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Standard Operating Procedure (SOP) 003

Patient screening and enrolment

Scope

To provide guidance on screening patients for inclusion into the PICNIC study and completing the Screening and Enrolment Log.

Eligibility

Ecology Surveillance Periods (All sites - Week 1, Week 10, Week 20)

Inclusion criteria:

- All patients admitted to the PICU, regardless of ventilation status, during any of the three ecological surveillance periods

Exclusion criteria:

- None

Period One (Weeks 2 – 9)

Inclusion criteria:

- >37 weeks corrected gestational age to ≤ 16 years
- Receiving mechanical ventilation, expected to last at least 48 hours (from ventilation start time)
- Expected to remain on mechanical ventilation until the day after tomorrow (from time of screening)

Exclusion criteria:

- Known allergy, sensitivity or interaction to polymyxin E (colistin), tobramycin or nystatin
- Known to be pregnant
- Death perceived as imminent

Period Two (Weeks 11 – 19)

Inclusion criteria:

- >37 weeks corrected gestational age to ≤ 16 years
- Receiving mechanical ventilation, expected to last at least 48 hours (from ventilation start time)

- Expected to remain on mechanical ventilation until the day after tomorrow (from time of screening)

Exclusion criteria:

- Known allergy, sensitivity or interaction to polymyxin E (colistin), tobramycin or nystatin
- Known to be pregnant
- Death perceived as imminent

Patients should be expected to be ventilated for at least 48 hours from the start of any invasive ventilation. Also, from the time of screening they should be expected to still be ventilated the day after tomorrow. (If it is not fully clear whether they will receive mechanical ventilation for more than 48 hours they should still be enrolled).

For example:

- 1) If a patient was ventilated 24 hours before being screened, at the time of screening they should then still be expected to be on mechanical ventilation the day after tomorrow.
- 2) If a patient was ventilated on a Friday evening but not screened until the Monday morning, they should still expect to be ventilated until the Wednesday.

Study Number Allocations (enrolment)

A patient is considered enrolled once they have been allocated a study number.

Ecology Surveillance Periods (All sites - Week 1, Week 10, Week 20)

- All patients who have samples taken during Ecology Surveillance Periods are enrolled into the PICnIC study and assigned an Ecology Surveillance Number. Do not assign an Ecology Surveillance Number if samples are not taken.
- Patients should be assigned an Ecology Surveillance Number based on the next available number listed within the PICnIC Ecology Surveillance Number list kept in Section 6: Screening and Enrolment, of the ISF.
- Once a Surveillance Number is allocated to a patient, the date it was assigned, the research team member assigning it and the patient hospital identifier should be completed.
- Note: Patients who have been previously enrolled into PICnIC should not be enrolled into the study again.

Period One (Weeks 2 – 9) and Period Two (Weeks 11 – 19)

- Following eligibility confirmation, patients are enrolled into the PICnIC study and assigned a Study Number.
- Patients should be assigned a Study Number based on the next available number listed within the PICnIC Study Number list kept in Section 6: Screening and Enrolment, of the ISF.
- Once a Study Number from the list is allocated to a patient, the date it was assigned, the research team member assigning it and the patient hospital identifier should be completed.
- Note: Patients who have been previously enrolled into PICnIC should not be enrolled into the study again.

Screening and Enrolment Log Completion

Ecology Surveillance Periods (All sites - Week 1, Week 10, Week 20)

- All patients admitted to the PICU should be entered on to the 'Ecology Surveillance Enrolment' tab of the PICnIC Screening and Enrolment Log.
- The log should be completed for all patients who have had samples taken for the study in the week 1, 10, and 20 Ecology weeks.
- Do not assign an Ecology Surveillance Number to patients who have not had samples taken, please ensure all other fields are completed and the reason is explained in the comments section.

Period One (Weeks 2 – 9) and Period Two (Weeks 11 – 19)

- Potentially eligible patients will be screened against the inclusion/exclusion criteria by the clinical team looking after the patient, supported by the site research team.
- Patients who fulfil all the inclusion criteria and none of the exclusion criteria will be enrolled and information will be recorded on the PICnIC Screening and Enrolment Log's 'Screening and Enrolment' tab.
- Patients who fulfil all the inclusion criteria but meet one or more of the exclusion criteria will be recorded on the PICnIC Screening and Enrolment Log's 'Screening and Enrolment' tab
- All eligible patients including those who fulfil all the inclusion criteria and none of the exclusion criteria but are not enrolled, will be recorded on the PICnIC Screening and Enrolment Log's 'Screening and Enrolment' tab, giving reasons for this (please see 'Instructions' tab on Screening and Enrolment Log)

Submission

The Screening and Enrolment Log should be submitted to PICnIC via email (picnic@icnarc.org). All sites will be sent a reminder before submission is due.

Ensure the log does not contain any patient identifiable information prior to submission.