**Diagnostic criteria for common neonatal conditions for use in low-resource settings**

**Neonatal sepsis**

**Background**

The reliable diagnosis of common neonatal conditions is critical for identifying disease burdens and providing appropriate care. Diagnostic criteria used internationally may need to adapted for use in low-resource settings where investigations and other resources are often limited.

**Completing these record sheets**

The NeoNuNet project aims to evaluate the frequency of common neonatal conditions and how they are diagnosed in practice. Diagnoses are made by clinicians according to their usual clinical practice. This record sheet documents the criteria that the clinician has used to make a diagnosis. Not all criteria will be relevant (e.g. equipment or investigation not available) and some information may be missing. All diagnoses are reviewed by senior clinical staff and any changes/corrections made.

**Working Group members:**

* Alison Talbert
* Zainab Imam

**Methods**

The working group members identified guidelines for the diagnosis of common neonatal conditions (see appendix). The guideline(s) were reviewed by nine senior NeoNuNet clinicians during a workshop in Ibadan, Nigeria and a draft of a diagnostic record sheet (draft 1) for use in the NeoNuNet project was drawn-up to document the diagnostic features / criteria used by clinicians to diagnose common neonatal conditions.

**This information will complement the routine data collected in the study database that will contain the antepartum, intrapartum and immediate postpartum events.**

The diagnostic record sheet will be pilot-tested in network neonatal units and a final record sheet developed (draft 2). These will be used in the data collection phase of the NeoNuNet project and the information collated to describe how diagnoses are made and to estimate the frequency of common neonatal conditions.

**References**

1. Wynne JL. Defining neonatal sepsis. Curr Opin Pediatr 2016; 28:135–140. doi:10.1097/MOP.0000000000000315.
2. A case definition for national and surveillance of international neonatal bloodstream infection. Modi N, Doré CJ, Saraswatula A et al. Arch Dis Child Fetal Neonatal Ed 2009; 94: F8-F12. doi: 10.1136/adc.2007.126458
3. Pontrelli G, De Crescenzo F, Buzzetti R, Jenkner A, Balduzzi S, Calo Carducci F, Amodio D, De Luca M, Chiurchiu S, Davies EH *et al*: Accuracy of serum procalcitonin for the diagnosis of sepsis in neonates and children with systemic inflammatory syndrome: a meta-analysis. *BMC Infect Dis* 2017, 17(1):302. <https://doi.org/10.1186/s12879-017-2396-7>
4. Vergnano S, Buttery J, Cailes B, Chandrasekaran R, Chiappini E, Clark E, Cutland C, de Andrade SD, Esteves-Jaramillo A, Guinazu JR, Jones C, Kampmann B, King J, Kochhar S, Macdonald N, Mangili A, de Menezes Martins R, Velasco Muñoz C, Padula M, Muñoz FM, Oleske J, Sanicas M, Schlaudecker E, Spiegel H, Subelj M, Sukumaran L, Tagbo BN, Top KA, Tran D, Heath PT; Brighton Collaboration **Neonatal** **Infections** Working Group. [Neonatal infections: Case definition and guidelines for data collection, analysis, and presentation of immunisation safety data.](https://www.ncbi.nlm.nih.gov/pubmed/27491687) Vaccine. 2016 Dec 1;34(49):6038-6046.

**Draft 1:** **Record sheet of criteria used by clinicians to diagnose Neonatal Sepsis**

Complete this sheet for each episode of suspected neonatal sepsis. A new episode occurs if the infant has been symptom free for **48 hours or more** after any previous episode.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **Unit code** | **Patient ID** | | | | | | | |
| Infant ID: | | **XXX** | **X** | | **X** | | **X** | | **X** | |
|  | | | | | | | | | | |
| Mother’s initials: |  | Infant’s DOB: | **D** | **D** | **/** | **M** | **M** | **/** | **Y** | **Y** |
|  | | | | | | | | | | |
| Date of onset of symptoms:\* | | | **D** | **D** | **/** | **M** | **M** | **/** | **Y** | **Y** |

To record the criteria used to make the diagnosis, **please complete** **all boxes** below:

enter **Y** (present), **N** (absent) or **ND** (not done/not known)

|  |  |
| --- | --- |
|  | Temperature instability (<36⁰C or >37.5⁰C) |
|  | Lethargy/irritability/hypotonia (clinician defined) |
|  | Impaired peripheral perfusion (Capillary Refill Time >3 seconds, pallor, mottling and/or core-peripheral temperature gap >2°C) |
|  | Increased frequency of apnoea/bradycardia |
|  | Tachypnoea ≥60 breaths per minute or increased requirement for oxygen or ventilatory support |
|  | difficulty with feeding/feed intolerance/abdominal distension or ileus |
|  | Hypotension |
|  | Glucose intolerance (blood glucose <2.2mmol/L or >10mmol/L) |
|  | White blood cell count <4 or >20 x10⁹ cells/L or Immature:Total neutrophil ratio ≥0.2 |
|  | Platelets <100 x10⁹/L |
|  | Metabolic acidosis (base deficit >10 mmol/L or lactate >2mmol/L) |
|  | Increase in C-reactive protein >15 mg/L |
|  | Procalcitonin ≥2ng/ml |

|  |  |
| --- | --- |
| Please add any further information relevant to this event | |
|  |  |
| Initials of health professional completing form: |  |

Diagnosis of sepsis confirmed by pathogens isolated from blood, CSF or urine cultures:

enter **Y** (present), **N** (absent) or **ND** (not done/not known)*during the episode of illness.* ***Complete all boxes in first column.***

|  |  |  |
| --- | --- | --- |
| **Site** | | **Name of pathogen(s)** |
|  | Blood |  |
|  | CSF |  |
|  | Urine |  |
|  | Others (specify) |  |

**Final diagnosis and outcome**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Outcome date: | **D** | **D** | **/** | **M** | **M** | **/** | **Y** | **Y** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | |
| Septicaemia: |  | Meningitis: |  | UTI: |  | Other: |  |
|  | | | | |  |  |  |
| If Other, give details: | | | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Outcome for this episode*(tick one only): | | | | | |
| Resolved: |  | Persisting morbidity: |  | Died: |  |

|  |
| --- |
| If persisting morbidity, give details: |
| Please add any further information relevant to this event: |

|  |  |
| --- | --- |
| Initials of health professional completing form: |  |

**Appendix: Guidelines for the diagnosis of neonatal sepsis**

Kenya Ministry of Health Basic Paediatric Protocols 2016

http://www.idoc-africa.org/images/documents/2016/MARCH%2011th%20SIGNED%20BPP%202016%20FINAL.pdf



**Neonatal sepsis guideline from ELFIN study** (<https://www.npeu.ox.ac.uk/elfin/data-collection-forms>)

Definitions: Microbiologically-confirmed Late-onset Invasive Infection

*Microbiological culture from blood or CSF sampled aseptically more than 72 hours after birth and any of the following*

*- potentially pathogenic bacteria (including coagulase-negative Staphylococci species but excluding probable skin contaminants such as diphtheroids, micrococci, propionibacteria or a mixed flora)*

*- fungi*

AND

*Treatment for 5 or more days with intravenous antibiotics after the above investigation was undertaken. If the infant died, was discharged, or was transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention was to treat for 5 or more days.There is no need to report urinary tract infection unless there is also a positive blood culture.*

Definitions: Clinically-suspected Late-onset Invasive Infection

*Either - Absence of positive microbiological culture, OR - culture of a mixed microbial flora or of likely skin contaminants (diphtheroids, micrococci, propionibacteria) only.*

AND

*Clinician intent to administer antibiotic treatment or intravenous antifungals for 5 or more days (excluding antimicrobial prophylaxis) for an infant who demonstrates 3 or more of the signs listed in A.2 or laboratory features of invasive infection:*

A2. Other reasons for antibiotic/antifungal treatment

* Increase in oxygen requirement or ventilatory support
* Increase in frequency of episodes of bradycardia or apnoea
* Temperature instability
* Ileus or enteral feeds intolerance and/or abdominal distention
* Reduced urine output to <1 ml/kg/hour
* Impaired peripheral perfusion (capillary refill time >3 seconds, skin mottling or core-peripheral temperature gap >2°C)
* Hypotension (clinician defined as needing volume or inotrope support)
* Irritability, lethargy or hypotonia (clinician-defined)
* Increase in serum C-reactive protein levels to >15 mg/l or procalcitonin ≥2 ng/ml
* White blood cells count <4 or >20 × 109 cells/l or platelet count <100 × 109/l
* Glucose intolerance (blood glucose <2.2 mmol/l or >10 mmol/l)
* Metabolic acidosis (base excess <-10 mmol/l or lactate >2 mmol/l)