Strengthening TB Drug Management in the Sudanese National TB Control Program: In-Depth Review of TB Drug Management, Khartoum, November 10–23, 2008

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CONTENTS

ACRONYMS

ARV	antiretroviral
CMS	Central Medical Stores
DMIS	drug management information system
E	ethambutol
EH	ethambutol + isoniazid
EHG	Euro Health Group
FCMS	Federal Central Medical Stores
FDC	fixed-dose combination
FMoH	Federal Ministry of Health
GDF	Global Drug Facility
GDP	General Directorate of Pharmacy
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
LHL	Norwegian Heart and Lung Patient Organization
MDR-TB	multidrug-resistant TB
NDRA	National Drug Regulatory Authority
PR	Principal Recipient
PSM	Procurement and Supply Management
RCMS	Regional Central Medical Stores
RH	rifampicin + isoniazid
SNTP	Sudan National Tuberculosis Control Program
TA	technical assistance
TB	tuberculosis
TBMU	Tuberculosis Management Unit
TRC	Technical Review Committee [GDF]
UNDP	United Nations Development Programme
UNION	International Union Against Tuberculosis and Lung Disease
WHO	World Health Organization

BACKGROUND

In November 2008, the Global Drug Facility (GDF) organized a joint monitoring mission with the fourth in-depth review mission of the Sudanese National Tuberculosis Control Program (SNTP). The World Health Organization (WHO), the International Union against Tuberculosis and Lung Disease (UNION), and the Norwegian Heart and Lung Patient Organization (LHL) carried out the last in-depth review of the SNTP in 2004. For the last four years, the Federal Ministry of Health (FMoH), through the SNTP, has made important progress in the fight against tuberculosis (TB) in Sudan.

In a collaboration between SNTP, WHO, UNION, and LHL, an in-depth review was carried out November 10–24, 2008 (see Annex 3 for the mission team members). The overall objective was to assess progress according to plans since the last review and assess strengths and weaknesses in the SNTP to prepare for its development toward quality services and sustainability. The objective of the TB drug management review was to provide an overview about the current TB drug management practices in Sudan. In addition, the specific GDF objectives for this mission were to follow up on the Technical Review Committee (TRC) conditions for Sudan's request for a grant of pediatric anti-TB drugs and to provide an overview of the current TB drug management practices in Sudan through the completion of a GDF checklist and to draft a table of activities (first draft work plan) on how to improve TB drug management in the program.

Methodology

The mission visited the TB sites and storage areas; conducted interviews with SNTP and its partners and national institutions regulating and coordinating distribution of medicines (see agenda in Annex 2); and reviewed previous reports on TB drug management available from GDF, LHL, the SNTP, the United Nations Development Programme (UNDP), and WHO.

Given the short time available to perform the combined missions of GDF and in-depth review, and the wide scope of TB commodities evaluation, this report represents an overview of the pharmaceutical management situation including the various aspects of TB commodities management.

Findings and recommendations on pharmaceutical management have been discussed with the in-depth review mission, and the following summary has been formulated jointly with the mission team members. In addition, a one-day workshop was held to discuss the findings and the recommendations and list of activities for strengthening TB drug management. The workshop included representatives from the SNTP and its partners (see Annex 3).

SUMMARY

Strengths

- The SNTP has a full-time position for pharmaceutical management (NTP drug manager).

- In a collaboration between SNTP, FMoH, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) programs, and UNDP (Principal Recipient [PR] for GFATM funds), a Procurement and Supply Management (PSM) unit has been established that is run by a team of pharmacists whose mission is to streamline efforts to improve pharmaceutical management at different levels of the distribution chain of each program (TB, HIV/AIDS, and malaria).

- Three GFATM programs (TB, HIV, and malaria) have benefitted from the technical expertise of the nongovernmental organization Euro Health Group (EHG) in the area of pharmaceutical management.

- A draft TB manual including treatment guidelines is currently under revision.

- Quality of drugs is ensured through UNDP's procurement processes in line with the GFATM's and international norms of good procurement practices.

- There are adequate numbers of pharmacists and pharmacist technicians at all levels. Personnel managing TB drugs at different levels, including state and local TB coordinators, are motivated to support the pharmaceutical management system.

- Only a few centers experienced short periods of stock-outs of a small number of drugs. The drugs available through GFATM grant have a long shelf life.

- GFATM funds are available to provide distribution logistics and build central and state medical stores in accordance with good storage practices.

Weaknesses

- Roles and division of responsibilities between SNTP, PSM team, and UNDP PSM unit are not clear.

- There has been some delay in finalizing the new TB treatment guidelines.

- Coordination and communication between SNTP, PSM team, and UNDP PSM unit in TB drug procurement process is not optimal.

- The organizational structure for the pharmaceutical distribution system for TB drugs is well established but not optimal.

- Inventory management does not function well at all levels of the distribution chain of TB drugs, and storage space at central and state medical stores is limited.

- Pharmacists at state level and pharmacist's assistants at state and Tuberculosis Management Unit(TBMU) levels are not fully involved in TB inventory management. TB state and local coordinators are filling this gap.

- Expertise at state level in quantification and at TBMU level in inventory management and good storage and dispensing practices is not optimal.

- The distribution plan for TB/HIV co-infection-related commodities is not yet established.

- Control of TB drug supply and distribution in the private sector is weak.

- Lab commodity management and good storage practices are weak at state and TBMU levels.

Recommendations for Drug Management

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

- SNTP with partners should secure external technical assistance (TA) to strengthen the capacity of the SNTP and PSM teams in TB drug management.

- SNTP and partners should finalize the national TB guidelines as soon as possible and provide a clear timetable for issues and implementation, including—

    - Emphasizing use of fixed-dose combinations (FDC) formulations

    - Developing a clear distribution plan

    - Involving representatives from General Directorate of Pharmacy (GDP), National Drug Regulatory Authority (NDRA), and private clinicians in the drug selection process

    - Informing pharmaceutical sector personnel about new guidelines and drug selection (Federal Central Medical Stores [FCMS], local manufacturers, and private clinicians, etc.)

- Fulfill GDF requirements in general, and for the pediatric TB drug grant in particular, and strengthen the Green Light Committee application for multidrug-resistant TB (MDR-TB) proposal.

- SNTP should formalize the existing team (SNTP, WHO, UNDP, PSM team, GDP, NDRA, and FCMS) that works on quantification, defining its terms of reference and composition to include representation from the GDP and the private sector, giving consideration to

information on commodity consumption and specification that will be required for the activities in TB-HIV, MDR-TB, and Laboratories.

- SNTP and the PSM team should review and improve the distribution plan of TB drugs (levels, schedules, transport, management information systems, dispensing conditions for DOT, TB/HIV-related commodities, etc.).

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

- Include laboratory commodity management expertise in the TA planned for strengthening the lab quality assurance system.

FINDINGS

Coordination of the Sudanese Pharmaceutical Systems in Brief

The pharmaceutical system and its organization represent the context of the TB drug supply system. The main actors in the Sudanese pharmaceutical system are the following institutions—

- The Federal Pharmaceutical and Poison Board: responsible for legislation, regulations, and law enforcement concerning drug registration, importation, manufacturing, distribution, and so on. The board organizes the profession and its practice in the private and public sectors.

- GDP: defines national drug policy, sets norms of pharmacy training and practices, ensures the application of the pharmaceutical strategic plan and the development and update of essential medicines list.

- The Federal Central Medical Store: supplies the country with generic essential drugs through its State Medical Stores. For the last years, FCMS has been building manufacturing plants producing generic drugs to promote local industry.

- Sudanese Pharmacists Union: represents the pharmacists and wholesalers of the private sector.

These institutions are well established and active, but they lack coordination among themselves. Roles and responsibilities are being redefined to optimize the organizational structure of the pharmaceutical sector. The availability of professionals in the pharmaceutical system is generally not a problem. There are adequate numbers of trained pharmacists and pharmacist's assistants in both the public and private pharmaceutical sectors.

Management of the TB Drug Supply System

Coordination of TB Drug Supply System

LHL funded anti-TB drugs and laboratory supplies for 10 years. Since 2007, support for TB drugs and laboratory supplies has been covered by the GFATM Round 5 (and Round 8 in the future). UNDP is acting as PR for both rounds and is also responsible for drug procurement. SNTP has applied for a GDF pediatric grant in 2007; final approval is waiting for some actions (requested by GDF) to be taken concerning treatment policies.

TB drugs supply follows the federal public distribution system of essential medicines while benefiting from separate management. In fact, in the public pharmaceutical sector, essential medicines are distributed through the FCMS and its state medical sores. The government funds a short list of essential medicines designated as emergency medicines and dispensed free of charge for patients. The government also funds some medicines for priority infectious diseases programs, such as vaccines and reproductive health. Programs' medicines, including anti-TB

drugs, are stored in the premises of the Regional Central Medical Stores (RCMS) at central and regional levels and the pharmacy of the health centers. The distribution of TB drugs is, however, managed by the SNTP.

The SNTP coordinates TB drug distribution at central, state, locality, and facility levels. The SNTP has a full-time position for drug management (the new pharmacist had been in place only four months at the time of the review). This new pharmacist is supported by TB state and locality coordinators. Reports from state medical stores are collected by the TB coordinators and sent to the central level where they are examined and used for quarterly distribution.

At central and state levels, the SNTP drug manager is supported by a PSM unit as well. In collaboration with the Ministry of Health, GDP, and GFATM programs, the UNDP (PR) has put in place a PSM team under the GDP, run by a team of pharmacists at central and state levels. The purpose of setting up the PSM team is to streamline efforts and optimize use of GFATM funds of the three programs to improve pharmaceutical management at different levels of the distribution chain of each program. The PSM team works in close collaboration with the PR and the programs at central, state, and facility levels to ensure the following—

- Improvement of storage conditions and practices
- Strengthening of human resources capacity in the area of inventory management at different levels of the programs' pharmaceutical distribution chain
- Improvement of the drug management information system and ensuring better control of drug distribution and consumption
- Ensuring adequate supervision of pharmaceutical management in each program

The PSM team has dynamic and dedicated professionals. They benefited from the external TA of EHG in 2007, including training on pharmaceutical management and the development of inventory management tools. The team has just started providing technical support to strengthen TB drug management (no major products have been issued yet).

Generally, pharmacists and pharmacist's assistants are present in adequate number at all levels of the TB supply chain. Personnel managing TB drugs at different levels, including state and locality TB coordinators, are motivated to support the pharmaceutical management system. Similarly, partners involved directly or indirectly in pharmaceutical management (UNDP, PSM unit, NDRA, RCMS) showed good collaboration.

Leadership in pharmaceutical management and coordination at the SNTP central level has been weak. Efforts to strengthen the supply system have not been streamlined or optimized. The role of the central level in pharmaceutical management has been reduced to quantification and approval of orders. Central-level pharmaceutical managers have no control of drugs once they are distributed from state medical stores. So far, no standardized tools for inventory management, reporting, or supervision have been developed by SNTP pharmaceutical mangers at central level. Very simple reports including only information on quantities in stock and

distributed (not always complete) are received from state and facility levels. These reports are not classified (randomly stored) or analyzed to detect problems in pharmaceutical management. The SNTP pharmaceutical manager and the GFATM PSM team need specific training on TB drug management in all its aspects (MDR-TB, pediatric TB, TB/HIV, DOTS, etc.).

Communication among actors involved in TB pharmaceutical management is weak. PSM and SNTP roles and responsibilities in TB pharmaceutical management are not well defined. Although laboratory commodities are stored and distributed through state TB drug stores, coordination between lab procurement and distribution managers and the drug management team is weak.

Recommendations:

To improve drug supply coordination in the program, the following actions should be undertaken—

- Train central-level personnel (SNTP drug managers and PSM team) on GFATM mechanisms and requirements, on specific TB drug management and DOTS (responsibility of UNDP PSM internal unit, WHO, and SNTP).

- Set up an official mechanism for coordination and communication among actors involved in TB drug management through regular meetings with clear agendas, resulting in concrete actions to tackle any issues related to drug management (responsibility of SNTP and PSM team).

- Strengthen the coordination between drug mangers and TB coordinators at all levels to streamline efforts to make drugs available at the right time and in the right quantity, quality, and dosage with the right counseling for patients (responsibility of UNDP, PSM team, and National Lab).

- **Urgent:** Call for a meeting to define roles and responsibilities of SNTP drug managers, PSM team, and UNDP managers; and sign a memorandum of understanding among parties (responsibility of SNTP).

TB Drug Selection

SNTP along with GDP is mainly responsible for updating treatment guidelines, and updating and issuing the new list of selected TB drugs. Treatment guidelines are being updated with GFATM funds. The first draft has been developed by a team of SNTP and WHO representatives and has been sent to clinicians for feedback. The review and feedback are experiencing some delay, caused by weaknesses in the development process, such as the lack of appointment of the designated reviewers within an *official* task force or working group.

Despite the excellent collaboration showed by the GDP and NDRA, none of these institutions was involved in the development or reviewing process. Private clinicians are not part of the review team either.

Currently, in accordance with the old treatment guidelines, the program is using streptomycin in first-line treatments, which leads to concerns about overuse of injections. In addition, because DOT is not optimal, the program is still using eight months of treatment with ethambutol + isoniazid (EH) in the continuation phase rather than four months of rifampicin + isoniazid (RH). Old guidelines that are currently in use are not adapted to new WHO recommendations about the use of FDC or TB/HIV co-infection treatment, pediatric TB treatment, or new pediatric formulations. These guidelines are often absent at the TBMUs. Two versions of the old guidelines (currently in application) were found in one of the visited facilities, and no guidelines have an edition date. In addition, the content is very limited (just summary treatment). No formulary (documents list the TB drugs with summary of specific information about each drug) has ever been developed for TB drugs.

Recommendations:

- Undertake the following actions to improve and accelerate development process for TB treatment guidelines and to include the new formulations of TB drugs in the essential medicines list in accordance with GFATM and GDF requirements (responsibility of SNTP and WHO)—

    - Design an official mechanism for the review process: meetings and their agenda, guidance and resource information for the review process, terms of reference, and incentives for team members.

    - Designate a team leader for the development of the guidelines.

    - Involve representatives from GDP, NDRA, and clinicians from private sectors to ensure political commitment and better adherence to TB treatment policies in public and private sectors.

- Improve the *content* and the presentation of the current draft guidelines, and issue pocket guidelines and TB drug brief formulary (details about each drug) (responsibility of SNTP and WHO).

- Emphasize the importance of using four FDCs and new pediatric formulations in the country's TB guidelines and treatment policies (responsibility of SNTP and WHO).

- Emphasize the use of drugs for pediatric and adult (TB/HIV) prophylaxis (responsibility of SNTP and WHO).

- To ensure adherence to treatment guidelines from public and private sectors, in collaboration with NDRA and pharmacists' and doctors' professional organizations, develop guidelines and regulations emphasizing the necessity to adhere to the SNTP policy in terms of pharmaceutical procurement and treatment and prescribing (responsibility of SNTP and WHO).

- Ensure proper implementation of the guidelines through adequate information and training on new guidelines, and ensure adequate distribution of copies in all health TBMUs including the pharmacy (responsibility of SNTP and WHO).

- **Urgent:** Develop precise timetable for the preceding activities, including development and implementation of the guidelines, to allow GDF pediatric grant to be finalized and future adjustment of the adult TB drug procurement plan (responsibility of SNTP and WHO).

Management of Quantification and Drug Procurement

National quantification is not done through an official mechanism but rather by a limited number of SNTP and UNDP personnel who do not necessarily do extensive drug consumption data analysis. Data are not collected on consumption at peripheral level (TBMUs). The latest quantification (in development) has not taken into account the high stock of EH at the state and the facility levels or the future changes in the guidelines. The definition process of drugs' specifications for tender is not optimal either, resulting in the purchase of loose forms and boxes of 1,000 tablets instead of four-drug FDCs, blisters, or kits (nor is there provision for dispensing bags to accompany loose packaging).

Procurement of drugs is the responsibility of the UNDP, the PR for the GFATM TB grant Rounds 5 and 8. TB drugs are purchased through GDF with long expiry dates. Quality control tests are carried out on the batches received according to UNDP policies in this area. TB drugs imported through GFATM and GDF grants benefit from a waiver and exemption from taxes. Communication related to order delivery between SNTP, UNDP, and the storekeeper and PSM group needs improvement. Documents related to delivered orders are not always adequately complete or shared with partners. SNTP does not have any system to organize information or documents related to received orders.

Recommendations:

- Set up a national TB quantification committee and state subcommittee including representatives from main partners involved in pharmaceutical procurement and under the lead of the PSM group and the SNTP drug managers. The committee will be responsible for performing consumption data analysis and verification, accurate calculations, and consensus building among partners. The quantification committee will be responsible as well for follow-up on consumption data collection and verification through a more efficient TB Drug Management Information System (see below) (responsibility of PSM team and SNTP drug manager).

- SNTP along with the quantification committee needs to be more involved in defining the specifications for procured drugs (responsibility of PSM team and SNTP drug manager).

- SNTP in collaboration with the UNDP procurement unit should set up regular meetings with structured agenda to follow up on procurement activities and share documents and information. Although procurement is the responsibility of UNDP, the SNTP should seek to

obtain information and necessary documentation to follow up on orders (responsibility of SNTP).

- **Urgent:**

  - Map out the stock of some drugs like EH and RH throughout the distribution chain including TBMUs. EH is held in big quantities in many facilities and state stores with short expiry dates, and ethambutol (E) and RH have depleted stock levels in many facilities (responsibility of PSM team, UNDP, and SNTP).

  - Review next quantification to take into account the changes in the treatment guidelines and the stock of some drugs, such as EH, E, and RH (responsibility of PSM team, UNDP, and SNTP).

  - Establish a detailed procurement and distribution plan while transitioning from old to new treatment policies (responsibility of SNTP).

  - Map out the actual number of pediatric TB cases in every state and TBMU, and prepare an accurate forecast along with a procurement and distribution plan for pediatric formulations, taking into account the rollout of the new guidelines and new formulations (responsibility of SNTP).

TB Drug Distribution System

As mentioned previously, drug distribution is done through the public distribution chain for essential medicines, although its coordination is ensured by the SNTP (figure 1). Storage space at central and state levels is very limited, which hinders adherence to good storage practices. However, on a positive note, funds are made available through malaria and HIV/AIDS programs' GFATM grants to build warehouses at central level and at every state and to provide trucks and pick-ups for distribution. Cost sharing between the government of Sudan and GFATM concerning operating costs for the PSM distribution system to be built is not clear.

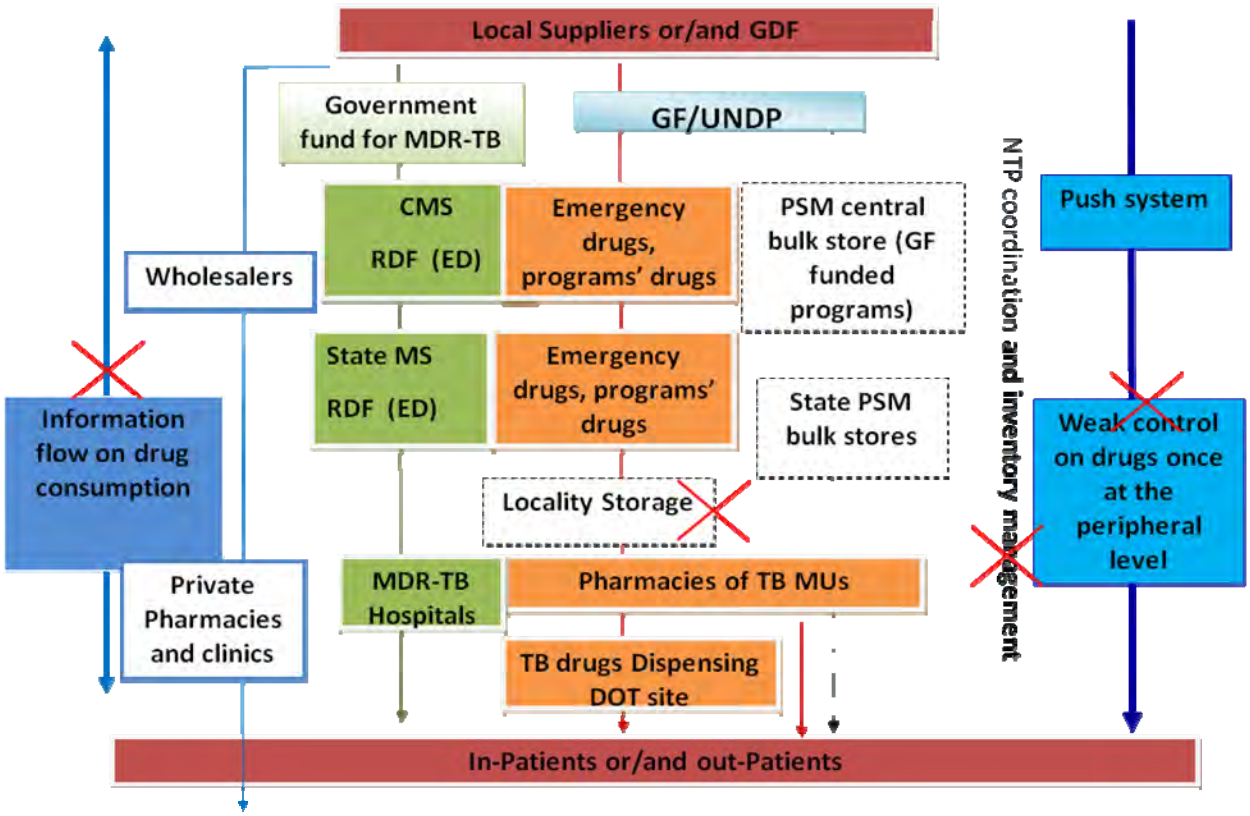

Figure 1. Organization of TB drugs distribution system in Sudan

In some states, an extra level of storage at locality level is created in an ad hoc manner. This storage level lacks minimum storage conditions and does not respect good inventory management practices. It has been created in most cases to fill the gaps in inventory management at state and central levels or where access to state medical stores is difficult. For example, at Khartoum state medical store, orders are grouped by locality. It is the responsibility of the locality TB coordinator to repack and deliver them to the TBMUs. However, the locality level has no medical stores for this purpose. TB coordinators might keep some of the stock as security stock but on an ad hoc basis.

Personnel managing drugs at all levels are motivated and open to improvement and learning; however, they are not trained on the specifics of TB drug management. Involvement of pharmacists at state level and pharmacist's technicians at TBMUs in inventory management is very limited; they merely receive and dispatch drugs. The TB coordinators do inventory management and quantification, but their role should normally be limited to supervision of drug distribution and management. Because of this separation between the physical management of drugs (done by the storekeepers and dispensers) and the theoretical (done by the TB coordinators), inventory management at state and facility levels is not optimal (stock maximum and minimum are not respected, and emergency orders happen regularly). In addition, control of stock after it leaves the warehouse is very weak.

TB Drug Inventory Management and Management Information System

TB drug inventory management is done through a push system where control of drugs beyond state level is weak. Drugs are distributed upon receipt of the quarterly reports from TBMUs. TB coordinators decide the quantities for each facility based on the quarterly reports. These reports inform about quantities in stock and expiry dates (but expiry date is not always completed). In many instances, the reports arrive late from facility level to state level; consequently, drug distribution from central level can be delayed pending the reception of quarterly reports. This results sometimes in stock-outs at state and facility levels because the quantification process has no provision for drug coverage during these delays. Drugs are often available at all facilities and state levels, but often in excess of maximum level and below stock minimum level at various levels of the distribution chain. Some drugs are available in quantities far exceeding the stock maximum, which sometimes results in their expiring.[1] For example, in one of the state medical stores, although the stock of EH should have covered 38 months of consumption, it would have expired in 24 months. In some state medical stores and TBMUs, stock-outs or levels of stock below stock safety levels were noticed, which resulted 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 inadequate quantification.

The TB drug management information system is very weak. Record keeping is adequate at state medical stores but very weak at facility level. The SNTP central level has not developed any standardized tools for TB drug record keeping for any level of the distribution chain. Drug managers and dispensers use different tools they developed themselves. In some cases, even when other emergency drugs dispensed without cost are recorded, it is not the case for TB drugs. Reports on drug management are very limited in content and information, and not standardized. At central level, these reports are not organized, filed systematically, or analyzed. Tools for drug management supervision do not exist. Supervision of drug management is limited to quantifying and distribution of the drugs. Yearly reports include a very limited section on drug management (merely a table on quantities received, distributed, and in stock with no interpretation in a 100 to 150-page report).

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

Recommendations:

- The PSM team, with support of SNTP and other programs, should seek government support to cover operating costs and define mechanisms to ensure the sustainability of their work and the future bulk stores (responsibility of PSM team and SNTP).

- SNTP should omit extra levels (locality level) of storage where it is not needed and create some when necessary (in areas with difficult access), respecting good storage practices (responsibility of PSM team and SNTP).

[1] Note that the GFATM-procured drugs have long shelf lives, and no expiry has been found in this stock.

- SNTP central level in collaboration with the PSM group should develop and distribute standardized tools for record keeping, ordering, reporting, and supervision (responsibility of PSM team, UNDP, and SNTP).

- SNTP central level in collaboration with the PSM group should seek technical assistance to develop practical training material tailored to TB drug dispensers at the facility level and train a national team of trainers on specifics of TB drug management (responsibility of PSM team, UNDP, and SNTP).

- SNTP central level in collaboration with the PSM group should organize a cascade training of personnel on TB drug management and dispensing at TBMUs (responsibility of PSM team, UNDP, and SNTP).

- The PSM team and SNTP should improve dispensing conditions and supervise dispensing practices: when feasible, and taking into consideration national regulation on drug dispensing, budget for storage conditions and for training of the TB DOT personnel on drug management, TB drugs can be put at the disposition of the DOT dispensing person (in a secured cupboard). DOT personnel need to be trained on inventory management and drug consumption reporting (responsibility of PSM team and SNTP).

- **Urgent:**

    - Add one pharmacist technician at Khartoum bulk store to facilitate preparation of the orders for each facility separately, and stop sending a grouped order for localities (responsibility of SNTP and PSM team).

    - Map out the localities in Khartoum that store drugs, and return the stock to the state bulk store (responsibility of SNTP and PSM team).

    - Send a standardized checklist for reporting on EH, E, and RH stock status at least in main storage facilities, including TBMUs with high number of patients (responsibility of SNTP and PSM team).

    - Map out delayed orders at central level and state levels, and take action accordingly to redistribute the stock (responsibility of SNTP and PSM team).

Rational Drug Use

In general, enough human resources (pharmacist technicians) are available at the TBMU drug dispensing level. Enough space is available for drug storage at pharmacy level. Dispensing conditions, however, are not adequate. Drug dispensing does not use patient kits. Drugs are dispensed to TB patients (inpatients and outpatients) through a small window while they stand outside. They are mixed with all other patients coming to collect free drugs. Such an environment does not allow good patient counseling and has some risk of infection for non-TB patients. After patients receive their drugs, they go to the DOT person for injection and follow-up on adherence. Pharmacist technicians and pharmacists are not trained on counseling for TB

drugs. They are not encouraged to do so, and they are not involved in the DOTS training. Neither treatment guidelines nor information on TB drugs is available at pharmacy level. Data on drug consumption are not analyzed to detect irrational prescribing at any level of the distribution chain or the SNTP central office. Examined data on stock levels and discussions with pharmacists and storekeepers suggest that treatment guidelines 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).

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

Recommendations:

- When feasible, TB drugs should be put at the disposition of the DOT dispensing person *in the form of patient kits*. Drug management should be coordinated between the DOT person and the pharmacy of the TBMUs. In the case of TB DOT centers where no pharmacy is available, the DOT person needs to be trained on drug inventory management and reporting and given adequate storage conditions for TB patient kits.

- To ensure the same message on adherence to TB treatment is delivered and emphasized by all health workers involved at each step of service delivery, the following actions should be undertaken (responsibility of SNTP and PSM team)—

    - Train personnel at the pharmacy level on TB drug dispensing and main principles of DOT, and emphasize their role in insuring patient adherence.

    - Improve dispensing conditions for TB drugs at the pharmacy level through preparation of patient kits.

    - Ensure better coordination and communication between pharmacy and DOT centers, especially to alert and report on defaulters (when dispensing is done primarily at the pharmacy level).

    - Train dispensers to analyze data on consumption and prescriptions and report on irrational prescribing.

- Provide the pharmacist's assistant at the pharmacy level with TB treatment guidelines and information on TB drugs (TB drug formulary) (responsibility of SNTP and PSM team).

- Provide guidance and tools to analyze drug consumption data to identify irrational prescribing and report it (responsibility of SNTP and PSM team).

- Include criteria on good dispensing practices at the pharmacy level in addition to criteria on good drug management as part of the norms to accredit a TBMU or a DOT center.

- **Urgent:** In preparation for pediatric TB drug dispensing, provide personnel at the pharmacy level with training and brochures on the new pediatric formulations. Include this activity in the timetable to be sent to GDF (responsibility of SNTP).

TB/HIV Commodity Management

TB/HIV projects exist in both TB and HIV programs under the GFATM grants. A TB/HIV coordinating body exists at central level. The TB/HIV coordinators as well as drug dispensers in TB/HIV centers are motivated and involved in drug distribution coordination. However, the TB/HIV drug distribution plan and coordination are neither well defined nor established. It is not clear where HIV/TB-related commodities, including TB drugs and antiretrovirals (ARVs), should be stored and dispensed. In health facilities where TB drugs and ARVs are dispensed, pharmacy personnel are not trained on dispensing for TB/HIV co-infected patients. In addition, collaboration and communication between TBMUs and HIV ART centers is weak in many facilities. Some expired drugs and test kits were found in the TBMUs and TB/HIV pharmacies.

Recommendations:

- Designate a TB/HIV commodity coordinator. He or she should be involved in most coordinating meetings, monitoring and evaluation activities, and decision making concerning TB/HIV programmatic issues (responsibility of HIV/TB coordinators and PSM team).

- Designate a task force with the TB/HIV project to define where and upon what conditions and criteria ARVs and TB drugs will be stored and dispensed in areas where only TBMUs are accessible for patient, or when only an ART center is nearby, or centers where dispensing all TB/HIV-related commodities can be integrated (responsibility of HIV/TB coordinators and PSM team, SNTP and HIV/AIDS program managers).

- Ensure that any tools developed for drug management at pharmacy level include sections on data collection, compiling data and reporting on TB/HIV-related commodity consumption, and a section to follow-up on patient adherence (responsibility of HIV/TB coordinators and PSM team).

- Ensure training on drug management and dispensing includes a section on TB/HIV management and dispensing (responsibility of HIV/TB coordinators and PSM team).

- Train on ART dispensing and TB for all dispensers involved in both from SNTP side and from HIV/AIDS program side (responsibility of HIV/TB coordinators and PSM team).

- **Urgent: Verify level of stock of TB drugs where they are present in ART or TB/HIV centers and the same for ARVs to scan expiry and stock-outs (responsibility of TB/HIV coordinator in collaboration with SNTP and PSM group).**

MDR-TB Drug Management

MDR-TB service is offered in only one hospital located in Khartoum state (Abou Anja Hospital). Currently, drug procurement is assured by the Sudanese government through the RCMS. Expansion of the MDR-TB project is planned for Round 8 of GFATM. The Round 8 proposal includes a budget for procurement of second-line TB drugs. Treatment guidelines for MDR-TB are part of the draft new TB treatment guidelines. Only two of the products (cycloserine and ethionamide) are from a WHO-prequalified supplier—Macleod. The RCMS key personnel met during the review mentioned some delays in payment for MDR-TB drugs by the hospital (the reason behind delays was not explored).

List of Drugs Available at Abou Anja Hospital

Ciprofloxacin 250 mg	Shangai Pharmaceuticals Co. Ltd; China
Floxacin 200 mg	Hovid Bhd; Malaysia
Dycloserine 250 mg	Macleod; India
Ethionamide 250 mg	Macleod; India
Amikacin	Troikaa pharmaceuticals; India

So far, the SNTP central drug manager team and the PSM team have not received any training on MDR-TB drug management. Tools for MDR-TB drug management and quantification are not available.

Recommendations:

- Request external TA for the following—
    - Develop training material on MDR-TB drug procurement and supply (responsibility of SNTP).
    - Train SNTP drug managers and PSM group on MDR-TB drug procurement and supply (responsibility of SNTP).
    - Develop tools (among the above) for MDR-TB drug management (responsibility of SNTP).
- **Urgent:**
    - Collect information on MDR-TB treatment patterns and on drugs consumed by current MDR-TB patients, and analyze it to ensure accurate quantification for future order of MDR-TB drugs (responsibility of SNTP and PSM group).

- Verify the source of drugs procured through RDF central medical store to scan what has been procured for quality and prequalification of suppliers (responsibility of SNTP and PSM group).

- Ensure the payment of the MDR-TB drug procurement to avoid interruption of supply (payment due to CMS) (responsibility of SNTP).

TB Drug Management in Private Sector

SNTP has no control of TB drug distribution in the private sector. TB drugs are sold with no rational dispensing in the private pharmacies, hindering the SNTP effort in TB service delivery. Stigma is a big factor pushing TB patients to seek drugs at private pharmacies.

Local manufacturers produce TB drugs, but no communication has been sought by the SNTP to coordinate production of TB drugs recommended by the treatment guidelines (especially future guidelines).

The NDRA, SNTP, and GDP are the institutions that are mandated to regulate TB drug procurement, and distribution and dispensing policies. SNTP has full support of both pharmaceutical institutions.

Recommendations:

- Plan for regular meetings with the NDRA to establish policies and clear regulation and law enforcement plan limiting drug procurement and distribution in the private sector.

- Invite representatives of private manufacturers for the launch of the new guidelines.

Lab Commodity Management

The 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 Reference Laboratory at Khartoum to the state labs. Reagents are prepared at this level and sent to the TBMUs. Laboratory commodities procurement and lab activities strengthening are budgeted in Round 8 of the GFATM grant.
Good storage practices for lab commodities are completely absent at the laboratories visited. Inventory management (quantification and ordering) is restricted to central- and state-level lab managers. Tools for inventory management are not available at all levels. Personnel managing the labs at state level and especially at facility level are not trained on good storage practices or inventory management.

Recommendations:

- Integrate lab commodity management in quality assurance activities for lab trainings and supervision. Request the inclusion of lab commodity management in the scope of work of future external TA through Round 8 funds (responsibility of UNDP, SNTP, and National Lab).

- Include commodity management supervision among other lab supervisory activities (responsibility of SNTP and National Lab).

- Designate a lab specialist at PSM team to coordinate lab commodity procurement and distribution with UNDP, national, state, and facility labs (responsibility of UNDP, PSM team, and National Lab).

ANNEX 1: SUMMARY OF VISITS

Health Facility/ Bulk Store	Quantification	Ordering/ distribution frequency	Record keeping	Stock-out (last 12 months)	Stock expiry and/or at risk (last 12 months)	Stock max/min respected	Good storage practices/ Good dispensing practices	HR
Central Medical Store of the TB program	Push system done by the pharmacist of the program	Normally quarterly but due to delays in quarterly reports, this schedule is not respected	Improvised but well kept. Since storage space is very limited; record keeping cannot be verified (difficult to count)	Some urgent orders occurred	No expiry in GFATM funded drugs (they are all long expiry)	No	Storage space is very limited	Adequate number
Khartoum State medical store	Push system (done by locality or state coordinator)	Quarterly orders from Khartoum CMS and quarterly grouped distribution per locality (stock is repacked at TB coordinator office for each facility; without adequate storage conditions)	Stock cards are similar to other state medical stores; but others are improvised Accurate	No	No	No	Observed, but space is lacking	Qualified and motivated, but lack of personnel
Eljazeera State Medical Store	Idem	Quarterly but frequent delays and urgent orders	Idem	Yes RH, E, Z (for 10 days); due to delays in TBMUs reports. Same drugs are stock out in the	Yes	No	Observed, but space is lacking	Idem

Health Facility/ Bulk Store	**Quantification**	**Ordering/ distribution frequency**	**Record keeping**	**Stock-out (last 12 months)**	**Stock expiry and/or at risk (last 12 months)**	**Stock max/min respected**	**Good storage practices/ Good dispensing practices**	**HR**
				nearest TBMU visited (Madany)				
Academia TBMU (Khartoum State)	Idem	Quarterly but frequent urgent orders	No standards tools for record keeping (improvised by Ph. Tech)	No	EH: *Exp Jan 2009* *Q:4032 tabs (> stock max)* Z: *Exp 04/09* *Q:7000 tabs (> stock max)* Yes S 1g: *Exp:03/2007* *Q:150 vials*	No	Not observed	Adequate number; not trained on specificity of TB drug management or/and dispensing
Singa Hospital pharmacy (Sinnar State)	Idem	Frequent orders	No record keeping	No (near to the state medical store)	No	No	Not observed	Idem
Extra-storage at locality level (Khartoum state)	N/A	This level is created to fill in the gaps of storage and inventory management at Khartoum state medical store	No record keeping Orders are distributed from Khartoum State Medical store grouped by locality	N/A Stock is repacked at the office of the TB coordinator and some of the stock is kept at the office			No minimal conditions for storage are available	

Health Facility/ Bulk Store	Quantification	Ordering/ distribution frequency	Record keeping	Stock-out (last 12 months)	Stock expiry and/or at risk (last 12 months)	Stock max/min respected	Good storage practices/ Good dispensing practices	HR
Dispensing point of TBMUS Madani _ (Eljazeera State)	Idem	Idem	Record keeping improvised but no used for stock management	Yes, when they run out of stock they buy from private pharmacy; in rare occasions patients were sent back without a missing medicine.	Yes	No	Observed	Idem
Bulk store of TBMU Madani _ (Eljazeera State)	Idem	Idem	NO record keeping	Yes, idem.	Yes	No	NOT observed	Idem
TB/HIV Pharmacy (Khartoum State)	Mix of push and pull systems ;	Idem	Improvised and well kept	Yes	Yes	No	Yes	Adequate number of personnel but not trained on specificity of TB/HIV co-infection related commodities management
Laboratory at Sinnar state	Push	Quarterly	No record keeping of consumption	No	Yes	No	Not existing	Adequate number, but no notions of TB commodity management

Health Facility/ Bulk Store	**Quantification**	**Ordering/ distribution frequency**	**Record keeping**	**Stock-out (last 12 months)**	**Stock expiry and/or at risk (last 12 months)**	**Stock max/min respected**	**Good storage practices/ Good dispensing practices**	**HR**
								and good storage practices
Laboratory at Eljazeera state	Push	Quarterly	No record keeping of consumption	No	Yes	No	Not existing	Adequate number ; but no notions of TB commodity management and good storage practices
Laboratory at Sinnar TBMU	Push	Quarterly	No record keeping of consumption	No	Yes	No	Not existing	Adequate number ; but no notions of TB commodity management and good storage practices

Note: Ph. Tech: Pharmacist technician

Stock analysis: Adult drug formulations considering the following:

- 23,000 patients on Cat I & III and 1700 on Cat II (data provided by SNTP from statistics department)
- Same current regimens
- Stock in hand includes latest deliveries

	Description	**Annual Drug needs**	**Current stock (at the time of visit)**	**# Months' stock on-hand**
RH150/75	*Rifampicin 150 mg / Isoniazid 75 mg, film coated tablets*	5,006,400	4,680,000	11
EH400/150	*Ethambutol 400 mg + Isoniazid 150 mg film coated tablets*	7,728,000	8,776,000	14
E400	*Ethambutol HCl 400 mg film coated tablets*	3,337,600	777,000	3
Z400	*Pyrazinamide 400 mg tablet*	4,292,400	4,508,000	13
S 1 g	*Streptomycin (as sulfate) powder for injection 1 g,*	1,383,200	1,307,000	11

ANNEX 2: ITINERARY AND LIST OF PERSONS MET

National TB Program of Sudan: TB Drug Management Assessment Agenda

In-depth review/GDF monitoring mission
10 to 24 November 2008

Week 1

Time	Activity	Key personnel met
Tuesday, November 11		
morning	Orientation: meeting with all team members and the NTP colleagues: **Orientation and first exploration of the situation of NTP management**	All NTP team and partners
Lunch break		
2 to 4 pm	Orientation: meeting with all team members and the NTP colleagues: **Orientation and first exploration of the situation of NTP management**	Idem
4:00 to 5:00pm	Meeting with NTP drug manager): **Understand the organization of TB drug supply in the country Discuss/re-adjust the agenda for drug management sites visits**	PSM team and Nagi Awed, NTP drug manager
Wednesday, November 12		
8 :30-9 :15	Meeting with CU officer and Khartoum State Officials	CU officer and Khartoum State Officials
10 :00-11 :00	Meeting with Khartoum State TB key personnel	Khartoum State TB key personnel
11:00-	PSM Unit	All PSM unit personnel except PSM manager (was out of the country)
12-1	CMS	CMS manager accompanied by PSM team and NTP manager
Lunch break		
	NDRA	Secretary General and Pharmacovigilence Team Registration key person was out of the country
	GF/UNDP	TB M&E Specialist,

Thursday, November 13		
	Meeting with Khartoum State TB Coordinator and Locality coordinators	Khartoum State TB Coordinator and some Locality coordinators
	Filed visit: Khartoum State medical store	State pharmacist and store keepers
	Field visit: Academy hospital	Pharmacist technician
Lunch break		
	Field visit: Dot center in Khartoum state	Dot Person
	Field visit: Locality TB Coordinator storage space	Locality TB coordinator
Friday, November 14 (team work ; indepth review mission)		
Saturday , November 15 (travel to Sinnar state)		

Week 2

Hour	Activity	Key personnel to meet
Sunday, November 16		
	Sennar: Meeting with state officials State Medical store Locality medical Store TB MU (Lab, HIV/TB, Drugs) TB DOT Center	Sinnar state officials Sinnar TB state coordinator Pharmacist technician at the TBMU pharmacy State lab coordinator Lab technician at the TBMU Pharmacist of the state medical store and his team (store keepers)
Lunch break		
	continuation	
	Private pharmacy NGO	
Monday, November 17		
	El Jazeera: State Medical store Locality medical Store TB MU (2) (Lab, HIV/TB, Drugs) TB DOT Center	Sinnar TB state coordinator 3 Pharmacist technicians practicing DOT at the TBMU pharmacy Madani Tb coordinator State lab coordinator (as well she is the lab technician at the TBMU of Madani) Pharmacist of the state medical store and his team (store keepers)
Lunch break		
	Back to Khartoum: 3pm	

Tuesday, November 18		
	UNDP-	Dr El Fatah Malek HIV/AIDS M&E Specialist, and procurement key personnel (TB drugs procurement officer was not available at the time of the visit)
Lunch break		
Wednesday, November 19		
9	NDRA PSM Group	secretary General
Lunch break		
	National CMS(Central Medical Supplies Public Corporation)	CEO and two representatives of his team (deputy manager and distribution manger)
Thurtsday, November 20		
	PSM team	All PSM team
Lunch break		

Week 3

Hour	**Activity**	**Key personnel to meet**
Sunday, November 23		
8 :00 -12 :00	Workshop to present findings and recommendations and discuss draft work plan on drug management (NTP and partners involved in drug management)	See list of participants
Lunch break		
13 :00- 17 :00	Debrief (NTP and partners)_continuation: Planning session	Idem
Monday, November 24		
8 :00 -12 :00	Debrief with the rest of the assessment team	See list of team members
Lunch break		
13 :00- 17 :00	USAID debrief	
Travel to Dubai		

List of Participants:

Workshop on TB drug management
GDF MONITORING MISSION / 3RD IN-DEPTH REVIEW OF SUDAN NTP
Sunday November 23, 2008

Participants	Names
PSM managers at the UNDP and Financial manager and GF focal point for TB program (to attend session1 and 2)	Dr. Ammar Saleh (to attend session1 and 2) Ashraf Abbas (to attend session1 and 2)
PSM group: PSM manager and key personnel involved in drug distribution , M&E and training an planning (to attend session1 and 2)	Dr. Mohammed Imad (to attend session1 and 2) All personnel of PSM Group (to attend session1 and 2)
Lab representatives (key personnel involved in managing lab commodities at central and State level) (to attend session1 and 2)	Dr. Asrar Al Eageel (to attend session1 and 2) Mortada Ahmed (to attend session1 and 2)
Representative from CMS (manger and decision maker in the CMS)	Dr. Abdellah Mohammed El Hassan (to attend session 1)
TB personnel or PSM pharmacist managing stock (central level and state level) (to attend session1 and 2)	Shaaban Taha (to attend session1 and 2) Dr. Awad Elmeenaf (Khartoum PSM coordinator) (to attend session1 and 2)
Representative of State coordinators (Khartoum state) Representative of Locality coordinators (Khartoum Locality) (to attend session1 and 2)	Dr Hiba Hamad El Nil Dr. Mouaya (to attend session1 and 2)
Private sector representative (Clinicians, private pharmacy association of pharmacy board (to attend session1)	Dr. Salah Souar Ezahab (General Secretary of Pharmacy Union) Representative of Clinician Dr. El Fatah Malek (to attend session1)
Representative from NDRA (to attend session1)	Dr. Jamal Khalafallah (Federal Pharmaceuticals and Poisoning Board) Dr. Feisal Kheder (drugs affairs manager)

Participants	**Names**
NTP representatives (NTP coordinator, Pharmacist TB/HIV , procurement logistician coordinator and others) (to attend session1 and 2; except Dr. Hashim Session1 only)	Dr. Hashim Soulaiman El Wagea (to attend session1) Ahmad Noureen Dr. Mahmoud Ettayer Dr. Abdellah Arbab Dr. Samia Elajab (to attend session1 and 2)
WHO representative (to attend session1 and 2)	Dr. Ayeed (to attend session1) Dr. Imad El Amin (to attend session1)
CCM representative (to attend session1)	Dr Esam Mohaned Abdallah Dr Amjad Wadaa.

ANNEX 3: IN-DEPTH REVIEW MISSION TEAM MEMBERS

External consultants:

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),
Dr. Noura Maalaoui (GDF consultant, MSH) and
Dr. Amal Bassili (WHO EMRO)

WHO: Dr Aayid Munim, WHO Sudan, international TB adviser and Dr Imad Alamin, WHO Sudan, national TB adviser
NTP: Dr. Hashim *Suleiman Elwagie*, Manager of the National Tuberculosis Program, Sudan and Dr. Nagi Awed , NTP drug manager
PSM team representative: Dr. Mohammed Imad
LHL: Rasmus Malmborg,