



The AMR Diagnostics Use Accelerator – ICMR/FIND Call for Partners (CFP)

"Diagnostic tools to improve targeted antibiotic treatment of
undifferentiated acute febrile illnesses in children and adolescents
presenting in outpatient clinics in India"

Indian Council for Medical Research (ICMR) and FIND are jointly soliciting submissions from institutions interested in a demonstration project aimed at improving care of children and adolescents presenting with undiagnosed acute febrile illness in outpatient clinics.

A competitive selection process will be used to identify partners based on the suitability of the institutional capacity and the proposed study team (clinician and social scientist) for the study. The study protocol will then be jointly developed by ICMR, FIND and the selected institutions in collaboration with the UNICEF/UNDP/World Bank/ World Health Organization Special Programme for Research and Training in Tropical Diseases (TDR).

THE DIAGNOSTICS USE ACCELERATOR

The demonstration project for which partners are sought is part of the AMR Diagnostics Use Accelerator. FIND launched the AMR Diagnostics Use Accelerator as a platform to find adapted, practical solutions for low- and middle-income countries (LMICs) to tackle the problem of antimicrobial resistance and to provide better healthcare to people presenting in health facilities with an acute febrile illness.

Irrational antibiotic prescribing practices contribute to both antimicrobial resistance (AMR) and ineffective management of febrile illnesses, generating avoidable morbidity and mortality. Improving this situation requires appropriate diagnostics and reliable algorithms to help the healthcare provider establish the correct diagnosis and prescribe the appropriate treatment, along with changes to prescriber's and patient's behaviour.

While development of new diagnostics is ongoing, there remains no clear path to deployment once they have been developed. This demonstration platform therefore aims to study 'how to' introduce new diagnostics and practices and remove/modify those that do not work. For the studies to be conducted within this call, currently available tools will be used as initials example to prepare for new diagnostics to be included as they become available. The AMR Diagnostics Use Accelerator will furthermore support studies to generate evidence that will inform the design and implementation of effective behavioural change interventions. The ultimate objective of the platform is to provide evidence to inform improved policies and practice that pair diagnostic tools, clinical algorithms and strategies towards social and behaviour changes in order to inform country policy with a focus on combatting AMR.

GENERAL INFORMATION ON THE CALL

Organised jointly by ICMR and FIND, this AMR Diagnostics Use Accelerator Call for Partners (CFP) is meant to stimulate studies to investigate the effect of innovative clinical algorithms using existing diagnostic tools and to inform research into the design and implementation of effective behavioural change interventions.

The lessons learnt from these studies can inform rapid evaluation and incorporation into decision making algorithms of new diagnostic tools as they become available.

Two to three awards of up to 200,000 USD each, will be offered with an expectation that studies will start by 3rd quarter 2019, and that final results will be reported no later than 15 January 2021.

Applications will be screened based on the site eligibility to participate in the study. The final study protocol will be developed jointly between ICMR, FIND and the participating sites in collaboration with WHO TDR.





Study design and site selection will be guided by the need to ensure the generated body of evidence informs national and international policy and the use of diagnostic tools.

Objectives. The overall objectives are

(1) to study how adding commercially-available, point-of-care (POC) diagnostics into clinical algorithms used in an outpatient setting (outpatient clinics or peripheral health centres)can improve care while reducing inappropriate use of antibiotics in children and adolescents with undifferentiated acute fever and (2) establish the basis for effective behaviour change activities and interventions.

The overarching goal is to use the information generated by these studies to support evidence-based policy changes that will improve acute syndromic febrile disease management and antibiotic stewardship. The specific objectives are to:

- 1. Demonstrate improved appropriate antibiotic treatment of children and adolescents presenting with undifferentiated acute febrile illness in outpatient clinics with the incorporation of point-of-care tests and decision-aid tools.
- 2. Quantify the impact of implementing diagnostic tools on outcomes and on antibiotic prescriptions in children and adolescents with acute febrile illness.
- 3. Generate evidence on individual's current behavioural intentions and practices, his/her own abilities to undertake the potential behaviour change (i.e. values, attitudes and knowledge, habits and behavioural norms, self-perception and capacity for sustaining change of behaviour, and expectations of success or failure before embarking on a change activity) and external environmental factors (e.g. socioeconomic standing, regulatory environment, access to media and advertising campaigns, community and peer expectations) associated with antibiotic prescription and consumption among caregivers, healthcare providers and users.
- 4. Strengthen diagnostic implementation research capacity to accelerate pathways for uptake of new diagnostics and improved clinical decision-making.

PROJECT SPECIFICS

- Setting: Outpatient departments (e.g. primary health care units or outpatient clinics in hospitals; possibly also pharmacies)
- Patient Population: Children and adolescents with undifferentiated acute febrile illnesses. Prolonged fever of unknown origin is not part of this call.
- Diagnostics in scope: Commercially-available point-of-care diagnostics with existing regulatory approval for use in India, including, but not limited to:
 - o Simple haematology (e.g. WBC differential counts, haemoglobin);
 - Biomarker-based tests such as CRP;
 - Locally-relevant pathogen-specific tests (such as malaria, dengue, influenza, StrepA, scrub typhus, enteric fever) and;
 - Other applicable tests (such as oximetry).

The studies will use only Drug Controller General of India (DCGI) approved commercially-available diagnostics. Proposals which focus on the development, evaluation or validation of new diagnostics are outside the scope of this call.

- Decision aid tools in scope: IMCI based or otherwise validated electronic or paper-based algorithms.
- Social Science approach in scope: research methodologies to explore perceptions and patterns of antibiotic prescription and use among caregivers and healthcare providers, as well as barriers to appropriate prescription and use. Evidence-based social and behavioural change (SBCC) strategy, implementation and communication plan.
- Time frame: 18 months (details in timeline section)





ELIGIBILITY

Only those organisations and institutions (both government and non-government) with a valid FCRA registration are eligible to apply.

INFORMATION TO BE INCLUDED IN THE EXPRESSION OF INTEREST

Applicants must provide:

- 1. Evidence of FCRA registration.
- 2. Evidence of access to outpatient departments (e.g., primary health care units or in hospitals).
- 3. Provide basic information

Related to the intervention:

- a. description of which potential intervention points are expected to be the most successful at ensuring the right patients are getting antibiotics including which outpatient setting will be targeted
- b. outline of patient seeking pathways for fever in outpatient settings in the proposed setting,
- c. number of children and adolescents with acute undifferentiated febrile illness presenting within the proposed setting

Related to the setting:

- a. the type of setting, describing the facility, staffing, laboratory support, as well as information on the current standard of care, case-management and prescribing practices, including routine use of diagnostics and diagnostic algorithms in particular with regards to the IMCI guidelines or adaptations thereof
- b. data on current/past usage of antibiotics in febrile patients at the proposed setting (e.g. last two years),
- c. information, if available, on AMR incidence rates for available antibiotics and the drug susceptibility testing method used at the setting.
- d. information on laboratory capacity and facility policy on drug susceptibility testing and presence of surveillance networks collecting this information.

Related to the clinical investigation team and research infrastructure:

- a. applicant's previous experience in clinical research, including but not limited to research related to antimicrobial resistance and/or user's and prescriber's behaviours
- b. applicant's experience with mechanisms in place for the approval of research projects, including ethics review boards and administrative procedures at the local and national levels
- c. information on experience of other investigative team members or partners
- d. any other information deemed relevant by the applicant to demonstrate the competence and suitability of the applicant should be included in the expression of interest

Related to the social science investigation team and research experience

- a. applicant's (or collaborator/co-applicant) previous experience with research related to design and implementation of behavioural change frameworks and strategies.
- b. applicant's (or collaborator/co-applicant) expertise and experience on social science and behavioural science research projects.
- c. applicant's (or collaborator/co-applicant) training in designing behaviour change approaches.
- d. any other information deemed relevant by the applicant of the social science researcher to demonstrate the competence and suitability of the applicant should be included as part of the expression of interest





TIMELINES

- Kindly submit full proposals in the given format to icmrdx@gmail.com by 5 April 2019
- A joint ICMR-FIND selection committee will review all applications
- Selected participants will be notified by 22 April 2019
- Joint study protocol development (between with the selected sites, ICMR and FIND in collaboration with WHO TDR) will occur April -July 2019
- Study approvals (administrative, ethical and any others) are required by no later than 15 September 2019.
- Patient enrollment to start by 15 October 2019 be completed by 15 October 2020
- Financial reports are due every 6 months with a final financial report due by 15 December 2020
- Final technical report due by 15 January 2021