

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 three days of life (DOL) will develop LOS.¹ Another study found that 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.² These infections are usually serious, causing a prolonged hospital stay and increased risk of mortality.³

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) <u>Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011</u>.⁴ 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.⁶



Other areas that likely influence the development of LOS include early enteral nutritional support and skin care practices.^{6,7}

Note: Tracking LOS and MEN events <u>does not</u> exclude facilities from reporting other events that are part of their monthly reporting plan (MRP). This includes BSI surveillance in eligible neonatal locations.

Details:

Inpatient locations eligible to participate in LOS/MEN Surveillance are Level II/III, Level III, or Level IV neonatal critical care settings in acute care facilities that admit infants who meet the NHSN definition of very low birth weight (VLBW) and are DOL 4-120. NHSN defines a VLBW infant as any infant with a birth weight from 401 to 1500 grams. Birth occurring outside of a healthcare facility does **not** exclude an infant from LOS/MEN surveillance. A list of neonatal locations and their descriptions can be found in the <u>Appendix A (CDC Location Label)</u>.

Definitions:

<u>Eligible Infant:</u> An infant in a Level II/III, Level III, or Level IV nursery that has been an inpatient > 2 days, with a birth weight between 401 and 1500 grams <u>AND</u> DOL 4-120 (DOL 1 = Date of Birth). An infant must meet the above criteria to be included in surveillance.

<u>Date of Event (DOE)</u>: The collection date of the first 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. Synonym: event date.

<u>LOS/MEN Window Period</u>: The 5-day period around the positive common commensal 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 occurring on DOL 4 or 5 as follows:

<u>Example 1:</u> If the LOS/MEN DOE is DOL 4, the window period is limited to 3 days and includes only the day of LOS/MEN DOE and the 2 days after LOS/MEN DOE (because the 2 days before LOS/MEN event are before DOL 4 and the infant is not eligible for surveillance on those days).

<u>Example 2:</u> If the DOE is DOL 5, the window period is 4 days and includes 1 day before the LOS/MEN DOE (DOL 4), LOS/MEN DOE and 2 days after the LOS/MEN DOE.

<u>Neonatal Laboratory Confirmed Bloodstream Infection (NLCBI) Event:</u> In an eligible infant, a recognized pathogen or common commensal identified from one or more blood specimens by culture or non-culture-based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment. Under this major type of infection, there are two specific types of infection (see below).



- <u>NLCBI 1:</u> One or more positive blood specimens with a recognized pathogen specifically a bacterial
 or fungal organism which is NOT a common commensal that can be accessed via the <u>NHSN</u>
 <u>Terminology Browser</u>.
- <u>NLCBI 2:</u> One or more positive blood specimens with a common commensal specifically, a
 bacterial organism which is a common commensal on the NHSN Organism List that can be
 accessed via the <u>NHSN Terminology Browser</u>. In addition, a new intravenous antimicrobial agent
 from *Table 6* must be initiated during the LOS/MEN window period on or after DOL 4 <u>AND</u>
 continued for at least 5 calendar days.

<u>Neonatal Laboratory-Confirmed Meningitis (NLCM) Event:</u> In an eligible infant, a recognized pathogen or common commensal identified from a CSF specimen by culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment. Under this major type of infection, there are two specific types of infection (see below).

- <u>NLCM 1:</u> A positive CSF specimen with a recognized pathogen specifically, a bacterial or fungal organism which is NOT a common commensal on the NHSN Organism List that can be accessed via the NHSN Terminology Browser
- <u>NLCM 2:</u> A positive CSF specimen with a common commensal specifically, a bacterial organism which is a common commensal on the NHSN Organism List that can be accessed via the <u>NHSN Terminology Browser</u>. In addition, a new intravenous antimicrobial agent from *Table 6* must be initiated during the LOS/MEN window period on or after DOL 4 <u>AND</u> continued for at least 5 calendar days.

<u>Neonatal Late-Onset Sepsis/Meningitis (LOS/MEN) Event</u>: A NLCBI or a NLCM caused by a fungal or bacterial organism in an eligible infant.

<u>Outborn infant:</u> An infant born outside your facility (Example: an infant that arrives at your facility in an ambulance).

Inborn infant: Any infant delivered at your facility.

<u>Infusion:</u> 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.

<u>Central line</u>: An intravascular catheter that terminates at or close to the heart <u>OR</u> 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

NOTES:

- 1. For the purposes of surveillance, a central line will be considered present at the time of the NLCBI or NLCM event if it was accessed in an eligible location for more than two consecutive calendar days and still in place on the DOE or the day before.
- 2. Neither the insertion site nor the type of device may be used to determine if a line qualifies as a central line. The device must terminate in one of the great vessels at or near the heart and be used for one of the purposes outlined above, to qualify as a central line. However, the line should still be considered present if it has migrated out of the great vessel during the surveillance period.
- 3. An introducer is considered an intravascular catheter and depending on the location of its tip and use, may be a central line.
- 4. Pacemaker wires and other non-lumened devices inserted into central blood vessels or the heart are not considered central lines, because fluids are not infused, pushed, nor withdrawn through such devices.
- 5. The following devices are <u>not</u> considered central lines:
 - Arterial catheters unless in the pulmonary artery, aorta or umbilical artery
 - Arteriovenous fistula
 - Arteriovenous graft
 - Atrial catheters (also known as transthoracic intra-cardiac catheters, those catheters inserted directly into the right or left atrium via the heart wall)
 - Extracorporeal life support (ECMO)
 - Hemodialysis reliable outflow (HERO) dialysis catheter
 - Intra-aortic balloon pump (IABP) devices
 - Peripheral IV or Midlines
 - Ventricular Assist Device (VAD)
- 6. The day of birth, regardless of the time of birth, is defined as DOL 1.

Example:

- Infant born at 11:59 pm on September 1st. DOL 1 is September 1st.
 DOL 4 is September 4th. The DOE for LOS/MEN for this patient cannot be before September 4th (DOL 4).
- 7. The weight at the time of birth should reported for LOS/MEN events while the weight of the infant at the time of the LOS/MEN event is not used and should not be reported. For example, if a neonate weighs 1006 grams at birth, but remains in the NICU for two months and has a body weight of 1650 grams when a LOS/MEN event develops, the birthweight of 1006 grams should be captured and recorded.



Table 1: Examples of Infants Eligible for Surveillance Once Admitted to the Facility

This table provides examples that illustrate denominator eligibility determined by Day of Life (DOL) and birthweight (BW).

Birth Weight (BW)	Location on Day of Life "1"	Additional Location Data	LOS/MEN Eligibility	Denominator Eligibility
1501 grams	NICU 1 at Facility A	Transferred to NICU 1 at Facility B on DOL 20	This infant is not eligible because this infant does not meet the requirement for VLBW.	This infant will not be included in any denominator count as the birthweight requirement is not met.
1250 grams	NICU 1 at Facility A	Discharged on DOL 45 Readmitted to NICU 1 at Facility A on DOL 48	This infant is eligible for both NICU admissions because the baby meets the requirement for VLBW and DOL in each location.	This infant will be included in the denominator count for the first NICU 1 admission beginning on DOL 4 through DOL 45. Additionally, this infant is included in the denominator count for the readmission beginning on DOL 50 (not eligible Day 1 or 2 after admission) through the day of discharge or until the baby reaches DOL 121, whichever comes first.
500 grams	NICU 1 at Facility A	 Transferred to NICU 1 at Facility B on DOL 45 Infant discharged home on DOL 90 	This infant is eligible in Facility A, NICU 1 and Facility B, NICU 1 because the baby meets the requirements for VLBW and DOL in both locations.	This infant will be included in the Facility A, NICU 1 denominator count beginning on DOL 4 through DOL 45 and included in the Facility B, NICU 1 denominator count beginning on DOL 47 through DOL 90.
748 grams	NICU 3 at Facility B	Transferred to Facility B, NICU 2 on DOL 26	This infant is eligible in Facility B, NICU 3 and Facility B, NICU 2 because the baby meets the requirements for VLBW and DOL in both locations.	This infant will be included in the Facility B, NICU 3 denominator count beginning on DOL 4 through DOL 26 and included in the Facility B, NICU 2 denominator count beginning on DOL 26 until discharge or DOL 121 whichever comes first.

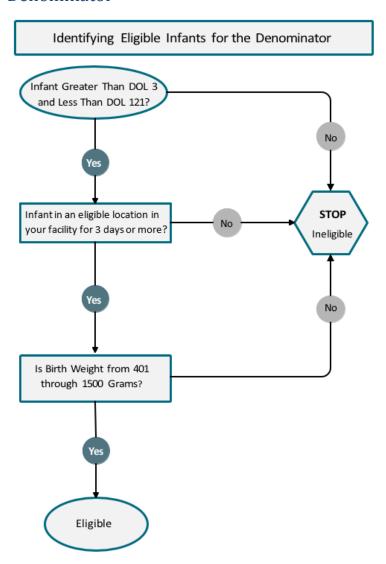


Facilities that select LOS/MEN surveillance as part of their MRP are committing to collect LOS/MEN event data for at least one month of the calendar year, for *all* eligible infants admitted to an eligible location. A neonate must meet the following criteria to be included in the surveillance:

- Physically housed in a Level II/III, Level III, or Level IV nursery
- Inpatient > 2 days
- DOL 4 120
- Birth weight 401 1500 grams

Figure 1 shows the decision flow for patient eligibility determination.

Figure 1: Decision Flow to Determine Eligible Infants for the LOS/MEN Denominator





DOL = Day of Life

Location of Attribution:

LOS/MEN events are attributed to the location where the patient is first housed the day before the DOE, with the exception of recently transferred patients. In those cases, apply the Transfer Rule, below.

Transfer Rule: If the DOE is the day of transfer or the next calendar day, the infection is attributed to the transferring location if transfer occurs within the same facility.

<u>For a transfer from another facility:</u> An LOS/MEN event occurring on the day of transfer or the day after transfer, will be considered present on admission (POA) for the receiving facility. If the event occurred after inpatient day 2, the event is attributed to the receiving facility.

<u>For a transfer from another unit within the same facility</u>: An LOS/MEN event identified on the day of transfer or the day after transfer, is attributed to the transferring unit. If the event occurred after inpatient day 2 Otherwise, the event is attributed to the receiving unit.

<u>For an admission from home following discharge</u>: An LOS/MEN event which occurred on the day of admission or the following calendar day, is POA. If the event occurred after inpatient day 2, the event is attributed to the admitting facility and unit.

Table 2: Examples of Patient Transfer within the Transfer Rule Timeframe

Day of Life	Event/Location Description
(DOL)	
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

Day of Life	Event/Location Description
(DOL)	
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.



Repeat Infection Timeframe (RIT):

The RIT is a 14-day timeframe during which no new infections of the same type, specifically, LOS or Meningitis, are reported for the same patient. LOS and MEN events are separate major infection types, and each will set their own RIT. More than one LOS or one MEN event may be reported during a patient's single admission if the Repeat Infection Timeframe (RIT) has elapsed between LOS or MEN events. This means that only one NLCBI will be reported during an NLCBI RIT, and only one NLCM will be reported during an NLCM RIT. However, an NLCBI event may be reported during an NLCM RIT and viceversa as these are different types of infections.

The date of event is Day 1 of the 14-day RIT. If the date of event for a potential infection of the same type occurs within the 14-day RIT, a new event is not identified or reported. Other pathogens recovered during the RIT from the same type of infection are instead, added to the event.

The RIT applies during a patient's single admission, including the day of transfer within the same facility and one calendar day after, in keeping with the <u>Transfer Rule</u>. A RIT does not carry over from one admission to another even if readmission is to the same facility.



Table 3: Neonatal Laboratory-Confirmed Bloodstream Infection Criteria

Criterion | Neonatal Laboratory-Confirmed Bloodstream Infection (NLCBI)

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 with a recognized pathogen specifically a bacterial or fungal organism which is
	NOT a common commensal on the NHSN Organism List (accessed via the NHSN Terminology
	Browser) 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	An eligible infant with a common commensal specifically, a bacterial organism which is a
	common commensal on the NHSN Organism List (accessed via the NHSN Terminology Browser)
	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)*.
	* New IV antimicrobial agent: Defined as any agent for which all 4 of the following are true:
	1. Is listed in Table 6.
	 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.)
	Note: Substitution of a different antimicrobial agent from <u>Table 6</u> within the LOS/MEN Window Period due to therapy/organism sensitivity factors will continue to meet the requirements for QADs.



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 with a recognized pathogen specifically, a bacterial or fungal organism which is NOT a common commensal on the NHSN Organism List (accessed via the NHSN Terminology Browser) 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	An eligible infant with a common commensal specifically, a bacterial organism which is a common commensal on the NHSN Organism List (accessed via the NHSN Terminology Browser) identified from a CSF specimen 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)*.					
	 New IV antimicrobial agent: Defined as any agent for which all 4 of the following are true: Is listed in Table 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. 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. 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.) Note: 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. 					



Table 5: Examples of the Use of Antimicrobials Days and the LOS/MEN Window Period

Date	DOL	Antimicrobial Administered	Positive Specimen Collection
Infant A			
June 12	6	Ampicillin	
June 13	7		
June 14	8	Ampicillin	
June 15	9	Ampicillin	
June 16	10	Ampicillin	(+) Blood Culture for
			Strep viridans
June 17	11	Ampicillin	
June 18	12	Ampicillin	

Explanation: Since Ampicillin was given in the 2 days preceding the first antimicrobial initiated in the LOS/MEN Window Period (denoted by the shaded area), it is <u>not</u> a new antimicrobial agent. Therefore, the QAD requirement is not met and an NLCBI 2 event is not identified.

Date	DOL	Antimicrobial Administered	Positive Specimen Collection
Infant B			Collection
June 12	12		
June 13	13		
June 14	14		(+) Cerebrospinal fluid 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 (denoted by the shaded area), it is not a new antimicrobial agent. Therefore, the QAD requirement is not met and an NLCM 2 event is not identified.



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	

Explanation: Since Ampicillin was not given in the 2 days preceding the first antimicrobial initiated in 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. Because Ampicillin was continued for 5 days meeting the ≥ 5-day QAD requirement, an NLCBI 2 event is identified.

Date	DOL	Antimicrobial Administered	Positive Specimen Collection
Infant D			
June 12	1	Gentamicin	
June 13	2	Gentamicin	
June 14	3	Gentamicin	
June 15	4	Gentamicin	(+) Blood culture for Streptococcus anginosus
June 16	5	Gentamicin	-
June 17	6	Gentamicin	-
June 18	7	Gentamicin	-
June 19	8	Gentamicin	-

Explanation: Since Gentamicin was administered in the 2 days preceding the first antimicrobial initiated in the LOS/MEN Window period (denoted by the shaded area), Gentamicin is not a new antimicrobial agent. Therefore, the QAD requirement is not met and an NLCBI 2 event is not identified.



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	

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.

Reporting Instructions

- Specimen Collection Considerations: All organisms identified from blood specimens, regardless of the sites from which they were collected, must be included when conducting in-plan Late-onset Sepsis/Meningitis surveillance.
- 2. If both 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. Likewise, an NLCM 1 shall be reported if both NLCM 1 and NLCM 2 events are both identified from the same specimen.
- 3. If both NLCBI and NLCM criteria are met, both should be reported with their respective pathogens even if the pathogens match. The event date(s) are reported as the date of specimen collection.
- 4. In NLCBI 1 and NLCM 1, the term recognized pathogen" does not include organisms considered common commensals.
- 5. If the required NLCBI 2 or NLCM 2 criteria are not met, do not add the common commensal to the RIT of the previously reported event. In other words, if the required Qualifying Antimicrobial Days (QADs) with a new antimicrobial agent are not met, then do not report the common commensal with the previous event, or as a new event.
- 6. The NHSN system will allow only 3 pathogens to be added for each event so additional organisms identified from the same site during the RIT will not be recorded.



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

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

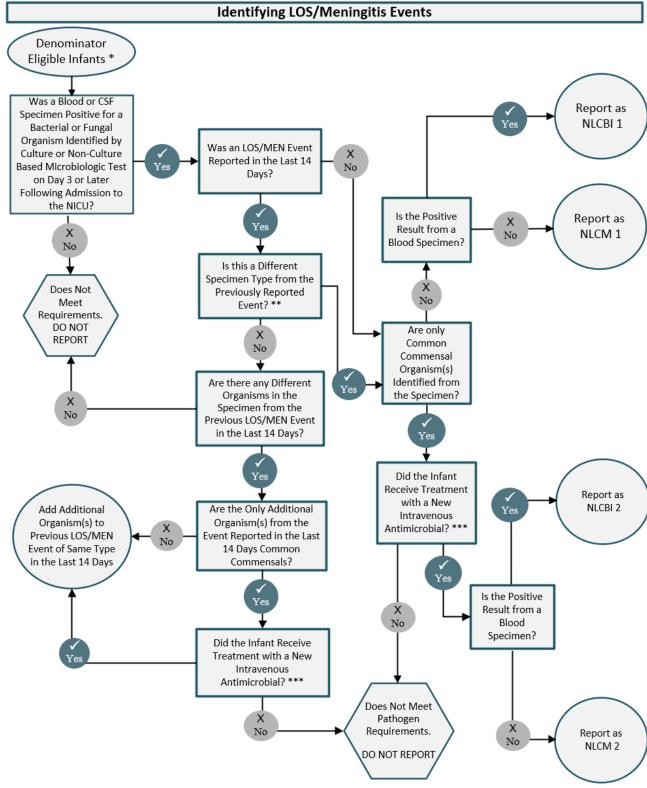
Numerator Data:

The Late-Onset Sepsis Meningitis Event Form specifies the data requirements for each LOS/MEN event that is identified during the month selected for surveillance. This form collects the following information: eligible infant demographic information, event criteria met, organisms identified from blood and/or CSF, antimicrobial susceptibilities, death, and discharge. Figure 2 shows the decision flow for the identification of an eligible LOS/MEN event. All numerator events are uploaded via Clinical Data Architecture, or CDA.



Figure 2: Guidance for Determination of LOS and MEN Events

Identifying LOS/Meningitis Events





*Refer to Figure 1: "Decision Flow to Determine Eligible Infants for the LOS/Meningitis Denominator" for details

**Previously Reported Event: For example, an event had been identified for a blood specimen and now reporting organisms for a CSF specimen, or vice versa

- ***New 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 include 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 continue for 5 or more qualifying antimicrobial days (QADs). Days between administration 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 current start date. (See **Table 4**: **Examples of Use of Antimicrobial Days and the LOS/MEN Window Period**).

Denominator Data:

The denominator for LOS/MEN is determined using patient-specific and location-specific data during a calendar month. Upon admission to the surveillance location, patient-level data is recorded into the electronic health record (EHR) and can then be extracted to support the summary denominator data reporting. Denominator data will not be reported by patient days. Denominator data is an eligible neonate or eligible neonatal admissions within a surveillance location for the calendar month.

The <u>Late Onset Sepsis/ Meningitis Denominator Form</u> specifies the data requirements for a denominator (eligible infant or admission[s]) that is identified during the month selected for surveillance. The requirements necessary to calculate LOS/MEN denominators include patient location, medical record number (MRN), date admitted to facility, date admitted or transferred to a surveillance location, date of birth, birthweight, sex, and disposition of patient (discharge, transfer or expired date if occurred within the current calendar month). Note the following guidance for patients that are transferred between patient care locations:

- Eligible infants transferred from another unit within the same facility are included in the inpatient location count for the month if they spent at least one day in the location during the time they are between DOL 4 and DOL 121.
- Infants who are admitted from <u>another facility</u> are not eligible until Day 3 following admission to the new facility NICU and they are between DOL 4 to DOL 121.



Validation:

LOS/MEN Synthetic Data Set (SDS):

An LOS/MEN Synthetic Data Set (SDS) was created to validate the software vendor or homegrown system's (homegrown system is a program created by the facility to capture and report data) uptake of LOS and MEN numerator and denominator data. An SDS, is a document of fake numerator and denominator data that is processed through the facility's electronic data collection system to ensure that data is accurately captured. The LOS/MEN SDS is comprised of 80 patients that test multiple positive and negative scenarios pertinent to the protocol. An answer key is provided for self-evaluation purposes. This validation process is optional but recommended upon initial implementation. To obtain the LOS/MEN SDS, contact Service Now, Subject Line: LOS/MEN Synthetic Data Set.

Data Analysis:

Unit of Analysis:

Each infant will be represented for each admission during each month in an eligible NICU location. Due to varied length of stays, the potential for multiple admissions within a facility or location is useful to characterize LOS/MEN risk events using multiple and different exposure levels (neonates, admissions, time admitted, etc.). An exposure is an eligible neonate, eligible admission, or time the neonate may spend in a unit up to discharge or occurrence of an LOS/MEN event. To illustrate these levels of exposure, the following measures are defined and available via NHSN analysis: crude monthly risk and cumulative admission risk. The following measure is planned for future use: time to event analysis metrics (for example: survival probability on a given day).

- 1. Crude Monthly Risk is calculated by dividing the number of LOS or MEN events by the number of eligible neonates within an eligible location each month. This is not an aggregated risk over time. It is calculated for each individual month and is used for descriptive purposes. It is not a comparative metric. This measure is for internal purposes only and should not be compared to other eligible locations, facilities, or organizations.
- 2. Cumulative Admission Risk is the risk of an event during an admission to a location, for an individual infant. This will be an initial comparative metric. The exposure is an admission to an eligible neonatal location. The cumulative admission risk is calculated by dividing the number of LOS or MEN events by the number of eligible neonatal admissions to an eligible location.
- 3. Time to Event Analysis includes a variety of measures that assess a neonate's chance of surviving their admission event-free or comparing their risk of acquiring an event on a given day during an admission. For example, estimating survival probability allows an assessment of acquiring an event at a given time.

Each of the above metrics will be calculated by time-period (e.g., month, quarter, etc.) and NICU location. Additionally, the event may also be stratified based on birth weight category.



Descriptive Analysis

Descriptive analysis output options of numerator and denominator data, such as line listings, and frequency and rate tables are available in the NHSN application.

Line List: https://www.cdc.gov/nhsn/pdfs/neonatal/analysis/linelist-losmen-508.pdf
Frequency Tables: https://www.cdc.gov/nhsn/pdfs/neonatal/analysis/freq-tables-losmen-508.pdf
Rate Tables: https://www.cdc.gov/nhsn/pdfs/neonatal/analysis/losmen-rate-tables-508.pdf
General guidance on using NHSN analysis features are available at:
www.cdc.gov/nhsn/PSAnalysisresources/reference-guides.html.

Appendix A – CDC Location Label

CDC Location Labels	NHSN Healthcare Service Location Code	CDC Location Code	Location Description
Neonatal Critical Care (Level II/III)	1039-7	IN:ACUTE:CC_STEP: NURS	Combined nursery housing both Level II and III newborns and infants, as per the NHSN level definitions above and below. This is analogous to a mixed acuity unit specifically for Neonatal Critical Care patients.
Neonatal Critical Care (Level III)	1040-5	IN:ACUTE:CC:NURS	A hospital neonatal intensive care unit (NICU) organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with complex and critical illness. The capabilities of Level III and Level IV, listed below, are from the American Academy of Pediatrics definitions of levels of neonatal care.1 NOTE: These classifications are all considered Level III NICUs in NHSN. Level III NICU Level II capabilities plus: Provide sustained life support Provide comprehensive care for infants born <
			Provide comprehensive care for infants born < 32 wks. gestation and weighing <1500 g and



	Provifull rapedia anest opht Provimay frequ Performant on an armonic provimant of the pr	ide prompt and readily available access to a ange of pediatric medical subspecialists, atric surgical specialists, pediatric thesiologists, and pediatric chalmologists ide a full range of respiratory support that include conventional and/or highuency ventilation and inhaled nitric oxide orm advanced imaging, with interpretation in urgent basis, including computed ography, MRI, and echocardiography
Neonatal Critical Care (Level IV)	with personne support and conewborn infar illness. The capabilitie American Acaneonatal care Level IV Re Level III cap • Locaneonatal care • M su su th	conatal intensive care unit (NICU) organized el and equipment to provide continuous life comprehensive care for extremely high-risk ints and those with complex and critical es of Level III, listed below are from the idemy of Pediatrics definitions of levels of an an an institution with the equipment of complex congenital or acquired conditions dialitatin a full range of pediatric medical subspecialists, pediatric surgical subspecialists and pediatric subspecialists at the site excilitate transport and provide outreach ducation



References

- 1. Stoll BJ, Hansen NI, Bell EF, et al; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Neonatal outcomes of extremely preterm infants from the NICHD Neonatal Research Network. Pediatrics 2010; 126: 443-456
- 2. Ku LC, Boggess KA, Cohen-Wolkowiez M. Bacterial meningitis in infants. Clin Perinatol. 2015 Mar;42(1):29-45, vii-viii. doi: 10.1016/j.clp.2014.10.004. Epub 2014 Dec 6. PMID: 25677995; PMCID: PMC4332563.
- 3. Shane AL, Stoll BJ. Recent developments and current issues in the epidemiology, diagnosis, and management of bacterial and fungal neonatal sepsis. American journal of perinatology 2013;30:131-41
- 4. O'Grady NP, Alexander M, Burns LA, et al. Guidelines for the prevention of intravascular catheter-related infections. Clin Infect Dis 2011;52:e162-93.
- 5. Kaplan HC, Lannon C, Walsh MC, Donovan EF. Ohio statewide quality-improvement collaborative to reduce late-onset sepsis in preterm infants. Pediatrics 2011;127:427-35.
- 6. Brady MT. Health care-associated infections in the neonatal intensive care unit. Am J Infect Control 2005;33:268-75
- 7. Dong Y, Speer CP Late-onset neonatal sepsis: recent developments. Archives of Disease in Childhood Fetal and Neonatal Edition 2015;100: F257-F263.

