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INDIAN COUNCIL OF MEDICAL RESEARCH
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INVITATION FOR SUBMITTING LETTER OF INTENT FOR ESTABLISHMENT OF HOSPITAL-BASED STIs SURVEILLANCE NETWORK IN INDIA

Background

The 21st Century witnessed a global resurgence of sextually transmitted infections (STIs). The incremental rates of over 1 million new cases of gonorrhea, syphilis, and Chlamydia infections were recorded in high-income countries and low-income countries as well. Moreover, the increase in antimicrobial resistance has heightened concern. The factors contributing to the sustained transmission of STIs within a population are multiple, complex, and context-specific. They include the probability of transmission, the rate of change in sextual patterns, and the duration of infectiousnes. Furthermore, the example of factors, are unprecedented connectivity between persons facilitated by global travel and online social networking, and increased use of preexposure prophylaxis against human immunodeficiency virus (HIV) infection are some of their facilitators. Furthermore, though the STI cases are widely evidenced in India, systematic epidemiological studies to determine their exact prevalence are yet not available. The World Health Organization (WHO) set targets for a 90% reduction in the incidence of syphilis and gonorrhea between 2018 and 2030. There is an utmost need for data on clinical signs & symptoms, laboratory investigations, management protocols, the clinical course of STI diseases, disease spectrum, and outcomes of patients. The data will serve as an invaluable tool in predicting the burden of the disease existing in our society. In view of this, the Indian Council of Medical Research (ICMR) proposed to launch the program. To establish a Hospital-based Surveillance Network of STI clinics including Govt. Healthcare institutions, DSRCs, and Private hospitals/clinics for data collection and to document the patterns of various etiologies of STIs, analyzing the trends, and to see AMR patterns among identified STIs in India. In view of this, ICMR invites a letter of intent from the institutions/hospitals; clinics dedicated to STI in pan India.

Objectives

Primary

To study the frequency, clinical laboratory features, antimicrobial resistance patterns (AMR) and treatment outcome related to STIs in the population along with the establishment of National hospital-based surveillance network.

Secondary

1. To utilize the data to answer the research questions on STIs including,
   - Disease spectrum
   - Prognostic factors
   - Risk Factors
   - Outcome data- Medications, treatments, health systems
   - Current AMR patterns
2. To serve as a platform for additional clinical research and advanced AI-based studies in selected sites.
3. To collect follow up data of the patients, if possible

Methodology

The study provides prospective data collection from the dedicated hospitals/clinics in centers among six regions, East, West, North, South, Central, and North East. The duration of the study will be 3 years. Collection of data on trends and patterns of etiologies of various STIs and to document AMR patterns, will be important parameters in the study. Data entry of clinical and laboratory parameters as well as patient management will be filled in a designed structure format on an electronic platform by participating sites pan India. Furthermore, the data will be stored in the central server/cloud and analysis will be done by a team of experts, scientists, at ICMR. The data will be used to generate hypotheses related to STI disease and the repository platform will be utilized in the future for further research studies. The data entered by the individual sites will be accessible to them on the central server. Moreover, the data will be shared periodically with all the sites.

Outcomes

The outcome of the study:

- To generate reports and interpretations to be released on the ICMR website
- To formulate patient management and rapid diagnostic protocols and develop a policy for decision making
- To understand the disease severity, and optimize the protocol accordingly
- To understand the variations, symptoms, and spectrum of the disease in India
- To generate content specific research (STI, venereal disease)
- To publish the findings (data) periodically in peer-reviewed journals.
- To make rapid, accurate, and evidence-based decisions on importing the various tools in diagnosing STI patients.
- To develop a database for STI diseases which serve purpose to support in policy development.

The designated and dedicated hospitals/ clinics will serve as primary sites for the data collection. These sites will be monitored and mentored periodically.

Eligibility/ Prerequisite

- ✓ Institutes should have facilities for diagnosis and treatment of STI patients.

- ✓ The institute should have trained and qualified doctors, microbiologists, and technicians specialized in STIs
- ✓ The Hospital/ Clinic should have the facility of RT PCR, the infrastructure of performing the Anti Microbial Resistance study. They should have a facility for the treatment of venereal diseases.
- ✓ The institute should perform Antiretroviral therapy treatment regarding the problem
- ✓ The institutes shall be willing to become a part of network of tertiary and secondary care hospital databases related to STI. It would help to develop a comprehensive clinical and Demographic profile for STI and venereal disease.
- ✓ The application shall be endorsed by head of the institution.
- ✓ The working group of members from the institute should be multidisciplinary with a balanced inclusivity and participation. The team shall comprise people from disciplines ranging from microbiology, skin and venereal disease specialists, public health and community medicine practitioners, pathology, obstretics and gyneacology medical doctors, and so on, but not limited to these disciplines.
- ✓ Preferably, medical superintendent or deputy superintendent shall be willing to provide their guidance for carrying out the work.
- ✓ Expert groups will shortlist the potential network partners. The selected centers may be invited to submit a subsequent standard grant application form which the Expert committee will make the final recommendations. The competent authority would give the final approval at ICMR as per rule

Satellite Sites Will Be Selected Based On The Following Criteria

Site Location

- ➢ Sites/Institutes/Hospitals will be selected from each zone of India (East, West, North, South, North East, and Central,) to ensure adequate representation of all the zones.
- ➢ The site selection methodology will ensure diversity and adequate representation of all States and Union Territories as well.

Site Infrastructure

- ➢ Institutes involved in diagnosis and treatment of STIs patient are mandatory.
- ➢ Sites with in-house serology and microbiology units are mandatory.
- ➢ Sites with STIs clinics are mandatory.
- ➢ Presence of infrastructural support related to clinical laboratory and IT are mandatory.

Human resource engagement

- ➢ Sites capable of recruiting trained and qualified person(s) is mandatory.

Investigator's experience

- ➢ Clinicians who are directly involved in STI patient care management.

The Process Followed After Receiving The Letter of Intent

After receiving the application ICMR will conduct reviews on a competitive basis by a panel of experts. Furthermore, the below-mentioned steps will be followed:

i. Short listing of Letters of Intent by an expert review panel

The expert review panels will shortlist the Letters of Intent-based on a set of pre-defined review criteria. If the number of Letters of Intent received is large, the panel will divide into two sub-panels, each sub-panel with five experts.

ii. Selection of proposals for funding by an Administrative & Technical review panel

The proposals will be assessed by the Administrative and technical review panel at a meeting organized by the ICMR. Each proposal will have two primary reviewers from within the panel. Reviewers will be asked to provide detailed written comments to the panel. The final selection of proposals will be a ranking system developed by the panel.

iii. Technical support and monitoring

The selected proposals will be managed by ICMR, based on the primary area of focus of the proposal and staff availability. However, given that preference will be given to cross-cutting proposals, the management team will include staff members from two or more Departments. The external review panel will review technical and financial reports of all funded proposals yearly.

iv. Release of sanction letter

After the selection, a sanction letter shall be sent to the institutes.

Initiation of preparatory Training and development program

1. All selected institutes will recruit the staff and they should start training regarding STI.

2. The training will be conducted for the data collection simultaneously. ICMR Project Management Unit (PMU) will develop an online dashboard for data recording.

How to Apply

Interested investigators/scientists/clinical researchers working on recognizing R & D institutions can submit the LoI through email on **drsumit.ecd@gmail.com**. Correspondence on the mentioned email id shall also be made in case of any queries or clarifications.

One hard copy along with a soft copy of the same should be sent to the following address:
Administrative Officer,
ECD-II Division,
V. Ramalingaswami Building, Indian Council of Medical Research
New Delhi- 110029
The cover/subject of the LOI shall bear the Advertisement No. and Title "Call for Letter of Intent for establishment of hospital-based STI surveillance network in india".

The soft copy and hardy copy shall reach latest by 10th June 2022 till 5pm.

Note: The application must be endorsed by the Head of the Institute

Proforma

The PI should prepare the proforma and the letter of intent in the format provided below with all the information as required.

1.	Name:
2.	Designation of PI & Co-PI:
3.	Details of PI & Co-PI (include any involvement in the Extramural project for Research)
4.	Names(s), Institute address, Contact numbers, a brief CV of the identified experts/ the Investigator(s) from Doctors, Microbiologist, Pathology, Serologist (A one page CV of the investigators)
5.	Publications of PI and Co-PI (5/10 most publication related to STI) (if Any)
6.	Role & Responsibility of PI and Co-PI
7.	Team Composition:
8.	Type of Institute (Govt. Hospitals/Medical College/ Pvt. Hospitals and Multispeciality/ Research and Diagnostics /Designated STI &RTI Clinic):
9.	Accreditation of the Centre (NACO/NABL) if yes, provide the necessary documents
10.	Does the Institute have DSIR valid certification if yes, please provide the documents
11.	Broad area of working and strength of the institution: (100 words)
12.	Details of the institute about their background and achievements (Yearly count of STI patients): (250 words)
13.	Institutional capacity in the terms of Infrastructure, (STI) patient load, Basic science lab, Clinical facility & Digital Database management, etc.
14.	Does the Institute have in house ethical board or committee/ or any attachment with the external Institute ethics committee
15.	The feasibility of doing the study in your present institution/workplace (100 words)
16	Justification of the study, including a logic model, a very brief summary of the related work of the literature, and an assessment of the feasibility of the proposed activity, Timetable, and Budget
17.	Any course symposium or training conducted
18.	Explain why do you want to involve in this program
19.	How you will contribute to this program?

Financial and technical support

All the Institutions involved in this study will be supported by the Indian Council of Medical Research (ICMR), New Delhi based on the criteria like Infrastructure, facilities, manpower, and skilled and qualified doctors and technicians. Moreover, a uniform budget will be prepared for the sites (hospitals, clinics, etc.).

Terms of Reference (TOR)

1. The applying Institution should have facility for management of STI patients at routine basis.
2. The Institute will be bound to provide all the data related to STI as per study protocol.
3. The institute should have an institutional ethics review board or associated to an ethical committee panel.
4. If selected, the institute should adhere to the timelines for implementation of the study as per the protocol.
5. If selected, the institutes should provide all the documents for codal formalities and have a valid DSIR certificate.
6. ICMR will have a memorandum of understanding (MoU) with participating institutes upon selection.
7. ICMR will have all the Intellectual Property Rights (IPR) to collect, analyze, interpret and publish the data generated from all the sites of the network.
8. ICMR will have the right to review and provide suggestions or modifications of the protocol at any point in time.
9. The initial period of this activity shall be for 3 years, however, ICMR may discontinue this call without assigning any reason to the Institute, if required.