Clinical Guidelines for Neonatal Sepsis Screening and Antibiotic Stewardship

Nebraska Perinatal Quality Improvement Collaborative
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Table of Contents

The Nebraska Perinatal Quality Improvement Collaborative created this document as part of the Neonatal Sepsis Screening and Antibiotic Stewardship Initiative. Special thanks to the Illinois Perinatal Quality Collaborative, Colorado Perinatal Care Quality Collaborative, and the Perinatal Quality Collaborative of North Carolina for allowing us to use and modify their work.

Overview

The incidence of neonatal early-onset sepsis (EOS) has declined substantially over the last 30 years, primarily due to the implementation of evidence-based intrapartum antibiotic prophylaxis (IAP). Although rare, EOS continues to be a serious and potentially life-threatening complication of birth. Assessing term and late-preterm newborn infants for risk of EOS is one of the most common clinical tasks conducted by pediatric providers.

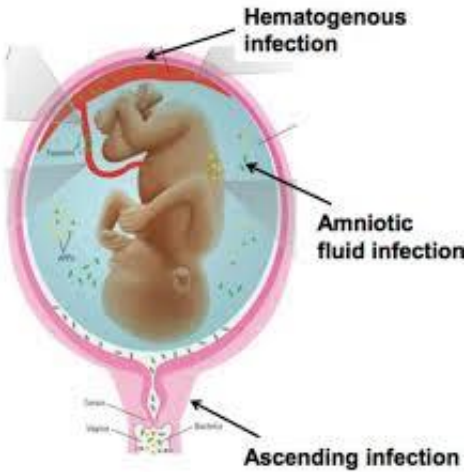
Our Approach

The Nebraska Perinatal Quality Improvement Collaborative (NPQIC) has developed this toolkit of resources to provide Nebraska birthing hospitals with the necessary education and support to implement best practices for identification and management of newborns at risk for early onset sepsis. The toolkit will focus specifically on risk stratification of newborns using the Neonatal Early-Onset Sepsis Calculator.

Early-Onset Sepsis (EOS)

Early onset sepsis (EOS) is defined as a blood or cerebrospinal fluid (CSF) culture obtained within 72 hours of life growing a pathogenic bacterial species.

- Current incidence among term infants is 0.2-0.5 per 1,000 live births and ~ 1 per 1,000 live births for late-preterm infants.
- Acquired by vertical transmission
    - GI and GU bacteria ascend during labor or when amniotic membranes rupture: Intra-Amniotic Infection
    - Can begin *in utero* when fetus inhales or swallows infected fluid
    - Hematogenous transmission.
- Most often caused by:
    - Group B streptococcus
    - E coli
    - Listeria
- Diagnosis remains a challenge
    - Delayed onset of symptoms
    - Laboratory tests alone are neither sensitive nor specific enough to guide EOS management decisions
- Probability of EOS is based on:
    - Maternal risk factors
    - Infant clinical characteristics



Risk Factors for Early Onset Sepsis

Maternal and infant clinical characteristics can help identify newborn infants who are at risk and guide the administration of empirical antibiotic therapy.

Maternal Risk Factors

- Highest maternal antepartum temperature
- Rupture of membranes (hours)
- GBS status
- Type of intrapartum antibiotics

Neonatal Risk Factors

- Gestational age
- Postnatal distress
- Clinical Signs:
    - Tachycardia
    - Tachypnea
    - Respiratory distress
    - Supplemental oxygen
    - Temperature instability
    - Hemodynamic instability

Antibiotic Stewardship and Risks to Newborns

In 2019 the CDC developed guidance to measure and improve how antibiotics are prescribed by clinicians to better treat infections, protect patients from harms caused by unnecessary antibiotic use, and combat antibiotic resistance.

Antibiotics are essential in fighting infections in newborns. But wide variations in antibiotic prescribing for newborn infections can lead to unnecessary or prolonged antibiotic exposure resulting in short- and long-term adverse outcomes such as:

- Mother-baby separation that interferes with bonding and successful breastfeeding
- Creation of antibiotic resistant bacteria
- Alterations in gut microbiome
- Increased incidence of necrotizing enterocolitis in preterm newborns
- Higher incidence of chronic conditions, including asthma, allergies, and obesity

It is imperative that we improve our ability to:

- IDENTIFY babies at the highest risk for EOS
- MONITOR and SCREEN EFFECTIVELY when indicated
- TREAT with the RIGHT antibiotics for the RIGHT amount of time

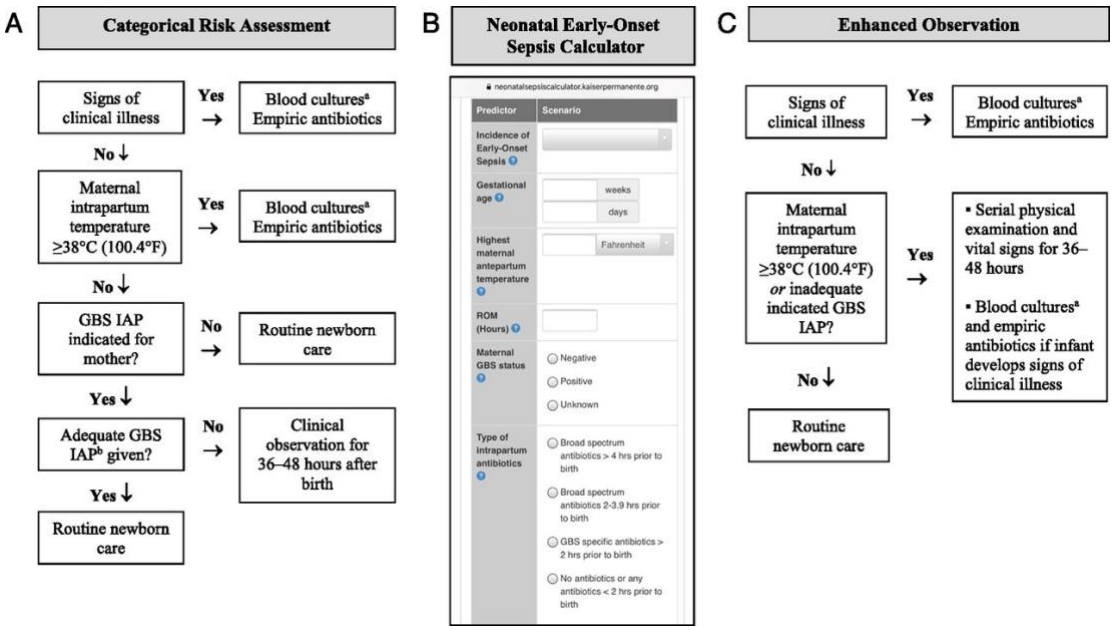
American Academy of Pediatrics (AAP) Clinical Recommendations

The 2018 AAP Clinical Report provides recommendations to protect infants at risk for infection by focusing on strategies to help clinicians:

- Carefully weigh the risks and benefits before administering antibiotics
- Identify risk and response for neonatal early onset sepsis diagnosis
- Improve clinical practices to support decisions involving appropriate antibiotic administration

Identified three acceptable approaches to neonatal sepsis evaluation in newborns ≥ 35 weeks gestation:

- Categorical algorithms
- Multivariate risk assessment (Neonatal Early Onset Sepsis Calculator)
- Serial physical exams



Other recommendations:

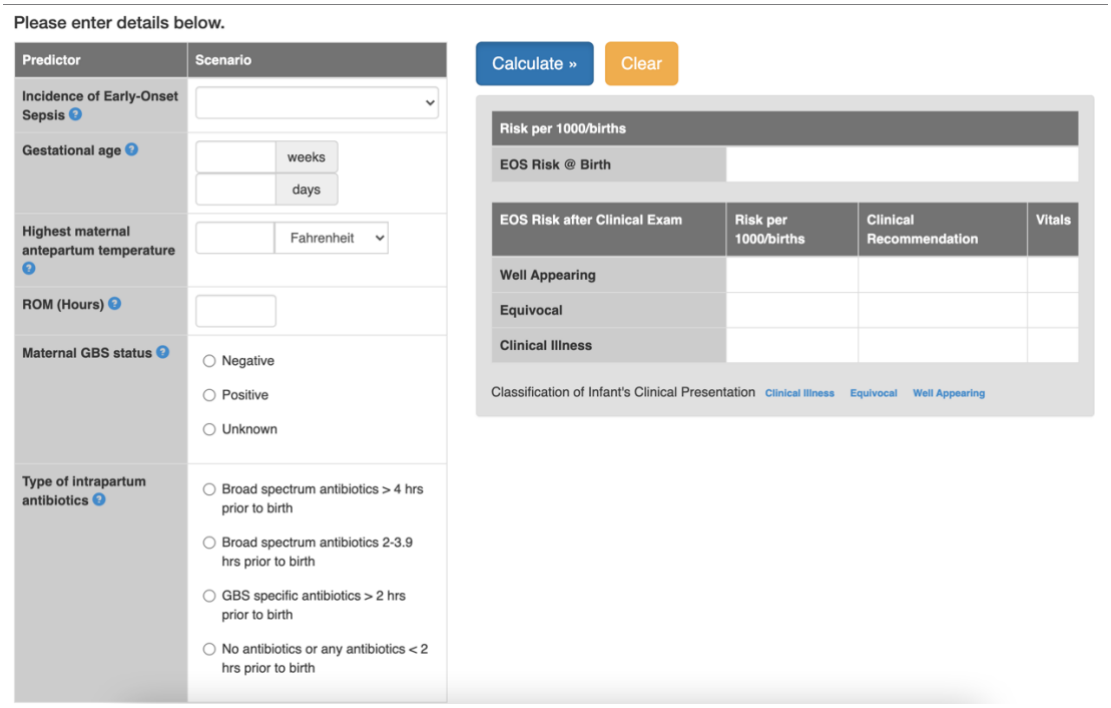
- Birth centers should develop locally tailored guidelines
- Use properly collected blood or CSF cultures to diagnose sepsis
- Ampicillin and gentamicin as first line empirical antibiotics
- Stop antibiotics at 36-48 hours with negative cultures, unless these is clear evidence of site-specific infection

Resources:
AAP Management of Newborns Born at ≥35 0/7 Weeks' Gestation With Suspected or Proven Early-Onset Bacterial Sepsis (2018)
https://pediatrics.aappublications.org/content/142/6/e20182894
AAP Management of Infants at Risk for Group B Streptococcal Disease (2019)
https://pediatrics.aappublications.org/content/144/2/e20191881

Neonatal Early Onset Sepsis Calculator

https://neonatalsepsiscalculator.kaiserpermanente.org

- Validated for use in newborns ≥ 34 weeks gestation
- Can be implemented into the electronic medical record
- Used to determine probability of early onset sepsis based on population risk and specific maternal risk factors
- Should be performed by the clinician or nursing staff within the first hour after birth
- Modification of baseline risk of sepsis based on newborn's clinical presentation for the first 24 hours:
    - Well-appearing
    - Equivocal
    - Clinical Illness



Clinical recommendation will be highlighted as:

- Routine Care (no cultures, no antibiotics, routine vitals)

- No culture, no antibiotics, vital signs every 4 hours for 24 hours
- Blood culture, vital signs every 4 hours for 24 hours

- Blood culture and strongly consider starting antibiotics, vital signs per NICU
- Blood culture and empiric antibiotics, vital signs per NICU

Please enter details below.

Predictor	Scenario
Incidence of Early-Onset Sepsis	0.5/1000 live births (CDC national
Gestational age	37 weeks; 0 days
Highest maternal antepartum temperature	37 Celsius
ROM (Hours)	1
Maternal GBS status	○ Negative ● Positive ○ Unknown
Type of intrapartum antibiotics	○ Broad spectrum antibiotics > 4 hrs prior to birth ○ Broad spectrum antibiotics 2-3.9 hrs prior to birth ○ GBS specific antibiotics > 2 hrs prior to birth ● No antibiotics or any antibiotics < 2 hrs prior to birth

Calculate » Clear

Risk per 1000/births	
EOS Risk @ Birth	0.21

EOS Risk after Clinical Exam	Risk per 1000/births	Clinical Recommendation	Vitals
Well Appearing	0.09	No culture, no antibiotics	Routine Vitals
Equivocal	1.04	Blood culture	Vitals every 4 hours for 24 hours
Clinical Illness	4.40	Empiric antibiotics	Vitals per NICU

Classification of Infant's Clinical Presentation Clinical Illness Equivocal Well Appearing

Classification of Infant's Clinical Presentation

Clinical Exam	Description
Clinical Illness	1. Persistent need for NCPAP / HFNC / mechanical ventilation (outside of the delivery room) 2. Hemodynamic instability requiring vasoactive drugs 3. Neonatal encephalopathy /Perinatal depression ▪ Seizure ▪ Apgar Score @ 5 minutes < 5 4. Need for supplemental O_2 ≥ 2 hours to maintain oxygen saturations > 90% (outside of the delivery room)
Equivocal	1. Persistent physiologic abnormality ≥ 4 hrs ▪ Tachycardia (HR ≥ 160) ▪ Tachypnea (RR ≥ 60) ▪ Temperature instability (≥ 100.4˚F or < 97.5˚F) ▪ Respiratory distress (grunting, flaring, or retracting) not requiring supplemental O_2 2. Two or more physiologic abnormalities lasting for ≥ 2 hrs ▪ Tachycardia (HR ≥ 160) ▪ Tachypnea (RR ≥ 60) ▪ Temperature instability (≥ 100.4˚F or < 97.5˚F) ▪ Respiratory distress (grunting, flaring, or retracting) not requiring supplemental O_2 Note: abnormality can be intermittent
Well Appearing	No persistent physiologic abnormalities

Intrapartum Antibiotic Chart

Neonatal Early-Onset Sepsis Calculator Intrapartum Antibiotic Definitions

Type of Intrapartum antibiotics	Examples of antibiotics
0= No antibiotics or any antibiotics <2 hours prior to birth	If **used alone,** these antibiotics do not provide enough coverage for Group B strep in the neonate: - Azithromycin - Cefoxitin - Clindamycin - Erythromycin - Vancomycin
1=Group B strep specific antibiotics >2 hours prior to birth	- Ampicillin - Cefazolin (Ancef) - Penicillin
2= Broad Spectrum antibiotics 2-3.9 hours prior to birth **3=** Broad Spectrum antibiotics >4 hours prior to birth	**Gentamicin/Tobramycin/Amikacin +** any of the following: - Ampicillin - Azithromycin - Cefazolin - Cefoxitin - Clindamycin - Penicillin - Vancomycin **OR** Broad Spectrum Antibiotics used alone: - Ampicillin-Sulbactam (Unasyn) - Cefepime - Ceftriaxone - Ciprofloxacin - Levofloxacin - Meropenem - Piperacillin-Tazobactam (Zosyn)

Tips for Completing the Early Onset Sepsis Calculator

Calculator Input	Value to be entered	Notes
Incidence of Early Onset Sepsis	Use local incidence if known. If not, use 0.5/1000 live births (CDC national incidence)	NPQIC recommends that most Nebraska hospitals use the CDCnational incidence
Gestational Age	Gestational age at birth, in weeks and days	"Weeks" value range 34-43 "Days" value range 0-6
	Enter the value and remember to choose "Fahrenheit" or "Celsius" for the temperature unit.	Value may be whole number or number with single decimal place
Highest Maternal Intrapartum Temperature	Note: Maternal fever that occurs within 1 hour after delivery can be counted as the "highest intrapartum temperature" for the purpose of calculating the risk estimate at birth, if postpartum temperature is at least 1°F higher than intrapartum temperature.	• Examples: 101, 101.0 and 101.5 are all acceptable entry values
ROM (hours)	Duration of time between ruptureof membranes and birth, in hours.	Round to the nearest whole hour • Example: ROM time 4 hours and 29 minutes should be entered as 4 hours • Example: ROM time 4 hours and 30 minutes should be entered as 5 hours
GBS	Enter maternal GBS screening result	
Type of Intrapartum Antibiotics	Choice must include the type of antibiotic given and duration of time prior to birth that **first dose** was given. **GBS-specific antibiotics:** • ONLY penicillin G; ampicillin; or cefazolin given for the purpose of GBS prophylaxis. This should apply only to mothers who are GBS positive or GBS unknown.	

	● If erythromycin, clindamycin or vancomycin ALONE are given for GBS prophylaxis, choose "None or antibiotics given < 2 hours priorto delivery." These medications do not reliably provide neonatal protection from GBS infection, although they may provide some protection to the mother. [1] Broad-spectrum antibiotics: Defined as two or more antibiotics given in combination for concern for intra-amniotic infection. Usually, this concern is prompted by maternal intrapartum fever. *To determine the timing of broad-spectrum intrapartum antibiotic administration, compare the time of the administration of the second antibiotic in the combination, to the time of birth.* ● Example: ampicillin is given at 2:00 PM; gentamicin is given at 3:30PM. Birth is at 4:30 PM. Because the second antibiotic of the combination was given 1 hour prior to delivery, choose "None or antibiotics given < 2 hours prior to birth." ● Example: ampicillin is given at 1:00 PM; gentamicin is given at 2:00PM. Birth is at 4:30 PM. Because the second antibiotic of the combination was given 2.5 hour prior to delivery, choose "Broad-spectrum antibiotics given 2-3.9 hours prior to birth." ● Example: ampicillin is given at 10:00 AM; gentamicin is given at 11:00 AM. Birth is at 4:30 PM. Because the second antibiotic of the combination was given >4 hours prior to delivery, choose Broad-spectrum antibiotics given < 4 hours prior to birth." *If a mother has been given BOTH GBS-specific antibiotics and broad- spectrum antibiotics due to concern for evolving chorioamnionitis/intraamniotic infection, record the most complete treatment.* ● Example: Mother is given ampicillin at 8:00 AM and 12:00 PM for GBS positive status. She develops a fever to 101F at 2:00 PM, and gentamicin is given at 3:00 PM. Ampicillin is given at 4:00 PM. Birth is at 4:30 PM. In this case, GBS-specific antibiotics weregiven > 4 hours prior to delivery, but broad-spectrum antibiotics were given only 1 ½

	hours prior to delivery. In the calculator, choose "GBS-specific antibiotics given > 2 hours prior to birth."
Antibiotic Dosing	When empiric antibiotics are recommended by the EOSC, draw a blood culture and initiate ampicillin and gentamicin. Refer to up to date published print or online references for neonatal dosing. Example references include: Nelson's Pediatric Antimicrobial Therapy, Harriet Lane Handbook, and Neofax

Adapted for use by the Nebraska Perinatal Quality Improvement Collaborative. Based on personal email communication with Dr.K.M. Puopolo and Dr. N. Gollehon-NPQIC Neonatal Advisory Group, August, 2020. Credit is also given to the Colorado Perinatal Care Quality Collaborative for their Antibiotic Stewardship For Neonatal Early Onset Sepsis Toolkit. https://cpcqc.org/nast/antibiotic-stewardship-home/

Resources:

ACOG Committee Opinion No. 712: Intrapartum Management of intraamniotic infection. (2017). Obstetrics & Gynecology, 130(2). https://doi.org/10.1097/aog.0000000000002236

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How to Videos and Frequently Asked Questions

Videos:

Perinatal Quality Collaborative of North Carolina “Antibiotic Stewardship Newborn Sepsis Webinar: Kaiser Calculator Demo”

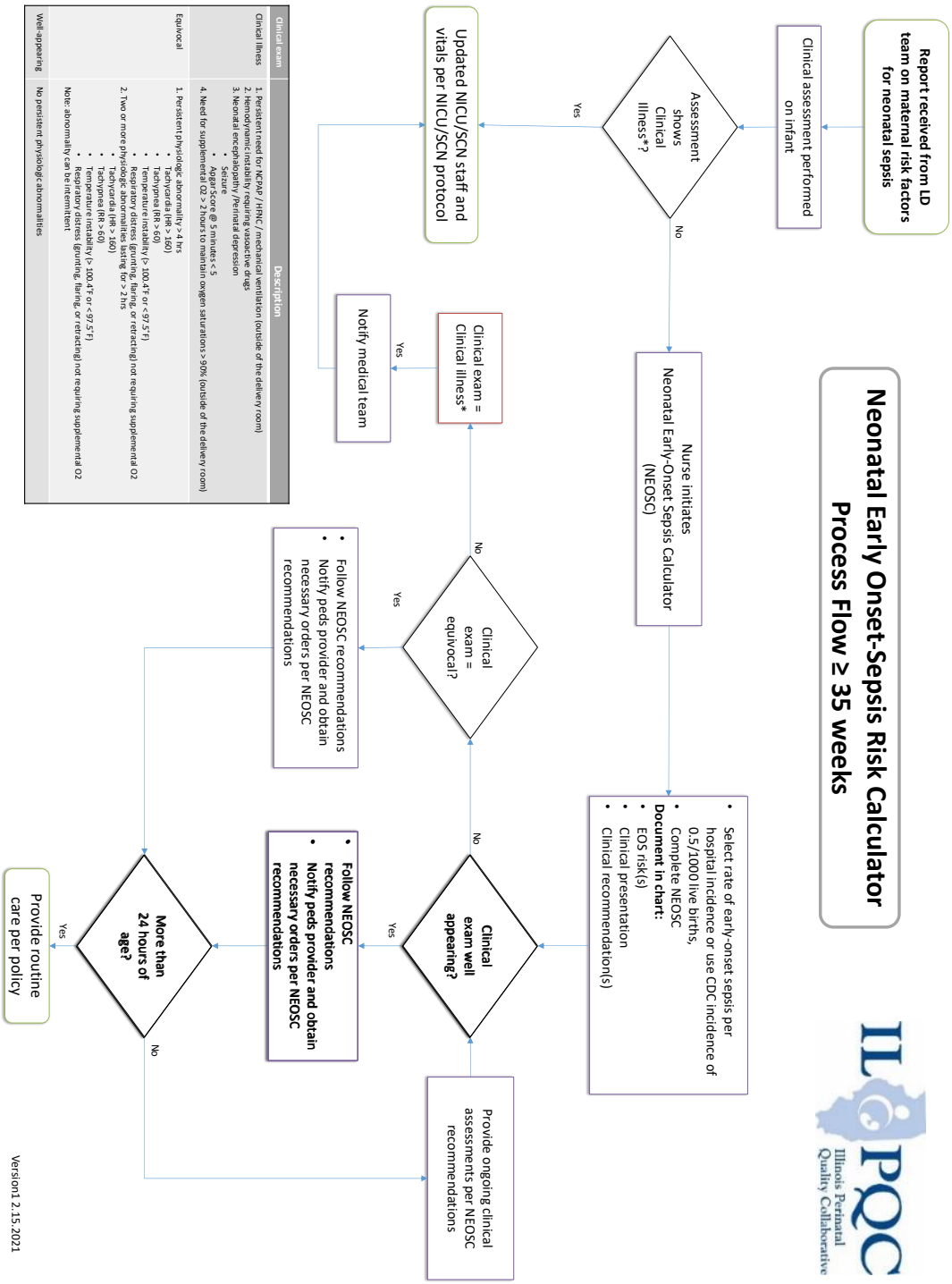
Available here: https://vimeo.com/215400110

Colorado Perinatal Care Quality Collaborative “Sepsis Risk Calculator Implementation and Practice”
Available here: https://www.youtube.com/watch?v=yUG1Dx7gq3Q

Frequently Asked Questions:

Kaiser Permanente Research Neonatal Early-Onset Sepsis Calculator
Available here: https://neonatalsepsiscalculator.kaiserpermanente.org/GenFAQ.aspx

Sample Process Flow for Neonatal Early Onset Sepsis Calculator



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Sample Communication Tools

Newborn Admission Report

LD RN → Newborn RN

Use this template to standardize communication between L&D nurse and receiving newborn/postpartum nurse

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Newborn Background

- ☐ Newborn name
- ☐ Delivery provider & anticipated Pediatric provider
- ☐ Gestational age (weeks/days)
- ☐ Birth weight

Maternal and Delivery History

- ☐ Maternal history and pertinent risk factors
  - Delivery type (SVD, CS, Vacuum/Forceps)
  - Medical History/medication (Preeclampsia, Magnesium, GDMA, PTL, exposures, other)
  - Apgars and Newborn resuscitation requirements?
- ☐ Maternal blood type and status of infant cord blood
- ☐ GBS status (positive, negative, unknown)
  - If positive type of antibiotics, time of first dose, and number of doses
- ☐ Rupture of membranes (date/time)
  - Color
  - Total hours
- ☐ Chorioamnionitis/Intraamniotic infection concerns
  - Highest maternal temp recorded (24 hrs prior to birth & 1hr postpartum)
  - Antibiotics given?
    - Type & Time of first dose

Newborn Status

- ☐ Basic infant assessment
  - Vital signs and assessment
  - NEOSC completed? Recommendations?
- ☐ Feeding preference
  - Last feed
  - Glucose check?

SBAR Example for Newborn Nurse Report to Pediatrician

S **Describe situation** Always identify yourself, your location, and the name of the patient. Then quickly state the main reason and the level of urgency for the call.	My name is …. from….. I am calling about the patient …. Please select one: o You have a new admission to your service. o Your new admission has an increased risk for sepsis. o I want to provide an update on your patient (includes any abnormal assessments that require the RN to call pediatrician).
B **Provide background** Give brief pertinent background information – medical history, vital signs, and interventions that have already occurred.	Baby … Infant weight, sex, and gestational age Born to a patient ... year old GsPs Born by vaginal delivery, forceps/vacuum or cesarean delivery (describe indication) In the delivery room, infant received (describe any resuscitation measures) Maternal labs are o Blood type, Hep B, RPR HIV, Rubella, and GBS GBS Unknown/Yes … describe antibiotics Had (clear/meconium/bloody) fluid and was ruptured for a total of hrs Maternal history was significant for … o Pregnancy complications? Yes… describe o Delivery complications? Yes… describe o Pertinent medications Yes…describe o Social concerns or substance use Yes... describe Cord gas results and blood type (if available)
A **Share infant assessment**	According to the Neonatal Early-Onset Sepsis calculator, my assessment indicates … Well Appearing o No persistent physiologic abnormalities Equivocal o Persistent physiologic abnormality > 4 hrs o Tachycardia (HR > 160) o Tachypnea (RR > 60) o Temperature instability (> 100.4˚F or < 97.5˚F) o Respiratory distress (grunting, flaring, or retracting) not requiring supplemental O_2 o Two or more physiologic abnormalities listed above lasting for > 2 hrs Note: abnormality can be intermittent Clinical Illness o Persistent need for NCPAP / HFNC / mechanical ventilation (outside of the delivery room) o Hemodynamic instability requiring vasoactive drugs o Neonatal encephalopathy / Perinatal depression Seizure Apgar Score @ 5 minutes < 5 o Need for supplemental O_2 > 2 hours to maintain oxygen saturations > 90% (outside of the delivery room) The NEOSC calculator predicts the risk of EOS at X per 1,000 births.
R **Make recommendation** Say what you think should happen or ask for specific orders.	Based on this EOS risk and my clinical exam, the NEOSC recommendations include Share clinical recommendations listed in NEOSC calculator for the relevant Clinical Exam. Share vital sign frequency recommendations from the NEOSC risk calculator for the relevant Clinical Exam.

Antibiotic Choice and Dosing for Treatment of Early Onset Sepsis

When empiric antibiotics are recommended by the EOS Calculator:

1. Draw a blood culture
2. Utilize ampicillin and gentamicin.
    a. Refer to up to date published print or online references for neonatal dosing or consult tertiary center.
        i. Lexicomp
        ii. Nelson's Pediatric Antimicrobial Therapy- AAP, 2021
3. Stop antibiotics at 36-48 hours with negative cultures, unless these is clear evidence of site-specific infection

Neonatal Blood Culture Collection

Neonatal Peripheral Blood Culture Collection Checklist	
Blood Culture Draw Criteria	
Optimally, the blood culture should be drawn prior to the administration of antibiotics. **Note:** this is a 2-person procedure.	
Supplies Needed	
Printed patient label for blood culture bottle	Pediatric blood culture bottled
Alcohol swabs	Chlorhexidine swabs
Clean gloves	Laboratory biohazard transport bag
Butterfly needle	3-5 mL syringe
Gauze pads	bandage or paper tape
Tourniquet	
Step by Step Procedure	
1. Gather supplies and prepare a clean work surface.	
2. Perform hand hygiene and don clean gloves.	
3. Apply tourniquet 1 inches above intended insertion site and assess infant's veins. **Do not leave tourniquet on for more than one minute.**	
4. Once a proper vein has been selected, remove tourniquet.	
5. Clean the venipuncture site with chlorhexidine for 30 seconds. Scrub the area using a back and forth motion. **Allow to air dry for 30 seconds.** *Do NOT fan or blow on the site. Do NOT touch the intended venipuncture site after preparation.*	
6. Prepare butterfly needle with 3-5 mL syringe attached.	
7. Prepare blood culture bottle: a. Check expiration date. b. Remove cap & wipe off the septum of bottle with an alcohol pad for 10 seconds. ***(Do not use chlorhexidine).*** c. Rest the alcohol pad on top of the bottle prior to inoculation to avoid airborne contaminants.	
8. Reapply tourniquet.	
9. Position needle with bevel up.	
10. Immobilize vein by pressing 1" to 2" below the venipuncture site with your thumb and drawing the skin taut.	
11. Insert needle quickly and smoothly at a 25-30 angle through the skin.	
12. Collect **at least** 1 mL of blood. Max of 5 ml.	
13. After drawing the samples, remove the tourniquet, place a gauze over the puncture site, and activate the needle safety device prior to removing the needle.	
14. Attach a blunt needle to the syringe.	
15. Remove alcohol pad from bottle and transfer the blood into the bottle.	
16. Invert bottle 8-10 times to mix sample.	
17. Apply pressure to the puncture site until bleeding stops. Apply gauze and tape or bandage.	
18. Discard needle in sharps container and garbage into the garbage receptacle.	
19. Remove gloves and perform hand hygiene.	
20. Label bottle at the bedside (date, time, site of draw- R or L). Place bottle in biohazard bag and send to lab.	

Watch the process on you tube: Click on the link or use the QR code
https://www.youtube.com/watch?v=IL3jAW1Kk9c

Adapted for use by the Nebraska Perinatal Quality Improvement Collaborative. Credit is given to the Illinois Perinatal Quality Collaborative and Advocate Lutheran General Hospital. https://ilpqc.org/basic2021/

National Guidelines and Resources

- AAP Management of Infants at Risk for Group B Streptococcal Disease (2019) https://pediatrics.aappublications.org/content/144/2/e20191881

- AAP Management of Newborns Born at ≥35 0/7 Weeks' Gestation With Suspected or Proven Early-Onset Bacterial Sepsis (2018) https://pediatrics.aappublications.org/content/142/6/e20182894

- AAP Management of Newborns Born at ≤34 6/7 Weeks' Gestation With Suspected or Proven Early-Onset Bacterial Sepsis (2018) https://pediatrics.aappublications.org/content/142/6/e20182896

- AAP Estimating the Probability of Neonatal Early-Onset Infection on the Basis of Maternal Risk Factors (2011) https://pediatrics.aappublications.org/content/128/5/e1155

- JAMA Pediatrics: A Quantitative, Risk-Based Approach to the Management of Neonatal Early-Onset Sepsis (2017): A review of the science behind the NEOSC (Kaiser calculator). https://jamanetwork.com/journals/jamapediatrics/fullarticle/2604260

- ACOG Committee Opinion: Intrapartum Management of Intraamniotic Infection (2017) https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/08/intrapartum-management-of-intraamniotic-infection

- ACOG Committee Opinion: Prevention of Group B Streptococcal Early-Onset Disease in Newborns (2020) https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/02/prevention-of-group-b-streptococcal-early-onset-disease-in-newborns

Resources for Families

Patient education handout with QR code to video:
https://ilpqc.org/ILPQC%202020%2B/BASIC20/ilpqc_antibioticsflyer_WEB.pdf

WHAT YOU NEED TO KNOW ABOUT YOUR BABY AND ANTIBIOTICS

Congratulations on the birth of your baby! The healthcare team is here to support you and your baby during these special first days and wants to provide important information about the use of antibiotics and how you can best advocate for your baby.

Your baby is receiving antibiotics because the healthcare team is concerned that your baby may have an infection. When a baby is at risk for an infection, the healthcare team may give antibiotics even before they can confirm an infection. It's safer to start antibiotics right away in these cases. Newborns can quickly become very sick if they have an infection, so the healthcare team is being very careful.

To find out if your baby has an infection, the healthcare team will:

- **look** for reasons your baby might be at risk
- **check** how your baby is doing
- **look** at results from blood tests if needed

Some questions to ask your healthcare team to better understand what is going on with your baby and why your baby is at risk for infection:

- Why is my baby at risk for infection?
- What kind of infection could my baby have?
- What symptoms could my baby have?
- How long will my baby have to take the antibiotics?

ILPQC
Illinois Perinatal Quality Collaborative

Scan here to watch the video.

youtu.be/coan_TmVe6o

Educational videos for parents whose newborns are receiving antibiotics:

- ILPQC Patient Education Video (English)
- ILPQC Patient Education Video (Spanish)

References

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