

Group E (1). Laboratory Support to STI services

Syndromic case management of STIs is important because it allows investigators to know the patterns of disease in the target population and the antimicrobial resistance of the associated pathogens.

Monitoring conventional STIs in a population is important in HIV/AIDS control because STIs share common behavioral determinants with HIV and enhance the transmission of HIV. STI surveillance can act as a sensitive surrogate marker for changes in risk behavior. STI episodes are also a logical and convenient point at which to introduce voluntary counseling and testing (VCT) for HIV to a population that is at high risk. Serological testing for syphilis offers an opportunity for the introduction of prevention of mother to child transmission (PMTCT) activities for HIV.

Levels of Laboratory System: Tests and Services Performed

- Multi-country Regional Level
 - Provide training for central (national) level
 - Integrated training modules for existing workforce
 - Specialized training to support syndromic management, validation studies and antimicrobial susceptibility
 - Provide QA for activities at the central (national) level
 - Syphilis surveillance: general QA for central laboratory
 - Quantitative RPR
 - Rapid tests and TPPA/TPHA
 - Specimen panel for evaluation for proficiency
 - Analyses for treatment failures: QA for all testing performed at the central level
 - For GUD recurrence/etiology: Multiplex PCR GUD testing
 - Anti-microbial susceptibility testing
 - GC culture and MIC as gold standard + E-test, Disk diffusion
 - Amplified test for GC and CT
 - QA for syndromic management validation testing
- Central (national) Level
 - Provide training for district and peripheral levels
 - Procurement procedures
 - Capability to perform:
 - Syphilis surveillance: general QA for district and periphery
 - Quantitative RPR
 - Rapid tests and TPPA/TPHA
 - Analyses in cases of treatment failure
 - Wet mount
 - Gram stain
 - For GUD recurrence/etiology
 - Tzanck prep

- Giemsa stain
 - GC culture
 - Syndromic management validation
 - Gram stain
 - Anti-microbial susceptibility testing:
 - GC culture
 - E-test
 - Disk diffusion of MIC
 - (Non)-amplified test for GC and CT
- District Level
 - Procurement of RPR/rapid tests and other laboratory needs for own testing and peripheral laboratories
 - Syphilis surveillance RPR/Rapid test for confirmation
 - Treatment failures:
 - Wet mount
 - Gram stain
 - For GUD recurrence/etiology:
 - Tzanck smear for HSV
 - Giemsa for Donovanosis
 - Syndromic management validation:
 - Gram stain
 - Specimen manipulation
 - GC culture
- Peripheral Level
 - Routine STI testing
 - Syphilis and HIV serology only
 - Screening with RPR or rapid test
 - All cases of genital ulceration
 - All cases of urethral discharge in men
 - All cases of vaginal discharge in women, when the rate of positive syphilis serology is <5% and the prevalence of GC/CT/TV is >20%
 - All cases of vaginal discharge in women, when the rate of positive syphilis serology is >5%
 - Laboratory functions
 - RPR surveillance
 - RPR if there is electricity and a refrigerator
 - Rapid treponemal tests if there is no electricity and a refrigerator
 - Algorithm validation specimen collection and storage

Training

- STI Laboratory training
 - Training for partners on SOP/CDC guidelines
 - Regional or National: Integrated training

- QA: includes proficiency tests, specimen panel
 - Maintenance
 - Supervision and monitoring modules
 - National level: Specific training
 - Linked to implementation of programs nationwide performed by CDC/partners
 - School curriculum level: Medical, nurses, and technicians
 - Peripheral/District levels: specialized QA and program training courses performed by central partners
- Integrated training
 - Formations of a working group to investigate:
 - Integrated training at the district/peripheral levels, including:
 - Malaria
 - TB
 - Syphilis
 - HIV
 - Standardization of activities should include:
 - Record keeping
 - QA
 - SOP
 - Supervision, including EQA

Critical tools and products

- National standard operating procedures:
 - Screening guidelines
 - Antimicrobial susceptibility testing and syndromic management treatment guidelines
 - Treatment failure management guidelines
- Training package:
 - CD/Video modules adapted to each training
 - Checklist for QA
 - Curriculum development for STI syndromic case management for medical students, post-graduates and nurses; laboratory training for STI diagnostics for technologists and technicians

Group E (2). Laboratory Support TB Diagnosis and Monitoring

General Recommendations

- Strengthen TB microscopy centers by building on the existing infrastructure at the national, provincial, and district levels.
- Promote the leadership role for the National Reference Laboratory.
- Integrate the TB model with other laboratory tests through training, QA, EQA, supervision, and supply management.

Levels of Laboratory System: Tests and Services Performed

- National Reference Laboratory (located in the capital city)
 - Services to clinics
 - FM/ZN smear microscopy
 - Culture/ID of MTB, referral services
 - Drug susceptibility testing (DST)
 - Supports to intermediate laboratories
 - Supply of reagents/materials for smear microscopy
 - Training
 - Supervision
 - EQA of smear microscopy
 - Culture
 - Drug susceptibility testing
 - Manpower: 5-6 laboratorians (for TB work only)
 - Covering population: entire country
- Intermediate Laboratory (located in regional TB health institutions, including hospitals)
 - Services to clinics
 - FM/ZN smear microscopy
 - Culture and identification (ID) of MTB, referral services
 - Supports to peripheral laboratories
 - Supply of reagents/materials for smear microscopy
 - Training
 - Supervision
 - EQA of smear microscopy
 - Manpower: 2-3 laboratorians (for TB work only)
 - Covering population: 500,000-1,500,000
- Peripheral Laboratory (located in peripheral TB dispensaries/centers, health centers, district hospitals, 1st referral hospitals)
 - Services
 - Sputum collection
 - FM/ZN smear microscopy
 - Managerial
 - Recording/reporting
 - Slide keeping for EQA

- Manpower: < or equal to 1(2) laboratorian(s) (for TB work only); >2-3 laboratorians/<20 smears per day
- Covering population: 100,000-200,000

First Year Plan (General)

- Develop AFB training materials on the following areas for in-country use:
 - Basic microscopy
 - Implementation of EQA
 - Laboratory safety issues
- Implement training courses and mentoring for expert TB laboratory consultants
- Market and distribute existing TB guidelines and training materials
- Develop training strategy within each country
- Assess and upgrade equipment
- Ensure adequate supplies and inventory
- Examine fluorescence microscopy utility in anticipation of increases workload and to increase sensitivity of case detection

First Year Plan (Integrated Laboratory Network)

- Develop standards for the set of essential testing services to support The Emergency Plan
- Develop a model to implement and support this integrated testing model
- Establish a regional working group to address laboratory service integration at every level (National, Regional, District, Peripheral)
 - Develop checklist for supervision/EQA/QA
 - Develop integrated training curriculum
 - Documents, records, information system
 - Supply and inventory
 - Procurement
 - Procedures, technologies
- **Human resources**
 - Strengthening professional/in-service curriculum
 - Address workforce incentives/retention
 - Training, monitoring, supervision, QA of community-based (lay) worker testing