Assessment of the Neglected Tropical Diseases Pharmaceutical Management System in Senegal

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

Neglected tropical disease, supply chain, pharmacovigilance, waste management, reverse logistics, mass drug administration

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ACRONYMS AND ABBREVIATIONS

ADR adverse drug reaction

CDD community drug distributor
CHW community health worker
DDP Drug Donation Program

DLM Direction de la Lutte contre la Maladie (Directorate of Disease

Control)

DPM Direction de la Pharmacie et du Médicament (Department of

Pharmacy and Medicines)

FEFO first-expiry, first-out

HP health post (poste de santé)

JRSM Joint Request for Selected Preventive Chemotherapy Medicines

LMIS logistics management information system

LF lymphatic filariasis

MDA mass drug administration

MoH Ministry of Health and Social Work (Ministère de la Santé and

de l'Action Social)

MOU memorandum of understanding NGO nongovernmental organization NTD neglected tropical disease

NTDDs neglected tropical disease drugs

PNA Pharmacie Nationale d'Approvisionnement (National Supply

Pharmacy)

PRA Pharmacie Régionale d'Approvisionnement (Regional Supply

Pharmacy)

PSSC Public Service Satellite Consortium

RTI RTI International
SAE serious adverse event
SCH schistosomiasis

SIAPS Systems for Improved Access to Pharmaceuticals and Services

SOP standard operating procedure STH soil-transmitted helminthiasis

USAID US Agency for International Development

WHO World Health Organization

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EXECUTIVE SUMMARY AND KEY RECOMMENDATIONS

This assessment is part of the support provided by the US Agency for International Development (USAID) for the ministries of health of developing countries to improve and reinforce pharmaceutical management systems. It responds to the concerns of the Senegal Ministère de la Santé and de l'Action Social (Ministry of Health and Social Work; MoH), the World Health Organization (WHO), RTI International (RTI), and stakeholders about the efficiency and effectiveness of supply chain management for donated medicines to treat neglected tropical diseases (NTDs) in Senegal.

USAID has given the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program the task of analyzing pharmaceutical management capacities in Senegal to improve and strengthen the access of the Senegalese population to NTD drugs (NTDD) for mass drug administration (MDA).

The assessment examined several aspects of the pharmaceutical sector and focused on—

- Quantification and procurement planning
- Human resources
- Inventory control and logistics management information systems
- Warehousing and distribution

The assessment identified both strengths and weaknesses and proposed recommendations (summarized below). In addition, to assist with achieving the goals of improved pharmaceutical management systems for NTDs, SIAPs has made suggestions for new and improved tools, such as the following—

- A national manual for NTDD management: This manual would cover issues on how to properly store and maintain NTDDs at different levels of the supply chain.
- Specific tools for ensuring proper storage of NTDDs: These include proper inventory management and storage techniques adhering to first-expiry, first-out (FEFO) guidelines and should refer to proper storage specific to different levels of the supply chain.
- Specific tools for reporting on waste management: These include proper disposal of expired or damaged NTDDs, bottles, spoons, etc., including real-world suggestions on how to dispose of drugs and clean and reuse materials.
- Guidelines on leftover drugs following MDA: This includes development of a clear guideline, time lines, and responsibilities on reverse logistics of leftover NTDDs following an MDA and a nontechnical document that can be distributed to community health worker (CHWs), community drug distributors (CDDs), and health post (HP) focal points.

Key Recommendations

The proper management of all pharmaceutical products is central to a strong health system. A reliable supply of quality medicines, rational use, and efficient distribution can result in lower costs and less waste and is an essential component to improve health services for the population. Conversely, inappropriate storage, poor distribution, and irrational use of drugs compromises safety and can reduce the effectiveness of national disease programs.

Although improvements clearly are being attempted, this assessment shows weaknesses in the pharmaceutical management of NTDDs at all levels. Having sufficient dedicated and enthusiastic personnel is critical to the proper planning and implementation of the health programs. Lack of adequate storage space and conditions risks the quality of the drugs, and improper quantification of needs and reporting of drug use results in expiry and wastes large amounts of drugs.

The following are recommendations for promoting pharmaceutical systems strengthening for NTDDs.

- Formalize and fund the NTD pharmacy position at the Direction de la Lutte contre la Maladie (DLM; Directorate of Disease Control), which is providing critical supply chain—related functions. This supportive position represents a crucial link between the DLM and the Pharmacie Nationale d'Approvisionnement (PNA; National Supply Pharmacy) and allows for coordination between them. The absence of a full-time NTD pharmacy position at DLM results in slowed communications, inefficient distribution of responsibilities, slowed distribution through the supply chain, and potentially delayed MDAs.
- Complete and sign the memorandum of understanding (MOU) between the DLM and the PNA. The WHO focal point can assist in facilitating this negotiation. By completing the MOU, clear roles and financial responsibilities of the PNA and DLM will be established and help maximize efficiency by coordinating NTDD management as done for other health programs. The delay in signing the MOU is causing NTDDs not to be fully integrated into the PNA and Pharmacie Régionale d'Approvisionnement (PRA; Regional Supply Pharmacy) system. (NTDDS are not input into computer systems, have no stock cards, and are not stored in the pharmacy.)
- Split large NTDD bottles into appropriate smaller containers before distribution from the district to the HPs. Splitting NTDDs into smaller packages reduces excess NTDDs following MDA, thus resulting in less necessity for reverse logistics of leftover NTDDs. The current system results in large amounts of leftover NTDDs following MDA, leaving large numbers of leftover opened NTDD bottles and increasing the risk of quality issues during storage until the next MDA. In addition, large quantities of leftover NTDDs are left at the lower levels of the supply chain.

Assessment of the NTD Pharmaceutical Management System in Senegal		

INTRODUCTION

Worldwide, more than 1 billion people—one-sixth of the world's population—suffer from one or more neglected tropical diseases. Schistosomiasis (SCH), onchocerciasis, trachoma, lymphatic filariasis (LF), and soil-transmitted helminthiasis (STHs) are all endemic in Senegal. The country's total population of 14,377,762 people is at risk of one or more of these NTDs, which can cause sickness and severe disability.

The Government of Senegal established a national integrated NTD program in 2010, with a dedicated NTD focal point within the MoH's Directorate of Disease Control (DLM). With the Government of Senegal's commitment to organize and implement a robust NTD control program, USAID designated Senegal as a focus country for NTD support in 2011. USAID supports the DLM and the community health network in the implementation and strategic coordination of NTD program activities. Mass treatment campaigns are run by the community health network, which coordinates a nationwide network of community health service delivery points, including more than 3,000 health sites, as well as delivery by school teachers. This approach helps Senegal rationalize resources without duplicating existing community-level social mobilization and deworming efforts.

Senegal's Strategic Plan for NTD Control (2011–2015) includes preventive chemotherapy for LF, onchocerciasis, SCH, STH, and trachoma; morbidity management; prevention; and surveillance. Preventive chemotherapy has been conducted in all 14 regions of the country, and impact surveys are being conducted as needed. NTD control and elimination programs are led by the MoH with support from partners including USAID, Sightsavers, and potentially the Organization for the Development of the Senegal River. In fiscal year 2014/15, USAID supported pharmacovigilance training for district-level health personnel and inventory of drug stocks following MDAs.

Supply chain—related challenges faced by the Senegal NTD program include performing accurate quantification of drug needs, ensuring reverse logistics of preventive chemotherapy NTD drugs following MDA, and managing drug supply, including storage, tracking, inventory, and disposal. As a way of addressing these challenges, implementation of a durable and comprehensive NTDD management system, including an integrated pharmacovigilance system, is recommended to ensure safety and effectiveness of treatment.

Integration of NTD Control in Senegal

With the goal of increasing both economic and health impact of NTD control interventions, the Senegal MoH recognized the need for a harmonization and integration initiative for NTDs. The objective of integration is to establish collaboration between program managers at the central level and integrate implementation of activities from the district down to the communities. The decision to integrate the five endemic preventive chemotherapy NTDs was made because they are the primary focus of MDA campaigns and they demonstrate large geographic overlap as well

as increased logistical and financial efficiency. Maximum benefits achieved in a synergistic approach to program implementation greatly depend on partnership building among all stakeholders at every level of planning and implementation. NTD programs that used to be run independently of each other by their respective program managers are now coordinated under the NTD program in the DLM with technical and financial support from partners, including USAID and its implementers, Programme de Santé/Santé Communautaire II (led by ChildFund, 2012–2015), ENVISION (led by RTI International, 2012 to the present), and Sightsavers International.

Scope of Work for Assessment

Supply chain constraints plague current NTD prevention and treatment programs. Several partners and initiatives contribute to the control and elimination of NTDs at the global level. However, the rapid expansion of NTD control activities has not been without pharmaceutical and health system challenges. Inadequate NTDD management in many countries has resulted in excess stocks, leading to waste resulting from drug expiry or stock-outs, leading to treatment interruption.

SIAPS has received funding from USAID to support the Senegal MoH in strengthening the systems for NTD pharmaceutical management. The purpose of the technical assistance is to undertake a rapid assessment of the NTD pharmaceutical management system and understand the integration efforts. Technical review and recommendations have been provided by SIAPS personnel based in the SIAPS West Africa Offices and the office in Arlington, Virginia. SIAPS held meetings with the MoH NTD focal points and supply chain managers to ensure efficient delivery of technical support to the NTD programs, cross fertilization, sharing of lessons learned, challenges, and recommendations and to ensure that the implemented interventions are of the highest technical quality that focuses on country objectives.

Key Objectives

- Understand the current systems and procedures in place for quantification, procurement (including annual application for donated drugs), and distribution of NTDDs
- Assess the practices of storage, handling, and distribution at all levels of the supply chain
- Assess community-level NTDD distribution, tracking, and documentation and reporting systems
- Assess the management procedures and practices for the disposal of expired or damaged NTDDs and related products

¹ Note that trachoma MDA is conducted separately, though in coordinated fashion, with the LF-ONCHO-SCH-STH MDA. This is standard practice.

• Document good practices in NTDD management and pharmaceutical management information systems that need to be strengthened and replicated

Methodology

Various aspects of the supply chain were assessed, including availability of NTDDs, mass distribution programs, inventory management, and reporting at all levels, including central, regional, district, and facilities. Documented successes and gaps were then noted in the assessment. The SIAPS team examined the literature and available documentation on NTD treatment in Senegal, including annual reports, previous pharmaceutical systems assessment reports, copies of national and NTD treatment guides, medicines management monitoring forms, and procedures. The team then made a field visit to the regional and district office in Diourbel² to collect qualitative and quantitative data on the NTD pharmaceutical system using questionnaires and unstructured interviews targeting national and subnational PNA and PRA and national NTD program offices. Secondary targets included the WHO country office and nongovernmental organizations (NGOs) involved in NTD programs.

The structured questionnaire was provided to interviewees before the site visit to set up the discussions and used as a template to review technical areas of the supply chain with special emphasis on distribution, inventory control, and logistics information. The assessment covered the five preventive chemotherapy NTDs (trachoma, SCH [bilharzias, snail worm], STH, LF [elephantiasis], and onchocerciasis [river blindness]).

The review focused on the following aspects of the pharmaceutical supply chain—

- Quantification and procurement planning
 - Assess current systems and procedures in place for the quantification and procurement of NTDDs
 - Review existing coordination mechanisms and their functionality for coordinated and effective procurement and distribution of NTDDs
 - Assess current systems for reverse logistics of NTDDs following MDA and reporting and/or disposal of used, unused, and expired or damaged drugs
- Human resources

 Assess human resource availability and training for managing NTDDs at national and regional levels

- Inventory control and logistics management information system
 - Review current systems and procedures for NTDDs information collection, reporting, analysis, and use as detailed through the Tool for Integrated Planning and Costing and the WHO Joint Reporting From

² Given the limited time frame for the site visits, the assessment team visited only one region, one district, and no *postes de santé* (health posts). However, in conversations with personnel at all levels of the supply chain, the team was informed that the issues raised at the Diourbel district and regional offices reflected those found throughout the country.

- Warehousing and distribution
 - Review the current practices and capacity for warehousing and distribution of NTDDs to identify issues that may affect product availability, including storage conditions at warehouses and facilities, and transportation
 - Assess ability and needs for the public distribution system to resupply and to respond to stock imbalances including redistribution
 - Review existing system and identify options for strengthening inventory management for NTDDs

FINDINGS AND RECOMMENDATIONS

Area	Recommendation	What it will achieve	Risk if not implemented
Policy and Regulations	Develop an action plan of NTDD distribution and governance policy that is included in the NTD and national pharmacy strategic plan and work plans.	Ensure compliance with good pharmaceutical management practices.	If NTD supply chain management is not an integral part of the national strategic plans and work plans, it will continually be neglected, thereby resulting in delays in delivery and wasted leftovers, costing money and time for program managers.
	Complete and sign the MOU between the DLM and the PNA. The WHO focal point with the assistance of RTI ENVISION can assist in facilitating this negotiation.	Establish clear roles and financial responsibilities of the PNA and the DLM and help maximize efficiency by coordinating NTDD management as done in other health programs.	This delay in signing the MOU is causing the NTDDs not to be fully integrated into PNA and PRA system.
Coordination and Staffing	The NTD pharmacy position at DLM is providing critical supply chain–related functions. However, the position is not formalized and funded. It is important that this position is formalized.	This supportive position represents a critical link between the DLM and the PNA and allows for coordination between the two.	Absence of a full-time NTD pharmacy position at the DLM will result in slowed communications, inefficient distribution of responsibilities, slowed distribution through the supply chain, and potentially delayed MDAs.
	The DPM and National Quality Control Laboratory have not previously been invited to the annual NTD strategic planning meeting although they are key players in drug-related national issues. They should be invited and encouraged to attend so they play their role in regulatory, medicine safety, and quality assurance areas.	Ensure timely and efficient approval of drug requests and entry into the country. Ensure adherence to proper pharmacovigilance and serious adverse event (SAE) reporting.	Delays in approval for drug requests and entry into the country can reverberate down the supply chain, resulting in delayed MDA. Substandard drugs or missed SAEs erode confidence of the people, who may stop coming for treatment if they do not feel safe taking the drugs.
Procurement	Although not standard quantification practice, district microplanning may provide alternative forecasting for this year's request (it is currently the standard in the trachoma MDAs). Starting in 2016, reporting from the previous year's MDA will inform	Proper quantification of NTDDs necessary for MDA is key to solving many supply chain issues, including forecasting how many people will need to be treated, ensuring each district gets the correct amount of drugs, and minimizing leftover NTDDs that need to	Quantification not based on accurate population, consumption, and past distribution data leads to leftover drugs with the potential for spoiling or expiring before the next MDA as well as creating unnecessary storage and administrative cost to hold the NTDDs.

Area	Recommendation	What it will achieve	Risk if not implemented
	quantification for the following year.	be returned up the supply chain and stored until the next MDA, greatly reducing cost and time for program managers and storage facilities.	
Storage	Need adequate storage and organization of drugs to promote better inventory management (stock cards, temperature, humidity monitoring, FEFO practice, organization).	Medicine safety and quality assurance in addition to improved inventory control resulting in minimized damage and loss.	Improper organization leads to NTDDs being misplaced or lost. If problems occur and MDAs are not successful, pinpointing where the problems originated and how to fix them will be difficult.
	Stop storage of NTDDs at NTD program offices and move all stock to central, regional, and district pharmacy storehouses.	Ensure quality control and proper inventory control of NTDDs. NTD programs will focus on their core program responsibilities, leaving logistics matters to entities mandated and trained to handle pharmaceuticals.	Improper organization leads to NTDDs being misplaced or lost. If problems occur and MDAs are not successful, pinpointing where the problems originated and how to fix them will be difficult. Core functions of NTD programs are compromised; inventory control is not effectively maintained, resulting in poor storage, loss, and quality problems.
Distribution	Allocate appropriate transportation of NTDDs from PRA to HPs. Arrangements for dedicated vehicles should be made in advance and standardized in the work plan. Coordinate distribution from center to end user with medical stores at all levels.	Ensure quality control and proper pharmaceutical systems strengthening for NTDDs.	Use of nonstandardized vehicles jeopardizes the guaranteed movement of NTDDs to the appropriate MDA site. Simply using "whatever is available" risks that nothing is available. Emergency vehicles should be used for their intended purpose and not for distribution of pharmaceutical products.
	Coordination of NTDD movements should be included in the MOU between DLM and PNA.		
	Central and regional levels should formalize ways to facilitate transfer of unused/overstocked NTDDs from region to region or facility to facility.	Leftover NTDDS can be used as quickly as possible without the need to store them for long periods, thereby reducing costs of moving leftover	Added costs of distribution, storage, and administration as well as inefficiencies in time management of NTDDs having to move up and then

Area	Recommendation	What it will achieve	Risk if not implemented
		NTDDS from district to district in an ad hoc manner.	down the supply chain rather than horizontally when possible.
Rational Use of NTDDs	Split large bottles into appropriate smaller containers before distribution from the district to the HPs.	Reduced leftover NTDDs following MDA result in less need for reverse logistics.	Increased leftover NTDDs following MDA results in greater strain on necessity for reverse logistics, which also increases the chance of drugs expiring before the next MDA.
Reverse Logistics	Develop a standard operating procedure (SOP) for the return, reuse, and/or disposal of damaged/expired NTDDs. Include reverse logistics in the MOU.	Lack of uniformity in program implementation can be avoided with SOPs. Allows better quantification for the next request of future MDA.	If NTDDS are not promptly returned up the supply chain, the quality of the drugs could be compromised. Also, expired and damaged NTDDs not disposed of pose a health and environmental risk.
	Link return of NTDDs up the supply chain with reporting forms.	Systematic cross check of the leftover pills with the reports at each level to make sure they balance out will prevent and identify loss, as well as ensure that medicines move to and arrive at their proper storage facility. Accurate post-MDA reporting is critical to ensure accurate quantification for the following year.	Incomplete or delayed reports make it difficult to correctly quantify the needs for the next year's request as well to follow progress toward the 2020 goals. Without proper reporting, program managers will need to guess the amount needed for the request, resulting in ongoing leftover NTDDs and reverse supply chain problems.
Reporting	Ensure tally sheets are being completed and returned on time. Clear reporting deadlines should be established at each level and enforced.	Ensures proper reporting and inventory management critical for establishing the quantity necessary for the next year's request for NTDDs.	Incomplete or delayed reports make correct quantification of the needs for the next year's request difficult, as well following progress toward the 2020 goals.
Quality Assurance	Before customs clearance of NTDDs, quality control checks should be the norm. If opened/unused bottles are planned to be used in subsequent years or distribution, quality assurance has to be conducted.	Currently quality control is done only just before MDA and only at the PNA. No quality control is done of leftover drugs at regional storage facilities following MDA.	Quality of leftover drugs may be compromised during MDA and storage, thereby resulting in reduced effectiveness of the drugs and ultimately the program.

Area	Recommendation	What it will achieve	Risk if not implemented
Waste Management	Segregation, documentation, and disposal guided by WHO or national disposal guidelines must be practiced. Proper incineration of damaged and expired drugs should be conducted promptly.	This is critical to ensure that damaged and expired drugs are not used in future MDA and to ensure that environmental public health standards are met.	Improper disposal or not disposing of NTDDs can lead to accidental use of drugs during future MDAs; and although NTDDs are known to have low toxicity, improper disposal could lead to high levels in the environment and interactions with other drugs to which the environmental and health impact is not known.
	Disposal/incineration of used empty containers and packing materials must be done following national guidelines and manufacturer's instructions.	Is must along with damaged and expired drug- elines however, given the low toxicity of	Improper disposal or not disposing of bottles can lead to accidental exposure to NTD chemicals.
		establish a policy and guidelines to properly wash and reuse them.	Although NTDDs are known to have low toxicity, improper disposal could lead to high levels in the environment and interactions with other drugs to which the environmental and health impact is not known.

NTD MANAGEMENT SYSTEM AND TECHNICAL COORDINATION

The national NTD program is under the MoH and is structured as shown in figure 1.

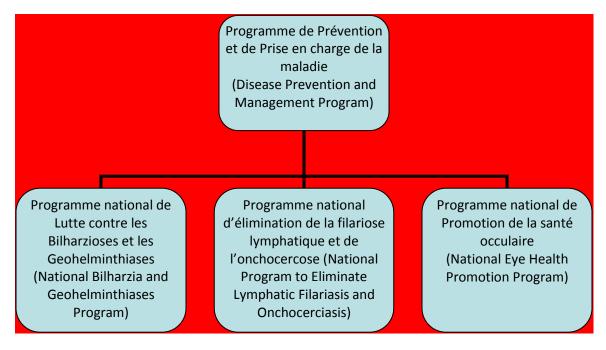


Figure 1. Structure of national NTD program

The NTD focal point (currently vacant) handles all the integrated NTD activities and is responsible overall for communication between all partners. The NTD focal point also liaises with the partner institutions, such as RTI, Sightsavers International, and WHO; manages the NTD support personnel; oversees procurement of medicines and supplies; and coordinates logistics with the DLM, NTD program managers, and the NTD officer in charge of logistics. The coordinator also disburses budgeted funds and participates in the planning and implementation of NTD activities, obtains regulatory clearance for the NTDDs from the DPM, and develops and disseminates the annual NTD program report to all partner institutions.

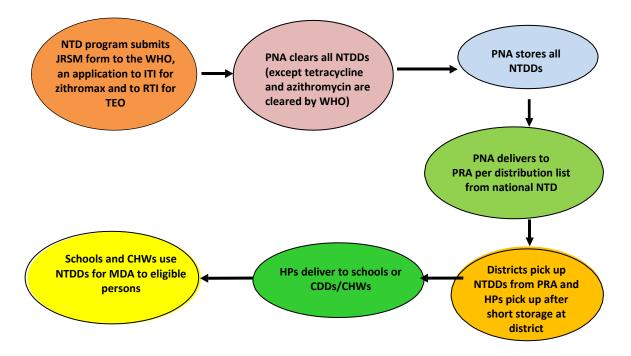
At district level, the District Health Management Team is responsible for coordinating district planning, advocacy, mobilization and health education activities, training of supervisors and teachers, coordinating the receiving and distributing of medicines from the NTD focal point or appointed representative. Other team responsibilities include receiving reports from and providing feedback to the communities, schools, and health facilities within the district; compiling community-level reports and forwarding district-level summaries to the NTD focal point; supervising lower health facilities; overseeing medicine distribution to schools; and pooling resources to support integrated implementation.

The health post (poste de santé) head nurse (Infirmière Chef de Poste, or ICP) has the following responsibilities: community mobilization and sensitization, health education and promotion to enhance compliance and coverage, teacher and community medicine distributor support for treatment of school-age children and communities. They account for medicine use and returns of unused NTDDs to the District Health Management Team; they also are responsible for making treatment reports to the District Health Officer. The NTD focal point also participates in pharmacovigilance and management of serious adverse events (SAEs).

Senegal follows a two-pronged approach for MDA, which includes—

- School infrastructure for treating school-going children
- Community-based medicine delivery using CDDs and CHWs to reach communities³

The flow of NTDDs down the supply chain is demonstrated in figure 2.



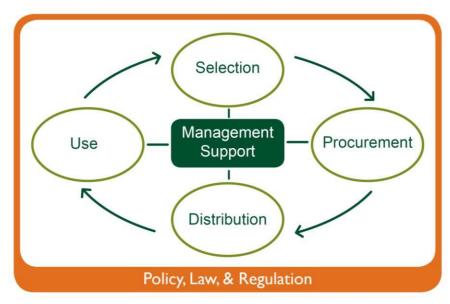
Note: JRSM = Joint Request for Selected Preventive Chemotherapy Medicines; ITI = International Trachoma Initiative; TEO = tetracycline ophthalmic.

Figure 2. Flow of NTDDs down the supply chain

³ In most circumstances, drug distribution is done by the CDDs. However, in some localities, the CHWs can distribute drugs in their health huts whereas in other places, they only supervise the CDDs.

Pharmaceutical Management of NTDs in Senegal

One of the major objectives of Senegal's health policy is to guarantee the availability of medicines necessary to provide services to the population that are accessible. The availability and accessibility of medicines are the result of the proper operation of the key pharmaceutical management functions of selection, procurement, distribution, and use within the appropriate policy and regulatory environment (figure 3). NTDs, which are treated through MDA campaigns, follow a different supply chain from many other public health programs. However, the pharmaceutical management cycle follows the same rules as for any other pharmaceutical product.



Source: Center for Pharmaceutical Management. 2011. Center for Pharmaceutical Management: Technical Frameworks, Approaches, and Results. Arlington, VA: Management Sciences for Health.

Figure 3. Pharmaceutical management cycle

Management Support

professional services if they not properly trained, which could result in substandard and potentially harmful services. ⁴ The discipline of pharmacy has key areas of expertise in rational use, compounding, selection, quantification, expiry tracking, pharmacovigilance, and quality assurance that cannot be replaced by task shifting or assigning nonpharmacy professionals. At multiple levels, the team noticed staff managing NTDDs who were not trained in proper pharmaceutical management SOPs. For example, in the district the team visited, the focal point for the drug storage facility never handled the NTDDs; rather the District Health Management

The management of pharmaceuticals by nonpharmacy professionals could reflect compromised

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⁴ This section pertains to management support within the pharmaceutical sector of NTDDs prior to MDA. Although community-based MDA is generally conducted by nonpharmacy professionals, proper training by management support personnel of nonpharmacy professionals in pharmacy practices during regular cascade trainings is critical.

Team stored them. The District Health Management Team assured the assessment team that the NTDDs are stored at the district facility for a couple of days at maximum; however, without proper documentation of receipt and distribution, this was difficult to confirm. Without discussing any storage or transportation issues with the district pharmacy, they risk compromising the quality of the NTDDs.

Policy, Law, and Regulations

The key NTD medicines—azithromycin, albendazole, mebendazole, ivermectin, praziquantel, and tetracycline—are included in the national list of medicines. The NTD medicines imported into Senegal are tax exempt.

Regarding registration, praziquantel, albendazole, mebendazole, and ivermectin are all registered with the DLM. Except for azithromycin, the other NTDDs are included in the essential medicines list.⁵

Political and financial commitment at all levels is also necessary. Although sufficient political and financial commitment for supply chain issues exists at the national level, funding for storage and dedicated drug transportation at the subnational level is insufficient. In addition, the national coordinator does not have the capacity to ensure regional and local teams properly dispose of medicines, bottles, and spoons.

The WHO country office helps facilitate many of the NTD policies and guidelines for the national and international levels; however, at the time of the assessment there was no focal point for NTDs. The interim focal point was not aware of the current work toward development of an MOU between the DLM and the PNA. He noted that now that he was aware of it, the WHO office would help facilitate and expedite its approval process.

Coordination and Staffing

The position of the NTD focal point has been vacant for some time and filling the position is a necessity. The vacancy represents a major hindrance to the proper implementation of the NTD program. Additionally, the NTD pharmacy position at DLM is providing critical supply chain–related functions. However, the position is not formalized and funded. It is important that this position is formalized.

The DPM and National Quality Control Laboratory currently do not have a seat on the NTD coordinating bodies although they are key players in drug-related national issues. They should be made members of the committees so they play their role in regulatory, medicine safety, and quality assurance areas.

Integrated NTD Medicine Management

No MOU has been signed between the PNA and the DLM to manage NTDDs. This delay in signing the MOU is causing failure of full integration of the NTDDs into the PNA and PRA

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⁵ http://apps.who.int/medicinedocs/fr/m/abstract/Js20181fr/

system, unlike medicines for other programs. Failure to integrate NTDDs into the PNA and PRA system leads to conflicting information on stock quantities and their locations at the different levels. This is manifest in the overall inadequate information about supply chain management in official guidelines. The medicine management sections of guidelines are not detailed enough. Clear guidelines on receipt, storage, distribution, reverse logistics, expiry management, and logistics management information are critical for improving the supply chain of NTDDs and avoiding loss and damage. Finally, persons handling NTDDs at all levels of the supply chain (for example, district-level pharmacists) were not always aware of guidelines on reverse logistics.

Selection

The NTD programs use the WHO-recommended NTDDs for MDAs. This was confirmed at the regional and district levels. Clear treatment regimen guides for managing these diseases exist at all levels of the NTD supply chain. The team observed that all in-country programs adhered to the recommended global treatment protocols.

One issue that was raised by several levels was the size of the praziquantel pills used by the donation program for administration to young children. The donation program for praziquantel is working with the Pediatric Praziquantel Consortium to develop praziquantel formulations for pediatric use. In addition, next-generation drugs are under investigation and new treatment regimens for existing drugs are being examined. Proper coordination with NTD program and regulatory authorities for these new drugs and treatment regimens needs to be considered in the strategic plan for both NTDs and the pharmaceutical sector.

Quantification and Procurement

Estimates of annual needs for NTDs are based on national census data. Only the trachoma program used microplanning techniques to confirm and refine the amount of medication necessary for procurement. The other drug programs used only census data, which created problems at every level. Quantification based on inaccurate population estimates may cause understocking and overstocking as well as poor reporting. In addition, because a proper inventory of leftover stock is not done at the lower levels of the supply chain, regional and district level storage facility managers are not able to provide the actual quantities of medicines remaining after each campaign for reporting purposes and for to use in quantification for the following year.

One worrying observation was that quantification is partly based on estimates of theoretical stock (NTDDs sent out less the number of patients targeted multiplied by the number of tablets needed for that patient category) rather than physical inventories. Another issue that was noted at several levels is that WHO requires official census numbers for the WHO Joint Request for Selected Preventive Chemotherapy Medicines (JRSM), yet such numbers do not always match the actual population. In the case of Touba district, the population during the annual pilgrimage varies, making quantification difficult if using official census data. A quantification training was scheduled for August 2015 on the Tool for Integrated Planning and Costing, and quantification will be included in the next work plan for ENVISION; however, whether the implementation of the training will produce better results concerned the national-level coordinators.

NTDDs are quantified at the national program level: each of the three NTD programs estimates its own needs. The JRSM⁶ requires that the quantities requested be justified by reporting what was received in the prior application, what was used, how many persons were treated, how much was lost/damaged, and what is left on hand. Once the application is approved and the product shipped, it is cleared through customs by PNA (or WHO in the case of tetracycline and azithromycin).

Procurement of NTDDs uses an "Applications for Donations" system where applications are initiated by the respective NTD program managers and submitted to the WHO using the JRSM. RTI ENVISION purchases all tetracycline eye ointment for MDA with support from the WHO.

The districts or the health facilities that eventually supply the CDDs/CHWs or teachers do not place orders but receive quantities determined based on the target persons determined for MDA. As mentioned previously, the targets are calculated based on census data for every NTD except trachoma.

Stock inventory registers are often not up to date, thus rendering the estimation of real needs difficult at the regional level. In addition, the regional pharmacists were not involved in either the ordering process or the receipt of NTDDs.

Storage of NTDDS in Senegal

Good storage and distribution management are critical functions that ensure that products are stored in appropriate conditions and are delivered in a timely manner to all sites. NTDDs such as Zithromax and tetracycline (used to treat trachoma), praziquantel (used to treat SCH), ivermectin (used to treat LF and onchocerciasis), and albendazole (used to treat STH and LF) are received and stored by the PNA. The fee for handling, storage, and distribution of NTDDs is prefinanced by the government. Any level can enter data into an online information warning (overstock/understock) system for management of NTDD stocks.

National Level

The national medical store (PNA) was built during the colonial period. It used to be the warehouse for the entire French-controlled West African region. When Senegal became independent, the warehouse transferred to use by Senegal only. The building is now quite old and not well organized. Plans exist for a new warehouse to be built in the future. At the PNA, the store for NTD products along with other program medicines and commodities is in the basement. Humidity and temperature are monitored daily in the basement and logged on sheets attached to the meters, but NTDDs are kept in a separate room (with a door) with no temperature or humidity meters and poor ventilation. A change in the temperature and humidity can be felt when entering the room, which also has more sunlight exposure than the rest of the basement.

Storage was not consistent, with some NTTDs stored on shelves, some on pallets, and some on the floor. Stocks of existing NTDDs did not follow the FEFO guideline, with boxes of different

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⁶ The JRSM is not used by the trachoma donation program. Rather, requests for Pfizer azithromycin donations are made directly to the International Trachoma Initiative.

expiration dates mixed together, lack of stock cards, and expired drugs piled up in the back of the stock room.

The SIAPS team was informed that a physical count is done at central level before MDA. During the assessment, it became apparent that the central level has difficulty receiving information on the actual amounts of medicines distributed during and after each campaign and on leftover inventory at lower levels of the supply chain. Because the orders for the following year depend on this information, serious doubts exist about the accuracy of the quantification data used for orders.

Regional Level

NTDDs are transported directly from the central level to the regional store via official MoH transports at prenegotiated fees. However, transfers of NTDDs from the PNA to the PRAs are not integrated in the delivery calendar because there is no agreement or allocated money to cover the fees. Even when the funding is provided, other medicines always take priority over NTDDs for space on the vehicles.

The PRA visited in Diourbel has a store for NTD products with adequate space. The PRA had excessive exposure to sunlight, and temperature and humidity monitoring equipment were present but not monitored on a regular basis. Because of a lack of adequate shelving, the use of the storage area is not effective. Storage was not consistent, with some NTDDs stored on shelves, some on pallets, and some on the floor. The facility had many previously opened bottles. Finally, stocks of existing NTDDs did not follow the FEFO guideline, with boxes of different expiration dates mixed together and no stock cards. Storage for expired medicines is overflowing, unorganized, and insecure (door does not close or lock). It was also noted that some regions have to rent apartments to stock medicines during construction of better warehouses. Finally, if one region with a stock-out requests NTDDs from another region with an overstock, no official mechanism (financial or logistic) exists to move NTDDs between regions. The region with a stock-out must request additional medications from the PNA.

District Level

At the time of the visit, no NTDDs stored at the facility. At first glance, this would be considered the ideal because NTDDs left over from MDAs should be sent up the supply chain to the PRA. However, in interviewing the facility head, it was noted that he never receives the NTDDs in the facility. Before the MDA, the NTDDs are delivered to the District Health Management Team, whose head stores them in his office or on the porch at the district facility. It was also noted that NTDDs are often left at the HP. The NTDDs are then distributed to the CDDs within one day of arrival (about one week before the MDA). If a district has a stock-out, it is supposed to first call the PRA for more medicines. It may also call another district, if necessary, but the PRA usually provides this coordination. However, no official mechanism (financial or logistic) exists to move NTDDs between districts.⁸

⁷ Certain regions do share supplies with one another in an ad hoc manner.

⁸ Within regions, it is fairly common for districts to share supplies with one another as needed in an ad hoc manner.

Distribution of NTDDs in Senegal

Transportation from the PNA to the PRA is sufficient, with dedicated vehicles provided to move NTDDs down the supply chain. From interviews, no major issues were noted. However, transportation effectiveness breaks down from the PRA to districts. With the exception of azithromycin, where Sightsavers has paid for transport costs from the MoH to the PNA, some taxes, and transport costs from the PNA to MDA sites where the NGO works. Under the terms of the MOU, the PNA will deliver NTDDs directly to the districts rather than to the PRA. If implemented effectively, this will relieve some of the transportation issues discussed.

All districts make requests for medicines to the PRA. When approved, they can then pick their drugs up from the PRA. No dedicated vehicles exist, and personnel must find whatever vehicle they can to move the NTDDs. During the visit, the team noticed the movement of other medicines (not NTDDs) using ambulances and fire trucks. In addition, no system exists to move unused and expired NTDDs up the supply chain back to the PRA following an MDA. Two trucks are available for official PRA use. They are used to move medicines only in emergency situations.

Mass Drug Administration and Rational Use of NTDDs

One or two days prior to an MDA, CDD and CHW training is conducted to address proper distribution techniques of NTDDs, reporting techniques, and monitoring for SAEs. Training involves a pretest and a posttest administered immediately after the training. In addition, the Public Service Satellite Consortium (PSSC) II conducted multiple supervision visits to ensure the training skills are being used.

MDA is conducted by CDDs, teachers, and CHWs who receive the quantity determined for their community from the district. Because of safety concerns about drug interactions, azithromycin treatment for trachoma is done about two weeks after the integrated MDA (this is a standard practice). Although CHWs do receive per diems, other programs such as malaria receive better per diems, thus leading to lower motivation for working on NTD campaigns.

The CDDs give out the required doses by counting the tablets from the bottles. Each day of the campaign, there is a debriefing. If there is a shortage, the district office alerts the regional level and gets medicines quickly. At the end of the MDA, CDDs are required to calculate what has been given out to patients, the quantity lost or damaged, and the quantity remaining. The quantity remaining is given back to the district with the report. Calculation of the appropriate dosage (with height/weight) takes place at distribution. Finally, some drugs the district office receives from the HP after the MDA are close to expiration (less than two months), which makes the reverse logistics in time to use leftover NTDDs difficult. Community members know the drugs well, know the prices well, and know they get a good deal by getting them for free (many can identify a pill as praziquantel and know which ones will get rid of parasites). NGOs (the PSSC II consortium, Sightsavers) have provided technical and financial assistance to implement community-level work and coordination.

A major issue noted was the scale-up for LF from just seven districts one year to all 50 endemic districts the following year. There weren't enough nationwide resources to treat the entire target population at all levels of the health system. Some districts managed to achieve the 80% coverage while others had considerably less. Additionally, LF treatment in Fatick district had poor treatment coverage because of staff turnover. The staff who were trained were not available at the administration of the MDA.

Reverse Logistics/Redistribution

At the end of the mass distribution, the medicines are kept at the HPs for some time before being sent back to the district storage facility. Once there, the regional health director informs the MoH of the number of leftover, expired, and compromised drugs. The drugs are then sent to the PRA for final storage and/or disposal. Once at the PRA, these unused and preopened medicines are kept until the next round of distribution. Ensuring stability, safety, and effectiveness of these remaining medicines is difficult. The PRA pays for reverse logistics, but often the funds are insufficient to cover supervision to ensure drugs are returned. Some partners help out financially. Sightsavers has picked up leftover azithromycin from the district office; however, for the other drugs, the information provided by the lower levels and the PRA on how long it takes for leftover NTDDs to move to the PRA sometimes conflicts, and what to do with the leftover medications often is not clearly communicated to CDDs, CHWs, and PRAs. The SIAPS team was pleased to note coordination with other countries to send surplus medicines where they are needed. Recently, with the assistance of the WHO, excess NTDDs were sent to Guinea-Bissau for use in its MDA.

NTD Information System, Reporting, and Evaluation Approaches for MDA Activities

Each CDD who undertakes an MDA is required to report the number of persons treated. A tally sheet is provided, and community distributors are trained in measuring height, registration, administering the drug according to the height, monitoring adverse drug reactions, and so on. At the end of the mass distribution, a national review/evaluation is conducted. Supervision is conducted by the region in collaboration with NGOs.

Tally sheets, which are similar to registers but have no identifiers and demographic information, are used during the MDA. When cross referenced with the numbers reported to the district manager, the tally sheet does not always align. This discrepancy leads to problems not just for reporting but also for forecasting future drug requests. At a few levels, difficulty existed in confirming whether someone takes the medicine only once (double counting).

RTI supports the use of two sets of global data management tools by MoH staff: USAID's online NTD database, which is populated via Excel-based Monitoring and Evaluation Workbooks, and WHO's Access-based Integrated Database, which links with an online system and can autopopulate country reports to WHO.

After an MDA, reporting from the community to the HP is done within a reasonable time frame. From the HP to district is where the difficulties begin. The HP turns in its paper records to the district without keeping a copy. Then, the district compiles the records and calls the information in to the region. This process is supposed to be quick (the same day or next day), but that often is not the case. A two-week delay occurred of the CDD report to the Diourbel district level, yet it still only took one month after an MDA for the reports to reach the national level. The reporting delays occur mainly at the lower levels (HP to district to PRA), while reporting between the PRA to MoH is usually timely.

Quality Assurance and Medicine Safety Monitoring (Pharmacovigilance)

Quality Assurance

All donated NTDDs are sourced from the parent manufacturers, which makes quality issues less of a concern. However, concerns on the downstream quality of NTDDs may arise because the medicines come in loose pills and are distributed from containers, and storage conditions are less than optimal (as previously explained). The nature of the mass administration does not ensure that the container lid is replaced tightly on the container between uses because it is used continuously. Mass administrations are conducted mostly outdoors, and the chances of exposure of the medicines to humidity, heat, dust, and other unhygienic situations are great. In Senegal, efforts have been initiated to maximize drug safety and efficacy throughout the supply chain. The DPM manages nationwide registration and regulation of all medication entering the country. It inspects all drugs, both those publicly and privately procured. The DPM controls national-level quality through the National Quality Control Laboratory meeting.

The DPM is not included in the annual NTD strategic planning meetings. This oversight will be remedied going forward, and the DPM will attend the next NTD strategic planning meeting.

Quality visual check is done at each level—even CHWs are taught what drugs are supposed to look like. A website exists with a form for reporting suspicious drug quality that anyone can use to alert the National Quality Control Lab of questionable NTDDs; however, training is needed on how to access and use it. Staff will be trained on the website in the upcoming annual training.

Actual quality control measures with samples tested are conducted at the central level, but no quality control testing starts at the regional level and below, except for praziquantel, which is tested as part of the Minilabs conducted by the National Quality Control Lab at the regional level. If a quality control problem is detected, it triggers an investigation to determine if PRA storage conditions are appropriate.

The National Quality Control Lab is a public institution that employs both pharmacists and pharmacy technicians. It conducts annual control testing for program medicines (TB, HIV, malaria, reproductive health, etc.). The lab works closely with the DLM, especially before an MDA, to ensure NTDD quality is adequate. The lab operation is funded by the MoH; however, some partners contribute. For example, USAID's Promoting the Quality of Medicines Program pays for training on quality control and provides other support to the lab (not necessarily for NTDDs). SIAPS conducted a site visit for the lab, and overall the facilities were adequate.

However, many of the instruments for each test type had different manufacturers, thus making maintenance more complicated.

Serious Adverse Events

Adverse drug reaction (ADR) monitoring and reporting are part of the training provided to distributors. The interviews at central and district levels indicated the number of persons experiencing ADRs is insignificant, and if it exists it is mild. However, the WHO representative noted that it is more likely that reporting of actual events is not done properly. CDDs are supposed to report adverse events are the HPs, which then report up the chain. A communications challenge they cited is that sometimes information does not flow down to the district level. Some reports indicated people have refused treatment because of the unfounded rumors of SAEs. This misapprehension has been corrected with community sensitization leading up to the MDA, which includes instruction to watch out for adverse events and go to the HP if they are experienced within a week of the MDA. Although the DPM is the MoH's mandated entity to receive, investigate, and document ADR reports, if SAEs occur for NTDDs, they are not reported to the DPM, which shows a weakness of coordination and harmonization of pharmacovigilance activities.

Waste Management

Proper disposal of expired and damaged drugs is a critical aspect of safe pharmaco-management. To ensure these drugs are disposed of in a safe and environmentally friendly manner, NTD program managers need to coordinate with the sanitation and hygiene service. Proper incineration is the most desirable method. However, in most cases, the medications are simply burned rather than incinerated. In the case of the region and districts that the SIAPS team visited, even burning is not happening. Expired medicines were stored in unused office space—and even outside. For inventory purposes, expired medicines have to be kept until the end of the calendar year. However, expired medications are piled in a store rooms for months and even years. The storage of expired medicines storage observed in the PRA of Diourbel contained drugs that expired as early as 2012. Some commodities (spoons, bottles) are not being disposed of properly and are even used for other purposes (spoons used in coffee, bottles for sugar storage, etc.).

CONCLUSION

Senegal has come a long way in improving the health of its people through the concerted efforts in its NTD control programs. However to reach the 2020 goals of NTD elimination and control, Senegal will need to find ways to increase the efficiencies of the programs that already exist. Proper pharmaceutical management is a major element in achieving this goal. Although the upfront cost for personnel, proper storage, and distribution may appear daunting, the long-term benefits will result in overall reduced costs, less waste, and an overall strengthened health system and healthier population.

ANNEX A: PERSONS MET DURING THE ASSESSMENT

Name	Title	Office
Dr. Bobacar Diop	NTD national pharmacist	DLM/MSAS
Dr. Mawo Fall	Resident Program Advisor	RTI ENVISION
Dr. Elhadj Doumba Dia	SCH/STH coordinator	DLM/MSAS
Fallou Sene	Work plan focal point	DLM/MSAS
Dr. Lionel Nizigama	Consultant	RTI ENVISION
Mame Venus Badiane	M&E and Capacity Building Officer	RTI ENVISION
Malang Mane	Data Manager	DLM/MSAS
Seynabou Ndour	Assistant	DLM/MSAS
Dr. Boubacar Sarr	Coordinator	PNPSOMSAS
Dr. Marie Khemesse Ngom Ndiaye	Directrice DLM	DLM/MSAS
Papa Ibrahima Ndao	Conseilleur technique chargé de la gestion des subventions et des financements extérieurs	CT/SFE
Laity Gning		CT/DPSAO
Thieru Sow Gueye		AQ/PNA
Dr. Daouda Diop	Conseilleur spécial du directeur chargé des questions techniques	SAMPE/PNA
Ndeye Souleye Thiam		CT/PNA
Assane Dieng	Pharmacien analyste	LNCM
Ndeye Magatte Diao	Pharmacien	LNCM
Jean Louis Preira	Pharmacien unité logistique	LNCM
Elhadj Ibrahima Toure	Pharmacien	LNCM
Dr. Yerim Mbargick Diop		LNCM
Dr. Serigne Ndiaye	Directeur de la Région Médicale de Diourbel	
Amade Henri Diouf	Point Focal MTN de District de Diourbel	
Bouna Sall		
Khady Ndiaye	Relais Communautaire	
Cotame Faye	Chef de Poste de Santé Keur Serigne Mbaye Sarr	
Salimata Bocoum	Program manager	Sightsavers
Dr. Aida Tall	Conseillère CCM	ChildFund
Dr. Babacar Fall	Coordinateur volet MTN	ChildFund
Dr. Mohammed Ngom		OMS Sénégal