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Standard Operating Procedure (SOP) 012

PICnIC Samples

Scope

To provide guidance on the sampling procedures and the microbiological laboratory analysis within PICnIC. This guidance is applicable to all personnel managing PICNIC samples, including but not limited to qualified investigator(s), nurse(s), research coordinator(s), laboratory staff and research assistant(s).

Definitions

Selective digestive decontamination (SDD): Infection prophylaxis regimen comprising application of topical non-absorbable antibiotics to the oropharynx and stomach.

Nasopharyngeal swab: Microbiology swab that is inserted to the back of the throat and then inserted 1-2cm into the nasal canal, assuring maximal contamination of the swab on the pharyngeal and nasal mucosa.

Faecal / rectal swab: Microbiology swab that is inserted through the anal canal into the rectum (1 to 3 cm beyond the anal verge) and assuring maximal faecal contamination of the swab.

Sample Collection

Data collected from samples that are taken as part of routine care will be used in PICnIC without consent (e.g. admission samples) and should be taken using standard procedures. Any additional samples should be taken following consent. (Please see SOP 005: Consent procedures for further details).

Swab samples taken will include:

- Nasopharyngeal
- Faecal / rectal
- Urine (if clinically indicated)
- Sputum / secretions from the endotracheal tube (if clinically indicated)
- Wound, if present (if clinically indicated)

Ecology Weeks (weeks 1, 10 and 20)
Samples should be taken on admission, and then following consent, ideally once more during the week. We suggest taking the second samples on a Friday if the patient has not had samples taken in the previous 48 hours.

For example, if a patient's routine care admission samples are taken on a Monday, the second sample would be on a Friday. If a patient's admission samples were taken on a Thursday, the second sample should be taken at the weekend if capacity allows.

Usual Care and Intervention Weeks (Period One: weeks 2 – 9 and Period Two: weeks 11-19)
Samples should be taken on admission and then following consent, twice-weekly until discharge. For patient stays of <7 days, samples should be taken on the day of discharge.

If an intervention patient is readmitted to the PICU from another inpatient area within your hospital, and SDD has restarted, sampling should continue using the same process until the end of their treatment period.

Arctic study samples
Samples required for the sites participating in the Arctic sub-study should be taken following consent for the it (please see separate Arctic SOP for further details). These would include one faecal/rectal swab and one nasopharyngeal swab, ideally taken at the same time as the routine care PICnIC samples (e.g. at admission). These swabs should be stored at -70°C and transported to Cambridge for batch processing and sent for metagenomic testing. All consumables, labels and further details will be provided to your site separately.

Laboratory Analysis

All nasopharyngeal and faecal/rectal samples for PICnIC (taken as part of routine care and/or additional consented samples) will be processed as follows by the laboratory:

Nasopharyngeal Swab
Plate analysis- Methicillin-Resistant Staphylococcus Aureus (MRSA)

- Nasopharyngeal/multisite swab samples will be plated for MRSA using standard laboratory procedures

Faecal/Rectal samples
The rectal samples will be processed on 4 separate plates in the following order:
Plate analysis- Extended Spectrum Beta Lactamase (ESBL) and AmpC producing organisms

- Samples will be plated for *Enterobacteriaceae* using standard laboratory procedures
- Test first for resistance to 3rd generation cephalosporins and other standard susceptibilities
- If resistance to 3rd generation cephalosporin confirmed, then perform confirmatory test for ESBL- (and AmpC production if routinely done in your lab) using accepted phenotypic and/or genotypic methods. All results (including identification, susceptibility and presence of ESBL/AmpC should be reported)

Plate analysis- Carbapenemase producing Enterobacteriaceae (CPE)

- Samples will be plated for *Enterobacteriaceae*, *Pseudomonas* spp. and *Acinetobacter* spp. using standard laboratory procedures (including identification and susceptibility testing) and presence of carbapenemases will be confirmed using PCR methods if available and if not, then through standard laboratory procedures. All results (including identification, susceptibility and presence of carbapenemases should be reported)

Plate analysis- Vancomycin-resistant Enterococcus (VRE)

- Samples will be plated for VRE and cultured using standard methods. Colonies growing on the selective media will be confirmed using standard methods (including identification and susceptibility testing)

Plate analysis- Candida auris code)

- Samples will be plated for *Candida auris* on Sabouraud or Candida chromogenic agar using standard laboratory procedures and presence of *Candida auris* and its susceptibility to polyenes (amphotericin B) should be confirmed using standard laboratory procedures.

Other clinically indicated samples for PICnIC (taken as part of routine care and/or additional consented samples) will be processed as per routine local protocols.

Routine Clinical Reporting of Results

Sampling information and results should be reported using the associated CRF in Section 8: Case Report Forms, of the ISF.

We also ask that the day of the study that the samples were collected are identified on the request form by the research nurse or clinical team.

Cost and invoicing

The study will pay at an agreed rate per patient recruited, see separate CTSA and SOP 013: Research costs.