Neonatal Component

Late Onset Sepsis & Meningitis Module (LOS/MEN)

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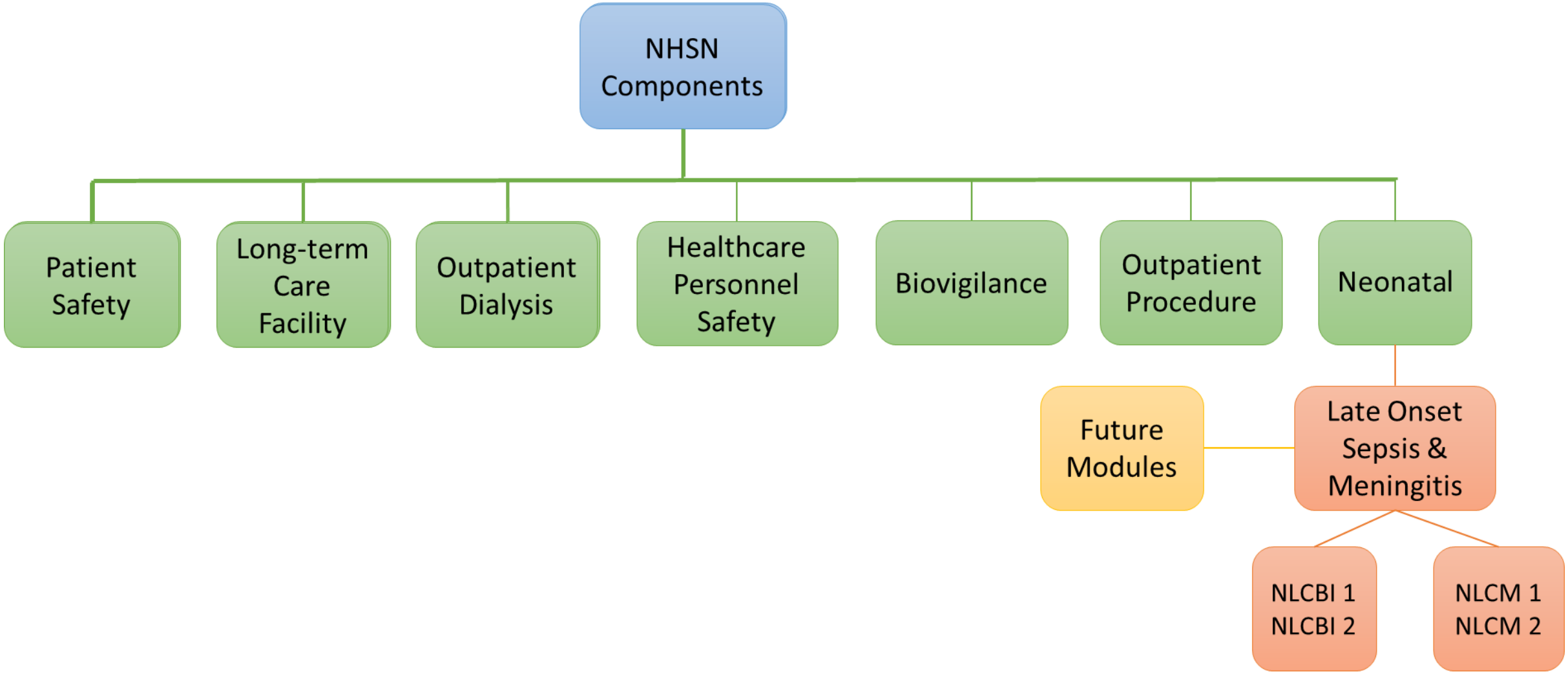
Objectives

- Provide an overview of the upcoming Neonatal Component
- Provide CDC's rationale and background for bringing Late Onset Sepsis and Meningitis (LOS/MEN) under surveillance
- Define the National Healthcare Safety Network (NHSN) criteria for LOS/MEN
- Review data requirements and plans for electronic detection and reporting of LOS/MEN numerator and denominator data

Neonatal Component

NHSN Component Structure

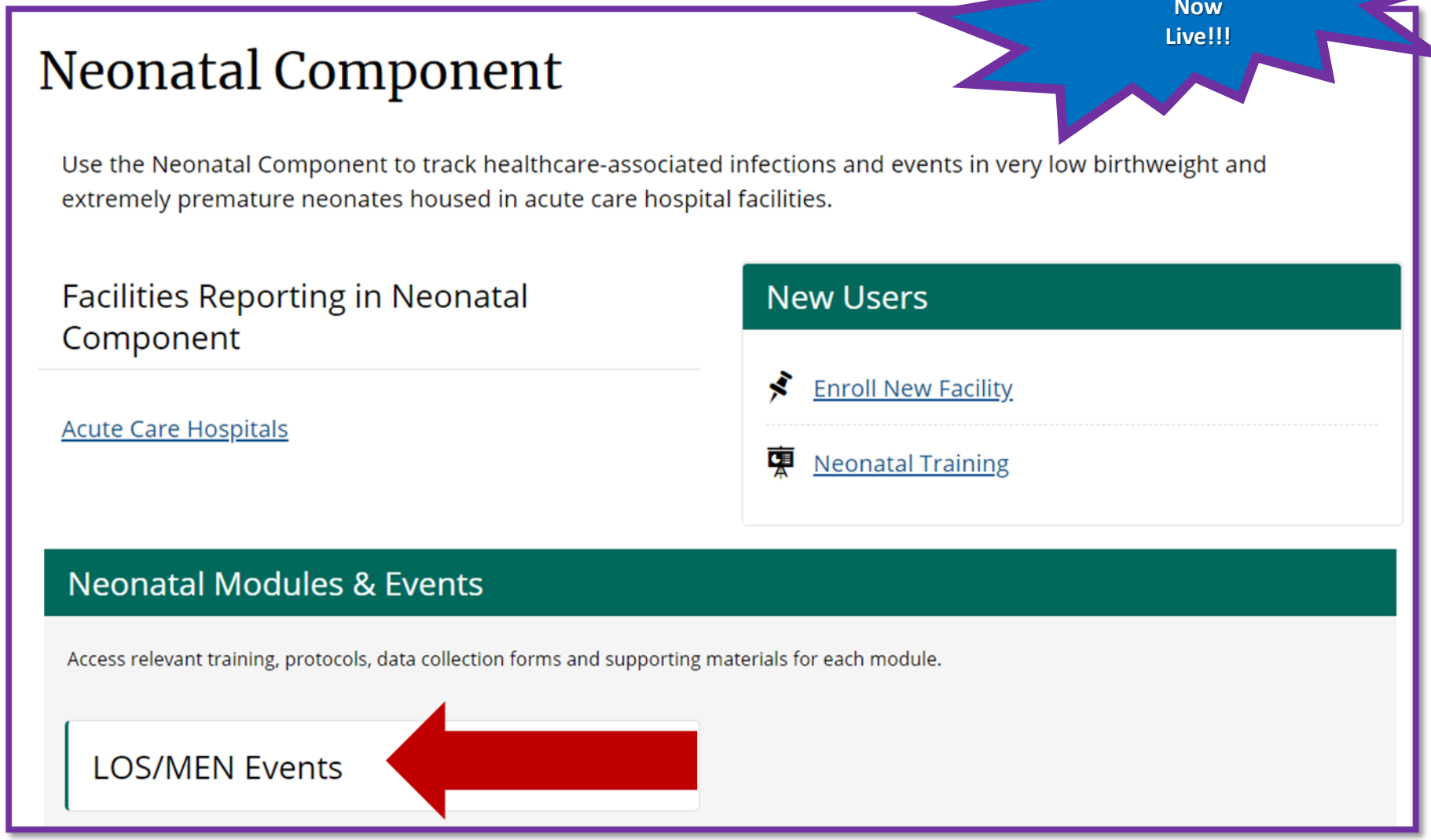


Neonatal Component

- Release planned for mid-September
  - Late Onset Sepsis and Meningitis – mid September
  - Possible future modules
    - Early Onset Sepsis
    - Necrotizing Enterocolitis

Announcements!!!

Neonatal Component Website Now Live!!!



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

Announcements!!! (Cont.)

LOS/MEN Website Now Live!!!

Late Onset Sepsis and Meningitis (LOS/MEN) Events

Protocols

Late-Onset Sepsis/Meningitis (LOS/MEN) Event – August 2021

Supporting Chapters

NHSN Overview – January 2021 [PDF – 520 KB]

CDC Location Labels and Location Descriptions – January 2021 [PDF – 584 KB]

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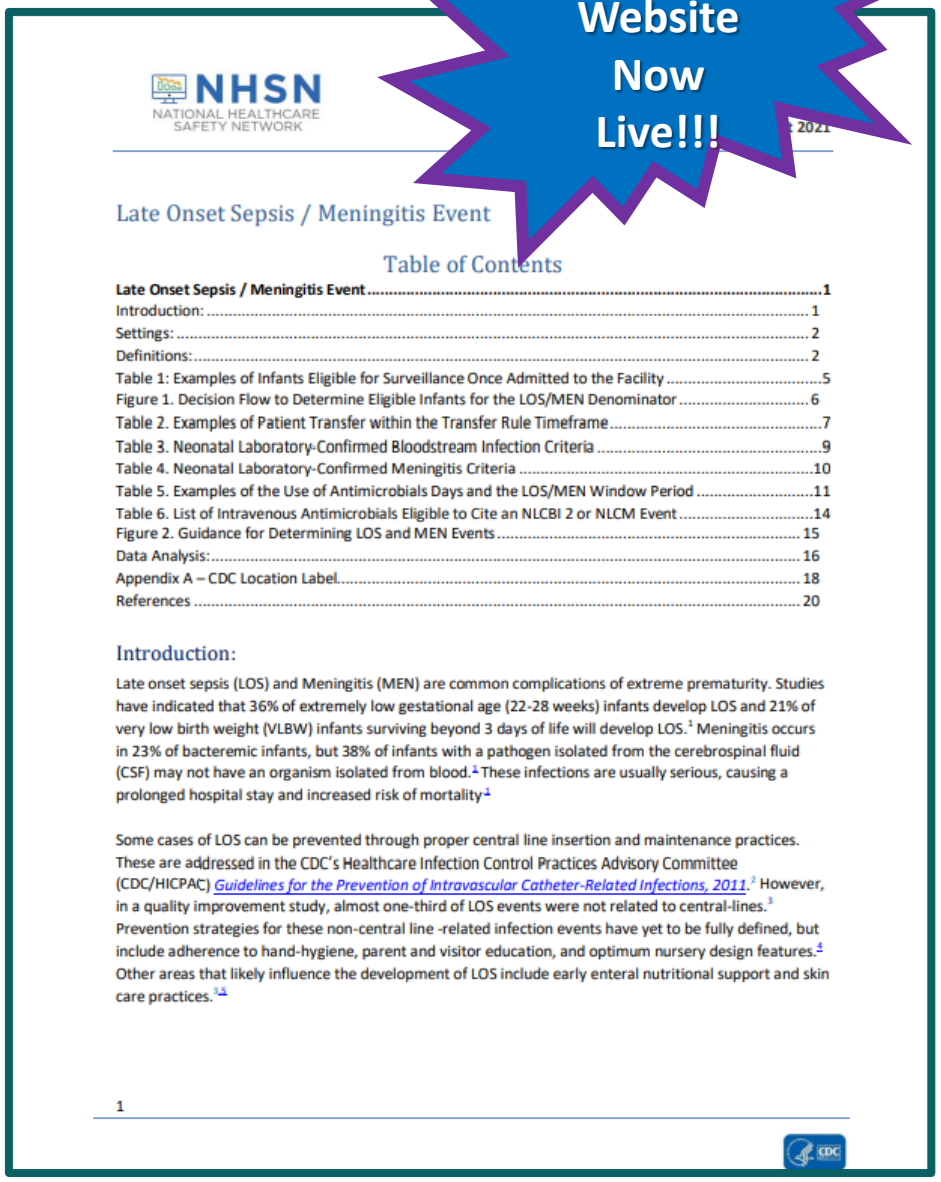

NHSN NATIONAL HEALTHCARE SAFETY NETWORK

Late Onset Sepsis / Meningitis Event

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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 3 days of life will develop LOS.[1] Meningitis occurs in 23% of bacteremic infants, but 38% of infants with a pathogen isolated from the cerebrospinal fluid (CSF) may not have an organism isolated from blood.[1] These infections are usually serious, causing a prolonged hospital stay and increased risk of mortality.[1]

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*.[3] However, in a quality improvement study, almost one-third of LOS events were not related to central-lines.[3] 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.[3,5]

1

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

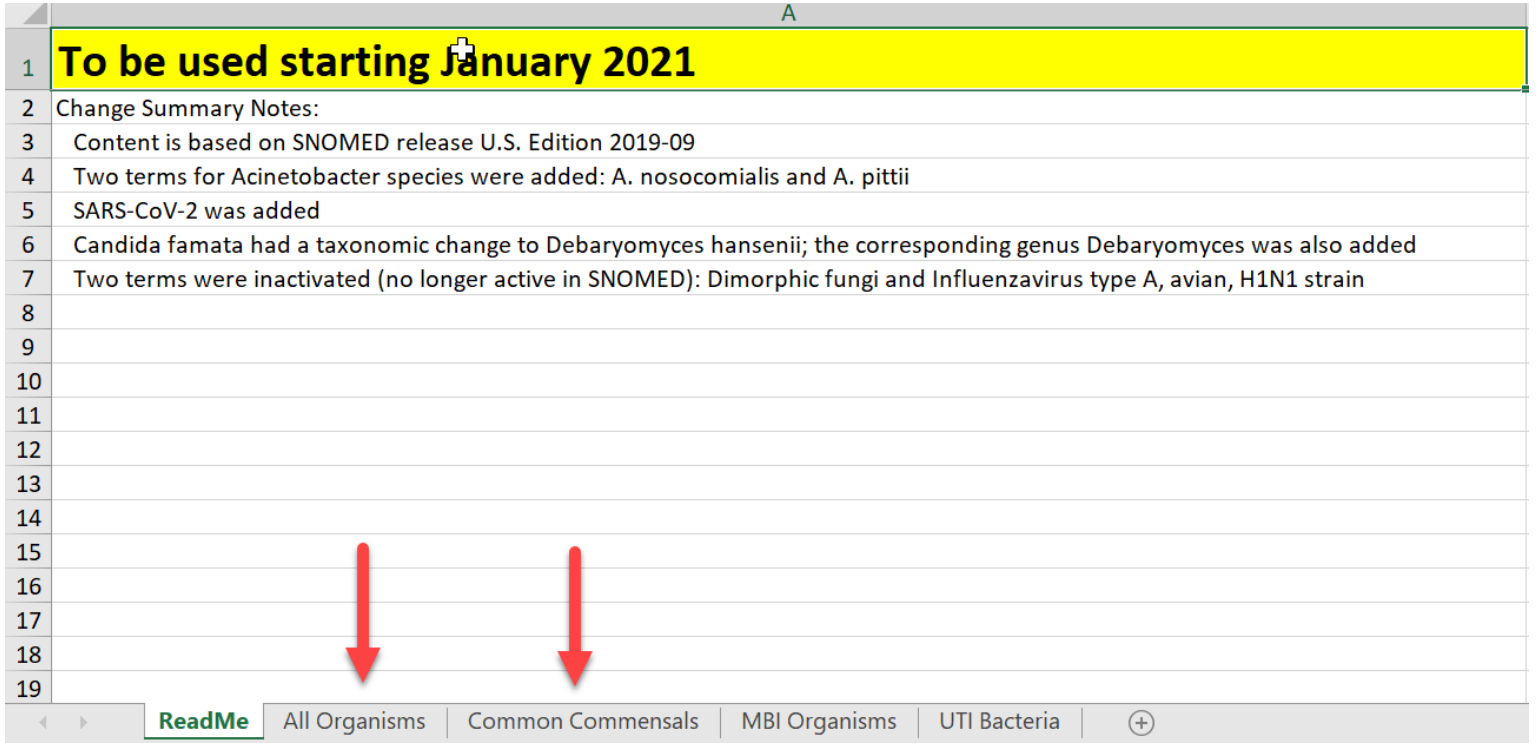
NHSN Organism List

Supporting Materials

NHSN Patient Safety Component Alerts [PDF – 1 MB]

Unusual Susceptibility Profiles Alert – January 2015 [PDF – 396 KB]

NHSN Organism List (All Organisms, Common Commensals, MBI Organisms, and UTI Bacteria) – January 2021 [XLS – 257 KB]



Announcements!!! (Cont.)

LOS/MEN Training Page Now Live!!!

Neonatal Component Training

Self-paced Training

LOS/MEN Event Overview [CBT – 30 min]

Introduction to the Neonatal Component
Late Onset Sepsis & Meningitis (LOS/MEN)

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

Late Onset Sepsis/Meningitis

Rationale

Late Onset Sepsis (LOS)

- 36% of extremely low gestational age infants develop LOS
- 21% of very low birth weight (VLBW) infants who survive beyond 3 days of life develop LOS
- 1/3 of LOS events are not associated with central lines

Meningitis (MEN)

- Occurs in 23% of bacteremic infants
- 38% of infants with a pathogen from CSF may not have an organism isolated in the blood

Background

- Began work on this component with Vermont Oxford Network (VON) and other key stake holders in 2015
- Data collection was completed in 3 healthcare facilities on 300 medical records
- Developed with electronic data capture in mind
- Allows IP to spend time on prevention instead of surveillance and data entry
- IP and facilities will be able to view their data and line listing in order to implement prevention activities

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

- Validation of electronic data capture will be required
  - Line Listing of Events validated monthly
    - If you have no events for the month, select, “No events” on your monthly reporting plan
  - Synthetic Data Set – Initial Set-up to Validate Numerator and Denominator Capture

LOS/MEN Module

Eligible Surveillance Locations

Surveillance Settings

- Level II/III Intermediate or Step Down Neonatal Intensive Care Units
- Level III Neonatal Intensive Care Units
- Level IV Neonatal Intensive Care Units

As defined by the American Academy of Pediatrics (AAP), 2004

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 DOL 3 but younger than DOL 121
  - Birth Date = DOL 1, regardless of the time of birth

LOS/MEN Event

- A laboratory-confirmed bloodstream infection or a laboratory-confirmed meningitis caused by a fungal or bacterial organism in an eligible neonate who is older than day of life (DOL) 3 but younger than DOL 121 on the date of the event

Neonatal Laboratory Confirmed Bloodstream Infection (NLCBI) Event

- In an eligible infant, a recognized pathogen or common commensal 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
  - Two specific types of infection (see below).
    - ***NLCBI 1:*** One or more positive blood specimens with a recognized pathogen (specifically a bacterial or fungal organism which is not on the NHSN Common Commensal list)
    - ***NLCBI 2:*** One or more positive blood specimens with a common commensal (specifically, a bacterial organism which is on the NHSN Common Commensal list). In addition, a new intravenous antimicrobial agent from Table 5 must be initiated during the LOS/MEN window period on or after DOL 4 **AND** continued for at least 5 calendar days

Example:

Inborn neonate with birthweight of 1000 grams housed in a Level III nursery has an MRSA positive blood culture on Day of Life 10. This is an NLCBI 1 event.

Neonatal laboratory-confirmed meningitis (NLCM) Event

- In an eligible infant, a recognized pathogen or common commensal 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
  - Two specific types of infection (see below).
    - ***NLCM 1*:** A positive CSF specimen with a recognized pathogen (specifically, a bacterial or fungal organism which is not on the NHSN Common Commensal list)
    - ***NLCM 2*:** A positive CSF specimen with a common commensal (specifically, a bacterial organism which is on the NHSN Common Commensal list). In addition, a new intravenous antimicrobial agent from Table 5 must be initiated during the LOS/MEN window period on or after DOL 4 **AND** continued for at least 5 calendar days

Example:

Inborn neonate with birthweight of 800 grams housed in a Level III nursery has a Pseudomonas positive cerebrospinal fluid culture on Day of Life 20. This is an NLCM 1 event.

Infusion

- The introduction of a solution through a blood vessel via a catheter lumen. This may include continuous infusions such as nutritional fluids or medications, or it may include intermittent infusions such as flushes, IV antimicrobial administration, blood transfusion or hemodialysis.

Central Line

- An intravascular catheter that terminates at or close to the heart OR in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring. The following are considered great vessels for the purpose of reporting central lines:
  - Aorta
  - Pulmonary artery
  - Superior vena cava
  - Inferior vena cava
  - Brachiocephalic veins
  - Internal jugular veins
  - Subclavian veins
  - External iliac veins
  - Common iliac veins
  - Femoral veins
  - Umbilical artery/vein

LOS/MEN Module

Key Concepts

Repeat Infection Timeframe or 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 1

Day of Life (DOL)	Event/Location Description
DOL 5	Infant in Facility A, NICU
DOL 6	Infant transferred from Facility A, NICU to Facility B, NICU 1
DOL 7	Infant still in Facility B, NICU 1
DOL 8	Infant in Facility B, NICU 1 and transferred to NICU 2 within the same facility.
DOL 9	If this is the Date of Event, attribution would be to Facility B, NICU 1 because it is attributed to the location where the infant was first housed the previous calendar day.

Transfer Rule Example 2

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

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

Events

- Late Onset Sepsis
  - Neonatal Laboratory-Confirmed Bloodstream Infection 1 (NLCBI 1)
  - Neonatal Laboratory-Confirmed Bloodstream Infection 2 (NLCBI 2)

- Meningitis
  - Neonatal Laboratory-Confirmed Meningitis 1 (NLCM 1)
  - Neonatal Laboratory-Confirmed Meningitis 2 (NLCM 2)

Neonatal Laboratory-Confirmed Bloodstream Infection

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 NHSN Common Commensal 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 10

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 NHSN Common Commensal 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 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"). 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.

Case Study 1: Baby Mila

- Inborn
- July 20th: Born. UVC/UAC placed
- Birthweight: 900 grams
- NICU (Level III) – July 20th - Current
- July 30th : MRSA blood culture
- July 30th: Vancomycin intiated

Would the Calculator identify an Event?

Case Study 1: Baby Mila Rationale

- **Answer:** Yes
- **Meets Birthweight Requirement:** 900 grams
- **Meets Location Requirement**: NICU 1 (Level III)
- **Meets DOL Requirement:** DOL 11 on date of event, 7/30.
- Positive blood culture with a recognized pathogen = **NLCBI 1.**

Date	DOL	Positive Specimen Collection	Admission Details
July 20	1		Born/Admitted to NICU 1. Birthweight: 900 grams UVC/UAC placed
July 21	2		
July 22	3		
July 23	4		
July 24	5		
July 25	6	-	
July 26	7	-	
July 27	8		
July 28	9		
July 29	10		
July 30	11	(+) Blood Culture: MRSA	Vancomycin initiated

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 5 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 10

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 NHSN Common Commensal 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 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"). 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.

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 Event

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

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New Antimicrobial Agent

Must meet all 4 criteria

1. Listed in Table 5 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

Qualifying Antimicrobial Days (QADs) Requirement

- 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 1

Date	DOL	Antimicrobial Administered	Positive Specimen Collection
Infant C			
June 10	32		
June 11	33		
June 12	34	Ampicillin	
June 13	35	Ampicillin	
June 14	36	Ampicillin	(+) Blood Culture for *Corynebacterium pyogenes*
June 15	37	Ampicillin	
June 16	38	Ampicillin	

QADs

Explanation: Since Ampicillin was not given in the 2 days preceding the first antimicrobial initiated in the LOS/MEN Window period and was started within the LOS/MEN Window Period, Ampicillin is a new antimicrobial agent. Because Ampicillin was continued for 5 days meeting the ≥ 5-day QAD requirement, an NLCBI 2 event is identified.

Note: LOS/MEN Window Period in grey.

Determining QADs – Example 2

Date	DOL	Antimicrobial Administered	Positive Specimen Collection
Infant B			
June 12	12		
June 13	13		
June 14	14		(+) Blood culture for *Staph epidermitis*
June 15	15		
June 16	16		
June 17	17	Vancomycin	
June 18	18	Vancomycin	
June 19	19	Vancomycin	
June 20	20	Vancomycin	
June 21	21	Vancomycin	
Explanation: Since Vancomycin was not started within the LOS/MEN Window Period, it is not a new antimicrobial agent. Therefore, the QAD requirement is not met and an NLCBI 2 event is not identified.			

Does not meet the QAD requirement

Note: LOS/MEN Window Period in grey.

Determining QADs – Example 3

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 the LOS/MEN Window Period 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.

Case Study 2: Baby John

- Inborn
- August 1st: Born. UVC/UAC placed
- Birthweight: 1050 grams
- Level III Nursery – August 1st - Current
- August 17th : CNS positive blood culture x 1
- August 21 - 26: Ampicillin administered.

Would the Calculator Identify an Event?

Case Study 2: Baby John Rationale

- **Answer:** No
- **Meets Birthweight Requirement: 1050** grams
- **Meets Location Requirement:** Level III
- **Meets DOL Requirement:** Yes, DOL 17 on Day of + blood culture
- **LOS/MEN Window Period:** 8/15 – 8/19 (shaded in grey)
- Positive CNS blood culture but Ampicillin not initiated during the LOS/MEN Window Period. So, the calculator did not identify an event.

Date	DOL	Antimicrobial Administered	Positive Specimen Collection	Admission Details
August 1	1			Born. Birthweight: 1050 grams. Admitted to Level III Nursery
August 2	2			
August 3	3			
August 4	4			
August 5	5			
August 6	6			
August 7	7			
August 8	8			
August 9	9			
August 10	10			
August 11	11			
August 12	12			
August 13	13			
August 14	14			
August 15	15			
August 16	16			
August 17	17		(+) Blood culture: coagulase negative Staphylococcus	
August 18	18			
August 19	19			
August 20	20			
August 21	21	Ampicillin		NLCBI 2 **not** met
August 22	22	Ampicillin		
August 23	23	Ampicillin		
August 24	24	Ampicillin		
August 25	25	Ampicillin		
August 26	26	Ampicillin		
August 27	27			

Neonatal Laboratory-Confirmed Meningitis

Neonatal Laboratory-Confirmed Meningitis 1 (NLCM 1)

An NHSN recognized pathogen, which is not an NHSN common commensal, identified from a cerebral spinal 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 NHSN Common Commensal 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 NHSN Common Commensal 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 5 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: 5. Is listed in Table 5. 6. 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. 7. 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. 8. 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 4: *Examples of the Use of Antimicrobials Days and the LOS/MEN Window Period***.) Substitution of a different antimicrobial agent from **Table 5** within the LOS/MEN Window Period due to therapy/organism sensitivity factors will continue to meet the requirements for QADs.

Case Study 3: Baby Apple

Outborn

March 13th: Born in Facility A, Transferred to NICU 1.

March 14th: Transferred to Facility B, NICU 1

Birthweight: 1100 grams

March 20th: Deteriorated; CSF collected: GBS + CSF; Ampicillin/Gentamicin initiated.

March 20 - 26: Ampicillin/Gentamicin administered.

What Event Did the Calculator Identify?

Case Study 3:
Baby Apple Rationale

- **Answer:** NLCM 1 Event
- **Meets Birthweight Requirement:** 1100 grams
- **Meets Location Requirement:** NICU 1 (Level III)
- **Meets DOL Requirement:** Yes, DOL 8 on date of event, 3/20.
- **LOS/MEN Window Period: N/A**
- Positive CSF culture with a recognized pathogen, GBS = **NLCM 1.**

Date	DOL	Antimicrobial Administered	Positive Specimen Collection	Admission Details
March 14	2			Outborn; Birthweight: 1100 grams; Transferred to Facility B, NICU 1
March 15	3			
March 16	4			
March 17	5			
March 18	6			
March 19	7			
March 20	8	Ampicillin/Gentamicin	(+) CSF culture: Group B Streptococcus	NLCM 1
March 21	9	Ampicillin/Gentamicin		
March 22	10	Ampicillin/Gentamicin		
March 23	11	Ampicillin/Gentamicin		
March 24	12	Ampicillin/Gentamicin		
March 25	13	Ampicillin/Gentamicin		
March 26	14	Ampicillin/Gentamicin		

Neonatal Laboratory-Confirmed Meningitis 2 (NLCM 2)

An NHSN Common Commensal is identified from a 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

AND

Treatment with one or more new eligible antimicrobial agent(s) that are continued for 5 or more calendar days (QADs)

Table 4. Neonatal Laboratory-Confirmed Meningitis Criteria

Criterion	Neonatal Laboratory-Confirmed Meningitis (NLCM)
I	*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 NHSN Common Commensal 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 NHSN Common Commensal 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 5 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: 5. Is listed in Table 5. 6. 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. 7. 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. 8. 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 4: *Examples of the Use of Antimicrobials Days and the LOS/MEN Window Period***.) Substitution of a different antimicrobial agent from **Table 5** within the LOS/MEN Window Period due to therapy/organism sensitivity factors will continue to meet the requirements for QADs.

Case Study 4: Baby Rocket

Inborn

June 1: Born; 740 grams; Transferred to NICU 1.

June 14th: Ampicillin initiated

June 16: CSF culture: coagulase-negative Staphylococcus. Ampicillin/Gentamicin added

June 14 – June 23rd: Ampicillin/Gentamicin administered

What Event Did the Calculator Identify in this Case?

Case Study 4: Baby Rocket Rationale

- **Answer:** NLCM 2 event
- **Meets Birthweight Requirement: Yes,** 740 grams
- **Meets Location Requirement:** NICU 1 (Level III)
- **Meets DOL Requirement:** Yes, DOL 16 on date of event, 6/16.
- **LOS/MEN Window Period: 6/14 – 6/18 (shaded in grey)**
- CSF culture for coagulase-negative Staphylococcus, new antimicrobial initiated in LOS/MEN Window Period and continued for 5 or more calendar days = **NLCM 2 event.**

Date	DOL	Antimicrobial Administered	Positive Specimen Collection	Admission Details
June 1	1			Born; Birthweight 740 grams; Transferred to NICU 1
June 2	2			
June 3	3			
June 4	4			
June 5	5			
June 6	6			
June 7	7			
June 8	8			
June 9	9			
June 10	10			
June 11	11			
June 12	12			
June 13	13			
June 14	14	Cefotaxime		
June 15	15	Cefotaxime		
June 16	16	Cefotaxime/Gentamicin added	(+) CSF: coagulase-negative staphylococcus	NLCM 2 met
June 17	17	Cefotaxime/Gentamicin		
June 18	18	Cefotaxime/Gentamicin		
June 19	19	Cefotaxime/Gentamicin		
June 20	20	Cefotaxime/Gentamicin		
June 21	21	Cefotaxime/Gentamicin		
June 22	22	Cefotaxime/Gentamicin		
June 23	23	Cefotaxime/Gentamicin		

Additional Notes

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 both a recognized pathogen and common commensal are isolated from a specimen, report NLCBI 1 or NLCM 1
- Results obtained from active surveillance cultures do not count toward meeting criteria for either NLCBI or NLCM

Data Collection and Reporting

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)

Numerator

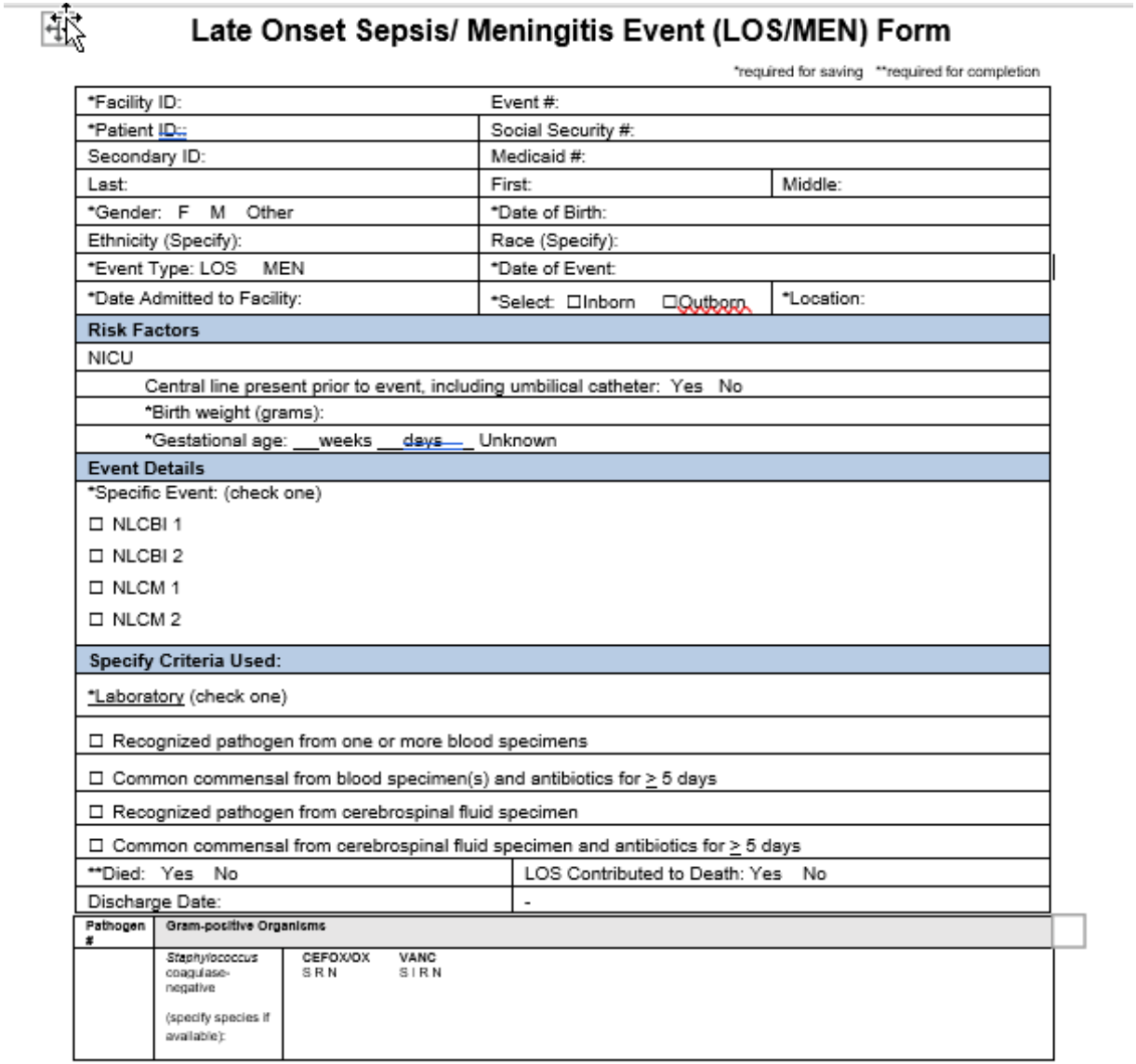
- Any positive NLCBI or NLCM events during the surveillance month in an eligible infant

Denominator

- Based on patient location and includes all eligible infants. Locations include Level II/III, Level III or Level IV nurseries

- Each infant in a location will count 1 time during the month. If transferred to another location in a calendar month the infant will count once in the previous location and once in new location for the month

Numerator Form



Late Onset Sepsis/ Meningitis Event (LOS/MEN) Form

*required for saving **required for completion

*Facility ID:	Event #:	
*Patient ID::	Social Security #:	
Secondary ID:	Medicaid #:	
Last:	First:	Middle:
*Gender: F M Other	*Date of Birth:	
Ethnicity (Specify):	Race (Specify):	
*Event Type: LOS MEN	*Date of Event:	
*Date Admitted to Facility:	*Select: ☐Inborn ☐Outborn	*Location:
Risk Factors		
NICU		
Central line present prior to event, including umbilical catheter: Yes No		
*Birth weight (grams):		
*Gestational age: __weeks __days__ Unknown		
Event Details		
*Specific Event: (check one) ☐ NLCBI 1 ☐ NLCBI 2 ☐ NLCM 1 ☐ NLCM 2		
Specify Criteria Used:		
*Laboratory (check one)		
☐ Recognized pathogen from one or more blood specimens		
☐ Common commensal from blood specimen(s) and antibiotics for ≥ 5 days		
☐ Recognized pathogen from cerebrospinal fluid specimen		
☐ Common commensal from cerebrospinal fluid specimen and antibiotics for ≥ 5 days		
**Died: Yes No	LOS Contributed to Death: Yes No	
Discharge Date:	-	

Pathogen #	Gram-positive Organisms		
	Staphylococcus coagulase-negative (specify species if available):	CEFOX/OX S R N	VANC S I R N

Note: The *form on this slide is for presentation purposes only and will not be available on the NHSN LOS/MEN website given the CDA upload of infection events and denominator data.*

Denominator Form

Neonatal Component

Late Onset Sepsis/Meningitis Denominator Form

*Facility ID:			*Location:
*Month:			*Year:
*Patient ID:			*Date Admitted to Facility:
*Date Admitted or Transferred to Location:			*Date of Birth:
*Birth Weight:			*Gestational Age: ____weeks ____days
*Gender:			
*Disposition of Infant (check one)	Yes	No	If discharged, transferred or expired, enter date on which this occurred:
Discharged from facility?	☐	☐	
Transferred within the facility?	☐	☐	
Expired?	☐	☐	
No location change?	☐	☐	
Comments:			

Note: The *form on this slide is for presentation purposes only and will not be available on the NHSN LOS/MEN website given the CDA upload of infection events and denominator data.*

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.

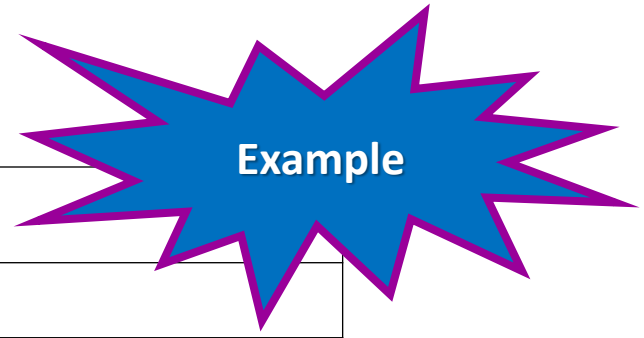
Data Validation

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, you must obtain and review each 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

Data Analysis

Crude Monthly Risk

Definition:

$$Crude\ Monthly\ Risk = \frac{Number\ of\ LOS\ or\ MEN\ events}{Number\ of\ eligible\ neonates\ each\ location\ and\ month}$$

Example: Suppose you have 1 event and 20 neonates in a given location and month

Crude Monthly Risk would be equal to 1 / 20 = 0.05 (or 5% for the month)

Note: Provides a monthly risk not be compared to other months or locations.

Cumulative Admission Risk

Definition:

$$Cumulative\ Admission\ Risk = \frac{Number\ of\ LOS\ or\ MEN\ events}{Number\ of\ eligible\ neonatal\ admissions}$$

Example: Suppose you have 2 events and 50 admissions in a given location and quarter

Cumulative Admission Risk = 2 / 50 = 0.04 (or 4% for the quarter)

Note: The Cumulative Admission Risk can be aggregated over time and reported monthly, quarterly, semi-annually, or annually.

Time to Event Analysis

Definition:

$$Survival\ Probability = \frac{Number\ of\ neonates\ without\ LOS\ or\ MEN\ event}{Number\ of\ eligible\ neonates}$$

Example: Suppose you have 24 neonates without any event and 25 eligible neonates for a given duration of stay in the NICU

Survival Probability = 24 / 25 = 0.96 (or 96% for the given duration of stay)

Note: Survival Probabilities can be calculated for any given duration of stay and can be used to produce a survival plot with increasing clarity as reporting increases.

Additional Analysis

- Each of these metrics, Crude Monthly Risk, Cumulative Admission Risk and Survival Probability (Time to Event Analysis) will be calculated by time period and NICU location. NHSN will seek to stratify or adjust these metrics for other relevant factors such as gestational age, birth weight category, NICU acuity level, etc.

LOS/MEN Metrics

- After your data has been submitted electronically to NHSN, the following reports that can be obtained in the NHSN Application:

  - Crude Monthly Risk
  - Cumulative Admission Risk

Summary

- The purpose of the LOS/MEN module is to track late-onset sepsis in meningitis events in very low birthweight infants, DOL 4- 120.
- LOS/MEN will track 4 events: NLCBI 1, NLCBI 2, NLCM 1, NLCM 2
- Fully electronic upload of numerator and denominator data using a software vendor system, homegrown software system or electronic health record
- Facilities are encouraged to validate their numerator information monthly.
- Facilities will have two metrics that can be used to improve infection prevention activities: Crude Monthly Risk and Cumulative Admission Risk

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

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

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.