

1. Background

Hospital based surveillance of Acute Febrile Illness in India is a research project with a primary objective to determine the incidence and frequency of aetiologies of acute febrile illness in the age group of 1 to 65 years in selected hospital study site throughout India. The study site will act as a primary data collection & clinical specimen collection centre.

2. Purpose of this SOP

This Standard Operating Procedure (SOP) has been developed to guide the AFI study staffs to identify cases of acute febrile illness at the project study sites.

3. Responsible Personnel

- This SOP applies to all **AFI Study Site staffs** who are responsible for identifying the AFI cases at the study sites.
- **Research Assistants & Study Laboratory Technicians/Study Nurses** are responsible for coordinating with the hospital staff & doctors for identifying the eligible AFI cases for the study.
- **Study Managers** are responsible for guiding the AFI study site staff in identification of AFI cases.

4. Case Definition:

Any patient older than 1 year and younger than or equal to 65 years of age admitted to one of the study site hospital with measured temperature of $>38^{\circ}\text{C}$ or recorded fever at the time of admission is considered as Acute Febrile Illness case in this study.

5. Guidelines:

- 5.1. Based on the suggestions given by the Treating physicians / hospital staffs, a convenient method is followed for identifying the AFI cases. The adopted method should be widely accepted by the hospital staffs without affecting their daily activities.
- 5.2. Different protocols are followed at different AFI study sites for AFI case identification.

For eg:- In Thirthahalli, the treating physician identifies the case and writes in the patient case sheet as "KMC Blood test" or "Inform KMC." AFI staffs will review the patient case sheet for eligibility. If the patient fits in our eligibility criteria, he is recruited. If not, he is recruited as an OP case using the MCVR's routine case investigation form.

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- 5.3. The Study Laboratory Technician/Study Nurse and Research Assistant at all the study site should visit the wards (Male ward, Female ward & Paediatric ward) every day in the morning, during and after the OPD hours or as frequent as possible to identify any AFI case admissions in the ward.
- 5.4. The study laboratory technician / Study Nurse should confirm whether the fever case admitted fits into the inclusion criteria of the study in consultation with the treating physician / hospital staffs.
(Inclusion Criteria: Patient should be in the age group of 1 to 65 years. Patient should present with fever (temp - >38 °C) for less than 14 days. Patient should be admitted in the hospital)
- 5.5. The study laboratory technician / Study Nurse should consider exclusion criteria while identifying the AFI cases.
(Exclusion Criteria: Patients with non- infectious known aetiology which includes trauma, toxic exposure & known malignancy or immune-compromised status. Patient unable to provide inform consent/assent and without a legally authorized representative available)
- 5.6. The study laboratory technician / Study Nurse should be able to identify all AFI cases referred by treating physicians of the hospital after their rounds.
- 5.7. AFI cases admitted during the night hours can be identified by collecting information from IP register of the hospital on the next day.
- 5.8. The study technician / Study Nurse should keep the record of daily fever case admissions in the hospital wards and identify the AFI cases as per the inclusion criteria of the study

6. Procedure

- 6.1. Once the case is identified, the study is briefly explained to the patient and the bystander. All questions and doubts regarding the study from the patient should be clearly answered. Following this, if the patient is willing to participate, the informed consent is obtained, if the patient above 17 years of age. If the patient is of 7 – 17 years of age, ascent from the patient and consent from the guardian is obtained. If the patient is below 7 years of age, only consent is obtained from the guardian.
- 6.2. The questionnaire in the case report form should be administered. The demographical, clinical history and epidemiological details of the patient should be asked and recorded as accurately as possible.

Refer the AFI Study case report form – interviewer’s guide (Document code: MCVR/CDC/CRF GUIDE) for the detailed information on case recruitment.

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