REPUBLIC OF SUDAN
FEDERAL MINISTRY OF HEALTH
NATIONAL TUBERCULOSIS CONTROL PROGRAM

NORWEGIAN HEART & LUNG PATIENT ORGANISATION
WORLD HEALTH ORGANISATION
3rd IN-DEPTH REVIEW MISSION FOR NTP
NOVEMBER 2008

In-depth Review of the Sudan National Tuberculosis Control Programme
Executive Summary – January 2009

The review was carried out between 10th and 24th November 2008. The single most important and urgent recommendation was:-

SNTP at Federal and State levels to strengthen and monitor DOT and treatment support by developing clear guidelines and training for each of the following hierarchy of organized and documented treatment support options:

i. *Providing DOT and treatment support through all health facilities of the primary health care network*
ii. *Providing DOT and treatment support through community structures such as volunteers and patient organizations.*
iii. *Providing DOT and treatment support through guardians*

Given the importance of this recommendation, SNTP should seek external technical support for developing these activities in an organized, evaluable and sustainable manner.

A. Main findings according to specific objectives

Main findings

a) Case notification has not increased as planned, but declined and treatment success rate has remained stable between 81% and 84%.
b) A number of TBMUs were already established by 2004 (1 per 100,000 population) and there has been no increase since.
c) The general health system in Sudan faces considerable challenges. The TB programme therefore retains some functional elements under its own control
d) The Global Fund for AIDS Tuberculosis and Malaria (GFATM) Round 5 and Round 8 will provide substantial funding, including for financial incentive payments to health staff.

Recommendations for main findings

1. *SNTP Manager should proceed to re-organise the Central Team to facilitate effectiveness*
2. *SNTP at Federal level should develop a competence-based human resource development plan*
3. *The SNTP should make a plan for external TA and should co-ordinate this carefully with the training requirements identified in the human resource development plan.*
4. *FMOH should consider a long term strategy to take over incentive payments to staff working within the Primary Health Care (PHC) system.*
5. *SNTP should consider how the payment of financial incentives can result in strengthening the health system.*

B. Pursue high quality DOTS Expansion and Enhancement

B.1 Political commitment and sustainable financing

Strengths

a) Large number of health staff at all levels with few vacant positions.
b) Financial support from GFATM Round 5, Round 8, WHO, LHL and a number of NGOs.
c) Government financial contribution in 2007 amounted to 1 million US$ out of 3 million US$ spent by the SNTP.
d) Presence of a Public Health Act for notification and control of infectious diseases.

Weaknesses

a) High staff turnover at all levels – including 3 different SNTP Managers since 2004.
b) Coordination between SNTP and National Reference Laboratory not optimal.
c) States provide variable amount of financial support to TB control.

d) SNTP Offices located far from other key linkages; now co-located with 2 programmes with which SNTP has no joint activities.

Recommendations for enhanced political commitment and sustainable financing

6. *FMOH should strengthen co-ordination between SNTP and NRL.*

7. *FMOH should look for opportunities for co-location of Federal level offices of SNAP, NRL, SNTP*

8. *FMOH should increase its financial contribution to SNTP.*

9. *STNP should further develop it strategies for securing increased financial support from FMOH.*

10. *Authorities at State and Locality level should ensure funding and implementation of TB control activities.*

B.2 TB Case finding through quality assured bacteriology

B.2.1 Case finding

Strengths

a) Diagnostic facilities are located within PHC facilities and case finding activities are integrated with general out-patient facilities.

Weaknesses

a) Low case notification rate of new smear pos cases in most localities (below 35/100.000).
b) In Out Patient Departments (OPDs) a considerable number of TB suspects are not being identified, nor correctly recorded.
c) The diagnosis of TB is being made on clinical / radiological criteria rather than by smear microscopy.
d) Many patients experience extended pathways to TB diagnosis, visiting different providers
e) Only a minority of facilities and staff within the primary care network are involved in TB case-finding.

Recommendations for enhanced TB Case Finding

11. SNTP at Federal and State levels should inform and continually educate all health providers about the National Guideline for TB suspect management.

12. SNTP at State Level should strengthen the capacity of localities and TBMUs, to identify areas with low case detection and propose solutions.

13. SNTP should engage all parts of the primary care network in detection and referral of TB suspects to TBMUs.

B.2.2 Quality Assured smear microscopy and bacteriology

Strengths

a) A MoU defines the co-ordination between National reference Laboratory (NRL) and the NTP.
b) Adequate numbers of staff are available in central, intermediate and most peripheral level facilities.
c) Good quality microscopes and lab reagents are available in most laboratories.
d) EQA by blinded rechecking has been introduced in 12 states.
e) State lab coordinators have been identified for 15 states and one motor cycle is available for supervision in each of these states.

Weaknesses

National reference laboratory (NRL):

a) The planning for strengthening of the microscopy network is weak.
b) There are no clear linkages with any hospital, and there is no clear policy for referral of patients or specimens to NRL.
c) The is very limited reporting and no evaluation of NRL activity

d) There is no system for maintenance of infrastructure, equipment and the supply chain.
e) There is no standardized agenda for training activities (State, TBMU staff).
f) NRL is ready to move to new premises without adequate pre-planning
g) The plans to introduce liquid culture are not linked either to a clear policy on its use or to defined roles and responsibilities of key stakeholders.
h) Piloting of a Drug Resistance Survey (DRS) is ongoing in Khartoum despite the lack of a written, approved protocol.

State level:

a) EQA by blinded rechecking is inefficient in Khartoum, good in Sinnar, and only just started in Gedarif.
b) Weak technical capacity of state lab coordinators to identify and solve problems.
c) Standard Operating Procedures in the National manual are not available or not followed.
d) State laboratory infrastructure is weak.

TBMU level:

a) Internal Quality Control is not widely practiced
b) Opportunities to diagnose infective cases are being missed at laboratory level because of low sensitivity of microscopy.
c) There is no standardization regarding supply of non-consumables.
d) Many laboratories lack either water supply or power or both and the size and quality of buildings and furnishings is inadequate.

Recommendations for quality assured bacteriology (including smear microscopy)

14. *National Health Laboratory and SNTP to revisit the MoU to clarify the role of the NRL in and develop mechanisms for managing its relationship with SNTP.*
15. *NRL to play an active role with SNTP in planning and implementation of all activities related to quality assurance in the microscopy network.*
16. *SNTP to assist NRL in enhancing NRL capacity for recording, reporting, data management and data analysis.*
17. *NRL to develop and implement internal QC system for all its activities.*
18. *NRL to move to the newly built premises only after proper planning and preparation of TB culture and DST facilities by NHL/NTP with external technical assistance.*
19. *Strengthening of State Labs for supporting QA sputum smear microscopy should remain the highest priority of SNTP/NRL. Establishment of 5 zonal culture facilities should only proceed if it can be guaranteed that there will be no shift of priorities, finances, equipment or human resources away from microscopy.*
20. *NRL to define clear policy on use of liquid culture).*
21. *NRL should only introduce liquid culture only after the policy has been defined and full budget has been secured.*

B.3 Standardized treatment, DOT and patient support

Strengths

a) Treatment is standardized according to NTP guidelines in all the visited TBMUs
b) Community health workers are present in remote areas, and sometimes act as treatment supporters;

Weaknesses

a) DOT and/or treatment support by health workers is not in place in the majority of the visited TBMUs. Drug collection schedules during the intensive phase are haphazard.
b) Defaulter tracing is rare.
c) The use of streptomycin injection instead of ethambutol raises concerns about injection safety; and safe sharps disposal.
d) Contact tracing is not in place in most facilities.

e) TB infection control measures have not formally been addressed.

Recommendations for standardized treatment, DOT and treatment support

22. *SNTP at Federal and State levels to strengthen and monitor DOT and treatment support by developing clear guidelines and training for each of the following hierarchy of organized and documented treatment support options:*
    - *iv. Providing DOT and treatment support through all health facilities of the primary health care network providing DOT and treatment support through community structures such as volunteers and patient organizations.*
    - *v. Providing DOT and treatment support through guardians or family members*

    Given the importance of this recommendation, SNTP should seek external technical support for developing these activities in an organized, evaluable and sustainable manner.
23. *SNTP should develop a plan for a carefully phased implementation of the 6 month regimen (2RHZE/4RH) Streptomycin should be phased out as part of this process.*
24. *FMOH to support SNTP to work with the Drug Regulatory Authority to regulate TB drugs in the private sector.*
25. *SNTP to strengthen the mechanisms for defaulter tracing and contact management.*
26. *SNTP should develop guidelines on infection control as part of the new guidelines, and increase the awareness among health workers on infection control guidelines.*

B.3 Monitoring and evaluation

Strengths

a) Presence of a system for monitoring and evaluation
b) Improved report completeness to 93% in 2008 compared to 70-80% in 2006-2007.
c) Report completeness is used to monitor performance;
d) Presence of an electronic reporting system between the Federal and State levels;
e) Coordination between Federal/state statistical coordinator and National/state preventive medicine department.

Weaknesses

a) The WHO revised recording and reporting (R&R) system has not been fully introduced
b) The quality of data is suboptimal:
c) Supervisory visits are in place but they are not effective:
d) There is delayed submission of reports from the majority of centres;

Recommendations for monitoring and evaluation

27. *SNTP should monitor, on a quarterly basis, the proportion of patients receiving DOT and treatment support from the TBMU register with an emphasis on capturing the quality of treatment support provided.*
~~28.~~ *SNTP should implement the core WHO recommended R&R materials.*
29. *The SNTP should consider the best way to use the OPD register to record TB suspects so that referral for smear microscopy can be strengthened.*
30. *SNTP should strengthen the supervisory system for corrective measures and joint problem-solving with a focus on data quality.*
31. *SNTP should strengthen the capacity of the TB Co-ordinators and Statisticians at all levels in data management and analysis and in TB epidemiology.*
32. *SNTP should work with International Partners to revise the existing supervisory check-list.*
33. *FMOH should reinforce the central unit with vehicles in order to increase the frequency of the supervisory visits to the state and peripheral levels.*

B.3.1 Impact measurement

The estimated incidence of sputum smear positive TB in Sudan is 108/100,000- based largely on from the 1987tuberculin survey. The impact of TB control measures taken since then has not been evaluated.

Recommendations for impact measurement

34. SNTP should work with WHO in revising the Sudan estimated TB incidence.

35. SNTP should carefully consider the planning, timing and implementation of the GFATM Round 8 TB prevalence survey to ensure that the international criteria are met.

B.3.2 Drug Management

Strengths:

a) The NTP has a full time position for drug management
b) A Procurement and Supply Management (PSM) unit has been established.
c) A draft TB manual including treatment guidelines is currently under revision.
d) Quality of drugs is ensured through UNDP's procurement processes
e) Pharmacists and pharmacy technicians are present in adequate number at all levels.
f) Few centres experienced stock-outs of only some drugs, for short periods of time. The drugs available have a long shelf life.
g) GFATM funds are available to provide distribution logistics and build Central and State medical stores in accordance with good storage practices.

Weaknesses

a) Roles, responsibilities, are not clear and co-ordination and communication are not optimal between the NTP PSM team and the UNDP PSM
b) Inventory management is not optimal at all levels of the distribution chain of TB drugs and storage space at central and state medical stores is limited.
c) Pharmacists at state level and pharmacy assistants at State and TBMU level are not fully involved in TB inventory management.
d) Expertise at State level in quantification and at TBMU level in inventory management and good storage and dispensing practices is not optimal.
e) The distribution plan for TB/HIV co-infection related commodities is not yet established.
f) Control of TB drug supply and distribution in the private sector is weak.
g) Lab commodity management and storage practices are weak at State and TBMU levels.

Recommendations for drug management

36. SNTP, UNDP and PSM team should better define their roles and responsibilities and improve lines of communication.

37. SNTP with partners should secure external TA to strengthen the capacity of the SNTP and PSM teams in TB drug management.

38. SNTP and partners should urgently finalise the National TB guidelines.

39. SNTP should formalise the existing team that works on quantification with a reflection on Terms of Reference and composition to include representation from the General Directorate of Pharmacy and the private sector.

40. SNTP and the PSM team should review and improve the distribution plan of TB drugs.

41. SNTP should, in collaboration with National Drug Regulatory Authority, identify ways to regulate TB drugs in the private sector. The principle of TB drugs only being available through the SNTP should be emphasized.

42. SNTP should include Lab commodity management expertise in the TA planned for lab quality assurance system strengthening.

C. Addressing MDR-TB, TB-HIV and other challenges

C.1 TB-HIV

Strengths

a) Presence of an active TB-HIV Collaborative Committee at Federal level and draft ToR's for a National TB-HIV body.
b) Presence of draft TB-HIV Action Plan and draft TB-HIV treatment guidelines.
c) GFATM funding for counselling and testing of TB patients and HIV treatment and care
d) Existence of a TB-HIV team within SNTP.
e) A body of practical and well-developed experience in TB-HIV activities in Omdurman Teaching Hospital VCT centre.

Weaknesses

a) TB-HIV activities outside Khartoum proceeding before National Body and Plan have been articulated.
b) Programmatic scale up of HIV treatment and care is being driven by SNAP drug distribution before development of competence and quality in HIV centres.
c) Laboratory and Pharmacy support for HIV are established as separate units away from existing Laboratory and Pharmacy facilities
d) Lack of a clear policy decision about which service (SNTP or SNAP) takes prime responsibility for HIV-infected TB patients and at what stages of treatment.
e) Despite provision of training in Provider Initiated Testing & Counselling (PITC), a Voluntary Counselling & Testing (VCT) approach is being used in TBMUs
f) Routines for safe disposal of sharps were inconsistent.
g) Lack of attention to infection control policies for TB patients mixed with HIV infected patients in HIV centres.

Recommendations for TB-HIV

43. The TB-HIV Collaborative Committee should merge the parallel development of TB-HIV plans and documents between WHO and SNTP and finalise these as soon as possible.
44. The TB-HIV Co-ordinating Body (once established) should pay particular attention to key issues as described in the updated Interim TB-HIV Collaborative Framework:
45. SNTP should engage specific, external TA from an individual who has been actively engaged in establishing successful TB-HIV to assist with recommendations 42 and 43.

C.2 MDR-TB

Strengths

a) SNTP, in collaboration with the Pharmaceutical Regulatory Body, succeeded in banning the availability of ofloxacin in private pharmacies.
b) Presence of a draft plan for Programmatic Management of MDR-TB.
c) Funding in GFATM Round 8 application for MDR-TB programmatic management, including second-line drugs.
d) A number of clinicians are already in training for management of MDR-TB.

Weaknesses

a) CMS have procured the FMOH-funded second-line drugs through their official processes, but some issues around quality need further clarification:
b) Not enough focus on prevention of MDR-TB compared to provision of second-line drugs.
c) No reliable baseline data on rates of MDR-TB in Sudan.

Recommendations for MDR-TB

46. SNTP to give urgent attention to the prevention of MDR-TB through the mechanisms described in Section on Treatment support and DOT.
47. SNTP to secure GLC approval for MDR-TB Management.
48. SNTP, with support from partners, should engage practical TA from an MDR-Treatment centre in the region order to develop and secure the GLC application. The lead physician for MDR-TB should spend time in a functioning MDR-Treatment centre in the region.

C.3 Refugees and displaced persons

Strengths

a) Presence of a focal person within the SNTP Central Unit for TB control amongst refugees and displaced persons
b) Signed MoU's between SNTP and some NGO's treating TB cases
c) Draft manual for management of TB in refugees.
d) Funding for TB control activities in war-affected areas in GFATM Round 8 application.

Weaknesses

a) NGO's with signed MoUs with SNTP are procuring their own TB drugs and using the 6 month regimen with unclear safeguards around treatment support and DOT.

Recommendations for TB control in refugees and displaced persons

49. SNTP and WHO should encourage NGO's to align themselves with National guidelines for case-finding, reporting and recording to SNTP with an emphasis on treatment support and DOT.

50. The SNTP should continue to negotiate new MoU's with NGO's which should stipulate the need for treatment support and DOT

D. Engaging all care providers

Strengths

a) Presence of GFATM funding for public-public and public-private mix activities
b) Presence of a draft PPM Operational Plan.
c) Good links and relationships between SNTP and Sudanese Association of Chest Physicians (SACP).

Weaknesses

a) Public institutions not consistently engaged.
b) Private for profit providers are not yet engaged.
c) Lack of a clear statement that the preferred model for engaging the private sector will be for identifying, diagnosing and referring patients to the SNTP public system.
d) An emphasis on payment of multiple financial incentives for engagement of the private sector in the pilot planned in the GFATM Round 8 application without consideration of associated risks.

Recommendations for engaging all care providers

51. FMOH should activate mechanisms for ensuring engagement of public health facilities outside of FMOH (military, police, prisons and health insurance.).

52. SNTP should engage the private sector primarily as an arm of TB case-finding, emphasizing unified treatment with treatment support and DOT within the public system.

53. SNTP should emphasize the provision of incentives in-kind more than the provision of financial incentives in engaging the private sector.

54. SNTP should seek formal and public SACP endorsement of the International Standards of Tuberculosis Care (ISTC).

E. Enable and promote operational research

Strengths

a) A research focal point has been recruited within SNTP at Federal level;
b) Several operational research projects have been completed with support from national and international partners..

Weaknesses

a) Some State TB Co-ordinators do not have oversight over relevant research and findings in their State.
b) Research reports have not been communicated to the state and peripheral levels;

Recommendations for promotion of operational research

55. SNTP Research Unit and Partners to revisit the operational research work plan at all levels, recognizing that with improved data quality within SNTP, the opportunities for identification of research questions and conducting research to solve problems will increase.

56. SNTP should strengthen the Research Unit within the SNTP.

57. SNTP should request researchers to prepare Arabic summaries of the final reports and disseminate these to state and peripheral levels;

58. Partners should provide technical assistance for publishing indexed journals;

59. SNTP should actively promote the use of research results in guiding policy and improving programme performance.

F. Contribute to Health System Strengthening

Strengths

a) Availability of human resources in all visited centres.
b) Presence of administrative and financial backbone for the program.
c) Training plan available at central and, to some extent, at state level.
d) Practical Approach to Lung Health (PAL) situation analysis has been completed and steps for awareness-raising with key decision makers have been planned.
e) Many different funders support SNTP.
f) GFATM Round 8 includes an element on health system development.

Weaknesses

a) High turnover of staff at all levels.
b) Staff performance is compromised structural and health system constraints.

Recommendations for TB's contribution to health system strengthening

60. SNTP should develop an annual training plan for relevant health cadres at all levels

61. SNTP to work with Partners to secure funding for PAL implementation.

62. FMOH and SMOH to work through the human resource plan within the National health system plan to reduce the turnover of health staff.

G. Advocacy, Communication and Social Mobilisation (ACSM)

Strengths

a) ACSM unit within SNTP at Federal level is well staffed.
b) SNTP has distributed a quarterly newspaper in all states.
c) Some DOTS Committees have been established at both State and TBMU level.
d) State and Federal leaders have been sensitized and involved in World TB day events. There is a good network of Community based organizations with interest in TB.

Weaknesses

a) SNTP has been operating without a comprehensive strategic ACSM plan.
b) No engagement between SNTP and the Community Based Initiative Unit in FMOH.
c) DOTS committees have no work plan and are not operational in all areas visited.
d) There are no guidelines, schedules or topics organized for health education delivery to patients at TBMU's.
e) Routine health education to the patients lacks participation from patients and resource people in the community.
f) Community based organization are not well oriented in TB control
g) Leaflet and poster development does not follow best practice both are scarce in TBMUs.
h) Low knowledge among TB patients about TB and key aspects of TB control.
i) Severe stigma issues around HIV/AIDS.

Recommendations for Advocacy, Communication and Social Mobilisation

63. *SNTP should implement the ACSM strategy, with an immediate focus on building capacity for strengthening treatment support and DOT and follow-up.*
64. *SNTP should explore ways to collaborate with the Community Based Initiative – especially for community involvement in DOT and treatment support.*
65. *SNTP and SMOH should ensure that DOTS committees are operational, sustainable and harmonised with the Community Based Initiative.*
66. *SNTP at Federal level should develop clear guidelines on health education. TBMUs should develop schedules and outline topics and issues which patients need to know according to the needs identified in the locality.*
67. *SNTP at Federal and State levels should train health workers in TBMU and DOT centres in health communication skills and health education using LHL's existing training modules adapted for use in Sudan.*
68. *SNTP to work with LHL and other Partners with specific health communication expertise.*
69. *SNTP at Federal and State levels should develop a new framework of collaborating with community based organizations*
70. *SNTP at State and Federal levels should continuously leaders from all sectors of society to speak openly about TB and HIV/AIDS to dispel stigma and misconceptions.*

In-depth Review of the Sudan National Tuberculosis Control Programme

Main report – January 2009

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Abbreviations

ACSM _ Advocacy, Communication and Social Mobilization
AIDS- Acquired Immunodeficiency syndrome
CMS- Central of Medical Supply
CU – Central Unit (of the NTP)
DHSD – Decentralised Health System Development
DOTS – A Global Tuberculosis Strategic
EMR- Eastern Mediterranean Region of WHO
EQA – External Quality assessment
FMoH- Federal Ministry of Health
GAVI/HSS –
GDP Gross Domestic Product
GDF- Global Drug Facility
GF – Global Fund against aids, tuberculosis and malaria
GF R8 – Global Fund (application) Round 8
GLC – Green Light Committee
GLRA- Germany Leprosy Relief Association
HFP- High False Positive
HFN- High False Negative
HIS – Health information system
HIV- Human Immunodeficiency Virus
ISTC – International Standards of Tuberculosis Care
IUATD (The Union) - International Union Against Tuberculosis and Lung Disease
IDP- Internally Displaced People
LFN- Low False Negative
LHL- Norwegian Heart and Lung Patients' Organization
LFP- Low False Positive
M&E – Monitoring and Evaluation
MDGs –Millennium Development Goals
MoH- Ministry of Health
MSF:- Medicins Sans Frontiers
NACP- National AIDS Control Programme
NGO- Non Governmental Organization
NHL- National Health Laboratory
NORAD- Norwegian Agency of Development
NRL- National Tuberculosis Reference Laboratory
NTP- National Tuberculosis Program
PHC- Primary Health Care
PITC – Provider Initiatied Testing and Councelling
PLWA- People living with AIDS
PPM – Public-Public mix or Public-Private-Mix, part of Stop TB strategy
PSM – Procurement and Supply Management
QA- Quality Assurance
QC- Quality Control
R&R – Recording and Reporting
SACP – Sudan Association of Chest Physicians
SMoH-State Ministry of Health
SNAP – Sudan National AIDS Program
SNTP – Sudan National Tuberculosis Program
STC- State Tuberculosis Coordinator

STPA – Sudan Tuberculosis Patient Association
TB- Tuberculosis
TBMU- Tuberculosis (TB) Management Units
TOR – Terms of reference
UNDP- United Nations Development Program
UNICEF- United Nations Children Funds
WHO- World Health Organisation
WFP- Word Food Program

Background

The last in-depth review of the Sudan National Tuberculosis Control Programme was carried out in 2004 by the World Health Organisation (WHO), the International Union Against Tuberculosis and Lung Disease (The Union) and the Norwegian Heart and Lung Patient Organisation (LHL). For the last four years the Federal Ministry of Health (FMOH), through its National Tuberculosis Programme (NTP) has made important progress in the fight against tuberculosis in the country. Regular evaluation is the keystone for the NTP progress. In accordance with WHO, the Union and LHL, a new in-depth review was therefore carried out November 10-24, 2008.

The Terms of Reference are found in attachment 1. The overall objective was to assess progress according to plans since the last review and assess strengths and weaknesses in the NTP to prepare for its development towards quality services and sustainability. The review was limited to the 15 states of North Sudan.

More specific objectives were:

- To assess the progress in the policies and plans in the NTPs five year plan.
- To assess the progress in implementing the recommendations from the last In-depth review in 2004.
- To evaluate the progress made in the strengthening of the NTP, particularly in terms of DOTS expansion and management structure.
- To assess the integration of the NTP in the general health system of Sudan and co-operation with other programmes.
- To critically evaluate the implementation of the agreement between the FMOH and LHL signed in January 2005.
- To assess the technical support given to the NTP.
- To review the NTP plans for sustainability and focus on quality of services.

The members of the review team were:
External:
Dr. Einar Heldal (Independent TB consultant, Team leader), Dr. S Bertel Squire (Liverpool School of Tropical Medicine, TB and TB/HIV consultant), Dr. Eliud Wandwalo (National TB Control Programme Tanzania, TB, health communication and community involvement and TB/HIV expert), Dr Sabira Tahseen (laboratory specialist, NTP Pakistan) and Dr Amal Bassili (WHO EMRO).
Dr Noura Maalaoui (GDF consultant, MSH) also participated in the review but with a special TOR from GDF, mainly followed a separate program, sent a separate report to GDF and chose not to be listed as co-author of this review report.

Internal:
Dr. Hashim Suleiman Elwagie, Manager of the National Tuberculosis Program, Sudan
Dr Elfatih Malik Director of Preventive Medicine
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Facilitators:
Rasmus Malmborg, LHL
Dr Imad Alamin, WHO Sudan, national TB adviser
Dr Aayid Munim, WHO Sudan, international TB adviser

The review team had meetings with the Federal Minister of Health, Assistant Undersecretary for Clinical Care, Director General of Preventive Medicine, National reference laboratory and Central Medical Store. The team made site visits to the states of Khartoum, Sennar and Gadarif, including visits to TB Management Units /TBMUs). Some patients were also interviewed. A 15-page draft report was presented and discussed with NTP and partners on the last day of the visit (attachment 2).
The itinerary is found in attachment 3 and the list of persons met in attachment 4. The list of references consulted are found in attachment 5. The team developed at the start of the visit data collection forms to be used during the visits to the states.

Findings, discussion and recommendations:

The findings, discussion and recommendation of the review are presented, following in general the components of the StopTB strategy. The first part includes a description of the socioeconomic situation, health sector, TB program, epidemiological development and DOTS implementation since the review 2004.

The findings are based upon visits to a limited number of states and TBMUs, The states of Gadarif and Sennar were also visited by the Technical Advisory Committee in 2005 and Khartoum in 2005 and 2006. WHO Sudan made visits to Khartoum and Sinnar states (plus two more states) earlier in 2008, making very similar observations and recommendations as in the current report. The states visited may therefore not be quite representative for all Northern Sudan, but perhaps performing better since they may have easier access and more technical visits than some other states.

General findings

Socioeconomic situation and health sector

The following is based on reports from WHO Sudan. Sudan is the largest country in Africa, spreading over 2.5 million square kilometres and administratively divided into 25 states. The northern part, which is the focus of this review, comprises 15 states, in turn divided into 134 localities or districts (5-12 per state). Total population in 2007 was 37,239,000, out of which 31,622,000 live in northern states, and 60% is rural. Health indicators are poor and the progress towards achieving MDGs is slow; or at best stagnant.

The country is a decentralized federation. Its health system is organized at three levels: Federal Ministry of Health (FMoH), State Ministries of Health (SMoH) and Locality Health Authorities. At the top are the teaching, general and specialist hospitals; some attached to teaching institutes, have varying number of specialties and beds rendering secondary and tertiary care. Primary care is provided through urban and rural health centers, dispensaries, dressing stations and PHC units. In addition to the Ministries of Health, police, army, railways, large banks etc. provide health services to their employees and their dependents. Also, there is a growing private sector.

According to the GF R8 application, there were 357 hospitals, 1,016 health centres (558 urban and 458 rural), 1,226 dispensaries, 762 dressing stations and 3,044 PHC units.

The health system was much affected by the civil war. Although a Comprehensive Peace Agreement (CPA) was signed in January, 2005 between Government and Sudan Peoples Liberation Movement (SPLM) in the south, two decades of war has devastated the social services including health. The conflict in Darfur continues to further bleed the health system. The conflicts have resulted in the displacement of more than 5.3 million people around the country (from the GF R8 application).

Some characteristics of the health system in recent years:

1. Service delivery: Overall, 45-65% of population has access to PHC services. Health facilities are unevenly distributed, resulting in a wide variation in the size of population served by a facility. Outpatient consultation is 0.8 per capita per year.

2. Information: The health information system (HIS) is weak. The data are incomplete and outdated. As a result, it is difficult to install and operate a robust system for monitoring and evaluation. Most of the PHC facilities and the private sector, including NGOs are not covered, while organizations like army, police etc. have their own information system. There are vertical information strands for data production, collection, processing, and reporting by the departments and programs, which due to poor coordination seldom gets consolidated.

3. Medical products and technologies: There is a national essential drugs programme that includes the pharmaceutical policy, national essential medicines list, standard treatment guidelines and national drug formulary. However, prescription of medical products is far from being rational. Recently, a Federal Board for Pharmaceuticals has been established to effectively regulate the quality of medical products. but it is in its infancy There is a drug registration system, but quality of medical products in the market is not fully assured. The Drug Quality Control Laboratory is weak in Good Laboratory Practice; and is not pre-qualified by WHO

A Central Medical Stores, which is the main importer and supplier of drugs, has introduced a revolving drug fund for health facilities. There is a parallel system of procurement, supply and storage of donor funded, e.g. GF medicines. Health facilities are inadequately equipped. While more than 50% facilities had less than minimally required equipment, there is no policy on health technology; and systems for assessment and management, including repair and maintenance of medical equipment is weak. The services offered at health facilities are, therefore not efficient and are of weak quality.

4. Human resources for health: There has been a massive brain drain, both internally and externally. The health work force is also inequitably distributed between urban and rural areas – the latter suffering the most. Career structures are unclear and incentives, including salary structure are weak. Curricula for pre-service training are not updated and the system for accreditation and licensing of institutions is weak. According to a recent survey (Sudan Health Workforce Survey, 2007) 76% health staff had no training during the past 5 years.

Financing of health:

The health sector is underfunded. However, with an increase in oil revenues, allocation to the health sector has increased. The total government expenditure on health and population sector was in the range 0.7 –0.9 percent of GDP during 1998 -2003. GDP per capita was US$ 434 in 2004, which is a low income (LI) country in sub-Saharan Africa (SSA) region. Its total health expenditure (THE), as a percentage of GDP was 4.3% in 2003, which is less than average for countries in SSA (5.0%) and LI group (5.2%). Households financed 55% of total expenditure on health through out-of-pocket payments. This compares with an average of 41% in SSA and 47% in the LI group. Sudan is less dependent on donor resources for health than is the average country

in the SSA region. Donor spending on health as %age of THE in 2003 was 2%, compared with the SSA average of 16% and LI group average of 19%[1].

The National Health Insurance Fund provides coverage, mainly to government employees. The informal sector is largely uncovered, and the benefit package and level of co-payment needs revision.

6. Governance and leadership: this function is weak at all levels of the health system. While the MOH has developed health polices and strategies, its ability to translate these into implementable programs at the state and locality level is limited. The constraints are evident in designing and setting up systems, e.g. financial, personnel, health information, logistics management systems, as well as support systems, like referral, monitoring and supervision, drug and pharmaceutical supply system, and repair and maintenance. Thus, the current situation poses challenges to the decentralized nature of the Sudanese health system. Also it has a limited capacity to build coordination and collaboration with other key government actors in health field (such as Health Insurances, Military and Police health and medical services) and the private sector.

Efforts to resolve health system weaknesses and gaps

In addition to the regular input by the government, a number of initiatives have been introduced, including:

a. Government of National Unity (Northern Sudan): The budget for FMOH increased 4 folds from US$ 28.46 million in 2000 to US$132.5 million in 2006. In terms of per capita spending on health, FMOH expenditure increased from 0.91 US$ in 2000 to 3.65 US$ in 2006. The same trend is also observed at states level where, on averages, the annual expenditure on health was US$ 4.5 per capita in 2005, compared to US$1 in 2000. However, most of this allocation is used to fund salaries and basic service, leaving little for developmental (infrastructure) and operational expenditure (for day to day operations).

b. Decentralized Health Systems Development (DHSD) Project: based on the findings of a Government of Sudan and World Bank Joint Assessment Mission (2005), a DHSD project with a total cost of US$70 million over four years (2007-11) funded jointly by the Government and Multi-Donor Trust Funds (MDTF) was launched in January, 2007. This project with a focus on four states (Red Sea, Kassala, Blue Nile and South Kordfan), aims to: (i) expand service delivery in the long term, in parallel with 'quick win' projects; (ii) develop infrastructure for health care; (iii) provide a system for delivering sustainable health care; and (iv) scale up human resource for health.

c. GAVI/HSS support: Sudan will receive US16.2 million over five years (2008-12). The interventions are complementary to the DHSD project with a focus on the other four states (Gedarif, White Nile, North Kordofan and Sinnar) and aim to address health system barriers by: (i) developing organization and management of decentralized local health system; (ii) building capacities at national, state and district level in health planning and development; (iii) developing human resources for health, including by investing in Academies of Health Sciences; (iv) improving capacities and knowledge base for equitable and sustainable health financing; and (v) strengthen health management information system and monitoring and evaluation.

d. Support by Health Metrics Network: with the aim to strengthen health information system, a grant (US$250,000) was received in 2007 for assessing the health information system and devising a plan for its strengthening.

e. Collaborative programs of United Nation and NGOs: WHO, UNICEF, UNFPA and others support FMOH for a variety of programs by mainly providing technical assistance and capacity building. In addition, both natural and man-made disasters are common so, these agencies are

[1] *http://healthsystems2020.healthsystemsdatabase.org*

involved in providing humanitarian assistance for emergency preparedness and recovery measures with a particular focus on the three Darfur states as well as Kassala, Blue Nile and South Kordofan states. Over 85 national and international NGOs operate in Northern Sudan and another 65 in Darfur. These are active in humanitarian assistance, providing support in emergency relief rehabilitation, education, orphan sponsorships, mother and child cares, health services, environment, supply of water and sanitation among other development activities. In addition, there are few more working in Eastern Kassala State and the Three Areas (South Kordofan, Blue Nile and Abyei).

f. Global Fund to fight AIDS, Tuberculosis and Malaria: In the North successful HIV/AIDS applications have been made, both for round 3 and 5, focusing on programmatic issues, mainly scaling up interventions for the prevention and treatment of HIV/AIDS. Likewise, the malaria application for round 2 aimed at improving the programme performance to reduce malaria burden, while the application for round 7 includes a health systems component. Medicine stores at the national, state and locality levels will be constructed and equipped. Also, procurement and supplies management system will be developed.

The Round 5 TB project which started June 2007 has as strategies:

- scaling up DOTS and ensuring quality of care
- strengthening partnership with other health sectors
- raising awareness and participation of community
- reducing the burden of TB/HIV in TB patients and people living with HIV/AIDS.

Activities include:

- training of TBMU workers in management of TB
- strengthening supervision and improving quality of DOTS through educative supervision
- strengthening health information system through the development of electronic national registration system
- conducting operational research on barriers to DOTS
- sensitizing policy makers to the impact of TB
- behaviour change communication
- coordination and partnership development
- training of health care providers on TB/HIV counselling and testing
- providing condoms at TBMUs.

Recently R8 GF for TB has been approved with some issues still being clarified and is expected to start within a few months. The overall goal of the Project is to drastically reduce the TB burden in Sudan, particularly among poor and vulnerable populations. The objectives are:
1: Expand DOTS, especially in war-affected areas in the Western region (Darfur States) and enhance SNTP provision of quality services: Thirty TBMUs and 90 TB service points (DOTS centers) will be established in collaboration with NGOs working in the target areas. The proposal also plans to strengthen the network of quality assured laboratories by renovating 105 laboratories, establishing 5 zonal culture laboratories, and equipping the national reference laboratory (NRL) for Drug Susceptibility Testing (DRS). Close supervision, monitoring and evaluation will be enhanced, including external quality assurance. Essential supplies which were not covered by R5 will also be provided. Training of health workers, laboratory and managerial staff will be a major activity, while the program will continue to provide other essential TB care support.

2: Prevent and control MDR-TB, and address TB contact management: In collaboration with the national reference laboratory, the SNTP plans to conduct an MDR TB survey, procure second line anti TB drugs, and work with one hospital, where treatment of MDR TB patients will commence. MDR surveillance will also be conducted. To address TB case contact management, the program will establish a pilot program of contact tracing and management in 5 states and further expansion will be conducted, subject to evaluation.
3: Engage all health care providers - Strengthen Public-Private Mix (PPM) approaches: This objective aims to expand the public-public mix and introduce public-private collaboration and partnerships in TB care delivery so as to increase TB case detection. Building on Round 5, SNTP plans to partner with a number of public health facilities to provide TB care services. SNTP also plans to partner with private health care providers, starting with a pilot program involving 20 private clinics in Khartoum State and 10 private clinics in Gezira state.
4: Raise TB awareness, build knowledge and create positive perceptions toward TB prevention, treatment efficacy and adherence, and reduce stigmatizing attitudes: This objective aims to expand on the ACSM achievements from R5. A more strategic, integrated, multilevel programming approach is proposed to achieve measurable behavioural impact. In order to expand on the community reach of the program, more stakeholders operating within existing networks will be engaged in program activities. Most important is the need to raise awareness, build knowledge and empower marginalized groups through targeted interventions in war affected and post conflict areas.

TB program

The National TB program in North Sudan is implemented at the following levels:
- the federal TB Control Central Unit (CU) whose responsibilities include planning, coordination and monitoring of state programs, staff training, procurement of anti-TB drugs, equipment and related reagents and logistics, quality control of laboratory services through central reference laboratory and program reviews.
- 15 states where a state Coordinator, who is usually a chest/community physician, manages the program supported by state TB laboratory coordinator.
- 90 localities where the programme is managed by the locality TB Coordinator who is usually a Medical Officer and works on a part-time basis. In Khartoum state staff at locality level included a director of community health , health officer, public health officer, preventive medicine coordinator (epidemiology, TB, AIDS, malaria). Contact and default tracing is managed from the locality level, including volunteers.
- 286 TB management units (TBMUs) with a part-time TB Coordinator who is either a medical officer or a medical assistant. The TBMUs were selected among health ceters and hospitals to cover 100,000 population.
- 765 DOTS centers with part-time supervisors, generally one per TBMU.

There is a Public Health Act for notification and control of infectious diseases, including tuberculosis.

The current NTP Manual was published around 2002, and has been under revision for several years. The review team was presented with a 33-page draft. One controversial issue is the treatment regimens (changing from 8 to 6 months).

The NTP developed a strategic plan for the period 2003-2007, and a new plan for 2006-2010.

Epidemiological situation and DOTS implementation

Sudan shoulders 15% of tuberculosis burden in the Eastern Mediterranean Region. The estimated TB incidence in 2006 was 242/100,000 population for all TB forms and 108/100,000 for sputum smear positive tuberculosis (Ref: Global TB report 2008). The prevalence and mortality of all TB forms were estimated at 419 and 68/100,000 population, respectively. See also discussion of the estimates in the chapter "Impact measurement".

The NTP presented to the Review Team an excel sheet with epidemiological data 2003-2007 on case finding and treatment outcome by state, quarter, age and sex. Also an extensive Annual Report 2007 of the NTP and a report covering the first 3 quarters of 2008 were presented.

The case notification of all TB forms declined from 74.2/100,000 population in 2003 to 68.5/100,000 population in 2007, with an annual decline of 2.6%. The smear positive notification rate also declined from 29.3/100,000 population in 2003 to 28.3/100,000 population in 2007 (annual decline of 1.9%) (Table 1).
The proportion of smear positive out of pulmonary TB increased from 53% to 55% during the same period, but still below the recommended level of 65%. The re-treatment rate was 6.1% in 2007 (Table 1).

Table 1. Case notification, North Sudan, 2003-2007 (ss+= sputum smear positive)

Year	Population	New ss+ as % of all pulmonary	New ss+ as % of all	EP as % of all	Re-treatment cases as % of all	New ss+ notification rate per 100 000	notification rate (all) per 100 000
2003	27,884,642	52.6	39.5	20.0	4.9	29.3	74.2
2004	28,418,390	54.8	42.3	17.5	5.3	30.8	72.8
2005	28,986,356	55.2	42.3	17.9	5.4	29.3	69.3
2006	30,165,986	54.0	41.4	18.0	5.3	27.2	65.7
2007	30,234,389	55.1	41.4	18.8	6.1	28.3	68.5

The case notification rate of smear positive tuberculosis was highest in older age groups in both sexes (Fig 2). It was significantly higher in males than females (male to female ratio=1.5). The data are for all Sudan.

Fig 2. Age-specific notification rate of smear positive pulmonary TB in males and females, North Sudan, 2007

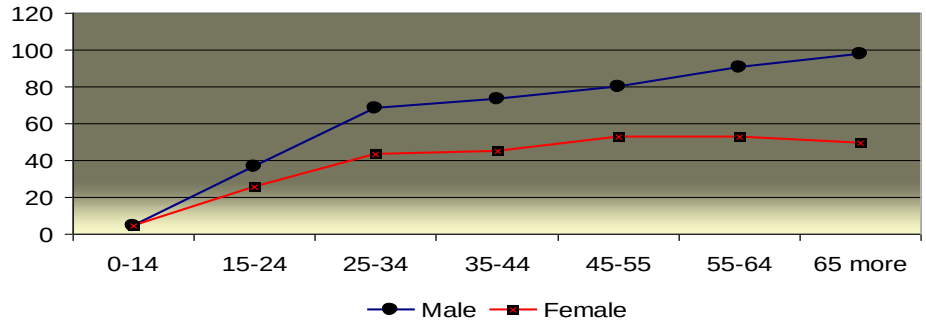


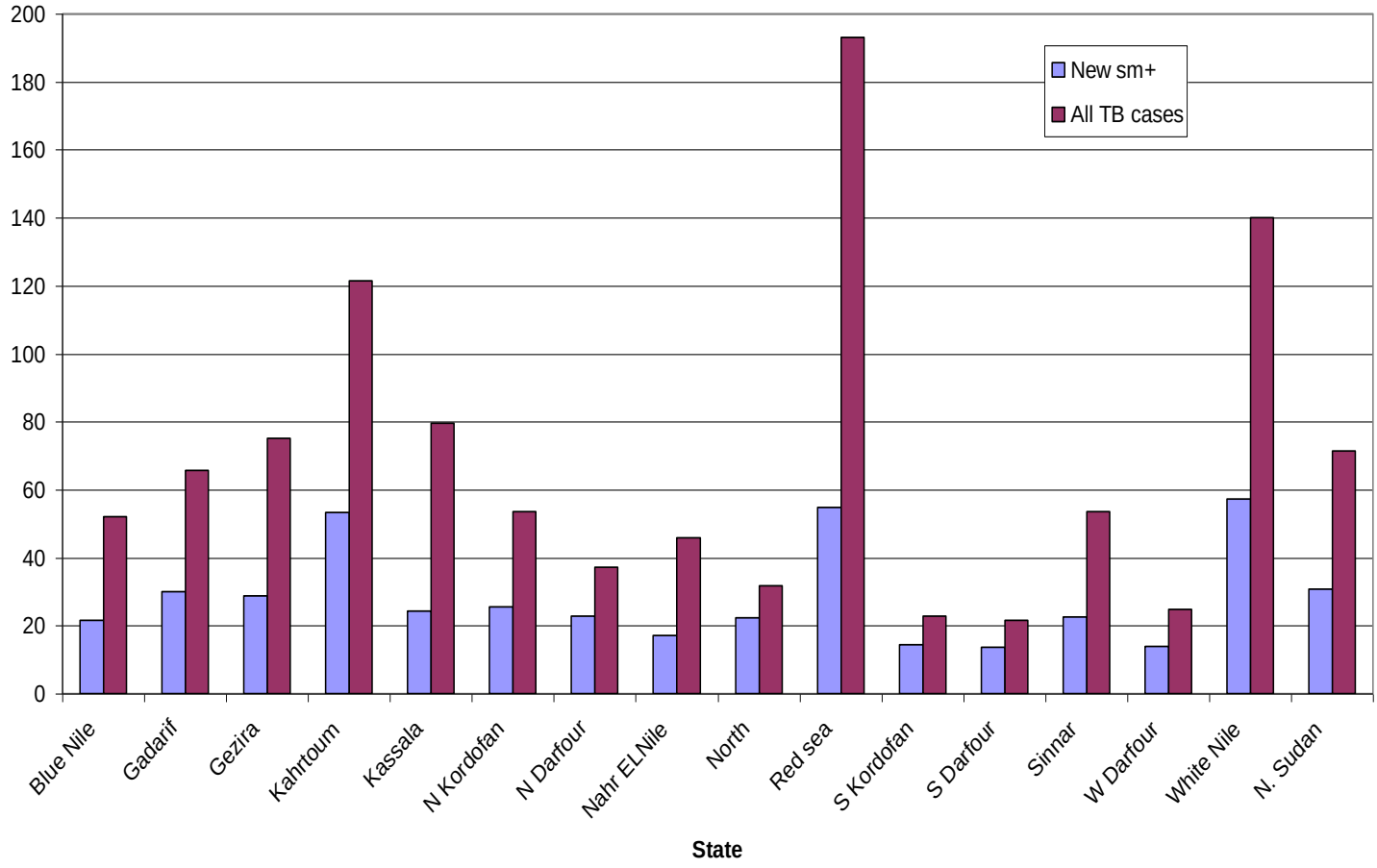
Table 2: Case notification 2007 in Northern Sudan by state; new smear pos and total cases, and new sm+ as % of all TB cases

		New sm+ cases		Total TB cases		
State	Population ('000)**	Number	Per 100 000	Number	Per 100 000	New sm+ as % of all TB
Blue Nile	783	169	21,6	408	52,1	29,3
Gadarif	1843	552	30,0	1209	65,6	31,3
Gezira	4130	1190	28,8	3105	75,2	27,7
Khartoum	6203	3299	53,2	7538	121,5	30,4
Kassala	1752	427	24,4	1394	79,6	23,4
N Kordofan	2424	618	25,5	1299	53,6	32,2
N Darfour	1821	417	22,9	676	37,1	38,2
Nahr ELNile	1026	175	17,1	471	45,9	27,1
North	654	146	22,3	208	31,8	41,2
Red sea	740	406	54,9	1428	193,0	22,1
S Kordofan	1704	243	14,3	389	22,8	38,4
S Darfour	3514	479	13,6	756	21,5	38,8
Sinnar	1404	316	22,5	752	53,6	29,6
W Darfour	1863	258	13,8	463	24,9	35,8
White Nile	1762	1010	57,3	2468	140,1	29,0
N. Sudan	**31623**	**9705**	**30,7**	**22564**	**71,4**	**30,1**

* population according to Central Bureau of Statistics (file provided to Team)

Figure 3: Rate per 100 000 population of new smear positive and all Tb cases by state in Northern Sudan 2007 (CBS population)

Rate per 100 000 population of new smear positive and all TB cases by state in Northern Sudan 2007 (CBS population)



The notification rate in 2007 in new smear positive cases was 31 per 100 000 for all North Sudan, but varied from 57 in West Nile, 55 in Red Sea and 53 in Khartoum to 14 in South Darfur, West Darfur and South Kordofan. The rate of all TB was 71 for the whole North Sudan and varied from 193 in Red Sea, 140 in West Nile and 121 in Khartoum to 22 in South Darfur, 23 in South Kordofan and 25 in West Darfur. The proportion of new smear positive case of all cases was 30% of the whole North Sudan, and varied from 41% in North state, 39 in South Darfur, to 22% in Red Sea and 23% in Kassala. In the states visited, Sennar had 23 per 100 000 new smear positive, 54 all TB, and 30% new smear positive, while Gadarif had a rate of 30 new smear pos, 66 all TB and 31% new smear positive. In Khartoum the numbers the rates were 53 and 121, with 30% new smear positive.(table 2 and figure 3).

The sub-national data analysis revealed weak notification from the majority of states with an annual decline in the number of notified smear positive cases and all forms during 2003-2007, a proportion of smear positive out of pulmonary and out of all forms below the acceptable levels, and high rates of re-treatment.

During Q3-2008, the case notification rate for Khartoum state was 116/100,000 population for all TB forms and 55/100,000 for smear positive cases, higher than the national average. During the same quarter, the case notification rate for Gadarif state was 65/100,000 population for all TB

forms and 22/100,000 for smear positive cases, lower than the national average and Khartoum state.

The North achieved 100% DOTS coverage in 2002, and has adopted the expanded Stop TB strategy.

The trends in case notification in the north should be assessed with caution because of a) migration which makes the population estimates uncertain (it may be unclear which way – more southerners coming north or northerners going south), b) migration which may make TB patients seek diagnosis in a different part of the country, c) reporting errors (causing under or over-reporting).

The proportion of new smear positive cases evaluated for treatment was 94% in 2007, compared to 99% in 2002. The success rate in North Sudan was above the WHO recommended level of 85%. It changed from 2003-2006 from 82% to 87, 85 and 87%. In all Sudan the success rate was lower: between 81 and 84% with no clear trend. The treatment success rate for the 2006 cohort was lowest at 78% in Blue Nile and Red Sea, 87% in Khartoum state; 88% in Gedaref state and 84% in Sinnar state. The default rate was 7,6% in 2006 and ranged between 5,0% and 16,0% between the states. It was 7% in Khartoum, 7% in Gedaref and 8% in Sinnar. A significantly higher default rate of ≥10% was reported from Blue Nileand Kassala (table 3 and 4 and annex 11 Analysis of the subnational data).

The death rates were low . The average death rate was 2,1% in the north. Higher death rates ranging between 4-5% were reported from South Kordofan and the Red Sea. Patients who die before treatment start are not included in case finding nor treatment outcome statistics which may contribute to the low death rate.

The low failure rate may be influenced by low sensitivity of smear microscopy causing false negative results (see lab chapter). The failure rate was on average 1,0% in the north. A significantly higher failure rate (over 2,5%) was reported from Sinnar, Darfour and Blue Nile states.

Table 3. Treatment outcome of New Smear positive TB, North Sudan, 2003- 2006 absolute numbers and percentages (2004 missing West Darfur)

Year	CURED	COMPLETE	DIED	FAILURE	DEFAULT	TRANSFERRED	Total	Success
Absolute numbers								
2003	5691	2020	279	97	891	376	9354	7711
2004	6195	2146	262	82	696	231	9612	8341
2005	6093	1813	298	103	753	297	9357	7906
2006	6250	1527	204	84	643	203	8911	7777
Percentages								
2003	60,8	21,6	3,0	1,0	9,5	4,0	100,0	82,4
2004	64,5	22,3	2,7	0,9	7,2	2,4	100,0	86,8
2005	65,1	19,4	3,2	1,1	8,0	3,2	100,0	84,5
2006	70,1	17,1	2,3	0,9	7,2	2,3	100,0	87,3

Table 4: Treatment outcome of new smear positive cases 2007 by state (abs numbers and %).

State	CURED	COMPLETE	DIED	FAILURE	DEFAULT	TRANSFERRED	Total	Suc
blue nile	103	23	2	5	26	3	162	1
gadarif	323	95	10	2	35	10	475	4
gezira	909	214	31	11	72	12	1249	1
kahrtoum	1131	271	21	3	115	55	1596	1
kassala	284	52	9	1	57	15	418	3
khartoum s.c.c	340	65	9	3	22	5	444	4
khatoum . fed	591	282	34	15	84	29	1035	8
n . kordofan	383	40	7	0	31	14	475	4
n darfour	155	50	9	5	16	2	237	2
naher el nile	109	42	5	1	8	3	168	1
north	108	33	5	0	15	3	164	1
red sea	252	62	18	5	39	26	402	3
s . kordofan	93	47	8	3	15	2	168	1
s. darfour	303	88	9	13	30	0	443	3
sinnar	195	50	4	8	23	11	291	2
w. darfour	56	22	4	0	2	0	84	7
white nile	915	91	19	9	53	13	1100	1
Total	6250	1527	204	84	643	203	8911	7
all Khartoum	2062	618	64	21	221	89	3075	2

	CURED	COMPLETE	DIED	FAILURE	DEFAULT	TRANSFERRED	Total	Suc
blue nile	63,6	14,2	1,2	3,1	16	1,9	100	7
gadarif	68	20	2,1	0,4	7,4	2,1	100	8
gezira	72,8	17,1	2,5	0,9	5,8	1	100	8
kahrtoum	70,9	17	1,3	0,2	7,2	3,4	100	8
kassala	67,9	12,4	2,2	0,2	13,6	3,6	100	8
khartoum s.c.c	76,6	14,6	2	0,7	5	1,1	100	9
khatoum . fed	57,1	27,2	3,3	1,4	8,1	2,8	100	8
n . kordofan	80,6	8,4	1,5	0	6,5	2,9	100	8
n darfour	65,4	21,1	3,8	2,1	6,8	0,8	100	8
naher el nile	64,9	25	3	0,6	4,8	1,8	100	8
north	65,9	20,1	3	0	9,1	1,8	100	8
red sea	62,7	15,4	4,5	1,2	9,7	6,5	100	7
s . kordofan	55,4	28	4,8	1,8	8,9	1,2	100	8
s. darfour	68,4	19,9	2	2,9	6,8	0	100	8
sinnar	67	17,2	1,4	2,7	7,9	3,8	100	8
w. darfour	66,7	26,2	4,8	0	2,4	0	100	9
white nile	83,2	8,3	1,7	0,8	4,8	1,2	100	9
Total	70,1	17,1	2,3	0,9	7,2	2,3	100,0	8
all Khartoum	67,1	20,1	2,1	0,7	7,2	2,9	100,0	8

In the Military Hospital, Khartoum State, out of the 7 cases registered for treatment in quarter 4, 2007, 5 were not evaluated. In ElShwak hospital, Gedaref state, the default rate reached 13% and only 93% of the registered cases were evaluated for treatment, resulting in a treatment success rate of 80%. In Khartoum state the success rate was much lower in TBMUs within hospitals than in TBMUs outside hospitals.

Military, police and prison hospitals partly notify their cases to the programme. In 2007, they have contributed by around 4% of all TB forms and sputum smear positive cases. The prevalence of chest symptomatics in the OPD clinics varied widely across the different TBMUs, and ranged between 2.5% to 35%.

HIV counselling and testing is done in certain facilities, and the number tested is increasing over time. In quarter 3, 2008, less than 10% of all TB patients were tested. The HIV prevalence among TB patients who were HIV tested, was 9 and 11% in Q2, and Q3, 2008, respectively (table 5). It is difficult to interpret the data because the TB cases with HIV test result were very selected. Probably TB patients with increased risk were selected, so that the proportion with positive HIV test is lower among all TB patients.

Table 5. HIV co-infection among TB patients, North Sudan, 2008

	Quarter 2, 2008				Q3, 2008			
State	Total TB cases registered	No. counselled and tested	% of TB cases HIV tested	% HIV positive of those tested	Total TB cases registered	No. counselled and tested	% of TB cases HIV tested	% HIV positive of those tested
Khartoum	1689	268	15,9	6	1682	321	19,1	18
Kassala	401	39	9,7	13	340	55	16,2	5
Gadarif	360	93	25,8	14	268	46	17,2	9
Red Sea	337	13	3,9	31	317	40	12,6	13
Blue Nile	147	5	3,4	20	88	6	6,8	0
While Nile	528		0,0		454	20	4,4	15
N Kordofan	395	49	12,4	6	309	29	9,4	0
Gezira	729	48	6,6	15	657	154	23,4	1
other states	949	0	0,0		280			
N Sudan	5535	515	9,3	9	4395	671	15,3	11

Main findings according to specific objectives in the terms of reference

Progress according to indicators in the Strategic plan 2006-2010

One overall objective of the in-depth review was to assess progress according to plans since the last review, and more specifically to assess the progress in the policies and plans in the NTPs five year plan. The review team therefore first assessed the Strategic plan 2003-2007, where a large number of indicators were listed but no goals seemed to be defined. The Strategic plan 2006-2010 however included goals. The team therefore selected some main indicators with clear goals and where data of reasonable quality was available, to assess progress, summarized in the following

table 6. One problem was that the plan was made for the whole country while this review only included the North.

Table 6: Main indicators in the Strategic Plan 2006-2010 and their implementation

Indicator	2003	2004	2005	2006	2007	2008	2009	2010
Planned case detection rate of new sm+ patients			40	45	50	55	60	70
Notification rate per 100,000 new sm+ cases (North)	29,3	30,8	29,3	27,2	28,3			
Case detection rate (new sm+) in the North using 108 as 100%	27,1	28,5	27,1	25,2	26,2			
Reported success rate in the North	82,4	86,8	84,5	87,3				
Planned cure rate planned	52	60	65	70	75	85		
Implemented cure rate in the north	60,8	64,5	65,1	70,1				
Planned number of TMBUs								
Implemented number of TBMUs	298	300	300	300	300	266?		
Diagnostic centers (TBMUs) doing quality assurance by blinded rechecking: Planned	45	50	55	60	65	70		
Implemented					58%?			
The proportion of DOTS centers reporting to TBMUs: Planned	82,3	85	88	92	95	100		
Implemented: Proportion of TBMUs report on case finding seen at central level	77,2	80,3	79.0	82,0	83,0			

Notification rate of new smear positive cases has not increased as planned, but rather declined (see previous chapter on epidemiology). Using the WHO estimated incidence of 108/100,000 population, the case detection rate is below 30%. The NTP considers that the estimate is far too high.

Treatment success rate has remained stable between 82% and 87% (see previous chapter on epidemiology). The cure rate has gradually increased from 61% in 2003 to 70% in 2006, but slower than the ambitious goals.

Although planned, there has been no increase in number of Tuberculosis Management Units (TBMUs) established.

According to the national report 2007 58% of diagnostic centres participated in External Quality Assurance (EQA) against a target of 55%

The proportion of TBMUs reporting to SNTP at Federal level increased from 77% in 2003 to 93% in 2007. Of the 283 centres, 88 were non-reporting in 2007 (report completeness around 70%). However, in Q2 and Q3, 2008, the number of reporting centres increased to 258 and 266 TBMUs, respectively (report completeness 91% and 94%, respectively). See also table 9.

Progress in implementing the recommendations from the last in-depth review in 2004.

The review report 2004 included 93 recommendations. Overall implementation was not very impressive: 21 had been done, 31 partly done, 34 not done and 7 were no longer applicable. A number of the main recommendations are repeated in the current review. A table with all recommendations and to what extent they have been implemented (as judged by consensus of the review team) is found in attachment 6.

See also below about TAC visits in 2005, 2006 and 2007, where many of the recommendations were repeated.

Progress made in the strengthening of the SNTP, particularly in terms of DOTS expansion and management structure.

Since DOTS had already been fully expanded in the North by 2002, the challenge has been to ensure the quality of the implementation and to include the new components of the StopTB strategy.

The TBMUs were already established by 2004 (1 per 100,000 population) and no further expansion of TBMUs has taken place. In the sites visited the more peripheral DOTS centers (basically treatment centers) were not functioning, and practically all TB patients were managed from the TBMU directly.

In the central unit there have been four SNTP managers since 2004 which has severely affected the continuity of the program.

The Central Unit is very well staffed and there are plans to re-organise the team into units. At the time of the visit there were 24 persons working with tuberculosis plus ca 7 working with leprosy. (listed in 3q 2008 report). As discussed later, there is room for improvement in developing technical material (supervision check list, content of ACSM, etc), training and supervision.

Since 2007 the TB staff at State and TBMU levels has been strengthened by the addition of a statistician to the pre-existing team of 2 (state coordinator and lab coordinator).

The central unit of the NTP is using a 2-year work plan 2008-2009 in excel which lists activities by source of funding.

Integration of the NTP in the general health system of Sudan and co-operation with other programmes.

The general health system in Sudan faces considerable challenges (see above). The TB programme therefore retains some functional elements under its own control. However TBMUs are situated within primary care facilities and some staff have responsibilities in health fields outside TB (e.g. lab staff and some statisticians)

Dialogue and cooperation between SNTP and some relevant programmes has commenced (e.g. Sudan National AIDS Programme [SNAP] and Sudan Tuberculosis Patient Association [STPA]), but has not started with others (e.g. The Community Based Initiative [CBI] within the FMOH.

Evaluation of the implementation of the agreement between the FMOH and LHL.

The last agreement was for the period 1.1.2005-31.12.2008, with expectation to be extended until the year 2010. In general the agreement has been well implemented. Some components have been taken over financially by the government as agreed, at central or state levels, while others are taken over by the Global Fund. Now drug supply for all TB cases are covered including smear negative cases.

The planning, budgeting, reporting and accounting system promoted and supported by LHL has also been used by the Global Fund. Internally displaced persons are part of the Global Fund Round 8 project. The plans to involve EPI-lab in advising the NTP together with LHL, has not been implemented. The collaboration with the Reference laboratory was ended because of lack of progress, but LHL awaits the process taking place in the reference laboratory. LHL has provided technical assistance as agreed.

To assess the technical support given to the NTP.

The Technical Advisory Committee (TAC), including The Union and WHO has provided technical support through annual visits (2005, 2006 and 2007) of two weeks, documented in extensive travel reports. Apart from central level visits, Khartoum state was visited in 2005 and 2006, Sennar and Gadarif in 2005, and River Nile and Red Sea in 2007.

Main topics addressed in the reports include:
- how to ensure TB services in the South and West of the country
- all units of the central unit prioritize activities in a coordinated manner, strengthen administrative capacity (standard operating procedures),
- CU prepare a comprehensive work plan for the available funds
- reduce turnover
- strengthen coordination between partners
- strengthen funding from State government, GF, Islamic Bank
- laboratory sector: ensure that the National Reference lab EQA of smear microscopy and quality of DST, strengthen state lab coordinators,
- drug management: strengthen central unit of NTP and state level
- treatment: strengthen DOT and late patient tracing,
- drug regimens (2006 recommends to make written plan for transition, 2007 report recommends to continue 8 months regimen because of need for DOT in continuation phase)
- make agreement with Epi-lab

The review team found the reports very informative, consistent and in line with international recommendations. The problem has been that the recommendations provided (as with the recommendations by the In-depth review team 2004) have largely not been followed up, so they are in many instances repeated in the reports.

The reasons include weaknesses in the NTP, especially the frequent change of NTP manager, the slow improvement in the national reference laboratory and general weaknesses in the health system. The GF Round 5 project improved the financial situation considerably.

WHO Sudan is providing technical support to the NTP, as for example documented in the Mission report February 2008 (by Dr Aaiyd Munim and Dr Imad Al Amin) from four states, making very similar observations and recommendations as the current in-depth report. The limited progress of the recommendations after the visit confirms that the main limitation is not lack of relevant technical advice but more fundamental weaknesses in the health system.

The review team discussed that the technical assistance gradually could be more topic specific, since the NTP is generally well aware of the content of the general TB program. There is however need for specific support to address certain topics, as described later in the report. It is a challenge for the NTP to ensure good coordination of this technical advice and to ensure that it contributes to strengthening the capacity inside the NTP.

SNTP plans for sustainability and focus on quality of services.

Before the GF support, the partners emphasized the need to increase the financial contribution from federal and state governments, in order to move towards ensuring national funding. With the GF Round 5 support, considerable additional funding has been provided, but the domestic contribution (federal and state levels) seems to have been maintained (see table 7).

The GF Round 5 includes financial incentives which are being paid to staff to encourage them to work in TB control. At present these are not linked to quality of service provision. The GF Round 8 application will provide substantial funding, including different results-based financial incentive payments to different cadres in the private and public sectors. This raises concerns about distortion of reporting in the future and long-term sustainability.

Recommendations for main findings

6. *SNTP Manager should proceed with plans to re-organise the Central Team into Units, each with delegated responsibilities, to facilitate the development of a more effective team.*
7. *SNTP at Federal level should develop a competence-based human resource development plan for Federal and State level and draw on recognised national, regional and international courses and expertise for relevant elements of the STOP-TB Strategy.*
8. *The SNTP, with existing Partners, should make a plan and timetable for external TA in the future and should co-ordinate this carefully and in line with the training requirements identified in the human resource development plan. Issues to consider in this plan include:*
    i. *Detailed, topic-specific technical assistance over the course of the next planning period*
    ii. *A further multi-disciplinary in-depth review towards the end of the planning period (approx 4 years from now).*

9. *FMOH should consider a long term strategy to take over incentive payments as top-ups to staff working within the Primary Health Care (PHC) system.*
10. *SNTP should consider how the payment of financial incentives can result, over time, in strengthening the health system.*

Pursue high quality DOTS Expansion and Enhancement

Political commitment and sustainable financing

One strength in Sudan is that there is a large number of health staff (doctors, specialists, medical assistants, statisticians and laboratory cadres) at all levels with few vacant positions. However staff turnover is high at all levels – including that there have been four different SNTP managers since 2004.

Government financial contribution in 2007 amounted to 1 million US$ out of approximately 3 million US$ spent by the SNTP (see table 7, data do not quite coincide). The state governments provide variable amount of financial support to TB control, relatively high in Khartoum, much less in Sennar and Gedaref, especially affecting the capacity to supervise TBMUs.

LHL has been supporting supervision (central to states) and administration (salary of 2 accountants plus one logistics officer in the central unit, running costs, plus technical support provided by The Union (108.000 USD excl. support to The Union).

GFATM Round 5 has a total budget of 15,410,466 USD, with 6,830,013 USD for the first two years (from June 2007). The future Round 8 project has a budget of 14.259.904 USD over 5 years and is expected to start during 2009. The Principal recipient of the GF is UNDP, while the PMU is placed in the FMOH. The chair of the CCM is the vice-minister of Health.

Support has also been received from partners such as German Leprosy Relief Association (GLRA), World Health Organisation (WHO) and the Islamic Bank (to the lab sector).

Coordination between SNTP and National Reference Laboratory not optimal. NRL is not contributing much to the NTP in terms of routine services and routine EQA. There is lack of clear linkage between NRL and hospitals. SNTP Offices are located far from other key linkages (e.g. SNAP, NRL) since May 2008 and is now co-located with two programmes with which SNTP has no joint activities.

Table 7: Budget and expenditure for TB control since 2004 by source

			actual		actual		planned		planned	estimated	estimated	estimated		estima
	2004	2005	2006		2007		2008		2009	2010	2011	2012	2013	source of
Funding source	Expenditure	Expenditure	Budget	Expenditure	Budget	Expenditure	Budget	Expenditure	Budget	Plan	Plan	Plan	Plan	
Domestic MOH				1522909		1990688	1341804		1408894	1479339	1627273	1990688	1341804	GF R8 ap 41
Domestic MOH	1465256	1522909												GF R5 ap
LHL	**980000	**796644	*104200	**595475	*96700	**216403	*106393	**222216	*109356	*109356				GF R5 ap 2008-200 plan
WHO	?	?		108769		108769		108769	108000	128000	128000	128000	128000	
GF R5					4016309		2810704		3087658	2614617	2878180	2878180		GF R8 ap
GF R8									3465445	3805080	2436591	2318266	2234521	GF R8 ap
GLRA			35000	35000	35000	35000	35000	35000	35000					2008-200 plan
Islamic Bank	?	?		?		?	?		?	?				
GDF	490000	490000	610998		0		0		0	0	0	0	0	GF R5 ap
Total	2935256	2809553	715198	1631678	4148009	2315860	4293901	365985	8214353	8136392	7070044	7315134	3704325	
budget plus expenditure				2346876		6463869		4659886						
Domestic as % of all	49,9	54,2		64,9		86,0	31,2	28,8	17,2	18,2	23,0	27,2	36,2	

Domestic MOH: need to clarify is federal or also state level?

* The budget from LHL represents the amount to be contributed directly to the NPT.
** The amount stated under expenditure is the total amount spent on the support to the NTP (local budget contribution, TB drug procurement, lab equipment, Union consultants etc.) excluding the LHL consultant.

Recommendations for enhanced political commitment and sustainable financing

11. *FMOH should Strengthen co-ordination between SNTP and NRL by*

i. *Re-visiting the Memorandum of Understanding (MoU) between SNTP and NRL*
ii. *Establishing regular interaction between SNTP and NRL*
iii. *Post one person within SNTP who will be clearly responsible for all activities between SNTP and NRL, including co-ordination with States.*

12. *FMOH should look for opportunities for co-location of Federal level offices of SNAP, NRL, SNTP in order to maximise co-ordination and co-operation between these organisations*

13. *FMOH should increase its financial contribution to SNTP to ensure long-term sustainability of the programme.SNTP should further develop its strategies for securing increased financial support from FMOH including*
-using evidence for effectiveness of TB control from good quality programme data
-encouraging FMOH to announce TB as a national emergency.

14. *Authorities at State and Locality level should ensure funding and implementation of activities including supervision, training, and community involvement – especially DOTS Committees*

Case finding

Low case finding was found to be a major challenge in Sudan, with low access to general health services and notification rates at around 30/100,000. In the states visited the notification rate of new smear positive cases varied extremely between localities. In Khartoum state during the first semester 2008 the overall notification rate was 37 per 100.000, but varied among 7 areas from 16-70, and among 19 districts from 0 to 139. In Sennar state the notification rate per 100,000 population during the first half 2008 was overall 13, but varied from 1 per 100,000 in two of the 7 localities, to 5 in another, to 31 in the highest (state capital). Differences in rates may be influenced by errors in population data and that TB suspects go to another area to be diagnosed. The data however clearly indicate that some localities and districts have extremely low case notification.

Diagnostic facilities are located within PHC facilities and case finding activities are integrated with general out-patient facilities. However, in Out Patient Departments (OPDs) a considerable number of TB suspects (patients with cough > 2 weeks) are not being identified, nor correctly recorded in the OPD registers. TB suspects in OPDs may be referred to the TBMU, to a specialist or directly to the lab for smear microscopy. TBMUs also received TB suspects directly from other health facilities, including private doctors (Sennar state).

The diagnosis of TB is being made on clinical (and often radiological) criteria rather than by smear microscopy. In 8 of 12 TBMU's visited, the number of TB suspects in the lab register was identical to the number of TB cases in the treatment registers indicating that smear microscopy is being used for classification of cases, rather than for case finding. Smear microscopy is only done after the doctor has decided that the patient has tuberculosis. The cost of an x-ray was 12-15 SDG in sites visited in Sennar state. If the patient cannot pay, the cost may supposedly be paid by the hospital. X-ray was available in 10 of 233 hospitals in Sennar state and in 5 of 13 TBMUs.

Most clinicians were not aware of the National Guidelines for identifying and investigating TB suspects.

Based on patient interviews, it seems that many patients experience extended pathways to TB diagnosis, visiting different providers for a variety of reasons, including costs of travel, distance, stigma, and other socio-economic factors. In Abu Hagur TBMU, Sennar only 2 of 10 patients diagnosed with positive smear during the first 3 quarters 2008 were diagnosed in the TBMU lab, because they preferred to be diagnosed in the state capital. Reasons given by patients interviewed were stigma, shorter distance and more trust in the lab result.

Only a minority of facilities and staff within the primary care network are involved in TB case-finding, usually only the health center designated to be TBMU.

Recommendations for enhanced TB Case Finding

10. *SNTP at Federal and State levels should inform and continually educate all health providers about the National Guideline for TB suspect management including development and distribution of posters with the approved diagnostic algorithm (linked to the revised TB manual) in all OPD's*

11. *SNTP at State Level should strengthen the capacity to assess notification rate by locality and TBMU, identify areas with low rates and discuss how to increase case finding through activities in the following areas: access to health services, referral of TB suspects to the smear microscopy network, quality of smear microscopy, etc*

12. *SNTP should engage all parts of the primary care network (hospitals, health centers, health posts, community health workers, Expanded Programme on Immunisation [EPI]staff) in detection and referral of TB suspects to TBMUs. For private sector involvement see later chapter.*

Laboratory services and quality assured smear microscopy (Sabira)

Back Ground Information :

The laboratory network (LNW) for TB control programme in Sudan is arranged at three tiers and is comprised of one NRL, 15 intermediate state laboratories and 280 peripheral laboratories. Laboratory services are integrated in primary health care at peripheral (locality and district) and intermediate (state) level. The peripheral laboratories are connected to the TBMU´s. The average lab coverage is one lab per 120,372 population, while the guidelines are recommending one lab per 100,000 population. The following states have low lab coverage: Kassala, N Kordofan, N Darfour, S Kordofan, S Darfour, Sinnar, W Darfour (table 8).

Table 8. Lab coverage per state in North Sudan, 2007

State	Population	No of labs	Population per lab
Blue Nile	846,015	8	105751
Gadarif	1,898,042	21	90382
Gezira	4,238,811	43	98577
Khartoum	1,794,396	52	99688
Kassala	6,414,164	18	123349
N Kordofan	1,874,318	17	170392
N Darfour	2,564,614	11	150859
Nahr ELNile	605,319	13	35607
North	768,245	17	36583
Red sea	1,044,307	21	80331

S Kordofan	1,437,743	10	130703
S Darfour	3,979,500	6	663249
Sinnar	1,808,414	11	180841
W Darfour	1,904,320	7	272045
White Nile	1,803,725	19	94932
N Sudan	32,981,933	275	120,372

The SNTP policy is to diagnose pulmonary tuberculosis through direct smear microscopy on three sputum specimen collected over two days. Treatment monitoring is done by one smear examinati on at the end 2nd, 5th and 7th month.

In the year 2003, the NTP, through a technical support from The Union, adopted external quality control by blind rechecking of slides as the main strategy for laboratory quality assurance. Only 53% of the laboratories are under external quality assurance (EQA) (according to SNTP Annual report 2007 12/15 states and 150/260 TBMU (58%). Of these 60% failed to show adequate performance in 2007 (one or more high false positive (HFP) or high false negative (HFN)) (Annex 9).

The **National TB Reference Laboratory** is under the administrative control of the National Healt h Laboratory (NHL). However a **memorandum of understanding** (Sept 2003) exists between N TP and NHL regulating the priority tasks of the TB reference laboratory which are maintaining

1. High proficiency in routine smear microscopy carried out in peripheral health facilities.
2. Training laboratory staff involved in the national network for tuberculosis.
3. Advice NTP on technical matters concerning the microscopy network (such as details of tec hnical guidelines and procurement of microscopy equipment and supplies).
4. Surveillance of drug resistance in tuberculosis.

The containment (biosafety control) laboratory was constructed within the premises of the NHL in accordance with the recommendations of external technical assistance and was equipped with equipment and reagents needed for culture and susceptibility testing of mycobacterium.
Presently AFB culture and DST is done only at National level with the use of conventional solid c ulture media. SNTP with support of global fund grant -8 plans to

- expand culture facilities by establishing Five culture facilities at zonal level
- Introduce liquid culture at NRL.

The Peripheral laboratory Network:

The network of 280 peripheral laboratories although seems adequate in terms of population **cover age** but taken into account wide geographical areas and low density population it is presumed th at geographical access of covered population to TBMU is limited.

Main Findings: For Field visit summary see annex 7 (Lab-I)
Infrastructure is generally weak, although some physical renovation has taken place but still space and quality of buildings and furnishings (very high working benches) is inadequate, 10 out of 12 laboratories visited lacked in either water supply or power or both .
Most of the laboratories have good quality **microscopes**. However some of the laboratories have very high workload with only one well functioning microscope (alfao and almufazza), other health facility with no power supply had very good quality (Olympus CX 21) microscope but without mirror (gala alnahal).
Manual for direct sputum smear microscopy was not available in any of TBMU visited but **Posters on pictorial guide on Direct Smear Microscopy** were seen in 50 % of TBMU visited .
Most of the **consumable supplies** are available e.g. ZN reagent, immersion oil, sputum cups, frosted end slides, however shortages were reported by centres visited of sputum cups (RH Shwake) , frosted slides (RH AL MUFAZZA) and immersion oil (RH Alfao). Filter paper is not included in regular supply list. Most of the laboratories are lacking in essential **non consumable** items like reagent bottles, slide storage box, wire loops, staining bridge and funnel.
Laboratories generally are well staffed (except in Gala alnahal) but under utilized for TB case finding. High turn over of **lab staff** was not observed in lab visited in Gadarif and Khartoum state. TB lab staff are now being paid incentives (US$ 50/month) through GF -5 .The incentive are not linked to performance and paid uniformly . Only some of the laboratories have reasonable workload (15-20 smears /day e.g. Gadrif hospital and TBMU academia Khartoum) but most of the laboratories have very low TB work load (2-3 smears/week). Laboratories thus are playing very little role in

- Case finding due to poor referral of TB suspect (RH Gadarif) and poor sensitivity
- Monitoring of treatment due to poor sensitivity o f microscopy.

Many Problems do exist regarding quality **of work** and are mainly related to

- **Deficiencies in internal quality control** e.g. Poor quality of specimen (saliva), and smears , Poor labelling despite availability of frosted- end slides, Filtration of carbol fuchsin not done in routine before use, Inconsistent staining techniques (heating time and staining time), Poor storage of examined slides, Incomplete entries in register (Address, Tb registration #in follow up), Positive slides not graded (Gadarif) and often not marked in red
- **Deficiencies in standardized supply of laboratory items: F**ilter paper not included in list of consumable items . **Non consumable items e.g.** : Slide storage boxes, Reagent bottles, staining bridge , sand alcohol jar, wire loop and wash bottles
- **Deficiencies in External quality assessment** and blind rechecking: Lack of feedback and follow up visits for corrective action and problem solving
- **Weak infrastructure** : lack of power or running water supply.

<u>Intermediate State level laboratory :</u>

State laboratories are responsible for quality assured microscopy in peripheral laboratory. Responsibilities include Stain preparation and supply management at state level. Supervision and blind rechecking for EQA and training of P. lab staff .
Main Findings : State lab coordinators are notified in all states and motorcycles have also been provided (Islamic development bank). As per protocol in National manual, fixed number of slides are required to be randomly collected from all TBMU /every quarter and rechecked blindly (15 slides) at state level.
State level laboratories are well staffed (Khartoum) to under staffed (Gadarif) Out of 3 state visited, it was observed that in Khartoum **EQA coverage** has improved (38 to 45 TBMU) with

inclusions of federal hospitals from Q-3 2008 (Annex-III) . However Gadariff state has started very recently with collection of Q-3 slides (5 TBMU) . No evidence of EQA activity in 2007 at Gadrif state. In Sinnar EQA activities cover all 11 TBMU.
No mechanism for monitoring of the laboratory performance (# pt/smears and positivity rate) exists at TBMU, state or National level.
Problems have been identified regarding EQA activities at state level and are mainly related to

1. National **Protocol for EQA** not being followed uniformly. Slide collection done every month (Khartoum), large (average 40slide/TBMU/quarter in Khartoum) or very few slides (7-8 slides/TBMU in Gadarif) collected, inclination toward collecting positive slides instead of random selection (Khartoum and Gadarif) .
2. Rechecking and **quality Assessment is not linked to corrective action and quality improvement**. e.g. in Khartoum state even regular EQA for five years have failed to result in desired improvement in quality and sensitivity of microscopy services as is evident from 2008 report indicating 28/45 centres checked are reporting "high false negative". (Annex 8 (Lab-III))
3. **Supervision of TBMU** is carried out jointly with state coordinator and checklist not being used frequently. Follow up visit for corrective action are not being conducted, further more even the state lab coordinator (SLC) have limited technical capacity to identify and solve the problems leading to High False Negative and High False Positive reports.
4. State level **EQA activities not supervised by National reference laboratory** nor on job training given on supervision to SLC
5. **Standard Operating Procedures** (stain preparation) in National manual are either not available (Gadarif) or not followed (e.g. Khartoum 0.3% Carbol fuchsin is prepared against 1.0% in manual).
6. **Weak infrastructure** of state lab (Space and furnishing), not adequately equipped for
   - Stain preparation (water distillers, twin beam balances or glass ware not provided)
   - Training of TBMU staff (Not enough space, insufficient microscopes, no module)

<u>National Reference laboratory</u>:

Human resource: NRL is well staffed with 2, Researchers, 8 lab technologist,8-lab technicians ,6 lab attendant ,1-statistician and 3-support staff .

NRL Workload and performance : See Annex-II

<u>Weaknesses</u>:
Problems have been identified not only in execution of technical function but management and administrative capacity as well.

I. Management and administrative Issues

- Weak management capacity and ineffective coordination with NTP
- NO clear linkages between NRL with any TBMU and /or hospital. No clear policy/protocol for referral of patient to NRL for microscopy/culture or DST
- Very limited reporting and no evaluation of
  a. Microscopy services at TBMU level.
  b. EQA activities at state level
  c. Technical activities at NRL including Routine services (microscopy, culture and DST),training activities and research activities
- Weak Planning for strengthening of the microscopy network for quality assured diagnosis
- No system for regular maintenance of infrastructure, equipment and supply chain.

- No standardized agenda of training activities (State, TBMU staff) or of meetings with state lab coordinator
- Ready to shift to New building without comprehensive plans for
    a. Logical flow of work in technical area. (reception to smearing ,culture, DST , sterilization, media preparation , and training area)
    b. Ventilation and infection control measures in culture and DST area.
- Plans to introduce liquid culture (MGIT) in NRL without a clear policy on its use and defining roles and responsibility of stake holders (NTP, NHL) regarding its maintenance and running cost (supplies).
- Piloting of Drug Resistance Survey (DRS) started in Khartoum state without a written approved protocol.

II. Technical functions/Issues:

- *AFB smear microscopy:* No control slides used in routine, No QC of stain prepared ,Poor smearing and staining technique.
- *Culture*:
    - Cold room out of order, prepared media slopes stored on bench-top in media room at room temperature.
    - Simple techniques for culture, centrifuge not used as capacity to hold four falcon tubes only and no aerosol -safe lid)
    - Low culture recovery in new smear positive case (between 50-60%)
    - Limited capacity and unstable temperatures of incubators
- Drug susceptibility testing
    - Drugs not stored in desiccators
    - Drugs weighed on top loading balances
    - Long delay between culture growth and DST (long turn-around time).
    - Many invalid results (no growth on control slopes)
- Identification
    - Presently not done: plan to start PNB with availability of solvent.

Recommendation:

- National Health Laboratory and SNTP to revisit the MoU to clarify and, if necessary, re-define the role of the NRL in relation to NTP and develop mechanisms for managing this relationship.
- NRL to play active role and coordinate with SNTP in planning and implementation of all activities related to QA diagnosis in microscopy network
    - NRL and SNTP to organize regular structured meetings with all SLC at NRL with well defined agenda, regular data Collection from peripheral labs, review of supervision plans, feed back and discussion on problem solving and clear documentation.
    - NRL to prepare Standardized list of non consumable items for peripheral lab use, to be supplied in form of a package / kit by SNTP.
    - NRL to develop Standardized training Programme for use by State Lab Co-ordinators for training of TBMU staff.
    - SNTP and Malaria Control Programme to discuss possibility of establishing joint training facilities at State Level for microscopy staff.
    - Review the criteria for location of microscopy centers to include factors in addition to population, such as population density, geographical accessibility.

- SNTP to assist NRL in enhancing NRL capacity for recording, reporting and data management and analysis.
- NRL to develop and implement internal QC system for all its activities (microscopy, culture and DST)
- Shifting of NRL facility only after proper planning and preparation of TB culture and DST facility by NHL/NTP. NTP to explore possibility of assistance from WHO/other Partners in securing technical assistance (e.g. through Global Laboratory Initiative) for engineering installations for negative pressure systems consistent with Biosafety Level 3.
- *Strengthening of state labs (infrastructure, equipment , HR) for supporting QA sputum smear microscopy should remain the priority agenda of NTP/NRL The fact that state laboratory have not yet been strengthened enough to effectively support QA activities needs serious consideration. Establishment of culture facilities at 5-Zonal level thus needs very cautious planning in a manner that there is no shift of priorities, resources or HR from microscopy to culture. .*
- NRL to define clear policy on use of liquid culture(purpose: pt management or DRS ,Scope : FLD or FLD and SLD both, bio-safety level) and estimate budget requirement accordingly, NRL to continue with LJ media . Introduce liquid culture after policy has been defined ,budget for maintenance and supplies are secured.

Standardized treatment, DOT, patient support, contact tracing and infection control

Treatment was standardized according to NTP guidelines in all the visited TBMUs. Treatment regimen for CAT I, CATIII and children is the 8 month regimen: 2HRZS/6HE, and for CAT II: 2HRZES/1HRZE/5HRE. The 6 month regimen is followed in some facilities for HIV co-infected TB patients. No errors were found in the categorization of patients for treatment. There are no paediatric formulations for children.

DOT was not in place in most of the visited TBMUs. A few selected patients received health facility based DOT in TBMUs visited in Khartoum. Otherwise patients or family members collected drugs during the intensive phase with various intervals; in one State it was every 10 days, in others it ranged between 7 and 28 days. Patients go to the nearest health facility or health worker (sometimes a volunteer) to receive the daily streptomycin injection. There was no system for sharps disposal and there was a risk of reusing syringes.
There were treatment supporters for the anti-TB drug use only in two out of 12 TMBUs visited.
Defaulter tracing was seldom done. If it happened, it was haphazard - by telephone or home visits in a few TBMUs. This contributes to the relatively high default rate and the failure to evaluate all cases for treatment.

Contact tracing was not in place in most of the visited facilities. When done, it was limited to informing the patient to ask symptomatic family members to visit the centre to be evaluated for TB. The use of isoniazid preventive treatment (IPT) for under 5 years of age as per the national guidelines was not being followed.

In Khartoum state, contact tracing was in place with contact registers and quarterly reports . During October 2008, the proportion of evaluated contacts aged younger than 5 years of age in Khartoum state was 23% (26/113) and 37% (130/356) among those older than 5 years of age. The incidence of TB among contacts was 700/100,000 population during 2007, significantly higher

than the general population. Health workers seem to be confused about the guidelines regarding contact tracing and management.

TB infection control measures were not formally addressed in the visited TBMUs. There are no administrative or personal protection measures for TB infection control. However, there was adequate natural and artificial ventilation in the majority of these facilities.

Discussion on treatment regimens

The team agreed that Streptomycin should be phased out and Ethambutol used instead in the Category I regimen, as soon as practically possible.
The team also agreed that DOT and treatment support had to be ensured for all patients in the first two months (i.e. the during the intensive phase of therapy) . This will be a major change since very few patients at present receive treatment under observation. The team suggested that NTP develop clear plans for DOT and treatment support based on a hierarchy of options:

- health facility- based DOT and treatment support
- community volunteer- based DOT and treatment support
- guardian – based DOT and treatment support.

There was a consensus that health-facility based DOT and treatment support should be the preferred option, provided health facilities were conceptualized very broadly to include health posts and publicly funded Community Health Workers who are already resident in many villages.
The guiding principle for DOT and Treatment support arrangements should be:-

1. maximum convenience to patients
   AND
2. maximum accountability to the health system in general and the SNTP in particular

The team had different opinions about the planned change from 8 months to 6 months regimen for Category I treatment. Some (Bertie and Eliud) favoured the 6 months regimen (both Malawi and more recently Tanzania had made the change in regimen) with the following arguments:

a) it has been demonstrated in a randomized, controlled trial (RCT) to be more efficacious, with fewer failure and relapse rates[2]
b) there is no clear evidence that it increases the risks of MDR-TB, provided DOT and strong treatment support are emphasized in the intensive phase and rigorous attention to treatment adherence is maintained by health staff throughout.
c) although HIV infected patients constituted only a small proportion of those in the RCT, their outcomes on the 8 month regimen were worse than those who were not HIV infected. With considerable uncertainty about what proportions of TB patients are infected with HIV in different contexts in Sudan, the 6 month regimen offers HIV-infected patients a better chance of survival, especially as ART and adjunctive cotrimoxazole therapy options are only available on a limited basis across the country (see chapter on Addressing Challenges, TB-HIV)
d) the 6 month regimen is already in widespread use by the private sector, HIV-treatment centres and by humanitarian assistance organizations working with displaced people both within and outside of conflict areas.

Jindani A, Nunn AJ, Enarson DA. Two 8-month regimens of chemotherapy for treatment of newly diagnosed pulmonary tuberculosis: international multicentre randomised trial

Lancet. 2004 Oct 2-8;364(9441):1244-51

e) The 6 month regimen is already in use in South Sudan. Although this in-depth review focused on North Sudan, it was clear that there is considerable mobility of TB patients between the North and the South.
f) Having a unified regimen across the whole country and in all different parts of the health sector (private, academic, HIV, etc) will reduce the potential for prescriber errors and confusion among different cadres of health care worker (and patients) about duration and dosing for TB.

It was noted that in Tanzania and Malawi the introduction of the 6 months regimen had been preceded by the introduction of the option (to patients) of a guardian system for DOT provision, which means that the patient at the start of treatment chooses a person of confidence as DOT provider. This person is approved and briefed by the health staff against certain criteria of trustworthiness, signs a document that he/she commits him/herself to be DOT provider and tick off daily administration in a patient/guardian card. The guardian would often be a family member. Health facility-based DOT and other forms of treatment support and DOT remain available. In Malawi and Tanzania there is a human resource crisis in the health sector (worse in Malawi than Tanzania) and the guardian system was also necessary to reduce the work load of the health staff.

Others (Einar, Sabira, Amal) were concerned that the change from 8 to 6 months in Sudan would not be helpful with the following arguments:

a) it will be a huge task for the TB program to ensure DOT and treatment support during the first two months of the treatment. Changing from 8 to 6 months increases the period using Rifampicin from two to six months, and would make DOT necessary for 6 months (the duration of Rifampicin-containing regimen) which seemed very optimistic.,
b) the 8 months regimen has higher rates of relapse and failure, but very few of the relapses and failures will have MDR-TB and most will therefore be cured with the retreatment regimen. After the 6 months regimen the fewer relapses and failures will have a higher risk of MDR-TB and most will not be cured with the retreatment regimen. Even under strict clinical trial conditions, more MDR-TB cases are produced after 6 months than 8 months regimen. Under routine conditions DOT may not be that strict and the sensitivity of smear microscopy less, increasing the risk of developing MDR-TB even more with the 6 months than with the 8 months regimen. Countries using 8 months regimens have in general lower MDR-TB rates that those who have used 6 months regimen, although it may take many years until MDR becomes measurable in national statistics.
c) Apparently the proportion of HIV in TB patients in Northern Sudan is still relatively low.

Others factors discussed were:

- The fact that the NTP would be more able to convince the private sector , HIV treatment centres, and humanitarian NGO's to collaborate and engage in TB control if they were using and endorsed the 6 month regimen
- If MDR should increase, it would increase the cost of TB treatment for the NTP outside the normal budgets of the NTP, increasing the dependency of external funding in the future. While one category I treatment may cost about 20 USD, one MDR-TB treatment may cost from 2000 USD upwards.

The review team reached a consensus of a very cautious approach where a change from 8 to 6 months regimen should be conditional on documentation of DOT and treatment support and carried out in a stepwise manner, state by state.

Recommendations

☐ SNTP at Federal and State levels to strengthen and monitor DOT and treatment support by developing clear guidelines and training for each of the following hierarchy of organized and documented treatment support options

- Providing DOT and treatment support through all health facilities of the primary health care network (hospitals, health centres, health posts, community health workers, extended programme on immunization [EPI] staff)
- Providing DOT and treatment support through community structures such as volunteers and patient organizations,
- Providing DOT and treatment support through guardian

Given the importance of this recommendation, SNTP should seek external technical support for developing these activities in an organized, evaluable and sustainable manner.

☐ The change from 8 to 6 months regimen of category I should be conditional on documentation that DOT and treatment support during the first two months of treatment have reached the required standards. Then a plan could be developed for a carefully phased implementation of the 6 month regimen, provided that the TB program can document a system for DOT/patient support also during the continuation phase.

☐ Streptomycin should be replaced by Ethambutol in category I treatment (but kept in category II and TB meningitis) as soon as practically possible, taking into consideration when Streptomycin supplies run out, when the states are prepared for the change and when the category I regimen is changed.

☐ The NTP should ensure that contact tracing is addressed more clearly in the revised NTP manual.

Monitoring, evaluation and supervision

Central Unit

The human resources for monitoring and evaluation at the central level consist of four surveillance unit staff in addition to the supervision officer. None of the staff received specific training in TB epidemiology or TB surveillance and few have received training in data management and analysis. The IT specialist received training in Oracle, epidata, and excel.

The revised recording and reporting system defined by WHO (revised version 2006 on who homepage) was not fully introduced. The revised treatment cards were distributed. The CU has printed but not yet distributed the revised TB and lab registers, TB identity card, request for sputum smear examination, and quarterly reports of case finding, sputum conversion and treatment outcome. The TB register lacks some important information (such as the source of referral of patients) which is needed to evaluate the Public-Private Mix (PPM) indicators and there are some serious errors in translation. In the lab register, the Arabic translation of the column allocated to TB register was “residence or register number”. As a result, only the residence was filled.

National guidelines specifies that quarterly reports must be submitted from the states to the central unit within two weeks after the beginning of the next quarter (for instance 4.quarter 2008 must be

submitted by January 15, 2009). There is always delayed submission of reports mainly from eastern states to central unit and from TBMUs to state level.

The CU is planning to introduce the suspect and contact registers and the annual report on programmatic management of tuberculosis. The staff in the states received training on the revised R&R and excel so as to use it for e-reporting but there were delays in printing the forms.

Quarterly reports on case finding and treatment result from TBMUs are received from the states level and are entered on Oracle and exported to excel. The Oracle is programmed to produce specific type of analysis such as distribution of cases by quarter, state, TBMU, age and sex, etc. All the staff in the CU are capable of performing such analysis but cannot carry out different types of analyses without the support of the IT specialist.

The reporting system at the CU was limited to the 15 Northern States. In previous years, some southern states were reporting incomplete data to the North which affected the completeness of their reports. The report completeness is used to monitor performance at the state level and CU has established a system to follow-up on the non-reporting centers. (see chapter on epidemiology)

It was noticed that 45 TBMU reported zero or very low number of cases. Nahr ELNile and Northern states showed the highest number of TBMUS with very low number of cases or zero reporting. The Union/WHO TAC report 2006 included extensive coverage of this issue.

There is no system for data quality assurance/validation. The surveillance officers do not participate in the supervisory visits to the states and TBMUs. The supervisory checklist does not allow cross-checking of data between registers and reports.

There was lack of transport at the Central unit. Out of three cars provided from GFATM Round 5 for the TB component, only one was handed over to the central unit of the SNTP. The other two cars were supposedly made available if requested, but was in practice rarely available and did not fulfil the needs of the SNTP.

State, locality and TBMU levels

One statistician had been appointed for the TB program in 2007 to all states and TBMUs. A national training course in TB epidemiology had been organized for them in Khartoum in 2007. Human resources for M&E in Khartoum state therefore consisted of one surveillance officer and data entry clerk at state level. There was one medical doctor and male nurse at the TBMU. Human resources were trained by NTP but they have not received specific training in TB epidemiology, or surveillance. In Gedaref and Sennar states, a statistical assistant was in charge of surveillance.

An electronic template for subnational level (centre, locality, by quarter, etc) has been developed so as to be able to collect more than 50 indicators on quarterly basis. This will allow regular monitoring and evaluating the subnational situation by the central unit and take actions accordingly. NTP has to carry out training before the use of this electronic reporting from governorates to the central unit.

The report completeness (proportion of TBMUs that sent quarterly reports of case finding) in North Sudan was 92.5% in 2007. The underreporting is mainly in North Darfour (39%), followed by South Kordofan. Of the 15 states, 8 did not submit all the expected reports in 2007 (Table 9). Report completeness ranged between 96% to 100% in the three quarters of 2008 in Khartoum

state. In Gedaref, report completeness was 100% in the same quarter and there was no missing data in the submitted reports.

Table 9. Report completeness by states, North Sudan, 2007

State	no of reporting TBMU	expected reported	received reports	Report completeness (%)
Blue Nile	**8**	32	32	100.0
Gadarif	**21**	84	84	100.0
Gezira	**43**	172	172	100.0
Khartoum	**52**	208	180	86.5
Kassala	**18**	72	68	94.4
N Kordofan	**17**	68	68	100.0
N Darfour	**11**	44	17	38.6
Nahr ELNile	**13**	52	48	92.3
North	**17**	68	64	94.1
Red sea	**21**	84	92	109.5
S Kordofan	**10**	40	28	70.0
S Darfour	**6**	24	24	100.0
Sinnar	**11**	44	48	109.1
W Darfour	**7**	28	24	85.7
White Nile	**19**	76	68	89.5
North Sudan	**275**	1100	1017	92.5

The team found that some sections of the TB Registers were incomplete such as the address, lab number and grades of positivity. In Lab registers some section were also incomplete such as the TB register number necessary to reduce the primary default rate, and grade of positivity. Some sections of the TB treatment card were incomplete. In Gedaref state, of the 21 TBMUs, only 2 submitted their reports on time during Q3, 2008.

The team compared the TB treatment register in the TBMU with quarterly reports and with Laboratory registers. In all TBMUs visited there were mistakes and inconsistencies, mainly minor but in some instances major differences, which make it difficult and confusing to assess trends accurately. The errors may have resulted in underreporting of cases recorded in the TB register and contributed to the low case finding in the country. Here are some examples of comparisons:

The team cross-checked the TB register and monthly report during October 2008 in ELAcademy TBMU in Khartoum state: the figures reported in the case finding monthly report added up at 34 while the observed total in the TB register was 24.

The table below shows the discrepancy between quarterly reports and registers in Gedaref TBMU:

Table 10: Reporting by quarterly report and TB register, Gedaref TBMU

Q3, 2008	New ss+	New ss-	Re-treatment	EP	Total
In q.report	65	33	0	46	144
Found in TB register	65	34	4	53	156

i.e. during one quarter, 12 cases were missed between the register and report in one TBMU;

Five out of 9 diagnosed cases in one quarter in the lab register were not registered in the TB register (primary defaulters) in ElAcademy TBMUs. Similarly, in Gedaref TBMU, 3 out of 22 diagnosed cases in the lab register in Q3-2008 were not registered for treatment (primary defaulters).
In the Military hospital, Gedaref State, Q4, 2007 cohort: 7 in TB register vs. 8 in the treatment outcome report. Similarly, in ElShwak Rural hospital, registered for treatment (15) and evaluated (14).

In ElDoka TBMU: Q3,2008 Report: total 6, of them 5 were ss+ and 1 ss-. TB register and treatment cards: total 5, 4ss+ and 1 ss-. In addition, 1 out of 2 ss+ diagnosed during Q3 2008 was not registered for treatment.
In Galaat el Nahl Rural hospital, 6 new ss+ and 2 ss- were registered for treatment and the treatment success rate for the Q3, 2007 cohort was 50%, 2 were transferred out but one out of the 6 was not evaluated for treatment.

In ElFao Rural hospital, during Q3-2008, the total number of cases reported were 39 cases, 5 were ss+. In the TB register, there were a total of 41, and the 2 missing cases were ss+ . X-ray request was added instead of the sputum smear examination results. For 18 cases, sputum smear examination was not performed and for some of these, X-ray was requested.

Supervision
Supervisory visits are in place but they are not effective: there is no on-job training of the health workers, and no feedback reports with corrective measures or problem solving in most of the centres;
In Khartoum, supervisory visits were done twice per year from the state level to each TBMU. All the visits had feedback reports and were kept as hard and soft copies. The plan for 2008 had been followed fully, travel plan was shown, ticked off for each visit. A check list is used, filling in information and making recommendations in the end. Ten patients are randomly selected among those on treatment and revised. The feedback of supervision was communicated through the locality coordinator. The reports are discussed in meetings with localities but not sent to the TBMUs. The locality coordinator supervised the TMBUs monthly. The state level supervised the localities every quarter, going jointly to visit selected TBMUs. Since the beginning of 2007 the State TB Program was allowed to supervise also federal hospitals but do not have any authority.

In Gedaref, quarterly supervisory visits take place where on job training is delivered but feedback reports were not seen in most of the centres.

Recommendations

- *SNTP should monitor, on a quarterly basis, the proportion of patients receiving DOT and treatment support as described in the previous chapter from the TBMU register with an emphasis on capturing the type of treatment support provided.*

- SNTP should implement the core WHO recommended R&R system . The cards, registers and forms/reports that are already printed should be distributed and used as soon as possible. The annual report on programmatic management needs to be finalized.

- SNTP to strengthen the capacity of the TB Co-ordinators and Statisticians at Federal, State, and, where possible, at Locality levels through training in data management and analysis and in TB epidemiology. The quarterly meetings provide an opportunity for this training to take place.

- SNTP should work with international partners (WHO, LHL and The Union) to revise existing supervisory check-lists to strengthen the technical content, considering also that different lists may be needed for state and TBMU levels.

- SNTP to strengthen the supervisory system with quarterly meetings at state level (and biannual at federal level), standardized reports, on job training and feedback mechanisms for corrective measures and joint problem-solving with a focus on data quality assurance. It is recommended to use the following indicators to monitor data quality for each state:
    - Timeliness of reporting
    - Completeness of reporting (received/expected number of reports)
    - Completeness of data in the reports (presence of missed information in the reports)
    - Accuracy of data (errors/discrepancy between registers and reports/inconsistencies)

- SNTP should make more frequent supervision of the TBMUs with low performance including reporting very few cases, in order to assess the actual situation and find adequate solutions;

- SNTP at state levels should check the quarterly reports developed by the TBMUs either through supervisory visit to the TBMU, regular meetings with groups of TBMUs where TBMUs bring their TB registers so that data can be checked. The responsible for R&R at state level should then enter the corrected quarterly report in excel format and sent the data by e-mail to CU. As long as state level is familiar with excel, it is advisable to use it at CU level. Staff at CU need more training on excel to be able to perform in depth analysis of data;

- SNTCP should critically consider whether the two weeks delay before submission of quarterly reports from state to central is sufficient for the state to ensure sufficient quality of reports from TBMUs.

- SNTP at state level should carry out the analysis on quarterly basis to evaluate performance and progress over time; ideally linked to the quarterly meetings with TBMUs.

- FMOH should reinforce the central unit with transportation facilities (vehicles) in order to carry out the necessary supervisory visits to the state and peripheral levels.

- The SNTP should consider the best way to use the OPD register to record TB suspects so that referral for smear microscopy can be strengthened and assessed. This should be considered as an alternative to introducing the suspect register at this stage. The following measures should be taken to ensure proper suspect management such as:
    - Adding the following information in the OPD register: full contact details of the patient, source of referral, investigations done, final diagnosis, and lab register number;
    - Circling the patients provisionally labelled as TB suspects by red ink in the register;

- Orienting the health workers on how to identify suspects and follow them up till final diagnosis. For example, the OPD nurse can be assigned the responsibility of guiding the suspects to the lab and follow-up on their final diagnosis as well as registering the requested data in the OPD register. The lab technician can also be assigned the responsibility of ensuring that all ss+ cases are registered at the TB register in order to minimize primary defaulting.

Impact measurement

The estimated incidence of sputum smear positive TB in Sudan is 108/100,000. These estimates were mainly based on projections of the estimated incidence that was reported by the tuberculin survey conducted in 1987. In the 1990s there has been expansion in DOTS coverage until reaching 100% in 2002. The expanded Stop TB strategy has been adopted and implemented. The impact of these control measures on TB burden need to be evaluated in order to measure the progress towards the Stop TB Strategy Targets and the MDG.

Recommendations

- ☐ SNTP to work with WHO in revising Sudan estimated TB incidence. The use of the annual risk of infection reported from tuberculin surveys is not applicable anymore according to recent reports. Based on that, it is advised to use the case notification rate to measure progress in case detection until the estimates are revised by one of the WHO recommended methods.
- ☐ SNTP should carefully consider the planning, timing and implementation of the TB prevalence survey budgeted for in the approved GF Round 8 proposal. The international standard criteria for conducting such surveys should be first met including the presence of quality assured microscopy.

Drug Management

Coordination of TB drugs supply system

Anti-tuberculosis drugs and laboratory supplies were funded by LHL for 10 years, while GDF funded some years until 2006. Since 2007, support for TB drugs and laboratory supplies has been covered by the Global Fund R5 (and R8 in the future). UNDP is acting principle Recipient for both rounds. UNDP It is responsible for drug procurement as well. During the last purchase drugs were procured from IDA Foundation (Rifampicin-Isoniazid combination, Pyrazinamid, Ethambutol, water for injection, syringes) and GTZ (Ethambutol-isoniazid combination and Streptomycin). GDF did not participate in the last tender. NTP has applied for a GDF paediatric grant in 2007; final approval is waiting for some actions (requested by GDF) to be taken concerning treatment policies.

Generally trained pharmacists and pharmacist assistants are present in adequate number in the public sector. The NTP CU has a full time position for drug management. In a collaboration between SNTP, FMoH , GFATM programs, and the UNDP a Procurement and Supply Management (PSM) unit has been established which is run by a team of pharmacists and whose mission is to streamline efforts to improve drug management at different levels of the distribution chain of each program (TB, HIV, and Malaria).

The PSM unit works in close collaboration with the PR and the programs at central and state and facility levels to ensure the followings:

- Improve storage conditions and practices
- Strengthen the capacity of human resources in the area of inventory management at different levels of the programs' drugs distribution chain
- Improve the *Drug Management Information System* and ensure better control on drug distribution and consumption
- Ensure adequate supervision of drug management in each program.

The three GFATM programs (TB, HIV, and Malaria) have benefited from the technical expertise of the Euro-Health group in the area of drug management.
The NTP would like the PSM to be more active at state and peripheral levels.

NTP is using the quarterly order for TB treatment supplies (TB09) and the Quarterly order for TB lab supplies (TB 10), as recommended by WHO. These forms use the number of TB patients by category registered during the previous quarter and stock levels to calculate amounts to be ordered. The forms were used by state levels but not by TBMUs. However, these reports were not classified (randomly stored), nor analyzed to detect problems in drug management. Roles and responsibilities between NTP, PSM team and UNDP PSM unit are not clear. Coordination and Communication between NTP, PSM team and UNDP PSM unit in drug procurement process is not optimal.
Although Lab commodities are stored and distributed through State TB drug stores, coordination between lab procurement and distribution manager and drug management team is weak.

Recommendations:

36. SNTP, UNDP and PSM team should better define their roles and responsibilities and improve lines of communication.

37. SNTP with partners should secure external TA to strengthen the capacity of the SNTP and PSM teams in TB drug management

TB drug selection:
The NTP guidelines currently in use are not adapted to new WHO recommendations, such as FDC, treatment of TB/HIV co-infection, paediatric TB treatment, nor new paediatric formulations. The current guidelines were often absent at the TBMUs, while a poster containing the treatment regimens were found in most treatment sites. There has been some delay in finalizing the revision of the TB manual including treatment. The draft available to the review team did not include a description of drug management nor Quarterly order for TB treatment supplies or lab supplies.

Recommendations:

38. SNTP and partners should urgently finalise the National TB guidelines and provide a clear time table for issues, including:

i. Emphasis on using Fixed Dose Combination (FDC) formulations

ii. A clear distribution plan

in order to fulfil GDF requirements in general and for the paediatric TB drug grant in particular and to strengthen the Green Light Committee (GLC) application for MDR TB management.

Management of quantification and drug procurement:

SNTP is doing national quantification of drug needs twice yearly (or yearly?) based upon the quarterly order for TB treatment supplies, received from the states, containing the number of registered cases in previous quarter and stock levels. The latest quantification (in development) had not taken in account the high stock of EH in the state and the facility levels. Still loose forms and boxes of thousands tablets are ordered instead of 4FDCs, blisters, or Kits, and there is no provision for dispensing bags to accompany loose packaging.

TB drugs purchased trough GF have long expiry dates. Quality control tests are carried on the batches received according to UNDP 's procurement processes in line with GFATM and international norms of good procurement practices. TB drugs imported through GFATM and GDF grants benefit from a waiver and taxes exemptions.

Recommendations:

- *SNTP should strengthen the collaboration with the partners involved in procurement and distribution of TB drugs and lab consumables (SNTP, WHO, UNDP, PSM team, NRL and Central Medical Stores [CMS]), giving special consideration to information on commodity consumption and specification that will be required for the activities in TB-HIV, MDR-TB, and Laboratories.*

TB drug distribution system

According to the GF R8 application, anti-TB drugs and laboratory supplies from external donation use to reach Sudan through two inlets: Port Sudan (seaport) and Khartoum (airport). The Directorate General of Pharmacy at the Federal Ministry of Health is responsible of clearance of these good and delivery at the CMS in Khartoum. The clearance process usually requires about one month until delivery to CMS in case of seaport consignments and less than 10 days in case of airport. The distribution system from the CMS to different states is facilitated by the drug revolving fund. The SNTP reached an agreement with DRF that the DRF shoulders drug distribution to states within its distribution system. Quantities of drugs to each state depend on its case finding of the previous quarter. The SNTP drug management officer uses standard IUATLD dispatch form to calculate drug needs for each state. Dispatch of drugs occurs on quarterly basis. An agent of the DRF for each state collects and prepares for drug transport to his/her state. Drugs after reaching its destinations are stored at the DRF state's central store. The TB state coordinator and the director of DRF are the responsible bodies of those drugs. The TB state coordinator is responsible of calculating the drug needs for each TBMU in his/her state based on previous quarter report of case finding. The DRF has its pharmacies in almost all those TBMUs. The DRF is responsible of transporting and distributing anti-TB drugs to those centers. For health facilities not yet covered by the DRF, medical directors of those centers are responsible of transporting anti-TB drugs to their units.

The drug management specialist in the review team found that storage space at central and state level was very limited which is hindering the adherence to good storage practices. However, fund are made available through Malaria and HIV/AIDS programs GF grants to built warehouses at central level and at every state and to provide trucks and pick-ups for distribution.

In Khartoum state an extra level of storage at locality level has been created. This storage level lacked minimum storage conditions and did not respect good inventory management practices.

Pharmacists at state level and pharmacy assistants at State and TBMU level are not fully involved in TB inventory management, while TB state and locality coordinators are having part of this function.
Expertise at State level in quantification and at TBMU level in inventory management and good storage and dispensing practices is not optimal.
Involvement of pharmacist at state level, pharmacist's technician at TB MUs in inventory management was limited to receiving and dispatching drugs. Inventory management and quantities' calculations was rather done by the TB coordinators.

TB drug inventory management and *Management Information System*

TB drugs inventory management from state to TBMUs was done through a push system where control on drugs beyond state level is weak.

Few centres experienced stock-outs and of only some drugs, for short periods of time. The drugs available had a long shelf life. Drugs were often available at all facilities and state levels, often beyond maximum and below stock minimum and that at different levels of the distribution chain. Some drugs were available in big quantities exceeding by far the stock maximum which results sometimes in expiry drugs[3], e.g. in one of the state medical stores the stock of EH was up to 38 months of consumption(while 24 months are available until expiry date). In some state medical stores and TB MUs stock outs or/and level of stock below stock security were noticed resulting in ad-hoc ordering and distribution in many states. The stock outs observed were the result of the delays in quarterly reports, lack of stock security, and/or inadequate quantification.

TB drug management information system is very weak. Record keeping is adequate at state medical stores, but very weak at facility level. The NTP central level has not developed standardized tools for TB drugs record keeping for any level of the distribution chain, drug managers and dispensers use different tools they developed themselves. NTP has developed the quarterly order for TB treatment supplies, as recommended by WHO, but it was not used from TBMU to state levels.
Supervision of drug management is limited to quantifying and distribution the drugs. Yearly reports include very limited section on drug management (reduced to a table on quantities received, distributed and in stock with no interpretation in a 100 to 150 page report)

PSM group with help of Euro Health Group has issued some ordering/report tools, but the development process was not enough participatory and their implementation was weak resulting in their resistance from TB drug managers to use them.

Rational Drug Use

TB patients (in-patients and out-patients) are dispensed drugs through a small window while standing outside. They are mixed to all other patients coming to collect free drugs. Once patients are dispensed their drugs, they go to the DOT person for injection and follow-up on adherence. Data on drug consumption are not analyzed to inform about irrational prescribing at any level of the distribution chain neither NTP-Central office. Examined data on stock levels, and discussion with pharmacists, pharmacists and store keepers suggest that treatment guidelines

[3] note that the GF procured drugs are long shelf life and no expiry has been found in this stock

are not adhered to in some cases (more consumption of RH and less of EH that results in stock-outs of the first and excess of the second).

Paediatric prophylaxis, diagnosis and treatment guidelines are not adhered to at all TBMUs. Prescribers prescribe differently from one state to another and facility to another.

Recommendations:

- As recommended in the chapter on directly observed treatment, TB drugs in the TBMUs should exclusively be given to the patient by the TB assistant or another DOT provider, and NEVER by the pharmacist. This is a key requirement to ensure the implementation of DOT. The role of the pharmacy is to keep the stock of TB drugs and supply the TB assistant (responsible for TB control in the TBMU) when needed. The TB assistant should fill in the quarterly order of TB treatment supplies and lab supplies based upon the number of TB patients registered in the previous quarter and stock levels.

TB/HIV commodity management:

The distribution plan for TB/HIV co-infection related commodities is not yet established. It is not clear where HIV/TB related commodities including TB drugs and ARVs should be stored and dispensed. Some expired drugs and test kits were found in the TB MUs and TB/HIV pharmacies Reference is made to the chapter on TB/HIV where drug management is one of the issues discussed.

For MDR-TB drug management, reference is made to the chapter on MDR-TB.

TB drug management at Private sector

TB drugs are sold with no rational dispensing in the private pharmacies, hindering NTP effort in TB service delivery. Local manufacturers produce TB drugs.

Recommendations:

- *SNTP should, in collaboration with National Drug Regulatory Authority, identify ways to regulate TB drugs in the private sector. The principle of TB drugs only being available through the SNTP should be emphasized.*

Lab commodity Management:

Lab reagents and supplies distribution chain is well established. Commodities distribution is coordinated by the National reference laboratory. Commodities are distributed in a push system from the National Laboratory at Khartoum to the state labs. Reagents are prepared at the state level and sent to the TBMUs. Laboratory commodities procurement and lab activities strengthening are budgeted in Round eight of GFATM grant.

Lab commodity management and good storage practices were weak at state and TBMU levels. Inventory management (quantification and ordering) was restricted to central and state level lab managers. Tools for inventory management were not available at all levels. Personnel managing Lab at state level and especially at facility level are not trained on good storage practices or inventory management.

Recommendations:

- *SNTP should include Lab commodity management expertise in the TA planned for lab quality assurance system strengthening.*

Addressing MDR-TB, TB-HIV and other challenges: TB-HIV

Background

a) General Epidemiology

HIV-AIDS has been evolving as a health issue in Sudan since the 1990's and is now an established problem throughout the country. Unsafe heterosexual intercourse is the most important factor in this national epidemic and Sudan is recognised as being the worst affected country in EMRO regarding total numbers of estimated HIV cases. Despite this, national data on prevalence of HIV infection are scarce. The overall national prevalence of HIV infection was estimated at 1.6% [0.8%-2.7%] in 2005[i] but there are major variations in different States and the picture is complicated by the large numbers of displaced people from areas with higher HIV endemicity to areas with lower HIV endemicity. The prevalence of HIV infection in northern Sudan was estimated in 2001 to be 1.6% compared to 5-7% in the south. In the same year the prevalence of HIV among TB patients was estimated at 7.7%[ii]. Limited sentinel surveillance testing during 2004 showed prevalence rates of 2.3% (33/1436) of HIV among TB patients (TB-HIV officer, SNTP – personal communication during the review).

b) Perspectives from Federal level

TB-HIV collaborative activities started within the Central Unit of the SNTP in 2006 with establishment of a Collaborative Committee. A TB-HIV plan and Terms of Reference for a National TB-HIV Collaborative Body were drafted in 2007. Round 5 GFATM grants to SNAP and SNTP disbursed funding in 2007. These grants have covered training of TBMU and VCT staff since so that staff in 83 TBMUs and 25 VCT centres in 8 states had received training by end of Q3 2008. Between Q3 2007 and Q2 2008 a total of 900 TB patients were recorded at Federal level to have undergone HIV testing – well in excess of the GFATM target for the period of 270. Constraints to progress identified by the Central Unit include high turnover of staff, stigma, and reluctance of health care workers to engage with HIV-infected individuals.

c) Key Findings from site visits

- Khartoum State

  Site visits to two facilities purporting to have implemented collaborative TB-HIV activities in Khartoum State were arranged: Academia Hospital and Omdurman Teaching Hospital. The main findings at each site in relation to HIV-TB activities are summarised below:-

  - Academia Hospital
    - Although several treatment facilities (both in-patient and out-patient) were offered at this teaching hospital, all treatment modalities for HIV-infected TB patients required patients to be referred to Al Bashir Hospital (20 minutes away by minibus transport). This was true both for ARV treatment and co-trimoxazole preventive therapy. Thus this centre acted essentially as a TB treatment site which also offered HIV testing and counselling.
    - HIV testing was stated to be offered to all patients but only 5 HIV test results were recorded in the TB-HIV section of the new treatment cards out of 96 cards held on patients currently on intensive phase TB therapy. Four HIV positives out of 42 tested in the last 2 months were identified in the VCT register, but none could be identified by name in the TB treatment register. The VCT register does not include the TB registry number for cross-linkage.
    - HIV testing was carried out in one room by a counsellor (a clinical psychologist and the only counsellor for the hospital) and a laboratory

technician who performs Rapid HIV tests in the same room. The room had no windows and no ventilation. The counsellor reported spending approximately 45 minutes with each patient in the room. All the HIV test kits available had expired in July 2008.

- Omdurman Teaching Hospital
  - A dedicated HIV treatment centre has been established within the grounds of Omdurman Teaching Hospital. In contrast with the model developed for treatment and care provision for HIV-TB cases at Academia, the Omdurman HIV treatment centre has effectively become a TB treatment centre within its primary function of providing specialised HIV treatment and care.
  - The Omdurman HIV treatment centre functions as an independent Unit with its own dedicated facilities including a pharmacy, a laboratory, waiting area , record keeping, and consulting rooms. Between 20 and 30 HIV-infected patients are seen each working day and a total of 1,800 patients are on the records, with 900 on ART.
  - The pharmacy stocks ARV drugs sourced through the SNAP GFATM grant and TB drugs from the SNTP. These drugs are dispensed free of charge. Other drugs (including, e.g., antibiotics have to be bought by patients through the main hospital pharmacy or through private pharmacies.
  - The Unit is staffed by 1 consultant physician, 3 medical officers on rotation, 2 MoH counsellors and 1 volunteer counsellor, 2 pharmacists (one full-time and one part-time), and one laboratory technician. Specialists (e.g. for sexually transmitted infections and paediatric cases), visit weekly.
  - The unit has devised its own HIV register which incorporates information required by the SNTP. Although a separate TB register is also maintained, the staff feel that this is an unnecessary administrative burden and would like SNTP supervisors to use the data from the integrated register.
  - Since 2005, 261 HIV-infected TB patients have been started on ART. The policy on starting ART is based on CD4 counts (CD4<200 – start ART after 2 weeks of TB therapy, CD4 200-350 – start ART after 2 months of TB therapy, CD4>350, wait until TB therapy is complete. The unit uses the 6-month rifampicin-containing TB regimen for all cases in combination with a lamivudine, zidovudine, and efavirenz combination ART regimen.
  - The small on-site laboratory performs HIV rapid tests and CD4 counts. All other tests, including sputum smear microscopy require patients to attend other laboratories in the main and neighbouring hospitals.
  - All patients wait in a communal, indoor waiting area with poor ventilation.

- Gedarif State

Although several TBMU's in Gedarif state offer HIV testing, all HIV treatment modalities (including cotrimoxazole preventive therapy) require patients to be referred to Gedarif Hospital – the only HIV treatment centre in the State. Findings related to TB-HIV management at Gedarif Hospital are summarised below:-

- Gedarif Hospital
  - TB treatment and HIV treatment are co-ordinated from two different sites within the hospital.
  - TB patients are all offered HIV counselling and testing at the TBMU. There is no dedicated HIV counselling room, so patients are counselled in a private area of a corridor in the waiting area (well ventilated). They then proceed to the TB

smear microscopy laboratory (which is separate from the main hospital laboratory) for rapid HIV testing.

- All HIV-infected patients are referred to the TBMU for TB smear microscopy.
- Cross-checking and follow-up between the two units was sub-optimal and there was confusion between the two units as to which was taking prime responsibility for the management of the cases during TB treatment.
- Overall 426 HIV positives detected in HIV centre since Feb 06 were recorded in pre-ART register. 120 had started on ART, of whom 53 had died, 1 had medicines stopped by the health personnel, 15 were referred on, and 50 defaulted from treatment.
- Out of 23 patients started on ART since the beginning of 2008, 12 were on TB therapy (info from ART treatment cards), but only 2 were recorded in the ART Register as being on TB Rx.
- The HIV centre had its own laboratory for HIV testing and CD4 counting (away from the other hospital laboratories). The CD4 counting machine was sitting on the floor of the laboratory with all its inner workings eaten away by mice. The room was dirty and poorly organised. Although the first-line SD Bioline, and second-line Unigold rapid test kits were in-date, all the third confirmatory test kits had expired on 7th November 2008.

TB/HIV at Sinnar state

TB/HIV activities in Sinnar state are implemented although at a limited scale. There are two main VCT centres at Singar and Sinnar hospitals, although VCT activities are sometimes carried out in other sites in Soki, Wadelbass, Eldiridar, Elmazmlem and Sugar company hospital

Many of staff at TBMU have not been trained on TB/HIV nor VCT. Only the clinical officer at Sinnar hospital admitted to have been trained on TB/HIV. Condoms are available in almost all health facilities visited but only 20-30% is being distributed and taken by clients. Majority of people who takes condoms at health facility are using them for family planning purposes and not for HIV protection

HIV is tested using Biolin and confirmed by Unigold. There is no CD4 machine in the state. WHO garding is used to start patients on ART

The hospital statistics at Sinnar hospital shows that there were 212 clients who went for VCT in the year 2007. Among them 13 were HIV+, 5 female and 9 males . For the period between November, 2007 when the VCT started to November, 2008 a total of 422 clients went for VCT and 50 were HIV+. Majority of these clients were patients admitted in the wards at Sinnar hospital and few were either people want to marry or want to know their status. Outcomes of the 50 HIV+ patients are shown in the table below

The main challenges for effective TB/HIV collaboration is that VCT is only carried out at HIV/AIDS clinic. TB patients from TBMU have to be referred to VCT. Many do not go and the results of the few who arrives at VCT is not shared with TBMU staff because of the need to maintain patient confidentiality. Another challenge is that TBMU staff do not have criteria to refer patients to VCT, patients are often referred 'randomly' without any objective criteria

Table 11: Outcome of 50 HIV + patients at Sinnar Hospital between November 2007 and November 2008

Outcome	Female	Male	Children	Total	Comments
ART	8	7	2	18	
TB/HIV				3	2 T/out
Death	4	6		10	
Lost	5	3		8	
Transfer out(T/out)	3	3		6	
NOT on ART				5	
				50	

Recommendations

- Establish objective criteria to refer TB patients to VCT
- Certify TBMU staff to be 'official' counselor
- In the longer term establish Provider Initiated Testing and Counseling (PITC)

Strengths

Overall, several strengths in the area of TB-HIV activities were identified:-

f) The presence of an active TB-HIV Collaborative Committee at Federal level with representation from SNTP, Sudan National AID-HIV Programme (SNAP), UNDP, and WHO
g) Presence of draft ToR's for a National TB-HIV body
h) Presence of draft National TB-HIV Action Plan
i) Presence of draft National TB-HIV treatment guidelines
j) Presence of GFATM funding for counselling and testing of TB patients (TB side R5) and treatment and care (HIV side R5)
k) Existence of a TB-HIV team within SNTP consisting of a medical TB-HIV focal point, a counselling supervisor and a consultant physician external resource person
l) A body of practical and well-developed experience in TB-HIV activities in Omdurman Teaching Hospital VCT centre

Weaknesses

Weaknesses were summarized as follows

h) TB-HIV activities are proceeding even before National body and National plan have been articulated. This has led to some confusion and fragmentation in service provision between HIV-treatment or VCT centres and TBMUs.
i) Programmatic scale up of HIV treatment and care is being driven by SNAP drug distribution before development of competence and quality in HIV centres. Although this is not SNTP's responsibility, it makes high quality collaborative activities problematic.
j) Laboratory and Pharmacy support for HIV have been established as separate units away from existing Laboratory and Pharmacy facilities in the HIV centres visited. This leads to difficulties for patients and staff trying to follow diagnostic and treatment algorithms. It also means that equipment and maintenance procedures are not well maintained in these "parallel" facilities.
k) Lack of a clear policy decision about which service (SNTP or SNAP) takes prime responsibility for HIV-infected TB patients and at what stages of treatment
l) Despite provision of training in Provider Initiated Testing & Counselling (PITC), a Voluntary Counselling & Testing (VCT) approach is being used in TBMUs leading to fewer TB cases being tested. It seems that staff are reluctant to incorporate HIV testing and management into routine health provision.

m) Routines for safe disposal of sharps were inconsistent. At least two centres visited (Gedarif Hospital and Al Mofassar Hospital) had sharps indiscriminately distributed around the hospital grounds.
n) Lack of attention to infection control policies for TB patients mixed with HIV infected patients in HIV centres. On the whole, were TB patients who are coughing are waiting in open-air waiting areas, this is not a major problem. However, in some wards and in the enclosed waiting area of Omdurman Teaching Hospital, the risks of TB transmission to and among HIV-infected patients are higher.

Recommendations for TB-HIV

42. The TB-HIV Collaborative Committee should merge the parallel development of TB-HIV plans and documents between WHO and SNTP and finalise these as soon as possible so that the National Collaborative body can begin to function, advocate, plan and monitor.

43. The TB-HIV Co-ordinating Body (once established) should pay particular attention to the following key issues as described in the updated WHO Interim TB-HIV Collaborative Framework:

i. Strengthening a PITC approach rather than a VCT approach as the key entry point into TB-HIV services
ii. Making the start of TB-HIV activities (including disbursement of materials, drugs and commodities) in new TB-HIV centres conditional on demonstration of competence assessed against pre-defined criteria in order to improve quality of service provision.
iii. Developing clear policy on when HIV-infected TB patients are primarily cared for and monitored by HIV teams and when by TB teams – ensuring that the needs of both services (e.g. with respect to Recording &Reporting and drug management) are met.
iv. Implementing infection control policies and activities in all TB-HIV activities, both aerosol and sharps related.

44. SNTP should engage specific, external TA from an individual who has been actively engaged in establishing successful TB-HIV activities in accordance with the updated Interim TB-HIV Collaborative Framework to assist with the activities outlined in recommendations 42 and 43.

Addressing MDR-TB, TB-HIV and other challenges: MDR-TB

Background

a) General Epidemiology

There are no robust data on the magnitude of the problem of MDR-TB in Sudan. No formal nation-wide MDR survey has been carried out. In the Fourth Global Report on anti-tuberculosis drug resistance (WHO.HTM.TB.2008.394) the MDR rate amongst new TB cases in Sudan is estimated at 1.9% (95%CL 0.3%-11.7%) while the rate amongst previously treated cases is estimated at 9.8% (95%CL 1.9% - 37.5%). In 2001 10.1% of all TB cases in Sudan were estimated to be MDR but this was an estimate with very wide confidence limits (95%CL <0% - 22.6%) based on case notifications and treatment outcomes in the preceding decade where the average percentage of re-treatment cases was 6.7% and the average failure rate was 2.7% [iii].

Despite the relatively low national re-treatment and failure rates (see also section on Epidemiology in this report) there are several reasons to remain concerned that the emergence of MDR-TB is a major issue in Sudan including:-

- The lack of a deeply embedded and established sense within the SNTP and amongst health providers in general of the massive importance of treatment support and attention to treatment adherence and concordance in the clinical and public health management of TB.
- Several different first-line TB regimens are in use throughout the country. Official SNTP TBMUs offer the 8 month first line TB regimen 2SHRZ/6EH. Several academic institutions, HIV treatment centres, humanitarian assistance NGO's, and private practitioners offer the 6 month regimen 2HRZE/6EH.
- The lack of a national consensus on a single first-line regimen combined with the resultant multiple sources of anti-TB drugs (CMS-procured, GDF-procured, privately procured, and NGO-procured) makes it likely that significant prescriber errors are being made and a quantity of poor quality drugs are in circulation. Both of these will increase the chances of the development of drug resistance amongst circulating strains of *M. tuberculosis*.

The SNTP, in collaboration with Epi-Lab and the National Health Laboratory (NHL), with support from LHL, IUATLD, and FMOH established a TB Reference Laboratory in 2003. (For further details, see section on Laboratory services in this report). The NHL reports that a pilot prevalence survey on MDR-TB has been started in Khartoum state in 2008, but no formal protocol or progress report on this study was available for review.

b) Perspectives at Federal level

There are no staff within the Central Unit dedicated to the issue of MDR-TB. The resident WHO Technical Assistant has taken a leading role in developing and drafting a plan for the Programmatic Management of MDR-TB which is currently out for consultative review by leading chest physicians in Khartoum and which constitutes the application to the GLC.

c) Key Findings from site visits

- Khartoum State

Only one facility in the whole country has been dedicated to the management of MDR-TB cases – Abu Anja Referral Hospital for Chest Diseases. One chest physician has recently been dedicated as the lead physician for the management of MDR cases. The main findings from a visit to Abu Anja Hospital are summarised below:-

- Abu Anja Referral Hospital for Chest Diseases
  - The lead physician for MDR-TB is an experienced chest physician who was previously State TB Co-ordinator in Upper Nile and Kassala States.
  - The hospital has 250 beds, of which 120 are functional and distributed between 4 units staffed by 5 consultants, 5 registrars and 7 medical officers. Most of the service provision, both in-patient and out-patient, is for TB cases with complications.
  - At the time of the site visit there were 6 MDR in-patients accommodated in single-storey ground level wards. Although these facilities afford good natural ventilation through doors and windows, they are old, and in poor state of repair, with relatively low ceilings
  - Confirmed MDR cases arrive at the hospital with their sputum culture and DST results from NHL which is situated far from Abu Anja. In some cases they have been formally referred, in most cases patients seem to make their own way to Abu Anja. The laboratory on site is well equipped and staffed, but performs sputum smear microscopy only.
  - Prior to August 2008, patients with confirmed MDR TB were treated with variable combinations of second-line drugs which were not prescribed

according to any plan, but based on individual prescriptions provided by chest physicians and patients had to source and pay for these drugs.
    - Following some serious public demonstrations by MDR-TB patients, SNTP had worked with FMOH to source second-line TB drugs which are now available at no cost to patients through the Abu Anja service.
    - The lead MDR physician takes overall responsibility for management of MDR-TB cases and he maintains a central register of patients with a locally developed patient record card for each patient. All patients receive a standardised second line regimen consisting of amikacin, ofloxacin, cycloserine, and pyrazinamide.
    - So far 30 patients have been started on this treatment programme. No cohort evaluation has yet taken place as the programme has only been running for 3 months
- The state TB programme in Khartoum informed that all MDR-TB suspects (failures of cat 1 and cat 2) were referred to Abu Anja Hospital. During the last year approximately 20 MDR cases were identified. There were no so-called chronics followed up in the health centers (often found in other countries especially in big cities).
- The drug management specialist in the team informed that only two of the second line drugs procured with Ministry of Health funding (Cycloserine and Ehionamide) were from a WHO prequalified supplier; Macleod (see table 12 below).

Table 12: Second line TB drugs procured by MOH&CW 2008

Drug	Producer
Ciprofloxacin 250 mg	Shangai Pharmaceuticals Co. LTd; China
floxacin 200mg	Hovid Bhd; Malaysia
Cycloserine 250 mg	Macleod; India
Ethionamide 250 mg	Macleod; India
Amikacin	Troikaa pharmaceuticals; India

Strengths

The following overall strengths in relation to the issue of MDR-TB were identified:

e) SNTP, in collaboration with the Pharmaceutical Regulatory Body, succeeded in banning the availability of ofloxacin in private pharmacies.
f) Presence of a draft plan for Programmatic Management of MDR-TB – currently out for consultation with senior chest physicians in Khartoum in preparation for GLC application.
g) Presence of some experience in MDR management at Abu Anja Hospital. The three months of management of MDR cases with a pre-defined, standardized 2nd line regimen in a single unit will give that unit and the SNTP some experience on which to develop the management of MDR further. This will, however, require the SNTP to work with Abu Anja hospital to evaluate the pilot and to modify management practices to bring them into line with international best practice as will be required in the GLC application. The current programme deviates from international best practice in a number of respects
h) Commitment at FMOH level has led to allocation of FMOH funds for the procurement of second-line drugs
i) Funding in GFATM Round 8 application for MDR-TB programmatic management, including second-line drugs.

j) A number of clinicians are already in training for management of MDR-TB.

Weaknesses

d) CMS have procured the FMOH-funded second-line drugs through their official processes, but some important issues were not clear and raise concerns about quality and sustainability:
   i. Whether payment has been finalised.
   ii. Whether the drugs have been secured from pre-qualified suppliers
   iii. Whether the drugs are more expensive than if procured through GDF.

e) Not enough focus on prevention of MDR-TB compared to provision of second-line drugs. The issue of MDR-TB in Sudan must be tackled first and foremost through the prevention of further emergence of resistance. Provision of second-line drugs in the absence of a properly designed MDR treatment programme could actually promote the development of further drug resistance.

f) No reliable baseline data on rates of MDR-TB in Sudan.

Recommendations for MDR-TB

45. SNTP to give urgent attention to the prevention of MDR-TB through the mechanisms described in Section on Treatment support and DOT

46. SNTP to secure GLC approval for MDR-TB Management. This will require attention in the following areas
   i. Finalization of the MDR-TB Treatment Guidelines
   ii. Quality of laboratory support for DST
   iii. Procurement of second line drugs through pre-qualified suppliers through the GDF

47. SNTP, with support from partners, should engage practical TA from an MDR-Treatment centre that has already been established in the region in line with GLC practice in order to develop and secure the GLC application. The lead physician for MDR-TB management in Sudan should spend time in a functioning MDR-Treatment centre in the region.

Addressing MDR-TB, TB-HIV and other challenges: Refugees and displaced persons

Background

a) General Situational Analysis

Refugees and displaced persons are a major issue in Sudan – across the whole country. Clearly the greatest challenges have been and remain in those States affected by war and political instability. What is less obvious, but nonetheless important is the fact that even those states that are not directly affected by war and instability within their borders are indirectly affected by movement of populations and individuals seeking livelihoods and health care. For example: although the conflict in the South has ended and this review does not deal with the issue of TB control in the south of the country, patients with TB were seen in all the States visited whose families either originated from the South or who had travelled recently from the south in order to seek health care.

Clearly, in addition to the issues affecting people from the south there are on-going problems in the war affected states of North Darfur, West Darfur, and South Darfur. In addition there are post-conflict issues in Kassala and Kordofan.

b) Perspectives at Federal level

There is a staff member in the Central Unit who is the focal point for TB Control in Displaced populations. The situation in each State is different and can be summarised as a spectrum. At one end of the spectrum the SNTP still has a major direct role to play in TB control because staff of the national health system are still in place and equipment and consumable for TB control can still be provided. At the other end of the spectrum the SNTP has no direct role in TB control because the severity of the security situation has led to a complete break down of the national health system. NGO's, therefore, take up a different range of tasks in the provision of TB control according to each local situation. The SNTP has recognised that the key issue has been to work in Partnership with the humanitarian assistance NGO's working in the health sector in war- and post-conflict areas. The general approach has been to develop and sign Memoranda of Understanding (MoU's) with these NGO's. Each MoU has to be developed according to the situation in the relevant State and according to the working practices and principles of the different NGO's. Ideally the SNTP negotiates for the NGO to adhere to SNTP guidelines for all aspects of TB control (diagnosis, treatment, and recording & reporting). In practice, though this has not been possible and some NGO's have refused to adhere to the national first-line TB treatment regimen 2SHRZ/6EH, especially where the SNTP has been unable to distribute drugs from the national supplies. In these instances NGO's have procured and distributed their own TB control drugs and most have been working towards provision of the 6-month first line regimen 2RHZE/4RH. Each MoU is, therefore different in scope, but at a minimum, NGO's are expected to report TB case-finding and treatment results to the SNTP. While it is recognised that these MoU are very important, it is also clear that not all of those that have been developed have been finalised and signed off. Very often this is because of the rapid change-over of staff within each NGO operation. Even where MoU's have been finalised and signed, it is difficult for SNTP to monitor whether all aspects of such MoU's are being followed.

c) Key Findings from site visits

The review team did not visit any health facilities in any war-affected or post-conflict States or areas, but a number of MoU's were reviewed in the Central Unit.

Strengths

Overall strengths were assessed as follows.

e) The presence of a focal person for TB control in refugees and displaced persons within the SNTP Central Unit
f) The existence of signed MoU's between SNTP and some NGO's treating TB cases in Darfur and Eastern Sudan ensuring adherence with guidelines on case-finding and recording and reporting.
g) The existence of a National Draft manual for management of TB in refugees
h) Funding for TB control activities in war-affected areas has been secured in the GFATM Round 8 application

Weaknesses

b) NGO's with signed MoUs with SNTP are procuring their own TB drugs and using the 6 month regimen with unclear safeguards around, issues such as drug quality, treatment support and DOT
c) It is very difficult for SNTP to have any oversight over some NGO's providing TB treatment semi-autonomously. This is an issue that is particularly aggravated by the strongly-held views in some NGO's that the international gold standard first-line TB treatment regimen is 2HRZE/4RH which is not the current national first line regimen.

Recommendations for TB control in refugees and displaced persons

48. *SNTP and WHO should encourage NGO's to align themselves with National guidelines for case-finding, reporting and recording to SNTP with an emphasis on treatment support and DOT.*
49. *The SNTP should continue to negotiate new MoU's with NGO's which should stipulate the need for treatment support and DOT when using the 6-month regimen in order to minimize the chances for generating rifampicin resistance.*

Addressing MDR-TB, TB-HIV and other challenges: Engaging all care providers

a) General Situational Analysis

To date, the main thrust of engaging health facilities outside of the immediate Ministry of Health institutions in TB control has been towards public health services in the Prisons, Military, and Police – so-called Public-Public Mix. This started with a FIDELIS project in 2004. Although this met with initial success, many facilities within these public institutions stopped reporting to the SNTP. The reasons for this are not completely clear, but some attribute it to a lack of continued supervision from the SNTP. In 2007 the GFATM Round 5 application included funding to strengthen the work initiated through FIDELIS and added a component of engaging health insurance institutions in the provision of TB control activities.

Engagement of private-for-profit medical providers in TB control is the subject of a pilot, incentive-based plan within the recently-approved GFATM Round 8 application. The extent to which TB patients access diagnostic and treatment services in this sector across the whole country is a matter of much debate and conjecture. No formally published studies have estimated the magnitude of private-for-profit provision of TB services, but unpublished work has examined the issue in Khartoum at least where it has been estimated that 960 TB patients were diagnosed in the private sector in a year; a figure equivalent to 2.5% of the existing TB notifications through the public system in the state (Dr Aayid – personal communication). Even if the actual number of cases that could be contributed from this sector across the whole country is relatively small, there are a number of other reasons why engaging with this sector in TB control is important:-

- Almost all doctors working in MoH health facilities also work in private practice in some capacity. These doctors are very often members of medical associations, including the Sudanese Association of Chest Physicians. There is strong pressure from this quarter to use the 6-month first line regimen: 2RHZE/4RH which seems to be popularly prescribed by private practitioners.
- Even if only a small number of TB patients are being treated with sub-standard regimens or drugs and without adequate treatment support, follow-up and outcome analysis, these cases will be at risk of developing MDR TB which can spread.

Engagement of the wider spectrum of health providers in Sudan, including informal, community based providers such as grocery stores, the NGO and faith-based sectors has not yet been given consideration as part of a wider, overarching conceptual framework of the non-MoH sector that could be engaged in TB control. Given that many TB patients are poor and may access such providers, this area will need more attention in the future.

b) Perspectives at Federal level

There is no strong articulation of an overall vision from the SNTP on the best approach or strategy with which to engage the whole spectrum of providers outside the direct umbrella of the Ministry of Health. Even with the specific engagement of the private-for-profit sector, it is not clear whether the favoured approach is to engage private providers to detect cases with a view to

referral to the MoH public system for treatment and follow-up or to engage private providers for both case-detection and treatment.

c) Key Findings from site visits

The review team did not directly visit any private for profit providers. However, efforts were made to visit public providers in the police services in Gedarif. Here the main finding was that the laboratory staff had refused to undertake smear microscopy for the whole of 2008 as a result of an ill-defined dispute about incentive payments. In Khartoum the state TB program informed that the doctors who worked privately were 222 GPs plus some chest physicians.

Strengths

The overall strengths of PPM engagement were identified as follows

d) Presence of funding for public-public and public-private mix activities in both GFATM Rounds 5 and 8
e) Presence within the SNTP Central Unit of a draft PPM Operational Plan based on a situation analysis
f) Good links and relationships between SNTP and Sudanese Association of Chest Physicians (SACP),

Weaknesses

e) Public institutions outside the direct jurisdiction of the Ministry of Health (e.g. Military and Police and Prisons and Health Insurance) are not consistently engaged in provision of TB control activities in line with National Guidelines.
f) Private for profit providers (neither specialist physicians nor general practitioners) are not yet engaged.
g) Lack of a clear statement that the preferred model for engaging the private sector will be for identifying, diagnosing and referring patients to the SNTP public system,
h) An emphasis on payment of multiple financial incentives for engagement of the private sector in the pilot planned in the GFATM Round 8 application. The risks of this approach have not been adequately considered in terms of:
    i. A projection of the likely full economic costs (both infrastructure, and human resources) of administering these payments.
    ii. Distortions to the system

Recommendations for engaging all care providers

50. FMOH to activate the mechanisms for ensuring engagement of public health facilities outside of FMOH (military, police, prisons and health insurance) including
    i. re-activation of the TB Board which is already enshrined in public health legislation.
    ii. Reaching bilateral agreements at the appropriate levels between the different parts of the government involved.
51. SNTP to engage the private sector primarily as an arm of TB case-finding, emphasizing unified treatment with treatment support and DOT within the public system
52. SNTP should consider emphasizing the provision of incentives in-kind (provision of training, materials, microscopes, accreditation etc) more than the provision of financial incentives in engaging the private sector.
53. SNTP should build on its existing links with the SACP and seek formal and public SACP endorsement of the International Standards of Tuberculosis Care (ISTC).

Enable and promote operational research

A research focal point was recruited at the central level of the SNTP. She has attended a training course in the American University of Cairo (AUC).

Several operational research projects were conducted in 2006-2008 with funding from the World Bank, The Union, GFATM Round 5 and WHO/EMRO (see tables 13 and 14). The implementers are NTP with partners at central or state levels, Epi-Lab, academia and other partners. The projects are in different stages of implementation: some are on-going, and others were finalized. The final reports of the finalized projects are under evaluation.

Through the Global Fund support, the NTP has organized two selection committee meeting where submitted proposals are selected on competitive basis. Two research methodology and proposal development workshops were held and 20 projects were finally accepted.

The dissemination plan for the research results is not fully developed. A system for evaluating the translation of research-derived recommendations into policy and practice of the programme is yet to be established.

Table 13:List of operational research projects by partners, and their status of implementation:

Title	Donor	Implementing Partner	Year	Status
Triage plus project	Union	Epilab	2007	Ongoing
Comprehensive approach to lung health	World Bank	Epilab	2006-2008	Completed
Prevalence, determinants and pathways to care of HIV infection among tuberculosis cases enrolled in DOTS settings in Sudan in 2008	WHO/EMRO	Epilab	2008-2009	First instalment released in 2008
ITC	Union	Epilab	2009	Ongoing
Supervision practices of the TB patients receiving DO in TBMU – Jabel Awlia locality -2008 –	GFATM	NTP/Academia	2008	Ongoing
care seeking behaviour of pulmonary TB patients in Gadarif and Kassala states	GFATM	NTP/partner	2008	Ongoing
assessment of tuberculosis patient accessibility to DOTS at Gadarif state	GFATM	NTP/partner	2008	Ongoing
evaluation of the TB contact tracing system at Khartoum state	GFATM	NTP/partner	2008	Ongoing
KAP of physician working in public health facilities a regarded TB at Kh state-2008	GFATM	NTP/partner	2008	Ongoing
the effects of stigma and discriminations associated with TB patients on compliance of DOTS in Nyala – during feb -june 2008	GFATM	NTP/partner	2008	Ongoing
System assessment of human resources development capacity for TB control in Sudan with focus on	GFATM	NTP/partner	2008	Ongoing

management staff				
Assessing the quality of information in TB cases register book in kassala state	GFATM	NTP/partner	2008	Ongoing

Table 14: Operational research projects supported by WHO/EMRO during 2007-2008

Year	SGSIDNo	PIN	Title	Donor	Disease	Status
2007	175	Albasher, Ibtisam	The impact of active case finding among household contacts of tuberculosis, Gezira state, Sudan	WHO/EMRO	TB	Final report submitted-revision requested
2007	54	Yousif, Magda	Promotion of Knowledge attitude and Practice among Female sex workers towards HIV/STI Prevention In Wad Medani Town, Gezira State Sudan February 2007	WHO/EMRO	HIV/AIDS	Interim report submitted
2007	159	Farag, ElMobasher	HIV SURVEILLANCE AMONG the Sudanese YOUTH age (14 14-24)	WHO/EMRO	HIV/AIDS	Interim report submitted
2007	166	Hussein, Salah	HIV/AIDS Bio-behavioural Survey among long distance Truck Drivers and their Assistants In Sudan	WHO/EMRO	HIV/AIDS	Interim report submitted
2007	168	Elrashied, Sayedgotb	HIV Prevalence, Knowledge, Attitudes and Behaviours Among Inserrtive Men who have Sex with Men (IMSM) in Khartoum State	WHO/EMRO	HIV/AIDS	Interim report submitted
2007	189	Abdel Rahim, Mohammed Sidahmed	Prevalence of HIV infection and HIV-related risk factors among female sex workers (FSWs) in Khartoum State	WHO/EMRO	HIV/AIDS	Interim report submitted
2008	161	Nemeri, Omer	Barriers for the adherence to antiretroviral drugs among OMACU center adult patients	WHO/EMRO	HIV/AIDS	First instalment released
2008	225	Nazik, Mubarak Hassan	Bio-behavioural surveillance towards HIV/AIDS among street children living in Wad Medani town - Gezira State - Sudan.	WHO/EMRO	HIV/AIDS	First instalment released
2008	1	Elsony, Asma	Prevalence, determinants and pathways to care of HIV infection among tuberculosis cases enrolled in DOTS	WHO/EMRO	TB	First instalment released

Year	SGSIDNo	PIN	Title	Donor	Disease	Status
			settings in Sudan in 2008.			

Recommendations

- ☐ SNTP Research Unit and Partners to revisit the operational research work plan at all levels, recognizing that with improved data quality within SNTP, the opportunities for identification of research questions and conducting research to solve problems will increase.
- ☐ SNTP should strengthen the Research Unit within the SNTP through
  - strengthening the research capacity of the research focal point in the CU.
  - Increasing the number of Central Unit staff who are engaged in research within the research unit
  - ensuring that State Co-ordinators participate in operational research meetings.
  - Emphasizing co-ordination with all research partners.
- ☐ Strengthening research capacity at all levels should be done within a human resource development plan.
- ☐ SNTP should request researchers to prepare Arabic summaries of the final reports and disseminate the summaries and reports of the projects to state and peripheral levels;
- ☐ Partners should provide technical assistance in publishing the manuscripts originating from the final reports in indexed journals;
- ☐ SNTP should ensure the use of research results in guiding policy and improving programme performance. This process should be well documented;
- ☐ The research unit of the SNTP should work in close collaboration with the surveillance unit in order to identify gaps and devise solutions through research. With improved data quality, and improved human resources capacity to analyze these data, research can play a central role in problem solving and enhancing programme performance.

Contribute to Health System Strengthening

Contributing to health system strengthening (HSS) is among the six components of the new WHO Stop TB strategy. The SNTP is generally well integrated into general health system especially at the point of service delivery. Many of the TB control activities such as TB laboratory services are integrated into general health services at primary health care level. In many of the states visited there was harmonisation of the TB control planning and budgeting process with wide health sector planning. The following were some of the observations of the review team with regards to health systems strengthening;

Strengths

g) Availability of human resources in all visited centres. A particular point of note was the presence of Statisticians supporting the Health information part of the Health System
h) Presence of administrative and financial backbone for the program.
i) Training plan was available at central and to some extent at state level.
j) Practical Approach to Lung Health (PAL) situation analysis has been completed and steps for awareness-raising with key decision makers have been planned.
k) Many different funders support SNTP (GFATM, LHL; GLRA, etc...).
l) GFATM Round 8 includes an element on health system development

Weaknesses

c) High turnover of staff at all levels
d) Staff performance is compromised for a number of reasons including:
    i. low salary scales in the public service
    ii. the need for most public staff to work in private practice as well
    iii. weak supervision and feedback mechanisms – in some places these are interrupted by lack of security and difficult access.
    iv. difficult working conditions in some places

Recommendations for TB's contribution to health system strengthening

59. *SNTP should develop a clear training plan for relevant health cadres at all levels on an annual basis.*

60. *SNTP to work with Partners to secure funding for PAL implementation according to the planned steps*

61. *FMOH and SMOH to work through the human resource plan within the National health system plan to reduce the turnover of health staff at different levels.*

Advocacy, Communication and Social Mobilisation (ACSM) and Community involvement in TB control

Background

The National Tuberculosis Strategic plan 2006-2010 clearly outlined the role of Advocacy, Communication and Social Mobilisation and community involvement in TB control in Sudan. The plan promotes stronger and more strategic partnerships between the government and other stakeholders such as NGOs, CBOs and the private sector in the fight against TB.

The NTP has been conducting ACSM activities through GLRA and LHL support and more recently from Global fund round 5 support. According to NTP reports, ACSM activities supported by the Global fund 5 have been implemented by 75%. The NTP has just been awarded another Global fund support (round 8) which has substantial ACSM component.

A number of ACSM activities have been conducted by NTP between 2004 and 2008. Activities includes advocacy among political and community leaders, production and dissemination of patients and community education materials through leaflets, posters, radio and TV messages. Advocacy was conducted mainly during the World TB day. NTP

has been producing quarterly newsletter for information and advocacy on TB. By November, 2008, six issues have been produced and distributed to the states. Both at the national and state level, prominent people and political leaders have been involved in TB campaigns. At the state level for example, the first lady was the guest of honour during TB day in 2008 and in most states the governors participated in commemoration of world TB day. In 15 states members of parliament have been sensitized on TB.

The NTP has an ACSM unit at the central level which is well staffed. The unit has 6 staff; 2 medical doctors , 2 journalists and 2 programme officers. At the state level, there is an information, Education and Communication (IEC) focal person who work very closely with a state TB coordinator. At the TBMU level, all TB related IEC activities are carried-out by a TB medical assistant. Interviews with the staff during the review has shown that while some staff at the central level have been trained on ACSM, staff at the state and TBMU level have not been specifically trained on TB ACSM. At the central level two staff attended a WHO organized ACSM course in Jordan in April, 2008.

Despite these achievements, for many years, the NTP has been operating without an overall ACSM strategic plan. Many of ACSM activities were implemented in an ad-hoc basis or depending on the funding. In august 2008, a new comprehensive ACSM strategic plan was developed as part of the GF Round 8 process.

Health education at TBMU

Health education at TBMU is provided by a TB medical assistant or a nurse. Education is provided to individual new patient and in groups among patients who comes for continuation of treatment. Health education sessions are complemented with health education materials such as posters and leaflets. Interviews with medical assistant in TBMU have shown that although majority says that they provide regular health education to the patients, no TBMU which was found to have health education plan with the topics which patients are supposed to know. Medical assistant at TBMU interviewed admitted that they have not received any training on health education and communication skills.

Some health education materials were found at TBMU level during our field visits. Posters which instruct practitioners on TB drug regimen were found in almost all the TBMU and hospitals visited. Posters which targets patients and community were however, found in few TBMU in Sinnar and Gedaref states not in Khartoum state. At the time of our visits we did not find leaflets on TB in Sinnar and Khartoum state but some leaflets were found in some TBMU in Gedaref. In Abosead health centre in Khartoum for example, they have not had leaflets on TB for over a year. Discussions with staff at state and TBMU showed that none were involved in development of TB education materials. Interviews with staff at the central unit showed that the development of these materials did not follow the standard best practice of health education materials development. These practices includes steps such assessment/baseline study, user participation, pre-testing, development of materials using communication skills, dissemination plan, monitoring and evaluation.

General knowledge of the patients on TB was fairly good. However, knowledge on specific issues such as follow up of medication was limited.

Officially, DOT is supposed to be provided in health facilities, although in practice, most patients get their supply of drugs to be supervised in the community. Interviews with patients in Sinnar and Khartoum showed all patients were getting their medication in the health facility every 10 days during the intensive period and few patients were actually supervised by the community/family members. Majority said that were getting their streptomycin injection from a trained community worker and the oral tablets under self-administration. The few patients who said that they were getting the TB drugs under DOT, mentioned family members as DOT supervisors. Although the community/family based DOT was common, the review team did not find any health education materials to assist TB staff, patient and community/family members on DOT. Another important finding from patient interviews was the high level of stigma patients experienced from the community. The stigma was especially higher for TB/HIV and HIV/AIDS patients. In Sinnar state for example most patients did not like to visit TBMU near their homes for fear of stigma

Community involvement in TB

The NTP is working with Non Governmental Organisations and Community Based Organisations (CBOs) to implement various TB interventions in the community. The NTP has also various outreach programmes targeting schools and Universities.

The NTP had established DOTS committees at all levels in order to spearhead and coordinate community based TB initiatives and link health facility related TB interventions to the community. At the time of this review, DOTS committee have been established in 15 states and 55 TBMU. At the national level, the committee has 13 members, At state level there were 10 members and three members at the TBMU level. At the national level few activities such as supervision of the states and conducting coordinating meetings were held, however, the review team did not find any DOTS committees activities carried out at the state and TBMU level. DOTS committees at the state and TBMU level had no plan of actions and in some TBMU they did not know if the committees exists

The Sudanese Patient TB Association (SPTA) is an interest, non-profit organization composed of TB patients and other members aiming at decreasing the stigma associated with tuberculosis and re-integrate TB patients into society. SPTA has been working with NTP since 2001. It has 18 branches distributed in many states including Southern Sudan. SPTA is receiving support from LHL and Global fund round 5. Although the NTP and SPTA have a formal agreement of cooperation, in practice, the two organizations have few joint activities mainly during the commemoration of World TB days and few national forums

In 2008, the NTP has signed a Memorandum Of Understanding (MOU) with Sudanese Women General Union (SWGU) to work together in advocacy and community involvement to control TB. This organization has a strong network in the community throughout Sudan. Discussions with the staff at SWGU has found out the organization has some experience working with community in HIV/AIDS related work. The organization can bring its comparative advantage in community organization and assist the NTP in advocacy and fight against stigma

The review team visited also the community based Initiative (CBI) under the health system strengthening unit within the Ministry of health. The CBI works with community in

all developmental issues including health with the goal of achieving better quality of life for the community. The CBI has a well established structure at all levels. At the community level, CBI works through community development committees which has representative at cluster level, each cluster has about 15-20 households. The initiative is supported by the Government, international partners and local organizations. The CBI is currently working in 12 states with the plan to expand to all states. Currently the CBI is working with other programmes as Malaria and Integrated Management of Childhood Illness (IMCI) not with NTP. Discussions with staff at CBI have shown that there is higher interest to work with NTP on TB related community interventions.

Recommendations

- SNTP should implement the ACSM strategy, dealing with priority areas first. The immediate focus should be in building capacity for strengthening treatment support and DOT and follow-up
- SNTP should explore ways to collaborate with the Community Based Initiative – especially for community involvement in DOT and treatment support.
- SNTP should develop strategic plan on community involvement in TB which would involve all the stakeholders. The SNTP should harmonise and coordinate the work of all stakeholders through regular coordinating committees. NTP should map out all important NGO/CBO and engage them according to their comparative advantage and geographical location.
- SNTP and SMOH should ensure that DOTS committees are operational and sustainable. The DOTS committees mandate should be limited to provide strategic directions, harmonization, coordination and oversight. The day to day work should be carried out by NGOs/CBOs and other partners such as SPTA, SWGU. The DOTS Committees should be expanded to involve all stakeholders.
- SNTP at Federal level should develop clear guidelines on health education. TBMU should develop schedules and outlines topics and issues which patients need to know according to the needs identified in the locality
- SNTP at Federal and State levels should train health workers in TBMU and DOT centres in health communication skills and health education using existing training modules (e.g. from LHL) adapted for use in Sudan
- SNTP to work with LHL and other Partners with specific health communication expertise to develop health education material including leaflets and posters based on standard health educational materials development techniques and best practice
- SNTP at Federal and State should develop a new framework of collaborating with community based organizations (including Sudanese TB Patient Association)
- SNTP should strengthen its collaboration with STPA including regular meetings for information exchange.
- SNTP at State and Federal levels (including the National TB HIV Co-ordinating Body) should continuously sensitises and encourage community leaders , political and religious leaders including the public should be to speak openly about TB and HIV/AIDS to dispel stigma and misconceptions surrounding TB and HIV/AIDS

Annexes:

1. Terms of reference

2. Draft report presented at the end of the visit
3. Itinerary
4. List of persons met
5. List of references consulted
6. Follow-up of in-depth review 2004
7. Laboratory annex I
8. Laboratory annex II
9. Laboratory annex III
10. Amal: two forms: report 2008 case finding (annex – shows DOT monitoring) and TB register.doc (annex – shows DOT monitoring)
11. Amal: subnational analysis

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[i] UNAIDS (2006). *Report on the global AIDS epidemic*. Geneva.

[ii] Sudan National AIDS programme. Report of Surveillance of HIV/AIDS 2001. Federal Ministry of Health. National AIDS Programme, Khartoum, Sudan (unpublished).

[iii] Dye C, Espinal MA, Watt CJ, Mbiaga C and Williams BG. Worldwide incidence of multi-drug resistant tuberculosis, Journal of Infectious Diseases 2002; 185:1197-1202