Operational Guidelines

Regional STI Training, Research and Reference Laboratories

February 2014

Department of AIDS Control

Ministry of Health & Family Welfare, Government of India

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सत्यमेव जयते

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भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
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FOREWORD

The National AIDS Control Organization (NACO) was set up in 1992 to halt and reverse the spread of HIV infection in the country. The National AIDS Control Programme (NACP) sets out objectives and guiding principles for a phased programmatic intervention. While the focus remained on checking the spread of the disease, successive phases of the NACP expanded strategies to include behavior change, increased decentralization by setting up of State AIDS Control Societies, NGO involvement, a national blood policy, anti-retroviral treatment, community mobilization and evidence based planning.

The objectives of NACP IV are reduction in new infections by 50% taking 2007 as the base and comprehensive care support and treatment to all persons living with HIV. Various strategies have been developed to achieve these objectives, which includes strengthening institutional capacities. In this context, development of standardized guidelines is an important activity to achieve optimal results from centers/institutions located in different geographical areas.

The operational guidelines for the Regional STI Training, Research and Reference Laboratories, along with its companion volume of Standard Operating Procedures, will be a useful resource for standardizing services across these laboratories situated in different regions of the country. My congratulations to Dr. S D Khaparde, DDG, the STI team at DAC and other organizations who contributed to the development of the guidelines.

LOV VERMA

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PREFACE

Sexually Transmitted Infections (STIs) and Reproductive Tract Infections (RTIs) are among the top ten reasons for health care visits in developing countries. Untreated or incompletely treated STI may result in serious long-term complications such as infertility, genital cancers and adverse pregnancy outcomes including stillbirths. Additionally, STIs are important co-factors for the acquisition and transmission of HIV infection. Laboratory tests for STIs/RTIs are important to improve clinical management and enable better program planning through routine and periodic studies.

Five Regional STI Training, Research and Reference Laboratories (RSTRRL) were established in the early 80's under the National STI/RTI control programme; in 2009 these were increased to seven for providing evidence based inputs to the STI/RTI control programme by conducting high quality etiologic testing, gonococcal antimicrobial susceptibility monitoring, external quality assurance for syphilis testing, operations research, training, capacity building and other research activities for improving the quality of STI/RTI service delivery. In addition, 45 State Reference Centres (SRCs) laboratories have also been recently inducted in the programme.

The operational guidelines have been developed to provide practical guidance to the staff of RSTRRL and SRC. The document describes the roles and responsibilities of the centres, job descriptions of key personnel, infrastructure requirements, equipment maintenance, quality assurance systems, bio-safety including infection control, recording and reporting requirements and research activities. I wish to express sincere thanks to all my colleagues who have drafted and reviewed the guidelines. I am sure that the document will help the RSTRRLs and SRCs to discharge their duties better.

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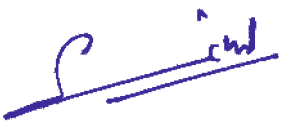
Laboratory services for Sexually Transmitted Infections (STIs) and Reproductive Tract Infections (RTIs) are essential for improving clinical management and to enable better programme planning. As an integral part of the programme implementation, Department of AIDS Control (DAC) has coordinated the preparation of operational guidelines for Regional STI Training, Research and Reference Laboratories. It is commendable to note that a comprehensive document has been produced with the coordinated and concerted efforts of various organizations and individuals. A list of contributors is given elsewhere in the document. My heartfelt thanks to all for their expertise and time.

The vision and constant encouragement of Shri Lov Verma, IAS, Secretary, Department of AIDS Control and Ms. Aradhna Johri, IAS, former Additional Secretary, Department of AIDS Control have greatly helped in undertaking this important activity. A special thanks to Dr. Shobini Rajan, Dr. T.L.N. Prasad and Dr. Aman Singh, STI Division, DAC and other team members for their constant effort and hard work in providing direction for the guidelines. I would like to acknowledge the group of national experts who jointly reviewed the technical contents of this manual along with the STI division, DAC. I express my sincere thanks to Dr. A. R. Risbud and Dr. Manju Bala for their invaluable contribution towards technical review and providing inspired leadership.

My sincere thanks to the Centers for Disease Control and Prevention-Division of Global HIV/AIDS (CDC-DGHA), India and FHI 360 for providing technical assistance and support in the compilation of this document



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Glossary

AD	Assistant Director
AIDS	Acquired Immunodeficiency Syndrome
BV	Bacterial vaginosis
CDC	Centers for Disease Control and Prevention
CHC	Community Health Centre
CIMS	Computerized Information Management System
CM	Community Medicine
CT	Chlamydia trachomatis
DAC	Department of AIDS Control
DD	Deputy Director
DFA	Direct Fluorescent Antibody
DSRC	Designated STI/RTI Clinic
DVL	Department of Dermatology, Venereology & Leprology
ELISA	Enzyme Linked Immuno Sorbent Assay
EQA	External Quality Assurance/ External Quality Assessment
FEFO	First Expiry First Out
FSW	Female Sex Worker
FTA-Abs	Fluorescent Treponema Antibody Absorption Test
GASP	Gonococcal Antimicrobial Surveillance Programme
GUD	Genital Ulcer Disease
HIV	Human Immunodeficiency Virus
HRG	High Risk Group
HSV	Herpes Simplex Virus
IBBA	Integrated Behavioural and Biological Assessment
IBBS	Integrated Biological and Behavioural Surveillance
ICMR	Indian Council of Medical Research
IEC	Information, Education, Communication
KOH	Potassium Hydroxide
MARP	Most At Risk Population
MOI/C	Medical Officer In-Charge
MSM	Men who have Sex with Men
NABL	National Accreditation Board for Testing and Calibration Laboratories
NAAT	Nucleic Acid Amplification Test
NACO	National AIDS Control Organization
NACP	National AIDS Control Programme
NG	Neisseria gonorrhoeae
NRHM	National Rural Health Mission
OBGYN	Obstetrics/ Gynaecology
OR	Operations Research

PCR	Polymerase Chain Reaction
PHC	Primary Health Centre
PO	Program Officer
POC	Point of Care Testing
PP	Preferred Provider
PSM	Preventive and Social Medicine
QC	Quality Control
RPR	Rapid Plasma Reagin
RSTRRL	Regional STI Training, Research and Reference Laboratory
RTI	Reproductive Tract Infections
SACS	State AIDS Control Society
SEARO	South East Asia Regional Office
SIMS	Strategic Information Management System
SOP	Standard Operating Procedure
SRC	State Reference Centre
STI	Sexually Transmitted Infections
TI	Targeted Interventions
TPHA	*Treponema pallidum* Haemagglutination test
UD	Urethral Discharge
VDRL	Venereal Disease Research Laboratory

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Background

Sexually transmitted infections (STI)/ Reproductive tract infections (RTI) rank among the top five conditions for which sexually active adults seek health care in developing countries[1]. A review of recent STI/RTI related literature from India showed a marked heterogeneity in the epidemiology of different STI/RTI in the country[2]. A community-based STI prevalence study conducted in India in 2003 showed a 6% prevalence of STI/RTI among adult population[3]. Untreated or incompletely treated STI/ RTI among women may lead to serious complications and sequelae such as infertility, foetal wastage, ectopic pregnancy, ano-genital cancer, and congenital infections in the newborn. The correlation among STI/ RTI and HIV is also well-established[4 5].

STI/ RTI prevention, control and surveillance are important components of the National AIDS Control Programme (NACP). The technical guidelines for STI/ RTI management advocate syndromic management at all facilities providing STI/ RTI services, in addition to utilizing minimal laboratory tests at sites where there are laboratory facilities available without compromising the timely treatment of patients. However, syndromic management needs to be validated periodically by etiological tests; antimicrobial susceptibility of gonorrhoea, which is of global concern, needs to be monitored on a regular basis; and on-going STI/ RTI studies including periodic prevalence among at-risk populations are essential to provide inputs for improved STI/ RTI services.

Five Regional STI Training, Research and Reference Laboratories were established in the early 80's under the National STI control programme; in 2009 these were increased to seven centres for providing evidence based inputs to the STI/RTI control programme by conducting high quality etiologic testing for STI/ RTI, gonococcal antimicrobial susceptibility testing, external quality assurance (EQA) for syphilis, operations research, training, capacity building and other research activities for improving the quality of STI/RTI service delivery.

One of the regional centres (laboratories), located at the Vardhman Mahavir Medical College and Safdarjung Hospital at Delhi has been designated as the **apex centre** (laboratory). The regional centres are located in the department of Microbiology/ Dermatology, Venereology and Leprology (DVL) of large medical colleges and function with coordination between the departments of microbiology, DVL, obstetrics and gynaecology (OBGYN) and Community Medicine. The nodal officers from the different departments meet regularly to review the activities of the regional centre and report to the concerned State AIDS Control Society (SACS) on the programme progress. The laboratory established at the regional centre (hereafter referred to as the regional laboratory) provides services to the linked departments of STI and OBGYN, Targeted Intervention projects, private sector and NRHM facilities, and also receives samples from the State Reference Centres (SRCs).

Chapter 1

The operational guidelines have been developed to provide practical guidance to the staff of Regional STI Training, Research and Reference Laboratories and SRCs. The document describes the roles and responsibilities of the Regional STI Training, Research and Reference Laboratories, job descriptions of key personnel, infrastructure requirements, equipment maintenance, quality assurance systems, bio-safety including infection control, recording and reporting requirements and research activities. The Regional STI Training, Research and Reference Laboratories are provided with regular technical support and supportive supervision by the Department of AIDS Control (DAC), apex centre and SACS; additional support is provided through external consultants designated by DAC, further details are given in the document.

1 WHO.Global Prevalence and Incidence of Selected Curable Sexually Transmitted Infections.Geneva, Switzerland 2001. http://whqlibdoc.who.int/hq/2001/WHO_HIV_AIDS_2001.02.pdf

2 National AIDS Control Organization. Report on Mid-Term Review of Sexually Transmitted Infection Services. New Delhi, India. Department of AIDS Control, Ministry of Health & Family Welfare, Government of India. December 2009. http://www.DAConline.org/DAC/Quick_Links/Publication/STIRTI_Services/Other_STI_Materials/STI_RTI_MONOGRAPH__NACP-III/

3 National AIDS Control Organization. Community based survey on the prevalence of sexually transmitted diseases in urban and rural areas of India. India 2003. Unpublished report

4 Laga M, Manoka A, Kivuvu M, et al. Non-ulcerative sexually transmitted diseases as risk factors for HIV-1 transmission in women: results from a cohort study. AIDS 1993; 7:95-102.

5 Freeman EE, Orroth K, White R, et al. The proportion of new HIV infections attributable to HSV- 2 increases over time: simulations of the changing role of sexually transmitted infections in sub-Saharan African HIV epidemics. Sex Transm Infect 2007; 83(Suppl 1):i17-i24.

Roles and Responsibilities of Regional STI Training, Research and Reference Laboratories

Under the STI/ RTI control programme, seven Regional STI Training, Research and Reference Laboratories (RSTRRL) were established across the country with the objective of providing evidence based inputs and direction to the STI/RTI prevention and control programme through high quality etiological testing of STI/RTI.

The seven regional centres are located in –

1. Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi
2. Maulana Azad Medical College & Lok Nayak Hospital, New Delhi
3. Medical College Baroda & Sir Sayajirao General Hospital, Vadodara
4. Government Medical College& Hospital, Na gpur
5. Institute of Venereology, Madras Medical College, Chennai
6. Osmania Medical College& Osmania General Hospital, Hyderabad
7. Institute of Serology & Kolkata Medical College, Kolkata

The RSTRRL acts as the nodal agency for providing etiological diagnosis of routine and treatment failure cases of various syndromes diagnosed in the region. Each of the RSTRRLs is linked to State Reference Centres (SRC) **(Annexure I)**; they are further linked to Designated STI/RTI Clinics (DSRC), Targeted Intervention projects and NRHM health facilities.

The core functions of the Regional STI Training, Research and Reference Laboratories are described below **(Annexure II)**.

1. Laboratory testing and linkages with peripheral facilities

1.1 Etiological testing: The regional centres will conduct etiological tests for bacterial, viral, parasitic and fungal STI/ RTI for (a) validation of syndromic diagnosis and (b) STI/ RTI cases not responding to syndromic management, (c) recurrent STI/ RTI (d) treatment failure cases. The tests to be carried out at the centres are detailed in **Annexure III A, B.** The centres will use VDRL test for syphilis screening and TPHA for confirmation. Other test like FTA- Abs is optional. Wherever PCR facility is available, multiplex PCR testing for gonorrhoea and chlamydia is desirable.

1.2 Gonococcal antimicrobial susceptibility monitoring: In addition, they will also perform routine monitoring of gonococcal antimicrobial sensitivity and provide timely technical

support to the sites concerned and the national programme for modifying treatment protocols if required; and establish linkages with WHO/ SEARO Gonococcal Antimicrobial Surveillance Programme (GASP).

1.3 Linkages with STI/ RTI facilities: Tests will be performed on samples received from the STI/ RTI facilities (DSRCs, other OPDs, TI-STI clinics [static or preferred provider clinics (PP clinics)], PHC/CHC, and SRCs). It will establish linkages with these facilities for receiving samples from these sites on all working days; if not feasible on all days, fixed days/ periodicity should be determined to avoid biases in data collection. It is however emphasized that all efforts should be made to maximise swab collection of cases of urethral discharge syndrome for gonococcal culture and antimicrobial susceptibility, as this is a priority both nationally and globally.

1.4 Specimen collection, storage and transportation: The regional centre is responsible for training the health care providers at the sites [mentioned in 1.3] for sample collection, storage, transportation and providing them with the necessary equipment and supplies. The samples should be sent to the regional laboratory, preferably on the same day, following the standard procedures as detailed in STI diagnostics standard operating procedures (SOP). Serum for RPR testing sent from the periphery that cannot be transported on the same day should be stored in a refrigerator until transportation to the linked RSTRRL. The concerned SACS will assist the peripheral sites in transportation of the samples. The cost for transportation of samples should be met from the RSTRRL budget.

The regional laboratory should, in general, aim for a workload of minimum 100 samples for testing per working day.

1.5 Recording and reporting of data: A robust reporting system will require quality data collection, recording and feedback of vital information regarding laboratory results and epidemiological data. Further details are given in Chapter 9.

2. Training

The centres will design and conduct hands-on annual training for laboratory personnel at SRCs as well as linked designated STI/RTI clinics for etiological diagnosis of STI syndromes, gonococcal culture and sensitivity and syphilis EQA.

3. Technical support to SRCs:

The centres will periodically monitor the SRCs with special emphasis on gonococcal culture/sensitivity, syphilis EQA and validation of syndromic management. They will provide onsite mentoring to the SRCs through visits twice a year.

The regional laboratory will act as a referral laboratory for SRCs, designated STI/RTI clinics, TI-STI clinics, NRHM and private facilities, particularly for STI/ RTI cases not responding to syndromic management, individuals with recurrent STI/ RTI and cases where STI/RTI laboratory evaluation is required.

The centre will design strategies, protocols and SOPs for monitoring and assuring the quality of STI/ RTI diagnostics as spelt under the national guidelines. They will also provide necessary inputs in drafting relevant technical, operational guidelines and SOPs as and when required.

4. Conducting External Quality Assurance (EQA) for syphilis testing

4.1 Retesting of samples at SRCs:

Each of the facilities (microbiology labs and ICTCs attached to DSRCs at Medical Colleges and sub-district hospitals) should send **100%** of positive samples and **5%** of all negative samples of serum tested by RPR/VDRL at **six monthly** intervals to their linked SRC. The "blinded" or "coded" samples must be collected in the first week of **January and July** from the peripheral laboratories and transported to the SRC, ensuring proper cold chain maintenance **(Annexure IV A).** The SRC will send the report of concordance/ discordance within a week to the linked centres. The regional laboratories will monitor and provide technical support to the SRCs for setting up the EQA system.

4.2 Proficiency testing:

The laboratories will participate in proficiency testing programmes to assess and validate the reliability and quality of laboratory test results. Panel proficiency will supplement the laboratories' own internal quality control procedures by adding an external assessment of their testing competencies.

The **apex laboratory** will send panel sera for syphilis to the regional laboratories **biannually (second week of June and December)**. The regional laboratory will send the report of the sera, within 10 days, to the apex laboratory which in turn will send a feedback of the results within 7 days of receipt of the report.

In addition, the regional laboratory will prepare panel sera for EQA for syphilis testing at the SRCs. The laboratory will build up a system of long term storage of a serum bank for EQA (positive and negative sera) through blood banks, TI/STI clinics, following which they will send the panel sera to SRCs for panel proficiency testing.

The **regional laboratory** will send the samples ("blinded") in vials to the SRCs **once a year (second week of December)**, wrapped thoroughly in cotton absorbent material packed in plastic boxes, taking due biomedical precautions, as per the WHO shipping guidelines for

transportation of biological samples. SRCs will send the results within seven days to the regional laboratory. The regional laboratory will send the feedback of the results to the SRC within 10 days of receipt of the report **(Annexure IVB)**.

The apex laboratory will also participate in **national and international EQA** programme **twice a year (April and October)** and ensure proficiency of all the centres in implementing quality standards (for linked centres at SRC/ DSRC/ TI) in STI/RTI methods.

5. Surveillance of STIs

The role of the apex, regional and SRC laboratories in the national STI surveillance is described in Chapter 11. The activities would include collection, storage, transportation and high level testing (using PCR) of samples from the peripheral centres for prevalence studies in at-risk sub-populations and etiological testing of common STI/RTI syndromes.

6. Coordination with other departments

The regional laboratory is responsible for coordinating with all other clinical and para-clinical departments (Departments of DVL, OBGYN and PSM). The regional laboratory on their own initiative shall conduct periodic inter-departmental coordination meetings as required and document the same. These meetings would ideally be conducted at quarterly intervals.

The STI focal person/s at SACS in conjunction with the Technical Officer (formerly, Research Officer) at the regional laboratory, identified as the Nodal Officer for coordination, will organize meetings of the team members at least once in a quarter to review the performance of the centre; s/he will discuss issues pertaining to sample collection by health care providers, sample transportation to the regional laboratory, treatment failure as well as the general functioning of the centre related to the programme. The nodal officer from microbiology will send regular reports on the progress of the regional laboratory to the concerned SACS.

7. Research activities including operations research

The centres will design, participate and conduct periodic operations research/ participate in community based surveys and studies in consultation with SACS/ DAC to determine the prevalence of various STI/ RTI in the assigned states/ region. The centres will carry out other research to provide evidence based recommendations which would improve the quality of STI/RTI service delivery.

The centres will publish scientific/ research papers with due acknowledgement to SACS/ DAC.

8. Evaluate new diagnostic kits and techniques

The regional laboratories will evaluate new syphilis test kits (such as the rapid, point-of-care test kits) as well as other test kits with technical support from identified donors and ICMR nominated institutes. Based on the results, the regional laboratories will formulate recommendations for their inclusion in STI programme.

9. NABL accreditation:

All Regional STI Training, Research and Reference Laboratories should draft the road map to get NABL accreditation by the end of 2014-15 FY. The apex centre and mentoring subcommittee will provide necessary handholding support so that all centres will have NABL accreditation within the stipulated timelines **(Annexure V)**.

Personnel and Job Descriptions

The specialists (Microbiologist, Gynaecologist, Dermatologist and Community Medicine Specialist) and other personnel must have requisite technical expertise and aptitude to undertake etiological diagnosis of STI/ RTI and operations research using appropriate technologies. The functions of nodal officers can be broadly categorized into **clinical, administrative, coordination and research activities.**

The responsibilities of the Nodal officers are listed below:

Microbiology

1. To oversee the performance of test/s for etiological diagnosis conducted in regional laboratories
2. To prepare panel sera as per WHO recommendations for syphilis EQA and supply reference positive standards for practising day to day quality control to all peripheral laboratories in the network
3. To develop the capacities of staff of RSTRRL and SRCs in implementing operational aspects of testing
4. To adhere to the approved protocols & Standard Operating Procedures (SOPs) for External Quality Assurance (EQA) for syphilis and provide inputs whenever the protocols and SOPs are under revision
5. Monitor processes for STI testing services and ensure quality control standards at the centre
6. To provide supportive supervision and onsite mentoring to linked SRCs and ascertain adherence to SOP and quality assurance
7. To review stock management, distribution & maintenance of equipment, reagents and consumables for the laboratory following FEFO principle thereby ensuring neither stock out nor stock piling
8. To provide technical inputs on all laboratory related issues related to the programme
9. To co-ordinate with DAC and other participating institutes (along with SRCs) in research activities
10. To periodically disseminate the outcomes of STI etiological surveillance and syndromic validation with clinicians, SACS and community health nodal officers and suggest research priorities to SACS/ DAC and propose changes in the existing policies and strategies
11. To arrange quarterly review meeting with all faculties and SACS representatives to discuss programme progress
12. To act as overall in-charge of regional laboratory activities
13. To prepare for accreditation – preparation of SOPs, documentation procedures, to put in place a quality management system, calibration of equipment etc.
14. To arrange for regular and periodic training of Laboratory Technicians (LTs) and laboratory attendants in biomedical waste management and quality systems

Technical Officer

1. To work in close coordination with the microbiologist
2. To facilitate collection and processing of samples from all the designated places including DSRC, TI-STI clinics and other facilities
3. To facilitate and actively participate in Operational Research and any other research undertaken by the regional laboratory
4. To assist in community based surveys
5. To collect and compile STI/ RTI data and submit monthly CMIS/ SIMS report to STI division, DAC
6. To monitor and facilitate laboratory screening of a minimum of 50% of DSRCs (co-located with RSTRRL) attendees
7. To review the internal and external quality systems and appraise the microbiologist regarding the same
8. To provide support in collecting, collating and analyzing data and work closely with other faculties in research and studies conducted by the regional laboratory
9. To participate/assist in accreditation activities like documentation procedures, SOP designing, calibration of equipment and record keeping
10. To follow any other additional work relating to STI/RTI program assigned by the nodal officers

Lab Technicians

1. To collect and transport samples from OPD (Out Patient Department) as well as field and perform various laboratory tests outlined
2. To facilitate patient/ sample referral and sample processing at the centre
3. To maintain relevant laboratory records and prepare monthly reports and also maintain records of stock/supplies and investigations.
4. To ensure timely indents for chemicals, reagents and other necessary items
5. To ensure proper and safe storage of materials received
6. S/he will maintain equipment and glassware in serviceable condition and in case any repair or maintenance is needed, s/he will inform MO I/C well in time
7. S/he will efficiently organize laboratory services to reduce waiting time for patients and avoid sample exchange
8. S/he will maintain cleanliness in the laboratory and follow recommended safety procedures during all processes
9. S/he will strictly adhere to Hospital and Waste Management Guidelines
10. S/he will maintain necessary records of investigations done and prepare and submit monthly / weekly reports to MO I/C well in time
11. To adhere to internal and external quality procedures
12. To follow any other additional work relating to STI/RTI program assigned by nodal officer

DVL and Gynaecology (DSRC)

1. To ensure referral of at least 50% of attendees to the regional laboratory (for laboratory testing)
2. To provide treatment for STI/RTI as per national treatment protocols
3. To provide expertise for management of cases referred from peripheral centres as well as treatment failure cases
4. To provide supportive supervision and onsite mentoring to linked SRCs in association with Microbiologist /Community Medicine nodal officers and ascertain adherence to SOP and quality assurance
5. To actively participate and coordinate with Microbiologist and Community Health nodal officer to facilitate sample collection, transport, investigations, dispensing of reports, partner tracing and research
6. To hold trainings for medical and paramedical workers from time to time to educate them about their roles and familiarize them with the existing programme recommendations
7. To actively participate in quarterly review meetings
8. To participate in OR

Community Medicine

1. To collate, compile and analyze data available (monthly reports, records etc.) and provide direction to the team
2. To assist in conceptualizing, developing and conducting community based survey/ field epidemiological research to map the prevalence of various STIs in the region/ district/ state
3. To assist in conducting operational research and draft proposals for the same
4. To strengthen STI surveillance system and assist in data analysis and interpretation
5. To undertake strengthening of monitoring and evaluation systems
6. To provide inputs for policy formulation, strategic planning, epidemiologic investigations and analysis, evaluation to assure accomplishment of program objectives for the treatment, prevention, control and elimination of STIs
7. Community participation: To facilitate meaningful participation of most at risk populations (MARPs), NGOs and private sector
8. **IEC activities:** Effectively organize IEC activities relating to prevention and management of STIs
9. **Co-ordination:** Ensure participation in quarterly coordination meetings with other nodal officers and facilitate SACS review of the program

SACS

1. To release funds to regional laboratories and facilitate procurement of consumables/ instruments, annual maintenance of equipment and recruitment of staff for regional laboratories

2. To facilitate linkages between the SRCs and regional laboratories, DSRC, TI projects, private sector and NRHM facilities with RSTRRL and SRCs
3. To facilitate the training of staff at RSTRRL & SRCs
4. To provide linkage between designated STI/ RTI clinic and SRCs
5. To facilitate the transport of patients/ samples
6. To facilitate monthly/quarterly report transmission from regional Laboratory to apex Centre/DAC

Infrastructure Requirements

STI/ RTI laboratory infrastructure requirements depend on types and volumes of tests conducted as well as the nature of the laboratory (diagnostic vs. reference). Equipment should be suitably located in the laboratory so as to allow easy accessibility and sequential utilization, thus minimizing the need for frequent movement of specimens or reagents. All equipment should be in good working condition at all times. Periodic inspection, cleaning and maintenance of equipment should be done. An equipment log book should be maintained for all major equipment. Laboratories should establish necessary instructions for operation and maintenance of equipment in the form of Standard Operating Procedures (SOPs). A copy of SOPs should be readily available. A user manual should also be available for reference. The staff should be aware of trouble shooting measures to be adopted for preventing equipment malfunction. New equipment should be calibrated and validated before routine use. Pipette, thermometer, weighing balance and centrifuge should be calibrated by accredited calibration laboratory. All the equipment except centrifuges and micropipettes should be calibrated annually; centrifuges and micropipettes should be calibrated every six months. Periodic performance check/calibration check for all equipment should be done and the frequency of performance checks should be based on the day-to-day performance of the equipment. Equipment performance should be verified from Internal Quality Control and External Quality Assessment results.

Minimum Laboratory Equipment for the Regional STI Laboratory is:

1. Refrigerator (4^{O}C)
2. Deep Freezers (-20^{O}C and -70^{O}C)
3. RPR/ VDRL rotator
4. Bio-safety cabinet Class 2
5. Laminar flow hood (for media preparation)
6. Autoclave -2 (should be different for sterilization and waste treatment purposes)
7. Serum separation centrifuge
8. Micropipettes (variable and fixed volume)
9. ELISA washer and plate/strip reader
10. Incubators (37^{O}C)
11. Water bath (56^{O}C and 100^{O}C)
12. Hot air oven
13. Weighing balance
14. Bright field microscope
15. Dark ground and fluorescent microscope
16. Lyophilizer

Equipment Maintenance

Equipment control and maintenance, as outlined in chapter 4

Inventory Control

- Maintain a stock register for all equipment received from the project
- Update the register periodically whenever new equipment/s are received
- Keep a file containing instrument manuals and operating guidelines provided with the instrument
- Equipment history card must be maintained for every equipment and should have:
  1. Name of the equipment
  2. Unique ID, model and the serial number
  3. Manufacturer's name and address
  4. Service person's name, address and contact number
  5. Date of installation
  6. Calibration frequency, calibration certificates
  7. Repairs and service details
  8. Every equipment should have work instructions for its operation and troubleshooting guide available at the workplace

Equipment maintenance

- Prepare a line listing of all equipment with serial number, specific location in the laboratory
- Incorporate clear instructions on how to use equipment in the SOP
- Conduct periodic calibration of equipment for exact level of precision (e.g. micropipettes). Maintain all calibration records
- Follow manufacturer's instructions for cleaning of equipment
- Develop and use quality control form to monitor equipment function (Recording Register)
- Document all equipment problems or errors, repairs, maintenance, downtime etc. Ensure steps to resolve and corrective actions to be taken to avoid such problems in future **(Corrective Action Form/ Register)**

Quality Control of kits/reagents/media and stains

1. **RPR/TPHA Bio-Kits:**
   - Enter lot number, expiry date of the kit in the stock register
   - Perform kit validation with the known positive and negative control serum using reagents from one kit
   - Record results: Known positive and known negative as well as kit control should provide acceptable results

2. **Gram Stain Reagent Kit:**
   - Perform gram stain using ATCC *Staph. aureus* and ATCC *E.coli* at each test run
   - Record results
   - Place a drop of crystal violet and examine under microscope for crystals

Quality Assurance and Quality Control

Quality assurance (QA) practices are based on monitoring all processes which influence the reliability and validity of the final laboratory result. QA systems need to be developed, implemented and monitored in all laboratories- state, regional and the apex. Stock management should be guided by **FEFO (First Expiry First Out) and FIFO (First In First Out)** principles. The building blocks of quality assurance systems are categorized under:

1. Pre Analytical
2. Analytical
3. Post Analytical phase

1. Pre Analytical phase

A. Organization:

Laboratory should develop a Quality Assurance policy which articulates the role and responsibility of Head of the Laboratory in ensuring high quality standards. The policy must be communicated to all laboratory staff and stakeholders and displayed in all sections of the laboratory. The organisation is required to provide human and financial resources required for implementing quality assurance system. Standard Operating Procedures manual is one of the components which must be developed and/or updated timely in the laboratory.

B. Personnel:

All laboratory staff should have qualification, experience and competencies for the specific tasks assigned. Laboratory Director/Quality Manager ensures that all staff are oriented on functioning of the laboratory, trained on specific tasks (E.g. ELISA, PCR, AST etc.) through refresher trainings and are periodically assessed for their competencies. All trainings conducted in-house or by external agencies should be documented for each staff. This should be part of the periodic appraisal of staff conducted by the supervisor. A personnel file should be maintained for every staff member, which should display his/her qualifications, previous employment details, experience, skills, vaccination status, trainings attended, job description and other relevant details.

C. Equipment:

Laboratory should have an equipment selection and acquisition guidelines. These guidelines consist of specifications, vendor names and addresses, installation requirements, maintenance and records. All equipment in the laboratory is recorded with manufacturer's manual in a register for verification and necessary follow up with vendors.

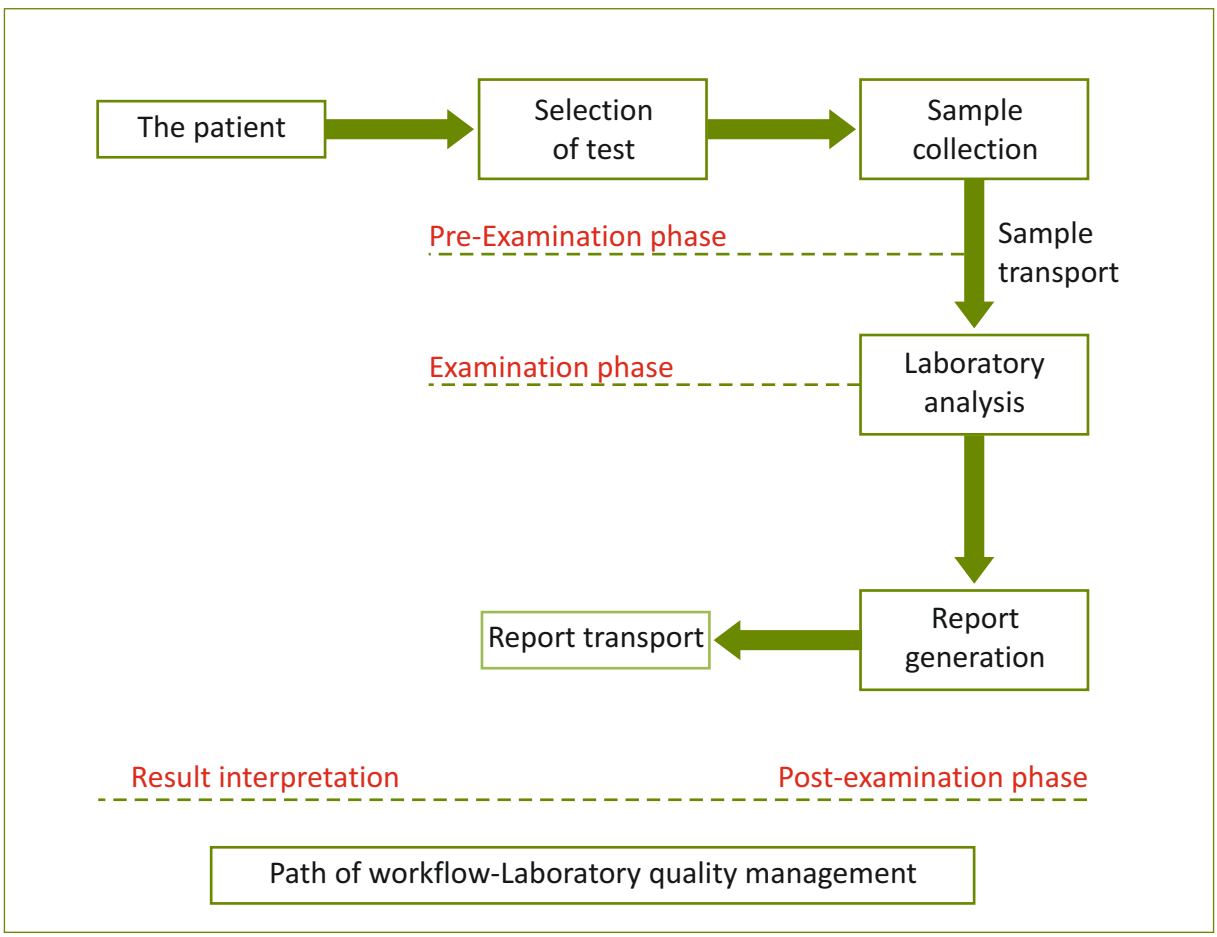
D. Purchasing and Inventory:

Laboratory should have a comprehensive inventory system to monitor media, reagents, testing kits and supplies for placement of orders for purchase. The system needs to capture all essential and critical laboratory supplies and should also have a triggering mechanism for identification of stocks below acceptable limit.

E. Laboratory Safety and Employee Protection:

All laboratories must have a written safety policy and guidelines in-built into the SOP manual. All employees must have a pre-employment health check-up and must be fully immunized (DPT, Polio and HBV) as well as screened by Tuberculin Test. Employee personal records must be updated with immunisation profile. All laboratory accidents and incidents must be immediately reported to Head or QC Manager and necessary steps should be taken within 12 hours. A responsible staff member may be designated as the Safety Officer and assigned these duties and responsibilities.

2. Analytical Phase:



(Adapted from WHO Laboratory quality management training module)

The analytical phase begins with patient/or requisition form for a specific test, selection of an laboratory test with high sensitivity and specificity , collection of appropriate sample/s, sample transport system (direct, using transport media) and handling of samples.

A. Specimen Management:

All specimens are collected, transported and handled as per the SOP. A critical element affecting test information from a laboratory is specimen quality. The laboratory SOP must indicate how to collect quality samples and what the indicators of poor quality samples are. E.g. *N. gonorrhoeae* samples should not be refrigerated.

The most important QA monitors are-

Quality, quantity, volume, transport media handling in the laboratory, specimen transport (field clinic to State and National Reference Laboratory) and storage/processing

B. Method Validation and Method Verification:

All laboratory tests used need to be either externally validated or mechanisms should be in place for internal validation.

Test Utilization: Monitor test request for appropriateness based on clinical indication, diagnostic yield and other relevant data.

C. Quality Control (QC):

A QC guideline for each test procedure is a mandatory document at the testing laboratory. All QC parameters need to be strictly adhered to by all staff performing primary, intermediate and complex laboratory tests.

The QC parameters include: personnel, SOP, equipment performance, in house prepared media, stains, reagents, kits, commercial systems and records and reports.

E.g. - QC of commercial systems – Gen APTIMA for urine and swabs, test validation, external quality control and proficiency testing. E.g. Reports- monitoring the accuracy of test reports (transcription errors), timeliness of reports and use of patient reports in the clinic, reasons for rejection if the specimen is unacceptable. All records and requisition forms should be retained for at least 2 years.

D. Proficiency Testing:

All laboratories must participate in an external proficiency testing program approved by DAC/NABL. Laboratories must analyze proficiency testing samples by routine methods and submit reports as per the schedule. Where external proficiency testing programs are

unavailable, other measures of quality assessment must be adopted. E.g. Inter laboratory comparisons, split sampling etc.

E. Report Generation and Interpretation:

Laboratory reports must have all the information on patient including type of specimen, date and time of collection, receipt and reporting. If necessary an interpretation of results should also be included in the comments column to facilitate appropriate management of patient.

3. Post Analytical Phase:

A. Reports and Records:

All reports must be considered confidential and dispatched in a sealed envelope. A copy of the report, laboratory worksheet and requisition forms are filed and placed in a locked cupboard. Laboratory director must ensure confidentiality of reports and information and should develop guidelines on communication on patient test results and access to CMIS.

B. Occurrence Management:

Laboratory should have a system to monitor errors (testing, transcription and communication) through periodic re-checking of records and reports as well as mechanisms for corrective action (immediate) and preventive actions. All laboratories must also have mechanisms to collect feedback from stakeholders. All adverse occurrences must be documented in the laboratory.

Laboratory Quality Assurance system must be considered in the light of opportunity for process improvement based on stakeholders feedback, resolution of problems (testing, sample collection, reporting etc.), taking preventive actions for continuously improving the diagnostic/reference tests for prevention of STI/RTI. The implementation of quality assurance system ensures high quality test results and is the first step towards achieving accreditation by NABL.

C. Quality Indicators:

A regular system must be in place to indicate the measures necessary for improving performance, in the form of quality indicators.

D. Biomedical waste management:

Appropriate disposal methods should be in place for management of biomedical waste. This is an important component of Post-Analytical phase and is explained in greater detail in the next chapter.

Biosafety including Infection Control

Personnel working in laboratories may be exposed to risks from various chemicals, infectious materials, fire hazard, gas leak etc. Safety in laboratories therefore includes **protection of both the staff and the environment** from hazardous materials. A responsible staff member may be designated as the Safety Officer for the laboratory.

General safety measures include-

- Documentation of Laboratory Safety Policies and procedures
- All laboratory personnel should be aware about the laboratory safety policies and procedures and follow these at all times. Laboratory personnel should follow safe hygienic practices which include hand washing, wearing protective clothing, gloves, eye protection etc. as and when necessary as well as exert caution while handling specimens in the laboratory.
- Eye wash facility/ station should be available as "stand-alone" facility or attached to a sink and be easily accessible. Portable, sealed, refillable bottles should also be available
- Biohazard symbol should be used on all container/equipment containing bio hazardous material

Bio Safety:

Laboratory personnel are at risk of exposure to a variety of infectious agents and need to observe special precautions for safe handling of pathogenic organisms in the laboratories. The World Health Organization has classified these organisms as Level 1, 2, 3 or 4 based on the infectivity of organism to cause disease or ill health. Four levels of bio safety laboratories (BSL) - 1, 2, 3 and 4, have been designed for handling bio hazardous material. STI pathogens are categorised as Level 2 and are appropriately designated to utilize BSL Level 2 Laboratories. Bio hazardous material should be handled in class I or II biological safety cabinets (BSC) within the laboratory. The laboratories should have their own bio safety manual. Policies should outline the use of sharps, disposal of bio-waste, reagents, sharps and other wastes generated in the laboratory. Clinical specimens and processing of isolates should be handled in class I or II BSC within the laboratory. Mechanical circulation of air with inward flow is preferred.

Infection Control:

Standard Precautions are a set of protocols designed to reduce the risk of (or prevent) transmission of pathogens. Under standard precautions, blood, body fluids and all body substances of patients are considered as potentially infectious. Standard precautions should be observed by all clinicians and laboratory staff for all patients and specimens as part of routine infection control.

Microbiology Laboratory:

- Access to the laboratory should be limited to authorized personnel and should be restricted when work with infectious agents is in progress
- Universal biohazard symbols should be posted on the laboratory door
- Work surfaces should be decontaminated daily, as well as immediately after a spill
- All infectious waste should be decontaminated before disposal
- Mouth pipetting is prohibited; mechanical pipetting devices are to be used
- Recapping of used needles should be strictly prohibited. If at all necessary, the one-hand technique should be followed
- Eating, drinking, smoking, handling contact lenses, and applying cosmetics should not permitted in the work areas
- Thorough hand washing should be performed after handling infectious materials and before leaving the laboratory
- Procedures to minimize the creation of splashes or aerosols should be followed
- An insect and rodent control program should be in effect
- Laboratory personnel should receive appropriate immunizations or screening for the agent handled or potentially present in the laboratory (e.g., hepatitis B vaccine)
- Baseline serum samples for laboratory and other at-risk personnel should be collected and stored, when appropriate, considering the agent(s) handled. Additional serum specimens may be collected periodically
- A bio safety manual should be prepared or adapted. Personnel should be advised of special hazards and should be required to read and follow instructions on practices and procedures
- Used sharp items, including needles and syringes, should be promptly placed in puncture-proof containers for decontamination
- Laboratory personnel should receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel should receive periodic updates, or as and when necessary
- Cultures, tissues, or specimens of body fluids should be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping
- Laboratory equipment and work surfaces should be decontaminated with an appropriate disinfectant on a routine basis after work with infectious materials is finished, and especially after spills

Storage of Pathogens and Records

The Apex and Regional Reference Laboratories should function as the repository for biological samples and records necessary for reference and quality assurance programs. The repository should become a part of the institution with the Director having the overall responsibility of the repository and the data. In general, long term storage facility should have elements of sufficient walk-in cold storage facility or freezer space to accommodate the material being preserved and provide safe movement of people and equipment. All freezers and computers should be also protected by UPS (Uninterruptible Power Supply).

The Apex and Regional Reference Laboratories' Long Term Storage System should develop SOPs detailing policies and procedures in relation to storage of specimens, serum, DNA, and isolates so that samples can be used for research, evaluation of new test kits and quality assurance.

Details of the following are given in the SOP manual:

1. Specimen handling policies and procedures including supplies, materials and equipment
2. Policies and procedures for shipment and receiving specimens
3. Record management policies especially storage of lab forms and data
4. Quality Assurance of long term storage system, equipment, reagents, labels, processes employed in retrieval and processing of samples
5. Policies and procedures for employee safety and reporting of accidents if any
6. Training of staff in repository procedures and policies

Specimen verification:

A random check of the specimen inventory system (database) should be conducted on a small percent of samples on an annual basis. This verification will confirm that the appropriate specimens are in the correct freezer locations, as indicated by the computerized inventory system.

Specimen Tracking:

Specimen tracking system encompasses use of (a) labels (bar-coded/pre-printed) that identify samples during transport and storage, (b) shipping logs that document specimens on arrival and departure from the long term storage facility and (c) an inventory system with in the storage facility that is known to appropriate staff. Standardized tracking system would enhance efficiency of the facility.

Labels:

Each serum specimen should be labelled (label should be bar-coded or pre- printed), which

should adhere tightly to the tube under all storage conditions (-20C, -70C or liquid nitrogen). Labels should be resistant to all common laboratory solvents. Pre testing of labels for their adherence to tubes and use of ink under specific storage conditions is recommended before they are put into regular use.

Record Management:

The Apex and Regional Reference Laboratories should develop a record management system for long term storage of specimens and its data. The system should also include informed consent for future research, processing and preservation, labelling, storage and distribution to research organizations. All records must be stored securely in locked filing cabinets to ensure confidentiality and safety.

Record Retention:

All sample collection, storage, distribution and quality audit records should be maintained for 5-10 years (NABL). Guidelines for retention of records of specimens that no longer exist in the storage facility also need to be developed.

Security:

Electronic data records of clinical STI samples, isolates should be backed once in 15 days on either a CD or diskette in the Reference Laboratory. The establishment of a remote storage system could also be considered.

Corrections and or changes:

Corrections and changes should be done by an authorized staff of the institute. S/he should put a signature and date of correction on change in the record. The correction should be made in such a way that previous entries are also visible and not obliterated totally. Separate files on changes in the electronic records should be maintained and tracked.

Recording, Reporting and Data Analysis

1. Data reporting

Stringent laboratory procedures are essential for identifying and isolating the etiological agents for STI/RTI. However, these efforts may not be valuable if such results are not accurately reported to programme implementers.

A good data reporting system will require quality data collection, recording and feedback of vital information regarding laboratory results and epidemiological data. Minimum records will have to be maintained at the Regional STI laboratory. These will not only help to monitor the overall activities at the centre but also provide crucial information for surveillance.

2. Reporting systems

Clinical and laboratory data will be reported by the Regional STI Training, Research and Reference Laboratories in the prescribed online monthly reporting format through the Strategic Information Management System (SIMS). The monthly reporting format is appended as **Annexure VIA, B**, along with instructions for filling- in.

The report will be sent by the 5th of every month to DAC through the online system and a hard copy of the same will be sent to the apex STI laboratory with a copy to SACS. Any error or discrepancy will be rectified before the 10th of the month.

3. Record keeping

The centre must maintain a log of the total samples received during the day as well as the total tests performed. All clinical specimens and samples received must be accompanied by a standardized sample request form. It must be ensured that the request form is correct, complete and duly signed by the concerned authority. Information pertaining to date and time of receipt of sample, transport conditions (e.g. proper cold chain maintenance), condition of sample/ specimen (e.g. adequacy, contamination) must be recorded. These data help in the determination of Turn-Around Time of reports (TAT). A unique laboratory identification number must be allotted to the sample for subsequent purposes; the same must be entered in all relevant laboratory registers and records so as to link the results to patient information. Results of all tests performed on samples/ specimens/ isolates should be recorded in the data management system as soon as they are obtained.

EQA for Syphilis: The particulars of serum panels distributed to the SRCs and number of

reports provided must be recorded; the feedback of results (concordant/discordant) must be communicated to the linked SRC.

[In case of samples for GASP, acknowledgement of receipt of samples to the SRC must be provided]

4. Data analysis

Routine monitoring of laboratory data can provide insights and direction to the program. The regional laboratory along with the nodal officers from Community Medicine departments will undertake analysis of STI data available at the centre with regard to the various STIs and etiological diagnosis, EQA for syphilis, monitoring of GASP, STI sentinel surveillance and any other data relevant for NABL accreditation of the laboratory.

The findings and results will be shared periodically with the STI division, DAC and concerned SACS.

Mentoring and Supportive Supervision

The Regional STI Training, Research and Reference Laboratories will be provided regular mentoring and supportive supervision by the following personnel/institutions:

1. **Apex centre:** A microbiologist and a clinician from DVL/ OBGYN department or a faculty from Community Medicine from the apex centre will provide technical support and mentoring to the other regional STI laboratories to ensure quality standards for etiological testing and gonococcal antimicrobial susceptibility monitoring. The visits will be carried out once every year and will be used to enhance and sustain the skills of staff at the centres and ensure adherence to standard operating procedures laid down for laboratory testing. The checklist to be used at these visits is appended as **Annexure VIIA**, B. Additionally, on-going technical support will be provided through refresher trainings and e-mail correspondence. The frequency of training will be once every year.

2. **SACS:** The DD (STI), AD (STI) and PO-STI from the concerned SACS will provide support on a regular basis to the RSTRRL. The designated person from SACS will participate in the quarterly meeting of the RSTRRL nodal persons. The SACS will also monitor the functioning of regional laboratory, routine surveillance activities and special studies being conducted at the regional STI laboratory.

3. **Mentoring subcommittee members:** DAC will designate the mentoring subcommittee members who will regularly visit the Regional STI Training, Research and Reference Laboratories. The mentors will visit the centres every four months initially and later at six-monthly intervals. The purpose of the visit will be to review the activities, ensure that standardized procedures for procurement of consumables/reagents are being followed and minimum quality standards are maintained. The mentors will also ensure that regular and on-going research and surveillance activities are carried out in accordance with the strategies of the national program. The mentoring checklist to be used at these visits is attached as **Annexure VII A, B**. Copies of the completed checklist will be sent to DAC, the concerned SACS and RSTRRL within two weeks of the date of visit.

   In addition, the mentoring subcommittee will review the progress of STI operations research to be carried out by the Regional STI Training, Research and Reference Laboratories, monitor the progress towards achieving NABL accreditation, explore the feasibility of involving the SRCs in surveillance activities and provide regular support to the regional laboratories through e-mail correspondence. Further, the committee will assist DAC in identifying the priority areas for OR studies.

STI Surveillance

Introduction

Sexually transmitted Infections (STI) are a major public health problem in most developing countries. STIs cause significant morbidity and are co-factors for HIV acquisition/transmission. Promoting sexual and reproductive health are important components of the National AIDS Control Programme (NACP IV) and Reproductive and Child Health Programme (RCH) of the National Rural Health Mission (NRHM). Epidemiological information of STIs is critical for effective management and planning of resources for the programme. Epidemiology of STIs provides information about sub-groups of population and geographical areas with a higher prevalence; and trend of STIs over a period of time in a given place and population group. Epidemiological information on STIs can also be used as an early warning sign for risky sexual behaviours for HIV infection.

STI surveillance is an on-going and systematic collection, analysis, interpretation and dissemination of data. A well-functioning disease surveillance system provides information for planning, implementation, monitoring and evaluation of public health intervention programmes.

The components of STI Surveillance are-

1. Case Reporting- Syndromic Case Reporting and Etiologic Case Reporting
2. Etiological Surveillance
3. Antimicrobial Resistance Surveillance
4. Special Studies- Second Generation Surveillance

1. Case Reporting: is a process of reporting of all STIs from health care providers to public health authorities. This is useful for understanding the burden and incidence of STIs. Surveillance has traditionally relied on cases reported from health-care facilities.

a. Syndromic Case Reporting: The case reporting is usually done by STI Syndrome Case Reports. The minimum standards required for STI Syndrome Case Reporting are:

i. Standardized Syndrome Case Definition
ii. Related Data Elements such as age, gender, residence, risk behaviours, first/follow-up visit

It is generally considered that the proportion of acute infections (like GUD Non-Herpetic) and Urethral Discharge Syndromes) to all STI cases reported in the period is useful to assess the burden of new infections (incidence) and can be used as an indicator for monitoring the STI control program.

b. **Etiological Case Reporting:** This method of surveillance is useful where laboratory testing and systems are available for STIs presented with disease stages (eg: Syphilis) re –infections and have different clinical manifestations.

The Etiological Case Reporting is ideally instituted in reference laboratories attached to a tertiary care hospital having advanced diagnostic and reference testing facility.

Examples of Etiological Case Reporting:

1. Syphilis (Primary/Secondary and Latent)
2. Gonorrhoea (men) - Gram Stain or culture
3. Chlamydia (men and women) - culture or DFA
4. Congenital Syphilis

Etiological Case Reporting can be instituted in the SRCs, Regional and Apex Laboratories; all cases should be based on predetermined case definition (probable and confirmed).

2. **Etiological Surveillance:** Periodic etiological surveillance of STIs should be considered as a core surveillance activity as the STIs are usually reported by the method of case reporting of syndromes. The components of etiological surveillance are;
   a. Consideration of syndromes for etiological surveillance
   b. Selection of STI clinic sites - Private and Public (based on reporting of chosen syndromes)
   c. Sample size (number of patients with syndromes to be tested)
   d. Laboratory Tests- (high specificity and sensitivity)

The periodicity of etiological surveillance is based on prevalence of syndromes, number of reinfections, and treatment failures. It is recommended that etiological surveillance be conducted once in two years. STIs caused by viral agents require etiological diagnosis and surveillance.

3. **Antimicrobial Resistance Surveillance:** In view of use of number of antibiotics for treatment of gonococcal infections and increasing rates of resistance world-wide, it is important to monitor antimicrobial resistance in *Neisseria gonorrhoeae,* a core component of STI surveillance. The methodology is based on guidelines for selection, timing, samples size and testing methods as well as reporting prepared by CDC-USA or WHO.

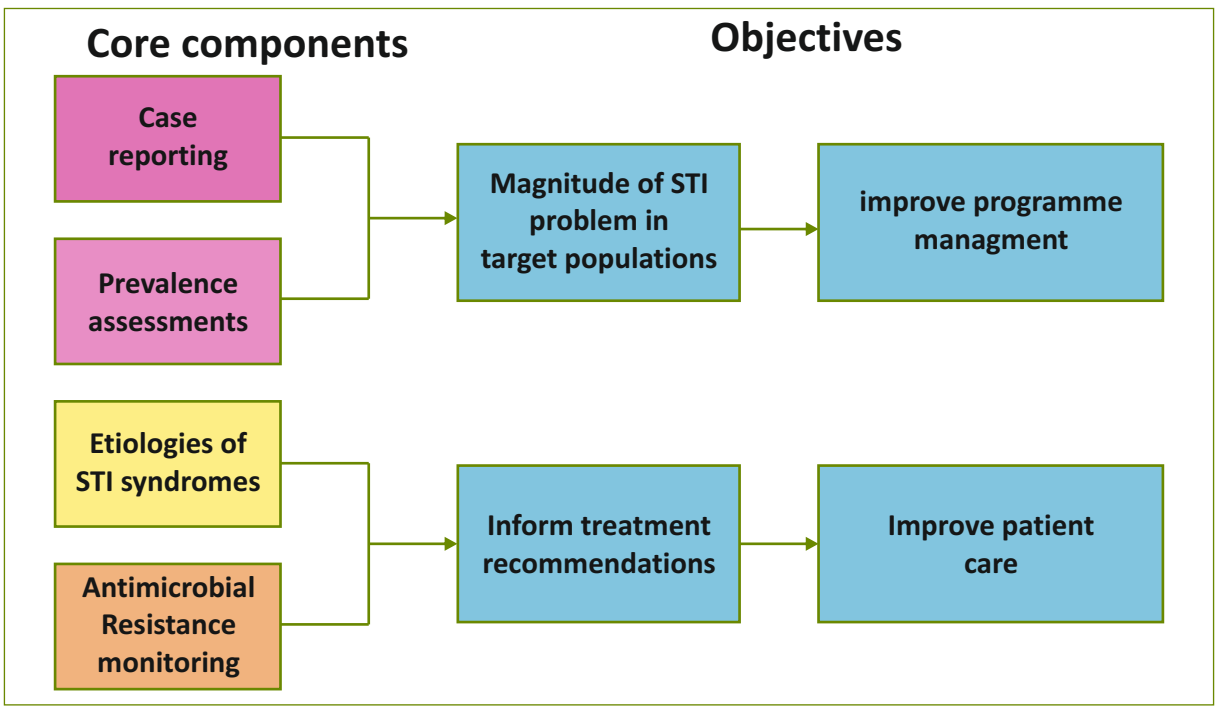
4. **Special Studies:**
   a. **Prevalence Studies:** Many STIs in men and women are asymptomatic in nature (>60%). Prevalence studies in populations with asymptomatic gonococcal, chlamydial,

and syphilis infections will provide disease burden in the community. The prevalence studies can be done in all settings (family planning clinics, GYN and OBG clinics) where asymptomatic patients seek services for reasons other than STIs. Similarly, patients without symptoms of STI attending clinics for military recruits, correction facilities and regular check up by sex workers could also be selected for prevalence studies.

Tests should be conducted for NG, CT and Syphilis, and should always be included as a part of prevalence studies to determine asymptomatic infections. It is usually done on high risk populations such as sex workers and HR- MSM in major urban centres followed by towns. The minimum acceptable sample size for assessing prevalence depends primarily on the expected prevalence of the disease in the population.

b. **STI -Second Generation Surveillance:** STI surveillance is the core of HIV program because trends in the incidence and prevalence of STIs reflect the occurrence of risky sexual activities. IBBA and IBBS is conducted once in two to three years among most at risk populations (FSW, MSM, Truckers, and Migrants).

The core components and objectives of an STI surveillance system are shown below:[6]



Methodology

The STI surveillance activities including periodic prevalence studies, periodic etiological validation of syndromes such as urethral/ano-rectal/vaginal/cervical discharge and genital ulcer disease will be supported by the Regional STI Training, Research and Reference Laboratories. Samples should be collected by the Regional STI Training, Research and Reference

Laboratories from the linked dedicated sites such as DSRCs, MSM/FSW/Migrants/Truckers clinics. If possible, linkages should be formed with popular STI private practitioners in the area to extend the surveillance activities to patients seeking care from the private sector and NRHM facility such as rural health centres attached to medical colleges. The geographical area of the service facilities for surveillance activities should be determined keeping in mind the practicalities of sample storage and transportation.

Samples and reporting

Sample collection, storage and transportation must follow the standard operating procedures. Sample transportation to the RSTRRL should be done ideally on the same day; if not feasible (for sites quite some distance away), samples may be transported periodically. The responsibility for this activity rests with the RSTRRL, supported by the concerned SACS staff. Reporting to SACS and DAC on the standardized surveillance reporting formats **(as shown in Annexure VIII)** must be done within a month of the etiological diagnosis. The clinics from where the samples have been collected will need to provide relevant data to the regional laboratories in order to obtain complete information of the patient and thus aid correct interpretation of results. Additional remarks may be added in the report to explain any unusual results.

STI sentinel surveillance

Reports of a number of high level consultative meetings involving national and international experts have recommended improving STI surveillance in India. Noteworthy among these consultations were; technical consultation to review HIV surveillance in India (2008, WHO-SEARO); report on mid-term review of sexually transmitted infection services (2009, NACO); and, technical working group on sexually transmitted infections for NACP-IV (2011, NACO). STI surveillance is possible through universal STI case reporting, sentinel case reporting or a combination of both. In universal STI case reporting, all service facilities report basic data on STI cases. The current system of STI reporting at NACO may be considered as a universal case reporting (private practitioners not included). Universal reporting of STI data is more representative of the entire population; however, as is well known, it is a challenge to get quality data from all the reporting units that could be reliably used by the program. As an alternative, sentinel sites which are representative of the country could be identified through purposeful selection based on pre-defined criteria. A higher quality of reported data could be obtained from these sentinel STI clinics through provision of intensive support for training of staff, supportive supervision and logistics. In addition, sentinel site reporting may allow additional data to be collected and reported, such as service statistics from private practitioners.

6 'Strategies and laboratory methods for strengthening surveillance of sexually transmitted infections' UNAIDS & WHO 2012

Operations Research

With the overall goal of providing evidence and direction to support the STI/RTI control and prevention program, the regional laboratories should conduct research activities on topics that are of use to the national program and as suggested by experts constituted by DAC. They will be supported for the same by mentors identified by the STI division of DAC at the regional level.

Operations Research can be defined as research aimed at improving the programs by identifying problems and viable solutions that address program efficiency, effectiveness, quality, and improve availability, accessibility and acceptability of services to users. The areas that are amenable to Operations Research are those that directly or indirectly influence the health status of the target population. These include the characteristics of the healthcare system (organization, programs, human resources); characteristics of the environment in which the healthcare system functions (political, cultural, social, economic, physical); characteristics of the target population (demographics, resources, attitudes, knowledge, behaviour); utilization of services; expenditures; and overall satisfaction with the services provided.

Guide to identifying priority areas for Operations Research

1. Identify public health problems
   - A problem is a discrepancy between what someone believes should be the situation and what is in reality the situation.
   - Write a small, simple paragraph that identifies the problem in terms of its occurrence, intensity, distribution, and other measures for which data are already available. The aim is to determine all that is currently known about the problem and the reason it exists. For this purpose you will need to review relevant literature, examine current service statistics, seek educated opinions from persons concerned about the problem, obtain probable reasons for the problem from social, economic, or health theory and to identify possible solutions to the problem.
   - Add details to the problem situation: What is the incidence and prevalence of the problem? Which geographic areas are affected? Which population groups are affected? What are the findings of other research studies? What has been done to overcome the problem in the past? How successful were past efforts to overcome the problem? What seem to be the major unanswered questions about the problem?
   - State the discrepancy between what is and what should be.
   - Write down the central problem question.
   - Write two or more plausible solutions to the problem.

2. Estimate public health importance of the problem in terms of burden of disease (death,

disease, disability, and economic losses), effective interventions, cost effective interventions using local reports and national / international estimates.

3. Justify the problem
   - Is the problem you wish to study a current and timely one?
   - How widespread is the problem - are many areas and many people affected?
   - Does the problem affect key populations?
   - Does the problem relate to on-going program activities?
   - Does the problem relate to broad social, economic, and health issues - unemployment, income distribution, poverty, the status of women, or education?
   - Who else is concerned about the problem - top government officials/medical doctors/other professionals?

4. Analyze the problem in terms of its consequences, determinants, direct contributing factors and possible interventions at different levels.

5. Review what is being already done – planned, on-going and completed interventions. Analyze their implementation status. Make sure you are not reinventing the wheel. Do an extensive review of the guidelines, recommendations, scientific literature, meeting reports, and solicit expert opinions in order to identify clearly what is known and not known about the problem at hand.

6. Identify the information needed to improve the current situation and the type of data needs that would help to design the type of research study.
   - If the problem is a consequence of failure to implement a validated strategy, then do an assessment, monitoring and evaluation study.
   - If the problem is a consequence of difficulties in applying a recommended strategy, then design prevention research study.
   - If the problem is a consequence of a limitation or of a lack of validated strategy, then applied investigation or experimental studies would be required.

7. Spell out the research question
   - Frame the problem in public health terms; focus on one issue; write in everyday language.
   - Link the question to the potential action points that would be initiated once the question will be answered
   - FINER criteria for a good research question (Hulley SB et al. Designing Clinical Research, 3rd Edition, 2007)
     - **F**easible - Adequate number of subjects/technical expertise/affordable in time and money/ manageable in scope

- **I**nteresting - Getting the answer intrigues the investigator and other stakeholders
- **N**ovel - Confirms, refutes or extends previous findings/ provides new findings
- **E**thical - Amenable to a study that ethics committees will approve
- **R**elevant - To scientific knowledge, clinical and health policy and the program

8. Avoid strategies/interventions that are not consistent with your institution and national program's goals, and objectives. Strategies/interventions that are likely to work would be those that can be implemented without overburdening the institution, simple to implement, sustained over time, under the control of program managers, and acceptable to the community and key stakeholders.

Example of designing Operations Research studies

PROBLEM: The high prevalence of sexually transmitted infections (STIs) and their role in HIV transmission have made integrating STI prevention and management into existing family planning and antenatal care programs a priority in most resource-poor settings.

METHODS: The literature is reviewed to examine 'what is' and 'is not' known about integration and to identify priority areas to be addressed through research.

PUBLIC HEALTH IMPORTANCE: Reproductive tract infections (RTIs), particularly those that are sexually transmitted infections (STI), continue to be a serious public health problem. Not only are the prevention and management of STIs an important public health concern in itself, the presence of some STIs enhances the sexual transmission of HIV, and STI management has been shown to be effective in reducing HIV transmission. Moreover, the Programme of Action of the 1994 International Conference on Population and Development (ICPD) emphasized reorienting health care systems to enable women to obtain comprehensive and quality reproductive and sexual health services. Finally, configuring services jointly rather than separately has perceived financial benefits for health systems.

WHAT IS KNOWN: Program planners and policymakers continue to look for ways in which STI and HIV prevention, detection and management can be better integrated with existing maternal and child health and family planning services. Providing additional services to an established and numerically large clientele through an existing program is easier for national public health programs, funders and technical assistance partners than venturing into the relatively unknown arena of reaching new clientele (the "high-transmitter" groups of males; young, single women; and sex workers) through new activities.

WHAT IS NOT KNOWN: Little is known about how integrated services can best be configured, and what impact they have on prevention of infection and unwanted pregnancy. The feasibility and effectiveness of strategies that focus on the addition of either STI prevention services or detection and treatment activities are uncertain.

OPERATIONS RESEARCH AREAS:

1. The development and testing of strategies that, instead of adding STI-related activities to existing family planning and antenatal care programs, seek to reorient the goals of routine consultations toward protection against the dual risks of unwanted pregnancy and infection and involvement of clients in deciding the outcome of the consultation.
2. Strategies that reach male partners and facilitate access by adolescents to sexual and reproductive health services need to be developed and tested.
3. Testing and comparison of the impact of alternative integration strategies on population-level indicators of behavior and health using prospective, preferably randomized studies.

REFERENCE:

Askew I, Maggwa NB. Integration of STI Prevention and Management with Family Planning and Antenatal Care in Sub-Saharan Africa—What More Do We Need to Know? International Family Planning Perspectives. 2002;28(2):77–86.

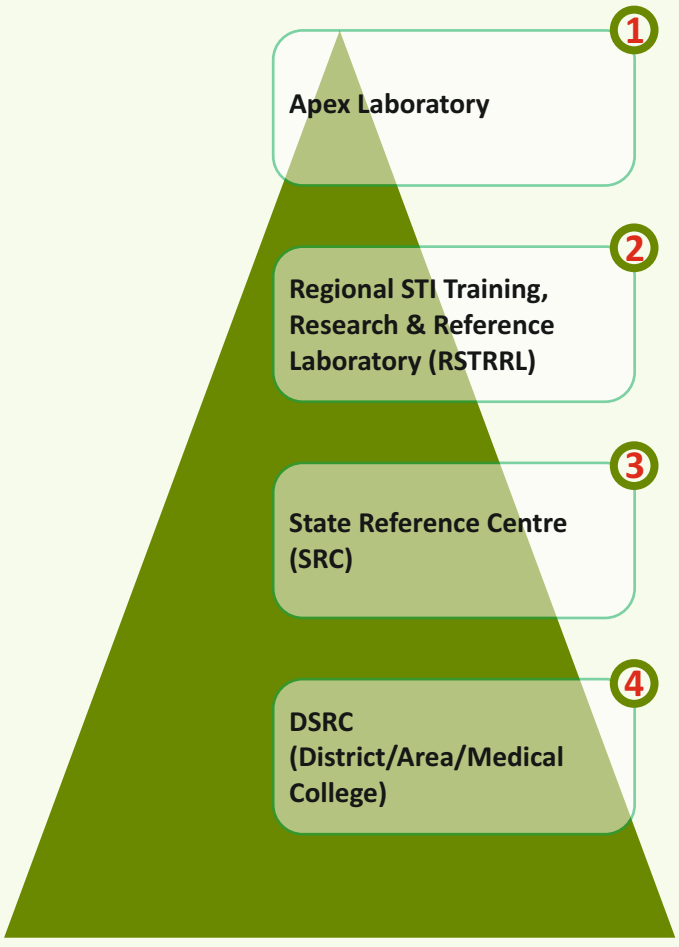
Linkages of Regional STI Laboratory with SRC

Sr. no	Name of the RSTRRL	State	Name of the linked State Reference Centre (Dept. of Microbiology)
1	Safdarjung Hospital, Delhi	Uttar Pradesh	1. Chhatrapati Shahuji Maharaj Medical University (CSMMU), Lucknow
			2. Institute of Medical Sciences (IMS) BHU, Varanasi
			3. J.N Medical College, AMU, Aligarh
		Punjab	Government Medical college, Amritsar
2	Maulana Azad Medical College, New Delhi	Delhi	University College of Medical Sciences, Delhi
		Chandigarh	Government Medical College& hospital, Chandigarh
		Uttarakhand	Himalayan Institute of Medical Sciences, HIHT, Dehradun
		Haryana	Pt. B.D Sharma Post Graduate Institute of Medical Sciences, Rohtak
		Himachal Pradesh	Dr. R.P Government Medical College, Kangra, Tanda
		J&K	Government Medical College, Jammu
3	Osmania Medical College, Hyderabad, AP	Andhra Pradesh	1. Andhra Medical College, Vishakhapatnam
			2. Sri Venkateswara Medical College (SVMC), Tirupati
			3. Gandhi Medical College, Secunderabad
			4. Guntur Medical College, Guntur
		Karnataka	1. Bangalore Medical College &Research Institute, Bangalore
			2. Karnataka Institute of Medical Sciences (KIMS), Hubli
		Andaman & Nicobar Islands	To be decided

Sr. no	Name of the RSTRRL	State	Name of the linked State Reference Centre (Dept. of Microbiology)
4	Government Medical College, Nagpur, Maharashtra	Maharashtra (Including Mumbai)	1. B.J Medical College, Pune
			2. Government Medical College, Aurangabad
			3. T.N Medical College &B.Y.L Nair Charitable Hospital, Mumbai
		Goa	Goa Medical College & Hospital, Bambolim
		Chhattisgarh	Pt. J.N Memorial Medical college, Raipur
		MP	1. Gandhi Medical College, Bhopal
			2. Mahatma Gandhi Memorial Medical College, Indore
5	Medical College Baroda & Sir Sayajirao General Hospital, Vadodara	Gujarat	1. Government Medical College & New Civil Hospital, Surat
			2. B.J Medical College, Ahmedabad
		Rajasthan	1. R.N Tagore Medical College, Udaipur
			2. Sawai Man Singh (SMS) Medical College, Jaipur
		Diu & Daman	To be decided
		Dadra & Nagar Haveli	To be decided
6	Institute of Venereology, Chennai, TN	Tamil Nadu	1. Tirunelveli Medical College (TVMC), Tirunelveli
			2. Madurai Medical College & Rajaji Hospital, Madurai
			3. Coimbatore Medical college, Coimbatore
			4. Kilpauk Medical College, Chennai
		Kerala	Trivandrum Medical College, Thiruvananthapuram

Sr. no	Name of the RSTRRL	State	Name of the linked State Reference Centre (Dept. of Microbiology)
		Pondicherry	To be decided
		Lakshadweep	To be decided
7	Institute of Serology, Kolkata, WB	West Bengal	1. R.G Kar Medical College& Hospital, Kolkata
			2. North Bengal Medical College, Siliguri, Darjeeling
		Jharkhand	Rajendra Institute of Medical Sciences (RIMS), Ranchi
		Bihar	1. Patna Medical College, Patna
			2. S.K Medical College, Muzaffarpur
		Orissa	Shri. Ram Chandra Bhanj Medical College (RCB), Cuttack
		Arunachal Pradesh	General Hospital, Naharlagun
		Assam	Gauhati Medical College & Hospital, Guwahati
		Manipur	Regional Institute of Medical Sciences (RIMS), Imphal
		Meghalaya	North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS), Shillong
		Mizoram	Civil Hospital, Aizawl
		Nagaland	Naga Hospital Authority, Kohima (NHAK)
		Sikkim	Sikkim Manipal Institute of Medical Sciences (SMIMS) &STNM Hospital, Gangtok
		Tripura	Agartala Government Medical College, Agartala

Structure & core functions of Laboratory Network



1

- WHO Regional Reference Laboratory for SEAR* for Gnococcal Antimicrobial Surveillance Programme (GASP)
- Referral Laboratory (Recurrent STI, Refractory/complicated cases)
- Quality Assurance & Quality Control
- Training & Technical support
- Evaluation of new diagnostic kits & rechniques

2

- Referral Laboratory (Recurrent STI, Refractory/complicated cases)
- Surveillance, GASP
- Panel Proficiency/EQA
- Training & Research
- Evaluation of new diagnoostic kits & techniques

3

- Diagnostic RPR/VDRL/TPHA
- In pouch Culture
- Isolation, Culture Sensitivity

4

- Diagnostic (RPR/VDRL, POC, Wet mount, KOH mount, Gram stain, pH)

* SEAR-South East Asia Region

Laboratory Tests to be Conducted at RSTRRL

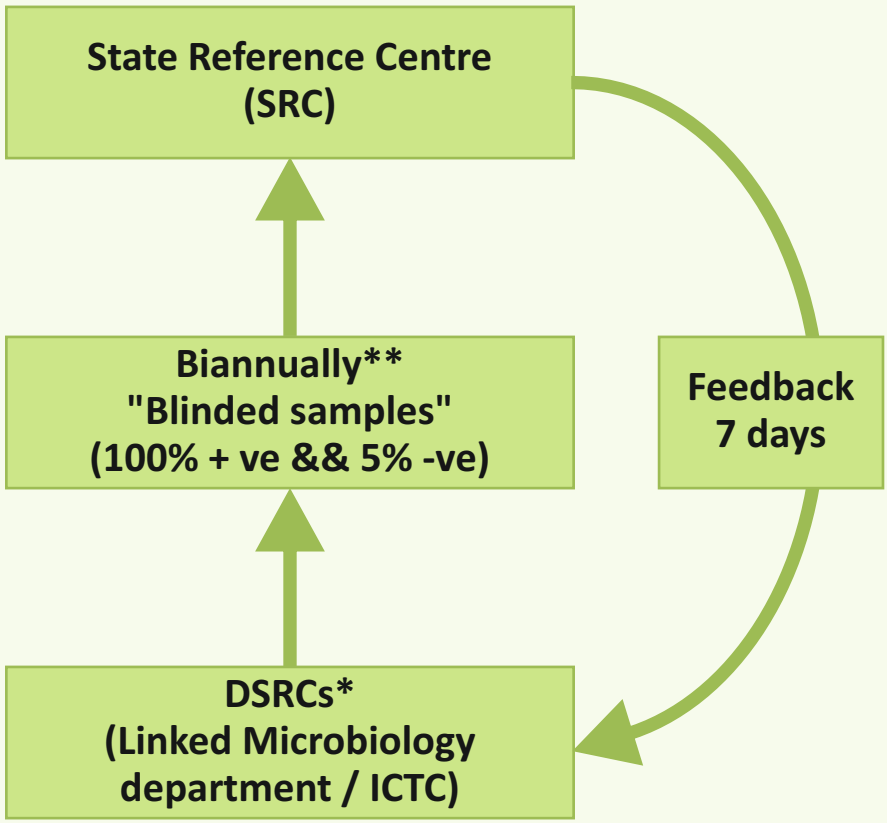
S. No	STI/RTI Syndrome	STI/RTI	Organism	Name of Laboratory Test/s
I a.	VAGINAL-CERVICAL DISCHARGE SYNDROME (VCD)	Trichomoniasis	*Trichomonas vaginalis*	Direct wet mount- Vaginal discharge, Giemsa stain, acridine orange staining
				Culture
b.		Candidiasis	*Candida species*	KOH mount
				Gram stain
				Culture and speciation & AST
c.		Bacterial Vaginosis (BV)	*Gardenerella vaginalis*	Gram stain, saline wet mount
				pH and Whiff test
d.		Gonococcal cervicitis	*Neisseria gonorrhoeae*	Smear for gram stain (discharge)
				Gonococcal culture and sensitivity
e.		Chlamydial cervicitis	*Chlamydia trachomatis*	ELISA for Antigen Detection
				Direct Fluorescent Antibody tests (DFA)
				Culture
II a.	URETHRAL DISCHARGE SYNDROME (UD)	Chlamydia	*Chlamydia trachomatis*	ELISA for Antigen Detection
				DFA
b.		Gonorrhoea	*Neisseria gonorrhoeae*	Smear for gram stain - Male (Urethral discharge/Urine)
				Gonococcal culture and sensitivity–Male
				β- lactamase test, AST, NAAT
c.		Trichomonas	*Trichomonas vaginalis*	Direct wet mount – Discharge
				Direct wet mount – Urine sediment
				Culture
III	GENITAL ULCER DISEASE SYNDROME-HERPETIC (GUD-H)	Herpetic ulcer	Herpes Simplex Virus I & II	Ulcer smear for MNGC (multinucleated giant cells)
				ELISA for HSV 1 & 2 IgM Ab & group specific HSV 2 IgG Ab, NAAT, Culture

S. No	STI/RTI Syndrome	STI/RTI	Organism	Name of Laboratory Test/s
IV a.	GENITAL ULCER DISEASE SYNDROME- NON HERPETIC (GUD-NH)	Syphilis	*Treponema pallidum*	Dark Field Microscopy
				VDRL Test: Qualitative/quantitative
				RPR Test: Qualitative/quantitative
				TPHA test
				FTA-Abs
				Molecular identification, NAAT
b.		Chancroid	*Haemophilus ducreyi*	Gram stain of ulcer smear
				Culture and Sensitivity, β- lactamase, Antimicrobial susceptibility test
c.		Donovanosis	*Klebsiella granulomatis*	Tissue smear for Donovan bodies
V a.	ANORECTAL DISCHARGE SYNDROME (ARD)	Chlamydia	*Chlamydia trachomatis*	ELISA for Antigen Detection
				Direct Fluorescent Antibody tests (DFA)
b.		Gonorrhoea	*Neisseria gonorrhoeae*	Smear for gram stain – Discharge
				GC Culture and sensitivity
VI	PAINFUL SCROTAL SWELLING		*Chlamydia trachomatis*	ELISA for antigen detection, DFA Gram stain- urethral smear
			Neisseria gonorrhoeae	
VII	LOWER ABDOMINAL PAIN (LAP)		*Chlamydia trachomatis*	Gram stain, Wet smear, urine microscopy for pus cells
			Neisseria gonorrhoeae	
			Anaerobic organisms	
VIII		Hepatitis B	*Hepatitis B Virus (HBV)*	Hbs Ag detection by rapid test/ELISA
IX		Hepatitis C	*Hepatitis C Virus (HCV)*	Anti HCV Ab detection by rapid/ELISA, NAAT
X		Genital warts	*Human Papilloma Virus (HPV)*	HPV DNA detection by nucleic acid hybridisation and amplificatio

Suggested Laboratory Tests/ Procedures to be Conducted at Different Facilities

Level of Facility	Test to be conducted	STI
Primary level	RPR or Rapid POC test	Syphilis
	Gram stain	Gonorrhoea
	Saline Wet Mount	Trichomonas
	KOH Mount	Bacterial vaginosis/ Candida
DSRC	RPR/ Rapid POC test	Syphilis
	Saline Wet Mount	Trichomonas
	KOH Mount	Bacterial vaginosis (Whiff test)
		Candida
	Gram Stain	BV (Clue cells)
		Gonorrhoea (Intracellular diplococci)
		Urethritis/ Cervicitis/ Proctitis (Pus cells)
	Urine sediment for WBCs	Urethritis
SRC	RPR/ Rapid POC test/ TPHA	Syphilis
	Saline Wet Mount	Trichomonas
	KOH Mount	Bacterial vaginosis (Whiff test)
		Candida
	Gram Stain	BV (Clue cells)
		Gonorrhoea (Intracellular diplococci)
		Urethritis/ Cervicitis/ Proctitis (Pus cells)
	In- Pouch Culture	Trichomonas
	Culture and antimicrobial susceptibility	Gonorrhoea
	Immunochromatography HBsAg	HBV
RSTRRL	As given in Annexure IIIA, EQA	Syphilis, Antimicrobial susceptibility for gonorrhoea
Apex lab	As above, PCR	Gonorrhoea, Chlamydia, Trichomoniasis, multiplex PCR for Treponema pallidum, Haemophilius ducreyi and HSV

Algorithm: Retesting of samples for EQA

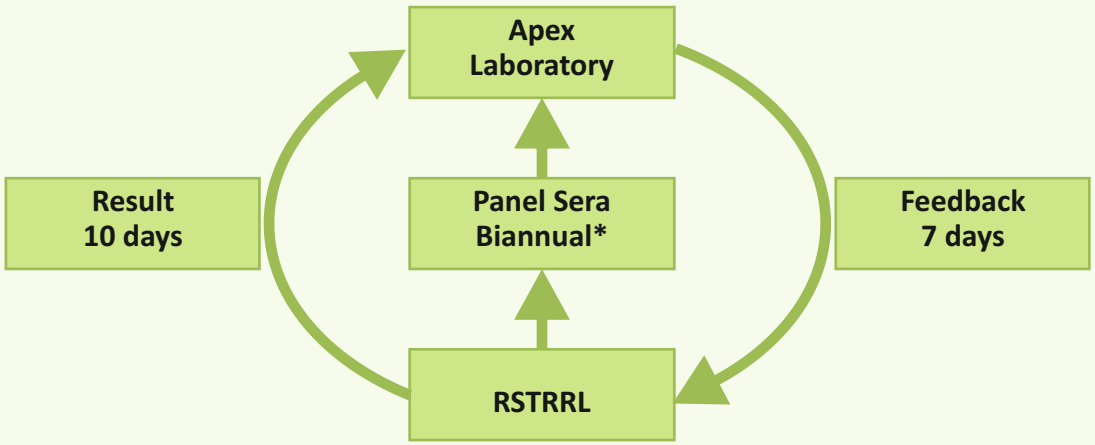


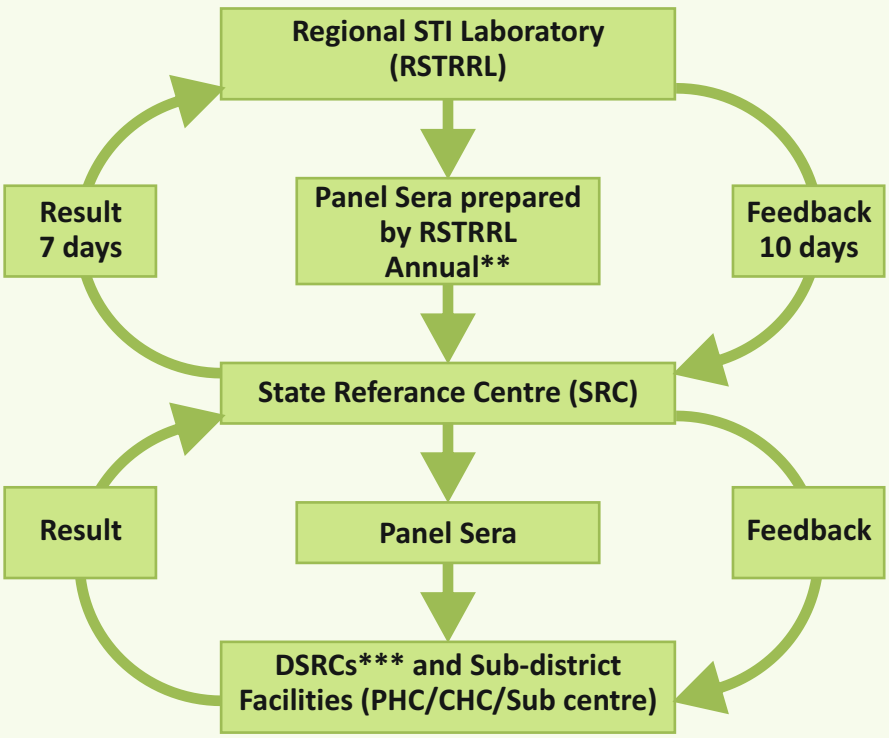
* DSRCs including those co-locatd in medical colleges

** Biannual - January and July

\# *DSRCs directly dependent / co-located within facility of RSTRRL will send samples directly to RSTRRL*

Algorithm: Panel Proficiency Testing for Syphilis





* Biannual - second week of June & December

** Annual - second week of December

* DSRCs including those co-located in Medical colleges

Annexure V

NABL is the apex organization that recognizes and accredits the technical competence of a medical laboratory for a specific task based on the ISO/IEC 17025:2005, ISO 15189:2007 Standards. The procedure for getting accreditation is detailed in the general information brochure published as NABL 100[7]. Refer to http://www.nabl-india.org. There are five (5) stages in the accreditation process followed by NABL[8]. These are:

Stage I

- Prepare your laboratory's application for NABL accreditation, giving all desired information and enlisting the test(s) / calibration(s) along with range and measurement uncertainty for which the laboratory has the competence to perform. Laboratory can apply either for all or part of their testing / calibration facilities. Formats NABL 151, NABL 152 & NABL 153 are to be used by Testing, Calibration & Medical Laboratories respectively for applying to NABL for accreditation.
- Laboratory has to take special care in filling the scope of accreditation for which the laboratory wishes to apply. In case, the laboratory finds any clause (in part or full) not applicable to the laboratory, it shall furnish the reasons.
- Laboratories are required to submit three sets of duly filled in application forms for each field of testing/ calibration along with two sets of Quality Manual and Application Fees.
- NABL Secretariat on receipt of application will issue acknowledgement to the laboratory. After scrutiny of application for it being complete in all respects, a unique Customer Registration Number will be allocated to laboratory for further processing of application.
- NABL Secretariat shall then nominate a Lead Assessor for giving Adequacy Report on the Quality Manual / Application submitted by the laboratory. A copy of Adequacy Report by Lead Assessor will be provided to Laboratory for taking necessary corrective action, if any. The laboratory shall submit Corrective Action Report.

After satisfactory corrective action by the laboratory, a Pre-Assessment audit of the laboratory will be organized by NABL. Laboratories must ensure their preparedness by carrying out its internal audit before Pre-Assessment.

Stage II

- NABL Secretariat shall organize the Pre-Assessment audit, which shall normally be carried by Lead Assessor at the laboratory sites.
- The pre-assessment helps the laboratory to be better prepared for the Final Assessment. It also helps the Lead Assessor to assess the preparedness of the laboratory to undergo Final Assessment apart from Technical Assessor(s) and Total Assessment Man-days required vis-à-vis the scope of accreditation as per application submitted by the laboratory.
- A copy of Pre-Assessment Report will be provided to Laboratory for taking necessary corrective action on the concerns raised during audit, if any.
- The laboratory shall submit Corrective Action Report to NABL Secretariat.
- After laboratory confirms the completion of corrective actions, Final Assessment of the laboratory shall be organized by NABL.

Stage III

- NABL Secretariat shall organize the Final Assessment at the laboratory site(s) for its compliance to NABL Criteria and for that purpose appoint an assessment team.
- The Assessment Team shall comprise of a Lead Assessor and other Technical Assessor(s) in the relevant fields depending upon the scope to be assessed.
- Assessors shall raise the Non-Conformance(s), if any, and provide it to the laboratory in prescribed format so that it gets the opportunity to close as many Non-Conformance(s) as they can before closing meeting of the Assessment.
- The Lead Assessor will provide a copy of consolidated report of the assessment to the laboratory and send the original copy to NABL Secretariat.

Laboratory shall take necessary corrective action on the remaining Non-Conformance(s)/ other concerns and shall submit a report to NABL within a maximum period of 2 months.

Stage IV

- After satisfactory corrective action by the laboratory, the Accreditation Committee examines the findings of the Assessment Team and recommends additional corrective action, if any, by the laboratory.
- Accreditation Committee determines whether the recommendations in the assessment report is consistent with NABL requirements as well as commensurate with the claims made by the laboratory in its application.
- Laboratory shall have to take corrective action on any concerns raised by the Accreditation Committee.
- Accreditation Committee shall make the appropriate recommendations regarding accreditation of a laboratory to NABL Secretariat.
- Laboratories are free to appeal against the findings of assessment or decision on accreditation by writing to the Director, NABL.
- Whenever possible NABL will depute its own technical personnel to be present at the time of assessment as Coordinator and NABL Observer. Sometimes, NABL may at its own cost depute a newly trained Technical Assessor as "Observer" subject to convenience of the laboratory to be accessed.

Stage V

- Accreditation to a laboratory shall be valid for a period of 2 years and NABL shall conduct periodical Surveillance of the laboratory at intervals of one year.
- Laboratory shall apply for renewal of accreditation to it at least 6 months before the expiry of the validity of accreditation.

7 http://www.nabl-india.org/nabl/index.php?c=publicaccredationdoc&m=index&docType=both&Itemid=199
8 http://www.nabl-india.org/index.php?option=com_content&view=article&id=100&Itemid=13

SIMS REPORTING FORMAT

Reporting format for Regional STI Training, Research and Reference Laboratory				
National AIDS Control Programme				
Name of centre				
Address				
Centre Unique ID Number				
Name of Faculty In-charge	STI/ DVL	ObGynae	Microbiology	Community Medicine / Social & Preventive Medicine
Email				
Phone Number- Land Line with STD code				
Mobile Number				
Reporting Officer				
Reporting Period:	Month (MM)		Year (YYYY):	

Section 1 A: Age & Sex Distribution of STI / RTI patients / samples received (from within State including facilities in the same premises)

Source of Patients/Samples				Age Group & Sex														Total		
				<19			20-24			25-44			45 and Above							
				Male	Female	TS/TG	Male	Female	TS/TG	Male	Female	TS/TG	Male	Female	TS/TG	Male	Female	TS/TG		

STI OPD / IPD																	
ObGynae OPD / IPD																	
NGOs																	
Private Sector																	
Others (Specify)																	

Section 1 B: Age & Sex Distribution of STI / RTI patients / samples received (from linked States)

S.No	Name of the State			Age Group & Sex												Total		
				<19			20-24			25-44			45 and Above					
				Male	Female	TS/TG	Male	Female	TS/TG	Male	Female	TS/TG	Male	Female	TS/TG	Male	Female	TS/TG
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		
9																		
10																		

Section 2 : Syndromic validation of patients /samples received by centre

S.No	STI/RTI syndrome			Name of Laboratory Test/s performed	Number tested				Number found Positive				Mention the number of syndromic diagnosis matched by lab tests
	Syndrome	No received	Specific STI		Male	Female	TS/TG	Total	Male	Female	TS/TG	Total	
I	GUD Non Herpetic		Syphilis	Dark Field Microscopy									
				VDRL Test –Qualitative									
				VDRL Test - Quantitative (No. of samples showing titers =1:8 +ve)									
				RPR Test- Qualitative									
				RPR Test - Quantitative (No of samples showing titers =1:8 +ve)									
				TPHA test									
				FTA-Abs									
			Chancroid	Gram stain of ulcer smear									
				Culture									
			Donovanosis	Tissue smear for Donovan bodies									
II	GUD Herpetic		HSV I & II	Ulcer smear for MNGC									
				HSV-1 IgG,									
				HSV-1 IgM									
				HSV-2 IgG									
				HSV-2 IgM									
				ELISA Antigen									

III	Urethral Discharge syndrome		N. gonorrheae	GC Smear - Male (Discharge/Urine)									
				GC Culture –Male									
			C. trachomatis	ELISA Antigen									
				DFA									
			T. vaginalis	Direct wet mount- Discharge									
				Urine sediment									
				Culture									
IV	Oral / Anorectal Discharge syndrome		N. gonorrheae	GC Smear – Discharge									
				GC Culture									
			C. trachomatis	ELISA Antigen									
				DFA									
V	Vaginal discharge syndrome		T. vaginalis	Direct wet mount - Vaginal discharge									
				Culture									
			Candida sp	KOH									
				Gram stain									
				Culture (APEX CENTRE WILL COLLECT THE SPECIATION OF CANDIDA FROM REST OF CENTRES AND SHARE THE SUMMARY WITH NACO/DAC)									
			B. vaginosis	Gram stain									
VI	Cervical discharge syndrome		N. gonorrhoea	GC Smear – Female									
				GC Culture –Female									
			C. trachomatis	ELISA Antigen									
				DFA									
			T. vaginalis	Direct wet mount-discharge									
VII	Hepatitis B			HBsAg									
				ELISA HBV									
VIII	Hepatitis C			Anti HCV 3RD GENERATION ELISA									
IX	Others (Specify)												
				Total number of patient/samples screened for syphilis (VDRL qualitative and quantitative tests) other than tested under GUD-NH diagnosis									
			HPV	NAAT									

Section3 : Number of Gonococci cultures and Anti-Microbial Resistance studies performed				
Number of GC cultures performed during the month				
		Cefixime	Ceftriaxone	Both
Number of cultures positive	Susceptible			
	Less Sensitive			
	Resistant			
Number of cultures negative				

Section 4 : Number of other STI/RTI pathogens cultured and Anti Microbial Resistance studies performed				
S.No	Name of the Organism	Number of positive cultures	Number found resistant / less sensitive to drugs advised in National guidelines	Remarks
1				
2				
3				
4				
5				
6				
7				
Total				

	Section 5 : Status of kits				
Kits	Opening stock	Number received this month	Number Consumed	Damaged/ Wastage	Closing Stock
VDRL Kits					
RPR Kits					
TPHA Kits					
ELISA kits					
HSV II IgM					
DFA					
ELISA for antigen					
Ct Ag					
HBs Ag					
Anti-HCV Ab					

Section 6 : AMC Status of Equipment	
Is AMC contract for equipment active - Y / N	
If answer is NO, mention since when	

Section 7 : Details of Trainings conducted

S.No	Particular	Number of Induction trainings	Number of Refresher trainings	Total number of persons trained
1	Microbiologists			
2	Lab Technicians			
3	Others			
4	Total			

Section 8 : Details : Details of Syphilis EQAS conducted

S.No	Number of labs participated	Number reports received	Number of feedback provided	
1				
2				
3				
4				

Section 9 : Details of STI/ RTI Research work by centre

S.No	Name of the research work undertaken	Current status of implementation	Brief description of outcome/results
S.No	Number of research papers sent for publication	Number of papers accepted	Number of research papers published*
STI / Gynae			
Community Medicine			
Microbiology			
Others			

* Hard Copy of research papers published should be provided to NACO

Guidelines For Filling Reporting Format For Regional STI Training, Research and Reference Laboratories

Who should fill this?

This reporting format should be filled by all regional STI training, research & reference laboratories and state reference centers and submitted to the corresponding reporting authority through SIMS with a hard and soft copy to Apex & RSTRRL.
All centers (regional and state) should fill all sections of the format.

What are the different sections of STI format?

The format is divided into nine sections as follows:

Section 1A: Age and sex distribution of STI/RTI Patients/samples received from within the state including facilities in the same premises

Section 1B: Age & sex Distribution of STI / RTI patients/ samples received (from linked States)

Section 2A: Syndromic validation of patients/samples received by centre

Section 2B: Syndromic diagnosis and investigation details

Section 3: Number of Gonococci cultures and antimicrobial susceptibility tests performed

Section 4: Number of other STI/RTI pathogens cultured and antimicrobial susceptibility tests performed

Section 5: Status of kits

Section 6: AMC Status of equipment

Section 7: Details of trainings conducted

Section 8: Details of Syphilis EQA conducted

Section 9: Details of STI/ RTI research work by centre

General information:

Indicators	Explanation
Name of centre	Mention the name of the Institute where the regional or state centre is located.
Address	Mention the detailed postal address of the centre
Centre Unique ID	Centre Unique ID number will be provided by respective SACS
Name of the Faculty in-charge - STI /OBGYN/Microbiology/Social & Preventive Medicine or Community Medicine	Mention the name of Faculty in charge from each of the four basic specialties (STI/OBGYN/Microbiology/PSM or CM)
Email of each of the Faculty in charge - STI /OBGYN/Microbiology/Social & Preventive Medicine or Community Medicine	Mention the email-id of each of the faculty in charge of STI/OBGYN/Microbiology/Social & Preventive Medicine or Community Medicine
Phone Number- Land Line with STI code	Mention the Land Line Phone number with STI code of each of the faculty in charge from STI/OBGYN/ Microbiology/Social & Preventive Medicine or Community Medicine
Mobile number	Mention the Mobile Phone number of each of the faculty in charge from STI/Gynae/Microbiology/Social & Preventive Medicine or Community Medicine
Reporting period	Reporting month and year in the form of MM and YYYY. Example: the data for the month of January, 2014 would be reported in Feb 2014. So the reporting month is 01 and year is 2014.

Section 1 A – Age and sex distribution of STI/RTI Patients/Samples received from within the state including facilities in the same premises.

- Fill the number of sample received for laboratory testing from individuals who attended RSTRRL under appropriate age and sex category or sample received for testing at the regional laboratory from different sources.
- Please specify source from where patient/sample was received.

Indicators	Definition/Explanation
STI OPD / IPD	STI Out Patient Department (OPD)/ Inpatient department (IPD),
OBGYN OPD / IPD	Gynaecology and Obstetrics Out Patient Department (OPD)/ Inpatient department (IPD)
NGOs	Non-Governmental Organizations implementing Targeted Intervention projects
Private Sector	Any provider in private sector
Others (Specify)	from any other source/s.

Section 1 B – Age and sex distribution of STI/RTI Patients/ Samples received from linked States

All Regional STI Reference, Training and Research laboratories are linked to state reference centre of other states.

- Please mention the name of referring state in the column marked "Name of State".
- Fill the number of samples received for laboratory testing from individuals who attended RSTRRL under appropriate age and sex category or samples received for testing at the regional laboratory.

Section 2 – Syndromic validation of Patient/Sample received by centre.

- Centre will receive either patient/sample with STI/RTI syndromic diagnosis for laboratory testing.
- Centre to record, number of such patients/samples received under each syndrome.
- Centre to perform laboratory test to validate the diagnosed syndrome and record the results as per the sex distribution of patient/sample.

For Example:
A patient /sample is sent to centre with a diagnosis of Genital Ulcer Disease Non Herpetic Syndrome (GUD-NH Syndrome).

The most common etiologic agents for GUD-NH syndrome are *T. pallidum* (Syphilis); *H. ducreyi* (Chancroid), *K. granulomatis* (Donovanosis).

The centre performs the tests to detect the above etiological agents (Microscopic or serologic) for GUD-NH syndrome.

If any or all of the above etiological agents are detected for GUD-NH syndrome, then the centre will report the number of such patients/samples matched with syndromic diagnosis.

- The results for all other STI/RTI syndromes (GUD-Herpetic syndrome; Urethral Discharge syndrome; Vaginal Discharge syndrome; Cervical Discharge syndrome; Oral/ Ano-Rectal discharge syndrome) to be recorded in a similar manner.

- Centre to record the number of tests performed for Hepatitis B and Hepatitis C and provide the results.
- If the centre has performed any other STI/RTI tests then that information should be recorded under "Others'. Please specify the etiological agent/s detected.
- Centre to record the total number of patient/samples screened for syphilis (VDRL qualitative and quantitative tests) during the reporting period other than patients/samples tested under GUD-NH diagnosis

Section 3 – Number of Gonococcal cultures and anti-microbial susceptibility tests performed

- Centre to record the number of gonococcal cultures performed during the month.
- Centre to record the results of antimicrobial sensitivity test results of the gonococcal strains isolated for Cefixime, Ceftriaxone and both.
- Record the number of Gonococci strains found 'Susceptible', 'Less sensitive', 'Resistant' to Cefixime, Ceftriaxone and both.

Section 4 – Number of Other STI/RTI pathogen cultured and Anti-microbial resistance studies performed

- Centre to record the number of other STI/RTI causing agents cultured during the month.
- Centre to record antimicrobial sensitivities results of the cultured STI/RTI etiologic agents for drugs as advised in National STI/RTI treatment guidelines and record number found 'Resistant' and 'Less sensitive' to the drugs.
- Any additional information, which is relevant under this section, to be recorded under 'Remarks' column.

Section 5 – Status of kits

- Centre to record status of kits.
- Centre to mention separately for each of the test kits (VDRL, RPR, TPHA, ELISA, HSV 2 IgM, Ct Ag, HBsAg, Anti-HCV kits etc.)

Indicators	Definition/Explanation
Opening stock	Total number of stock on the first day of the month.
Number received during this month	Number of kits/consumables received by the centre in the current month
Number consumed	Number of kits/consumables utilized during the month
Damage/wastage	Mention the number of kits/consumables damaged/ wastage in the month
Closing stock	(Opening stock plus number received in the month) minus (number consumed plus number damaged/wastage in the month).

Section 6 – Annual Maintenance Status of equipment.

- Centre to record AMC status of equipment.
- Y for Yes and N for No.
- If centre doesn't have AMC for any equipment mention since when the AMC is not present.

Section 7 – Details of Trainings conducted.

- Centre to record details of induction /refresher training conducted for various cadres of staff (Microbiologists, Laboratory Technicians and others).
- Centre to record number of staff trained.

Section 8 – Details of Syphilis EQA of conducted.

Indicators	Definition/Explanation
Particulars of serum panels distributed	Number of serum panels distributed by Regional STI centre (from Apex laboratory to other regional laboratories and from regional laboratories to state reference centres)
Number of reports received	Number of centres provided reports of panel testing (to be recorded by centre which has distributed the panels)
Number of feedback provided	Number of centres provided with feedback on panel testing (feedback to be provided by centre which distributed the panels)

Section 9 – Details of STI/RTI research work conducted by the centre.

Indicators	Definition/Explanation
Name of the research work undertaken	Mention the title of the research work undertaken by centre
Current status of implementation	Mention the progress of the research work undertaken
Brief description and outcome/results	Mention the outcome /results of the research work undertaken in brief.
Number of research papers sent for publication by (STI, Gynaecology& Obstetrics, Community Medicine ,Microbiology and other departments)	Mention the number of research papers sent by various departments during the reporting period.
Number of papers accepted	Mention the number of research papers accepted for publication during the reporting period
Number of research papers published	Mention the number of research papers published by peer reviewed journals during the reporting period.

Mentoring Checklist for Regional STI Training, Research and Reference Laboratories (RSTRRL)

Name of the regional laboratory: .....

Name of microbiologist in charge: .....

Date of visit: .....

Visited by: .....

S No.	Indicators	Score	Maximum Score	Remarks
A.	**Review of facilities and staff**			
1.	Is the space allocated adequate for the activities such as sample collection, storage and lab testing?	Yes = 1 No = 0	1	
2.	Does the centre have facilities for sample collection (phlebotomy, urine sample collection, vaginal/cervical/urethral/anal swab collection)?	Yes = 1 No = 0	1	
3.	Is all the equipment (as recommended in the guidelines) present and in working state?	Yes = 1 No = 0	1	
4.	Does the centre have an annual maintenance contract for the equipment?	Yes = 1 No = 0	1	
5.	Are the recommended infection control procedures followed?	Yes = 1 No = 0	1	
6.	How does the centre dispose of bio-medical waste? (Are recommended procedures of biomedical waste disposal followed)	Yes = 1 No = 0	1	
7.	Is all staff (as per recommended guidelines) in position?	Yes = 1 No = 0	1	
8.	Is the staff trained?	Yes = 1 No = 0	1	

S No.	Indicators	Score	Maximum Score	Remarks
9.	Are internal and EQA systems in place (review records)?	Yes = 1 No = 0	1	
B.	**Consumables and reagents**			
1.	Are the procurement procedures followed?	Yes = 1 No = 0	1	
2.	Has there been any stock out in the last three months?	Yes = 1 No = 0	1	
3.	Are there standardized guidelines for re-order levels?	Yes = 1 No = 0	1	
4.	Do the consumables and reagents conform to minimum quality standards?	Yes = 1 No = 0	1	
5.	Are the reagents stored appropriately (e.g. refrigeration, away from direct sunlight, etc.)	Yes = 1 No = 0	1	
C.	**Review of past activities**			
1.	Lab tests in last 30 days: *Review and record the numbers and types of lab tests conducted in the last 30 days (source: monthly reports, daily lab register)*	Average workload/ day <10 tests/ day= 0 10-20 tests/day = 1 20-40 tests/ day= 2 >40 tests/ day= 3	3	
2.	Referrals: Has the regional laboratory received any sample/patient referrals from the SRC/STI/TI clinics /Private sector/NRHM facility in the last three months? If yes, record numbers	Average samples received from periphery No samples= 0		
3.	SRC supervision: Has the regional laboratory conducted any training visits to the SRCs in the last six months?	Total number of training visits expected in the quarter No visits= 0 One or more visit/s= 1	1	
4.	Have any EQA activities for syphilis testing (panel sera/proficiency testing) at the SRCs/DSRCs been conducted in the last three months?	Yes = 1 No = 0	1	
5.	Research/surveillance activities: *Review and record progress of the research and/or surveillance activities undertaken in last three months*	Yes = 1 No = 0	1	

S No.	Indicators	Score	Maximum Score	Remarks
6.	Quarterly meetings: *Review records of the last quarterly meeting with the nodal officers from other departments.*	Yes = 1 No = 0	1	
D.	**Reporting and documentation**			
1.	Are daily lab tests and stock registers maintained and up-to date?	Yes = 1 No = 0	1	
2.	Have the monthly reports for the last three months been filled-in completely and sent on time?	Yes = 1 No = 0	1	
3.	Review any additional reports (on research activities) been sent to SACS/DAC?	Yes = 1 No = 0	1	
4.	Have any papers been published in the last three months? If yes, details to be recorded	Yes = 1 No = 0	1	
5.	Report of last mentoring visit: *Review report of last mentoring visits and check if recommendations have been addressed*	Yes = 1 No = 0	1	
6.	Salient findings and recommendations: *Record salient points of the visit, including any points raised by the regional laboratory staff. Develop an action plan along with the centre staff for the activities for next three months and address any challenges faced (such as stock-out)*			

Tools for Evaluating Standards for STI / RTI Laboratory Services at Regional STI Training, Research & Reference Laboratories (RSTRRL) / State Reference Centres (SRC)

A. Location-

State: .....

District: .....

Name of the Centre: .....

Complete Address: .....

Name and Phone Number of Service Provider: .....

Unique ID number: .....

B. Facilities uptake and service package-

Is the STI Centre diagnosing and treating all possible STI/RTI cases coming to the hospital?

I. **Infrastructure for SRC-**

1. Waiting area
2. Laboratory Diagnostic are
3. Specimen Collection area
4. Washing facility
5. Sterilization area
6. Packing/ swab making area
7. Media preparation area
8. Store room
9. Office area
10. Toilets (male and female)

II. Availability of equipment-

1. Binocular bright field microscope
2. Binocular dark field microscope
3. Binocular fluorescent microscope
4. ELISA reader, printer, washer
5. Biosafety cabinet /Laminar air flow hood
6. VDRL rotator
7. Incubator
8. BOD incubator
9. Hot Air Oven

10. Autoclave (separate for sterilization and waste treatment) (As per BMW guidelines- culture plates with growth should be autoclaved and rendered non-infectious before disposal)
11. Deep freezer (-200C)
12. Deep freezer (-800C)
13. Centrifuge
14. Serological water bath
15. Vortex machine
16. Digital/Electronic balance
17. pH meter
18. Micropipettes of various capacities.
19. Water Distillation plants.
20. Lyophilizer
21. Teaching microscope
22. Needle destroyers
23. PCR (optional)-.
24. Mobile STI van

III. Availability of human resources -

1. Qualified and dedicated Venereologist (male/female) to STI
2. Microbiologist
3. Epidemiologist
4. Dedicated staff nurse
5. Counsellors (male and female)
6. Laboratory supervisor
7. Laboratory technician
8. Laboratory assistants
9. LDC/UDC (Lower Division Clerk/ Upper Division Clerk)
10. Lady health visitor (LHV)/MHV
11. Health educator
12. Store keeper
13. Nursing attendants
14. Safai karamchari
15. Driver
16. Technical Officer (formerly known as Research Officer)

IV. Availability of office equipment and furniture-

1. Display plates and boards for all rooms
2. Photocopier
3. Computer-(PC with printer, DVD writer, scanner) /Laptop

4. Fax machine
5. Telephones (PABX and EPABX)
6. LCD facility
7. Almirahs
8. Revolving stools
9. File cabinets
10. Refrigerators
11. General office furniture (tables/chairs)

V. Availability of kits, media & reagents-

1. Reagents for Gram's stain
2. Reagents for Giemsa stain
3. Chemicals for wet mounts (KOH), buffers etc)
4. Media for GC culture
5. Media for Candida culture
6. Media for *H.ducreyi* culture
7. Media for *T. vaginalis* culture
8. Media for culture of pyogenic organisms
9. Kits for Syphilis- VDRL/ RPR, TPHA, FTA-Abs
10. Kits for Chlamydia- DFA, ELISA (antigen)
11. Kits for *Herpes simplex-2*-ELISA (antibody)
12. Kits for HBsAg detection
13. Kits for anti HCV antibody detection

VI. Availability of consumables-

1. Disinfectants
2. Gloves
3. Colour coded waste disposal bags and bins
4. Syringes
5. Needles
6. Vacutainers
7. Specimen collection receptacles
8. Sterile swabs
9. Glassware and plastic ware

VII. Availability of patient records, referrals & reporting- about STI/RTI

1. Complete and correct patient wise record
2. Laboratory registers (test-wise)
3. Investigation requisition proforma

4. Clinic register (Male/Female)
5. Storage cupboards/almirahs with lock and key for register
6. Monthly report proforma
7. Counsellors registers
8. Consent forms wherever applicable
9. Equipment stock register
10. Equipment log book
11. Indent registers
12. Equipment condemnation register
13. Occurrence and accident register
14. Suggestion/ complaint register
15. EQA record registers

VIII. Availability of Internal Quality Control (IQC) and EQA

1. Staff member designated for IQC and EQA

IX. Availability of Biomedical waste disposal system-

1. Colour coded bags
2. Colour coded containers
3. Needle destroyers
4. Dedicated autoclave for waste disposal
5. Microwave
6. Disinfectants
7. Heavy duty gloves
8. Spills kit
9. Posters for education
10. Training and refresher course material

X. Infection control system in place-

1. Barrier protection devices in place (gloves, masks, eye shields, boots)
2. Hand washing material
3. Spills kit
4. Waste disposal system

XI. Availability of condom distribution system-

1. Good quality Govt. supply of condoms
2. Educative pamphlets
3. Penis model

XII. Status of NABL accreditation

CHECK LIST

1. Laboratory performance
2. Laboratory staffing
3. Microbiologist performance
4. Lab technician performance
5. Clinician performance
6. Counsellor performance
7. Nurse performance
8. Class III and IV performance
9. Completeness of patient records
10. Laboratory records
11. Laboratory equipment maintenance
12. Media, kits and consumables
13. Referral network
14. Infection control system
15. Ethical standards and confidentiality
16. Training and refresher/reorientation course activities

Surveillance Report for Syndromic Validation

Name of RSTRRL: .....

Date of report: .....

Report of samples collected from ..... to ..... (dates)

Clinic code*	Name/ OPD no. of patient	Age	Sex	Symptoms	Clinical signs	Syndromic diagnosis	Samples collected (swabs, urine, blood etc.)	Etiological testing	Obs.**

* Assign different codes to each clinic in the collection area

** Please explain any unusual observations

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