CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

TAG Treatment Action Group

Partners In Health

Specifications for POC TB Diagnostic 2009
QUESTIONNAIRE for TB Field Practitioners

Part ONE - IN YOUR MEDICAL PRACTICE:

This section is intended to gather information about the context of your current practice and/or past field experience. This will allow us to understand better the difficulties you are facing in TB diagnosis and to relate them adequately with the priorities you will define in Part TWO of this questionnaire.

1. Which level of health care structure do you work in?
    a. Regional Hospital
    b. District Hospital
    c. Health Centre
    d. Private Clinic
    e. Urban Clinic
    f. Rural Clinic
    g. Rural Health Post

2. What is the distribution of the TB suspect population seen at your clinic:
    I. % of children 1-6 years old
    II. % of children 7-15 years old
    III. % of HIV/TB co-infected patients
    IV. % of Extra Pulmonary (EP)TB cases
    V. % of Drug-Resistant (DR)-TB cases

3. Is both TB and HIV care available in your institution? To what extent is TB/HIV care integrated?

4. Type of laboratory resources available to you:
    - Do you have a lab within your institution?

        ☐ Yes ☐ No

    If Yes:
    a. What are the diagnostic tests used to detect TB patients in your setting?
    b. If you don't have access to Drug Susceptibility Testing (DST) in your lab, can you refer the analysis to an external lab? If yes, which DST test do they perform?

    If No: If you have to send samples for microscopy, is the transport system available and efficient?

5. In order to strengthen your medical practice, which of the following gaps or problems should be addressed in priority (please rank the five gaps you think are the most important ones):
    a. Low sensitivity of sputum smear microscopy (SSM).
    b. Low overall diagnostic performance of SSM due to variability of analysis (due to lack of experienced microscopists, eye fatigue or work overload).
    c. No discrimination between dead and alive bacilli seen in SSM.
    d. Results confirm presence of acid-fast bacilli, mostly from *Mycobacterium sp.* but cannot say if part of the Mtb complex (could be *M.avium* for example).
    e. Lack of drug susceptibility evidence without further referral.
    f. Inadequacy of sputum specimen sample in diagnosis paediatric, infants, HIV co-infected, and EPTB patients.
    g. Multiple samples analysed per patient.
    h. Lengthy turn-around time to results.
    i. Cost.
    j. Infrastructure required.
    k. Training required.
    l. Health and lab workers risk exposure during handling, processing and decontamination of sputum specimen.

6. What would you define as an acceptable turn around time (time between sample collection and results back to the patient) for a POC TB test?

7. In a situation where you suspect a <u>false negative</u> test result, what steps do you take? (e.g.: re-test later, follow up, clinical algorithms or ignore lab results)

8. In a situation where you suspect a <u>false positive</u> test result, what steps do you take with the available tests at your site to rule out TB?

Part TWO - IN AN IDEAL SITUATION:

We now seek to gather information about your needs in daily practice and your vision of what an ideal test would be and how you would use it in daily practice. This will allow us to define the <u>intended use</u> of any new tests to be developed in the coming years.

9. What does “Point of Care (POC)” mean for you? Please complete this sentence:
   A POC test is a test used …
    a. at point of care where you treat the patients.
    b. at point of collection of samples where the patients can be seen by community health worker.
    c. anywhere else? Please complete with your own definition.

Please note that for the following questions, we refer to a POC test or POC level as being a test that can be performed at least (but not exclusively) at a most remote health care structure (e.g rural health post or mobile clinics).

10. Which of the following medical decisions would you most like to see being done at POC level? Choose one only.
    a. Treatment initiation (diagnostic test)
    b. Targeting the adequate treatment line (DST test)
    c. Detection of treatment failure (Treatment monitoring)
    d. Differentiation between active and latent TB

11. An ideal POC test for active TB would combine diagnosis, DST and treatment monitoring. If not all analyses could be integrated on a single device, which one would you accept to be part of a different test?

12. Which category of health workers is most likely to use a new TB POC test?
    a. Lab staff
    b. Nurses
    c. Medical doctors
    d. Community health workers

    Why?

13. How feasible would it be to introduce a new diagnostic test such as a TB POC test if nurses and/or community health workers were asked to perform the POC test (willingness, capacity, etc.)? How acceptable would it be to the patients?

14. Current TB diagnostic tools capacities are limited but best suitable for non-HIV adult patients. In your opinion, do we need a POC TB test that is able to diagnose a broader population?

    ☐ Yes ☐ No

    If Yes: Who are the additional patients you want to be able to diagnose with a new test? Please rank in order of priority.
    a. Children / paediatrics
    b. Latent TB infection cases
    c. HIV/TB co-infected
    d. EPTB
    e. DR-TB
    f. Paucibacillary / SSM negative cases
    g. Patients who are at risk of dying quickly
    h. Other: (please specify)

15. What would you consider to be the **best** sample(s) to use?
    (urine, sputum, venous blood, capillary blood, breath, stools, others)?
    Please explain why.

16. Would you accept a diagnostic made out of a combination of different samples?

    ☐ Yes ☐ No

17. Would you be happy to rely on a test with a detection based on:

I.	Whole organism (live or dead mycobacterium)	☐ Yes	☐ No
II.	Bacterial DNA	☐ Yes	☐ No
III.	Patient breath (organic compounds)	☐ Yes	☐ No
IV.	Bacterial antigens (proteins or lipids)	☐ Yes	☐ No
V.	Indirect marker (from human body response)	☐ Yes	☐ No

18. Would a TB POC test giving a quantitative or semi-quantitative value affect patient

treatment in any way (in comparison to a qualitative “yes/no” type of answer)?

☐ Yes ☐ No

If yes, what incremental advantage in patient treatment or monitoring would have such answer with a quantitative test value?

Would you accept a qualitative result through a yes/no answer?

☐ Yes ☐ No

19. Would you prefer to use a new test that totally replaces the sputum smear microscopy or a test that would complement microscopy by filling its performance gap?

20. In the overall TB management program, do you think a 2 or 3 test-algorithm in order to allow treatment initiation would be reasonable? (Please consider the following: confusion versus simplified management; supply and pricing; reluctance from the staff or the patients).

21. Which of the following new POC tests would you prefer (please rank):
    a. A test with similar performance to SSM, sputum-based, but more rapid and more accessible.
    b. A test with 90% sensitivity, 95% specificity, diagnosing active pulmonary TB, only in HIV negative, and only in adults.
    c. A test with 75% sensitivity, 95% specificity, diagnosing active pulmonary TB, irrespective of the HIV status, and in all-ages patients.
    d. A test with 60% sensitivity, 95% specificity, diagnosing active pulmonary and EPTB, irrespective of the HIV status, and in all-ages patients.
    e. A test with 60% sensitivity, 95% specificity, diagnosing active pulmonary, irrespective of the HIV status, in all-ages patients and in the same test also drug susceptibility information.

GLOSSARY:

DNA	Deoxyribonucleic Acid
DR	Drug Resistant
DST	Drug Susceptibility Testing
EPTB	Extra Pulmonary Tuberculosis
HIV	Human Immunodeficiency Virus
MTB	*Mycobacterium tuberculosis*
POC	Point of Care
SSM	Sputum Smear Microscopy
TB	Tuberculosis