Republic of the Philippines
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PHILHEALTH CIRCULAR
No. 2023- 0017

TO : **ALL ACCREDITED HEALTH CARE PROVIDERS, PHILHEALTH MEMBERS, PHILHEALTH OFFICES (HEAD OFFICE AND REGIONAL OFFICES) AND ALL OTHERS CONCERNED**

SUBJECT : **Quality Policy on the Diagnosis and Management of Neonatal Sepsis as Reference of the Corporation**

I. RATIONALE

Republic Act No. 11223 otherwise known as the Universal Health Care Act provides that PhilHealth shall support the implementation of standards for clinical care set forth by the Department of Health (DOH) based on approved clinical practice guidelines. Further, the revised Implementing Rules and Regulations of the National Insurance Act of 2013 provides the implementation of quality assurance standards as reference for ensuring quality of care services.

Since Neonatal Sepsis still pose a serious threat to the health and wellbeing of Filipino infants and burdens families, healthcare professionals, and the healthcare system as a whole, recommendations based on best available evidence were translated into policy statements and shall be used primarily to provide guidance to doctors, hospitals, and patients as to what tests, medicines and procedures are strongly recommended. As such, it shall be used by the Corporation as one of its references in ensuring quality of care through various activities such as educational resource, claims review, performance monitoring, and other activities as necessary.

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These evidence-based policy recommendations were developed in consultation with the Philippine Pediatric Society (PPS) and approved by the PhilHealth Quality Assurance Committee (QAC) shall be used by the Corporation as one of its references in ensuring quality of care rendered by PhilHealth-accredited health care providers.

II. OBJECTIVES

This PhilHealth Circular aims to establish the standards of care in the diagnosis and management of Neonatal Sepsis in line with the quality assurance program of the Corporation.

III. SCOPE

This Policy shall be applicable for neonate patients (aged 28 days old and below) who are hospitalized due to sepsis.

IV. DEFINITION OF TERMS

A. Confirmed Sepsis in a Newborn – systemic signs of infection in infants 28 days of life or younger, with isolation of a bacterial pathogen from the bloodstream[1].

B. Early Onset Sepsis (EOS or "0 to 7" days) – infection occurring in the first 7 days of life[2].

C. Late Onset Sepsis (LOS or "More than 7 to 28 days) – infection occurring more than 7 days of life[2].

D. Neonate – or a newborn infant on the first 28 days of life[3].

V. POLICY STATEMENTS

A. Clinical Indicators of Neonatal Sepsis

1. Maternal risk factors must be taken into consideration such as, but not limited to the following:

   a. Chorioamnionitis
   b. GBS Colonization. When Group B Streptoccocus (GBS) positive mothers with inadequate treatment, or infant of multiple birth where one has GBS sepsis, or previous infant with early onset GBS sepsis
   c. Delivery before 37 weeks of gestation
   d. Prolonged rupture of membranes greater than 18 hours
   e. Maternal intrapartum fever (temperature > 38°C), active urinary tract infection within 1 week of delivery, poor/ inadequate prenatal check-ups

2. Neonatal Risk Factors such as:

   a. Prematurity
   b. Very low birth weight (VLBW < 1500grams)
   c. Male

3. Presence of the following parameters:

[1]World Health Organization (n.d.). Newborn Health. www.who.int/westernpacific/health-topics/newborn-health
[2]Cantey, Joseph, et al. (2023). Clinical features, evaluation, and diagnosis of sepsis in term and late preterm neonates. UpToDate. www.uptodate.com/contents/clinical-features-evaluation-and-diagnosis-of-sepsis-in-term-and-late-preterm-neonates
[3]Philippine Society of Newborn Medicine. (2017). *Practice Recommendations on the Management of Neonatal Sepsis.*

a. Hypotension (which is <5th percentile for age) and signs and symptoms of hypotension such as pallor, mottling, poor perfusion, weak pulses, capillary refill time (CRT) more than 2 seconds
b. Abnormal core temperature (T>38°C for fever or T<36.5°C for hypothermia) or temperature instability unexplained by environmental factors
c. Signs of respiratory distress (apnea, grunting, tachypnea, cyanosis, increased oxygen requirement or ventilator settings)
d. Abnormal heart rate (bradycardia <110bpm when awake and <70 bpm when asleep, tachycardia >160 bpm when awake and >90bpm when asleep)
e. Altered behavior/sensorium or responsiveness including weak cry
f. Hypotonia (floppiness) or absent neonatal reflexes
g. Feeding difficulties, feeding intolerance (poor suck, vomiting, excessive gastric aspirates, abdominal distention)
h. Hypoglycemia in neonates (<50mg/dl or <2.8mmol/L)
i. Unexplained excessive bleeding, or skin changes (such as rashes, mottling, or ashen appearance)
j. Jaundice within 24 hours of birth, without blood incompatibility

These symptoms are non-specific, subtle, and could be of non-infectious origin. When newborns deviate from their usual pattern of activity or feeding, it is vital to have a high index of suspicion for sepsis. To consider newborn sepsis, it is critical to interpret the signs and symptoms in the context of maternal and neonatal risk factors.

B. Laboratory Tests

1. Blood Culture. A blood sample should be obtained before starting antimicrobial therapy. A positive microbiological blood culture poses the gold standard for the diagnosis of neonatal sepsis.

2. A Complete Blood Count (CBC) taken at least after 6 hours of life is a pragmatic tool for determining the likelihood of sepsis in neonates with risk factors or signs of infection. A single abnormal CBC parameter is not sufficient to diagnose newborn sepsis.

3. C-reactive Protein (CRP) levels greater than 10 mg/L for term or near-term neonates and greater than 5 mg/L for preterm neonates are suggestive of infection. In neonates with clinical signs and symptoms of sepsis, a combined CBC and quantitative measurement of CRP, if available, at the 24th hour of life may be useful in the diagnosis of sepsis.

4. Procalcitonin, if available, is a useful marker in patients with bacterial infection and an accurate test in diagnosing neonatal sepsis. It can be taken as early as 2nd hour following onset of signs and symptoms of sepsis until 24th hour. However, due to its availability and high cost, it may be regarded as an optional diagnostic examination.

5. If it is clinically indicated, do cerebrospinal fluid (CSF) analysis when any one of the following is present:

   a. There is a strong clinical suspicion of neonatal infection;
   b. The baby has positive blood culture;
   c. There are clinical symptoms and signs suggesting meningitis; or
   d. The baby does not respond satisfactorily to antibiotic treatment.

6. Skin swab microscopy or culture as part of the procedures for neonatal infection is NOT recommended if there are no clinical signs of localized infection.

7. It is recommended that:

   a. Cultures be obtained from any other potential foci of infection in patients with late-onset infection (eg, purulent eye drainage; pustules; skin lesions; bone, joint, or peritoneal fluid; or tracheal aspirates in mechanically ventilated infants).
   b. Urine culture obtained by catheter or bladder tap be included in the sepsis evaluation for infants > 6 days of age. Nonetheless, a urine culture need not be routinely performed in the evaluation of an infant < 6 days of age, because a positive urine culture in this setting indicates high-grade bacteremia rather than an isolated urinary tract infection.
   c. Blood glucose determination even through capillary test be done to monitor for hypoglycemia.

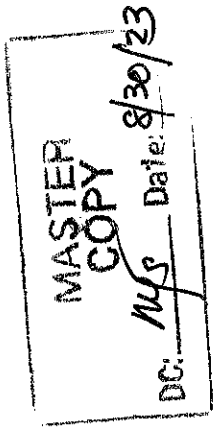
8. Additional laboratory tests may be recommended to support the diagnosis and monitoring of neonatal sepsis depending on the child's presentation and service capability of the facility.

C. Imaging Studies

Relevant imaging studies, including but not limited to x-rays, must be performed whenever appropriate in patients with suspected sepsis or septic shock.

D. Management

1. Antimicrobial therapy



   a. Neonatal sepsis is a life-threatening medical emergency that must be treated as soon as possible. Administration of intravenous antimicrobials should be initiated within 1 hour of the decision for treatment.
   b. The initial choice of parenteral antimicrobials for suspected neonatal sepsis should be based on the infant's age, likely pathogens, susceptibility patterns and resistance data of organisms in the particular area, and presence of obvious source of infection.

c. In neonates receiving antibiotics, the clinical condition and results of investigations should be evaluated on a regular basis. Change in the antibiotic regimen should take into account the baby's clinical condition (e.g. no improvement), the results of microbial investigations, and expert microbiological advice, including local surveillance data (i.e. antibiogram). Antibiotics should be chosen based on blood culture growth and sensitivity when indicated.

d. Antibiotic treatment should be given for at least 7 days for babies with a positive blood culture.

e. Healthcare professionals may consider continuing antibiotic treatment for more than 7 days in the event that the patient exhibits any of the following:
   e.1. Baby has not yet fully recovered yet;
   e.2. Pathogen identified on blood culture necessitates longer treatment; or
   e.3. Site of infection (i.e. central nervous system infection, intra-abdominal co-pathology, necrotizing enterocolitis, osteomyelitis or infection of central venous catheter) may require long-term therapy.

f. Consider discontinuing antibiotics if the blood culture is negative PLUS:
   f.1. The initial clinical suspicion of infection is not strong **and**
   f.2. The baby's clinical condition is reassuring, with no clinical indicators of possible infection **and**
   f.3. Levels and trends of C-reactive protein (CRP) concentrations are reassuring.

g. Routine antibiotic treatment to babies without risk factors or clinical indicators for infection or laboratory evidence of possible infection is NOT recommended.

2. Fluid resuscitation

Intravenous fluids should be given and guided by continuous reassessment of hemodynamic status of the patient.

3. Vasoactive and Inotropic medications

In cases of severe sepsis and septic shock, aside from initial resuscitation of IV fluids, vasoactive or inotropic agents or both are recommended to support cardiac output and/or improve vascular tone.

4. Intravenous Immune Globulin (IVIG)

Based on best available evidence, several trials have failed to demonstrate a clinical benefit of IVIG administration in neonates with sepsis, hence, we do NOT routinely recommend using it.

5. Blood transfusion

As an adjunct, giving whole blood double volume exchange transfusion is beneficial for the treatment of newborn sepsis.

E. Monitoring and Evaluation

1. The health care provider shall be bound by the provisions of the Performance Commitment and subject to the rules on monitoring and evaluation of performance as provided in PhilHealth Circular No. 2018-0019 Health Care Provider Performance Assessment System (HCP-PAS) Rev. 2.

2. Standards of care issued by authorized agencies or organizations shall be regularly monitored. As deemed necessary, a revision of the policy statements shall be made. Any updates, as a result of the review, shall be disseminated in another PhilHealth Circular.

VI. PENALTY CLAUSE

Any violation of this PhilHealth Circular shall be dealt with and penalized in accordance with pertinent provisions of Republic Act No. 7875, as amended by Republic Act Nos. 9241 and 10606, and their respective Implementing Rules and Regulations.

VII. SEPARABILITY CLAUSE

In the event that any part or provision of this PhilHealth Circular is declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.

MASTER COPY Date 8/30/23 DC

VIII. DATE OF EFFECTIVITY

This PhilHealth Circular shall take effect fifteen days after publication in the Official Gazette or in any newspaper of general circulation. A copy shall thereafter be deposited to the Office of the National Administrative Register (ONAR) at the University of the Philippines Law Center.

EMMANUEL R. LEDESMA, JR
President and Chief Executive Officer

Date signed: 8/22/23