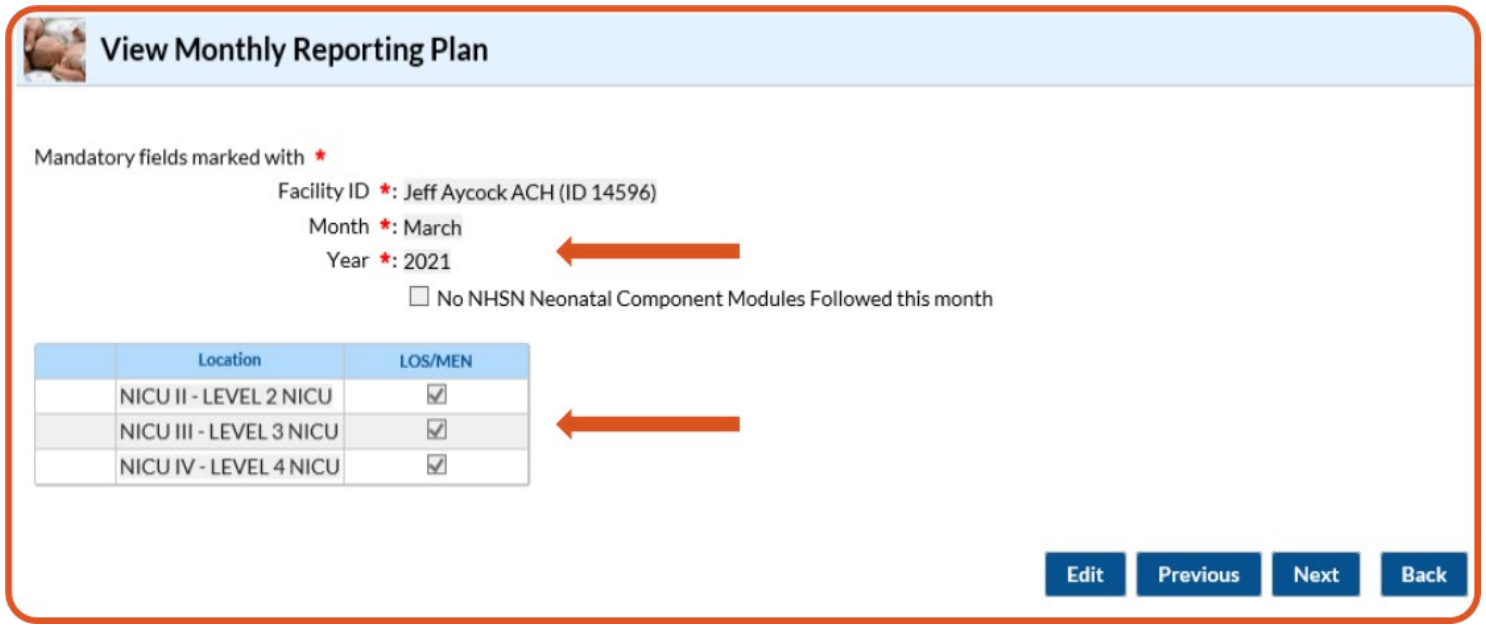
Data Collection and Reporting

- The LOS/MEN surveillance protocol is designed to enable use of computer-based algorithms applied to electronic healthcare data sources to identify infants who qualify for the LOS/MEN numerator and denominator

- LOS/MEN numerator and denominator data must be submitted to NHSN electronically. **Reporting manually, using NHSN's web interface, is not an option**

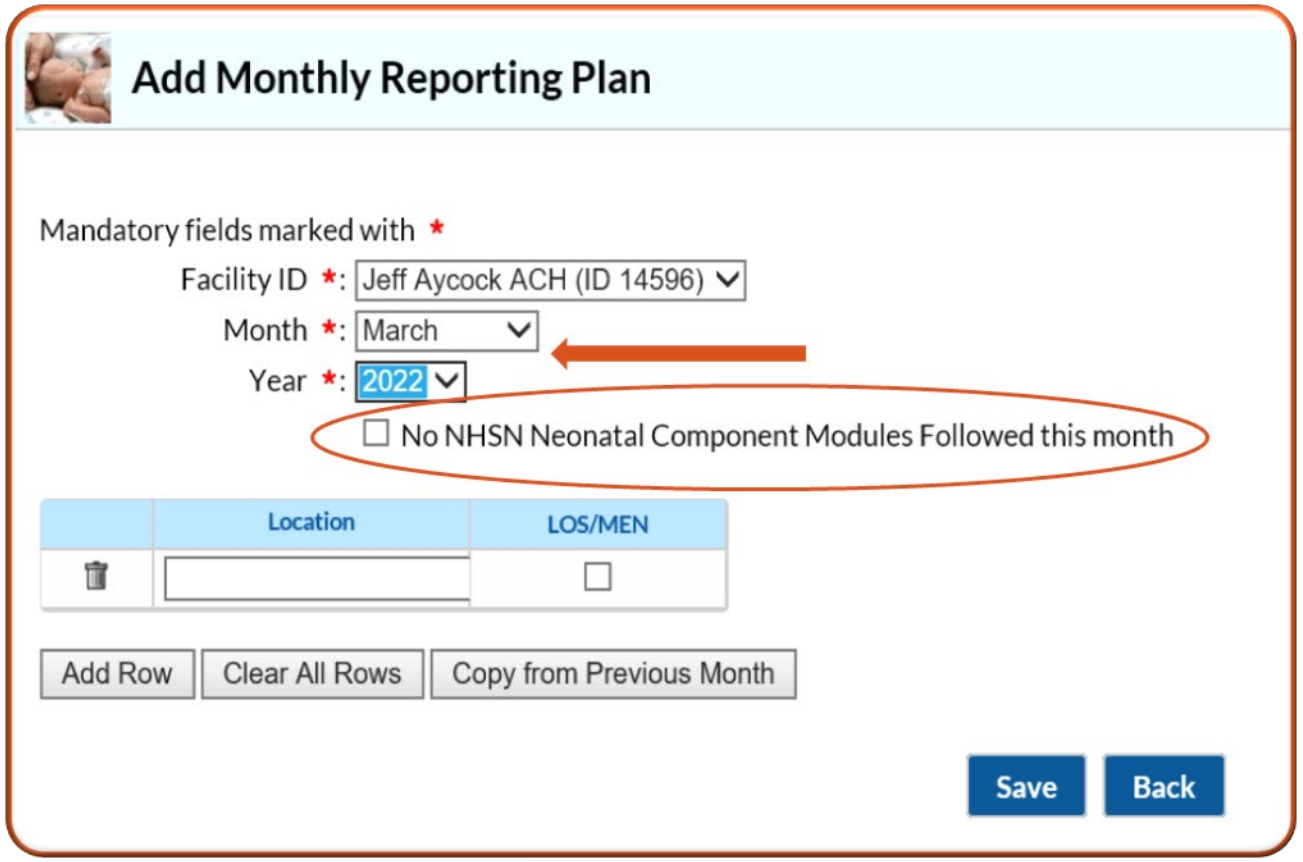
- Healthcare facilities must report LOS/MEN data to NHSN via an electronic data standard known as Clinical Document Architecture (CDA)

Monthly Reporting Plans (MRPs)



- Used by all NHSN facilities to inform CDC which NICU location will be used in a given month.
- Participating facilities must select the location used, if any, the events that will be monitored in that month.
- ***MRPs are manually completed in the application.***

Adding a Monthly Reporting Plan



- Select month/year, location and events if you are following LOS/MEN module for that month/year
- Select the option ‘No’ only if you are not following LOS/MEN module for a given month/year

Reporting Guidance

- You will be responsible for uploading events and denominator data via CDA on a monthly basis
  - Deadline: 1 month from the last date of the month
    - Example: September data, due October 31st .

- You can send the numerator and denominator data in the same file.
  - When submitting separate numerator and denominator files, Upload the denominator first, then numerator.

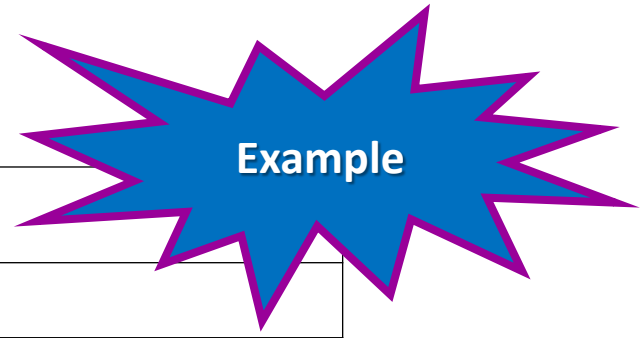
Data Validation

Initial Validation – Synthetic Data Set

- We encourage all participating facilities to utilize our synthetic data set and the corresponding test cases to validate software capture of numerator and denominator data.
  - Process where “fake” data is processed through the software vendor system to ensure accurate identification of numerator events and denominator data.
    - Answer key and test plan provided as resources for self-evaluation
    - Available to Software Vendors upon request via email

Event Validation -

- Before uploading monthly events, we encourage review of an eligible location's event line listing.
- If there is a returned event, you must correct the error and re-upload the events via CDA.



LOS/MEN Events - July 2021						
Patient ID	**Last Name**	**First Name**	**Location**	**Event Date**	**Event Type**	**Organism(s)**
908456	Williams	Mila	NICU 1	7/30/2021	NLCBI 1	MRSA
124765	Jones	Jared	NICU 1	7/22/2021	NLCBI 2	Streptococcus viridans
125786	Davis	Michelle	NICU 1	7/14/2021	NLCM 2	Coagulase-negative staphylococcus

If You Are Planning to Track and Report LOS/MEN Events…

- Please contact NHSN@cdc.gov. Subject Line: LOS/MEN Implementation, Attention: LaTasha Boswell
  - We'd like to support your facility during the development and implementation process!

Summary

- Neonatal Component and Late-Onset Sepsis/Meningitis Event (LOS/MEN) resources are available on the NHSN website
- LOS have two event types: NLCBI 1 and NLCBI 2
- MEN has two event types: NLCM 1 and NLCM 2
- There is no manual entry of LOS/MEN numerator or denominator data. All event and denominator data are uploaded via CDA
- NHSN recommends the use of the Synthetic Data Set for initial validation

NHSN@cdc.gov

Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.