



Developing Standard Operating Procedures for Supply Chains to Support Neglected Tropical Disease Mass Drug Administration in an Endemic Country: Lessons Learned in Senegal

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Abstract

Neglected Tropical Diseases affect more than 1 billion people and remain a major public health problem. Many efforts are being made to combat these diseases to improve the situation of endemic countries on a large scale. One of the main strategies is the use of preventive chemotherapy through mass drug distribution.

Effective supply chain management requires to develop and align to standard operating procedures (SOPs). The World Health Organization and the technical experts of the Neglected Tropical Diseases Supply Chain Forum have defined 11 SOPs. Senegal, in collaboration with PATH, revised the SOPs to adapt them to the country's needs and context.

World Health Organization and various health stakeholders in Senegal organised the SOP manual around seven steps: (1) review of the existing SOP manual, (2) adaptation of the manual to the country's context, (3) development of the SOP manual, (4) development of the twelfth SOP on pharmacovigilance, (5) validation of the SOPs, (6) response to and submission of the World Health Organization questionnaire on the review process, (7) and dissemination of the manual.

Developing SOPs for neglected tropical disease drug supply chain management was a major step towards ensuring availability of high-quality drugs in target areas across the country during mass drug administration. However, to achieve effective drug management in the next distribution campaign, additional efforts are needed, including the development of management tools and training manuals, training of drug distributors, and dissemination of SOPs to all levels of the health system.

Keywords: Standard Operating Procedures; Drug Supply Chain; Neglected Tropical Disease; Mass Drug Administration

Abbreviations

PATH: International Non-Governmental Organization - Global Non-profit Improving Public Health; MDA: Mass Drug Administration; NTDs: Neglected Tropical Diseases; SOPs: Standard Operating Procedures; WHO: World Health Organization

Introduction

Neglected tropical diseases (NTDs) are a diverse group of 20 major disease groups that are mainly prevalent in tropical areas, where they mostly affect impoverished communities and disproportionately affect women and children. In Senegal there are different types of NTD bacterial diseases like schistosomiasis, lymphatic filariasis, onchocerciasis, and helminthiasis that can be found in 47 health districts. These diseases cause devastating health, social and economic consequences to more than one billion people. The epidemiology of NTDs is complex and often related to environmental conditions. Many of them are vector-borne, have animal reservoirs and are associated with complex life cycles. All these factors make their public-health control challenging.

WHO estimates that over 1.7 billion of the world's population should be targeted by prevention and treatment activities for at least one of these diseases, every year.

In addition to significant mortality and morbidity - approximately 200,000 deaths and 19 million disability adjusted life years (DALYs) lost annually, NTDs cost developing communities the equivalent of billions of United States dollars each year in direct health costs, loss of productivity and reduced socioeconomic and educational attainment. They are also responsible for other consequences such as disability, stigmatization, social exclusion and discrimination and place considerable financial strain on patients and their families.

In spite of this, NTDs have historically ranked very low and almost absent from the global health policy agenda - only to gain recognition in 2015 with the Sustainable Development Goals (SDG target 3.3). SDG3 can therefore be achieved only if the NTD goals are met but, because interventions to tackle NTDs are widely cross-sectoral, increasing their global prioritization can in fact catalyze progress to achieve all SDGs.

Chemoprevention through mass drug distribution is one of the strategies to combat NTDs.

In collaboration with Ministry of health, Access and delivery partnership (ADP) and PATH supported the development of standard operating procedures to improve management of NTDs drugs use for chemoprevention. Indeed, an efficient drugs supply chain is crucial to support a quality Neglected Tropical Disease Mass Drug Administration. The manual was elaborated in an inclusive manner and involved participants from central level as well operational level including direction of disease control, national drug control laboratory, health workers from regional and health districts as well as partners supporting the fight against NTDs in Senegal.

In the perspective to reinforce drug supply chain, we are currently finalising management tools and training manuals on these SOPs. ADP and PATH, a global non-governmental organization specialized in public health, are also supporting dissemination throughout the pyramid and regular revision of these SOPs which are essential to update SOPs and maintain quality of mass drug campaign.

Key findings

- Using an inclusive and participatory approach, the Senegalese national neglected tropical diseases (NTDs) control program has developed a new standard operating procedure (SOP) manual for NTD supply chain management during mass campaign adapted to the country's needs thanks to the support of Partners, and the participation of technical experts from various levels of the Senegal Ministry of Health and Social Action.
- The planning of key steps was based on the process commonly used for the development and validation of policy and strategy documents within the Ministry of Health.
- The process is yet to be completed with the development of training manuals, training of stakeholders, and dissemination of SOPs at all levels of the health system to foster its use during the next campaign in 2021.

Key implications

- The 11 World Health Organization (WHO) procedures for NTD supply chain management are a useful reference document and a guide for endemic countries to develop an adapted version of SOPs in a short period of time.

- The development of SOPs enabled the design of solutions adapted to the specific context of the supply chain system.
- Program managers should ensure that the SOPs are well disseminated and the users trained to foster full uptake and use during the campaign.
- Regular revisions and updates of SOPs are required based on the lessons learned after each campaign.
- In the future, stakeholders may consider including SOPs for drug distributors to cover all the actors involved in the process of mass NTD campaign.

Background

WHO prioritizes 20 diseases affecting more than 2.7 billion people in 149 countries as NTDs [1]. NTDs are included in the Sustainable Development Goals and proliferate in low- and middle-income countries where people have little or no access to adequate health care, clean water, sanitation, housing, education, and information. NTDs have a huge economic impact on countries where they are prevalent because they cause visual and physical impairment.

These diseases have the particularity to be brought to broad control, elimination, or eradication by delivering one or more of the five interventions recommended by WHO. The interventions are: (1) preventive chemotherapy; (2) case management and rehabilitation; (3) vector and intermediate host control; (4) veterinary public health; and (5) safe water, sanitation, and hygiene [2].

In 2012, a declaration was signed in London to reinforce commitments for control and elimination by 2020 [3]. In 2018, African leaders added NTDs to the African Leaders Malaria Alliance's annual scorecard, recognizing them as a priority at the same level as malaria. WHO's 2020 roadmap on NTDs had a target to control or eliminate at least ten NTDs through sustaining, extending, and expanding drug access programs. More recently, in its 2021–2030 roadmap, WHO identified, access, logistic, and integration as the main problems to address for achieving a successful NTDs campaign [4].

One of the main strategies for achieving NTD elimination or control is the mass drug administration (MDA), specifically for lymphatic filariasis, onchocerciasis, trachoma, soil-transmitted helminths, and schistosomiasis [5]. MDA clearly plays an essential role in community-based interventions to address the burden of NTDs.

With support from six pharmaceutical companies, WHO facilitates large-scale donations of medicines for preventive chemotherapy for several NTDs. At the beginning of such support, each donation program had its own independent supply chain process, which was not optimal for timely availability and use of donated drugs. The NTD Supply Chain Forum, a public-private partnership, was established in 2012 to serve as a platform for engagement for NTD supply chain experts from WHO, pharmaceutical companies, nongovernmental organizations, ministries of health, logistic providers, and donor organizations, with the aim of increasing access to drugs and saving cost [6].

More recently a centralized information system (NTD deliver) was set up to give information from initial purchase order to delivery of the drug. This improved the timely delivery of drugs by 37% between 2018 and 2019 [7].

To date, more than 20 billion drugs have been donated to tackle NTDs. Recipient countries have a duty to properly manage and use drugs in an ethical way. This implies accurate capacities in supply chain management of NTD drugs, which is still an issue in many countries where targeted diseases are still prevalent.

In the area of NTD control and elimination, where affected countries need to distribute massive quantities of preventive and curative medicines to large segments of the population, poor management of the drug supply chain can present health risks for both humans and the environment.

Effective management of the NTD supply chain directly impacts the costs and effectiveness of national NTDs programs [8]. Assuring permanent availability of medicines for each MDA campaign can be challenging in low-resource settings if national control programs are not able to ensure timely delivery of adequate quantities of drugs to the communities and individuals that need them.

At the July 2018 Kigali NTD program managers meeting and during joint supply chain technical assistance missions in selected countries in the Africa region, the need for NTD-specific supply chain reference guidelines and SOPs to strengthen supply chain managers' skills in efficient management and rational use of donated medicines was identified.

Indeed, the focus on increasing production and donations to cover country programs needs should not overshadow the im-

provement of how NTD drugs are managed once delivered to countries. This calls for a strong country supply chain management system with good procedures developed by well-trained and experienced supply chain actors to ensure that high-quality drugs are received and distributed in an optimal way, up to the last mile, and on time. These procedures must be consistent with generally accepted standards for health product management, such as first in first out control, while helping to improve supply chain and drug management procedures to meet higher standards of transparency and accountability.

Researchers also observed that standard procedures used for routine public health products are often not applied to NTD drugs; in some countries, NTD drugs are not stored on pallets and stock cards are not used to track the inventory. SOPs for the management of routine delivery of health commodities are generally available to ministries of health pharmacists; however, these SOPs do not include specific procedures to manage MDA campaign and staff do not receive adequate training [9].

To strengthen the capacity of NTD supply chain managers, WHO and technical experts from the NTD Supply Chain Forum have developed a set of SOPs, targeting 11 key areas of concern comprising the WHO Global Donation Program life cycle, the common drug application, waste management, management of unused and expired medicines, and quantification and forecasting of needs for the next supply for medicines.

Recently with the support of PATH, Senegal has, under the Access and Delivery Partnership project, established reference guidelines on the supply chain specific to NTDs and SOPs to strengthen the skills of supply chain managers at all levels for efficient management and rationale use of donated drugs for preventive chemotherapy. Development of the process was carefully planned and all stakeholders intervening on NTDs drug supply chain management were involved. This article describes the process and the lessons learned.

Standard operating procedures development process

SOPs are written instructions that detail all of the steps involved in a procedure or process. They provide a description of regular tasks to ensure that operations are conducted correctly and consistently. SOPs are part of the best practices established by WHO for the management of public health events.

Steps to develop and implement SOPs include: (1) identifying the required steps to complete the process; (2) developing the first draft of the procedure with a detailed list of the steps in the order that they are done, (3) conducting an internal review to get input from workers who will perform the procedure and revise the procedure as necessary; (4) holding an external review involving all stakeholders and partners and revising the procedure as necessary; (5) testing the procedure by doing each step exactly as it says; (6) posting a final draft of the procedure in the workplace; and (7) training users to carefully follow the procedure [10,11].

The process of developing the SOPs for NTDs supply chain management in Senegal followed seven steps.

Workshop with national NTDs control program and stakeholders to review the SOPs manual for the management of medicines against NTDs

This meeting held in June 2020 by WHO Regional Office for Africa brought together ministries of health staff (e.g., NTD program managers, pharmacy and drug authority staff, central and regional supply chain specialists) WHO staff, country implementing partners, and NTD Supply Chain Forum partners. The objective of this webinar was to provide technical guidance to countries to conduct the review of SOPs; to ensure that countries inputs are considered and that end users have fully participated in the review process; and to develop a timeline for monitoring the review, the validation, and implementation process to ensure that SOPs meet country needs and address current NTD supply chain challenges. The meeting provided an opportunity to (1) inform how to proceed with the SOPs review, (2) share the SOPs and the response form, (3) provide additional information requested by countries, and (4) forward the revised package to the country.

Planning for the adaptation of the manual to the country context

Under the facilitation of WHO, preparatory meetings were held in August 2020 at the Ministry of Health to define the approach and steps of the process through a validated action plan. To this end, a select committee was set up and a consultant recruited to support and guide the process. These meetings, which brought together members of NTD control program and partners, reviewed, and validated the consultant's roadmap describing the methods and the main steps of the process.

Supply chain SOPs development workshop

In August 2020, the National NTD Control Program organized a workshop in collaboration with the Access and Delivery Partnership project. The main objectives of this workshop were to: (1) discuss challenges related to the management of NTD drugs during mass drug administration campaigns and (2) revise the 11 SOPs for NTD drug management.

Based on the WHO SOPs to be contextualized according to the country, the SOPs were revised through: (1) plenary sessions to identify the critical points to be considered and (2) group work to revise the 11 procedures. The approach was inclusive and participatory with participants from all levels of the health system: members of the NTD control program, representatives of the national drug store (both from central and regional level), the Directorate of Pharmacy and Medicines, National Drug Control Laboratory, the Anti-Poison Center, medical regions, health districts, and program partners.

The main recommendation of the workshop was to develop a twelfth procedure on pharmacovigilance to complement the national manual given its crucial role in drug management as well as in the health care system.

Workshop to develop the twelfth SOP on pharmacovigilance

This workshop was held in January 2021 at the Ministry of Health headquarters and was attended by representatives of the Directorate of Pharmacy and Medicine, the national pharmacy, the National Drug Control Laboratory, the Anti-Poison Center and members of the national NTD control program as well as partners. With reference to the national pharmacovigilance system, the workshop developed specific SOPs and tools using documents review, plenary sessions, and work groups.

SOPs validation workshop

The validation workshop was organized in January 2021 by the NTD program in collaboration with PATH and the Access and Delivery Partnership project. The main objective was to validate the SOPs manual including pharmacovigilance to be adopted by Senegal. The methodology used a guided reading of the 12 proposed procedures during working sessions to adapt and validate the content of each procedure. The same participants that were involved in the development workshop (step 3) were invited to review and validate the final manual of standard operating procedures.

Response to and submission of the WHO questionnaire on the review process

WHO designed a review process evaluation questionnaire in which the country was asked to provide feedback on the form, format, layout, and content of each procedure under review at the end of the process. The questionnaire included a series of 11 standard questions for each of the areas proposed by WHO.

- Could your NTD program use SOPs for this type of activity?
- Does these SOPs provide a starting point for adaptation to your country context or needs? Please comment on your answers above.
- Does your program currently follow this or a similar procedure for this activity? Please answer Yes/No.
- If YES, please provide details on the major differences we should consider improving these SOP.
- If NO, please provide details on what your program does instead in this activity area.
- What elements or steps did you find useful in these SOPs?
- What elements or steps could be clarified or reinforced in these SOPs?
- Are there additional tools or forms needed to effectively use these SOPs in your country?
- What are the challenges to using these or others SOPs effectively for this activity?
- Are there specific reference areas in these SOPs for comment?
- Are you more or less likely to adapt and use these SOPs?

This evaluation facilitated the country to better adapt its procedures and for WHO to update its guidelines.

Dissemination of the manual

SOPs manual have already been printed in hard copies. Currently, plans are in place to develop a related training guide for personnel on how to use the various tools included in the manual. The NTD program plans to disseminate the SOPs and training stakeholders during 2021 MDA campaign.

The new operational manual of procedures

The new SOPs cover a total of 12 operational areas, including drugs quantification, transportation, delivery, storage, waste man-

agement, and pharmacovigilance. For each step, required actions, responsibilities, operating modes, and timelines are specified.

Table 1 summarizes the operational manual with the 12 areas of interest with key steps and the respective responsible and periods of implementation.

	Areas	Main steps	Responsibles	Period
1	Submitting common drug request forms	Common drug review process Drafting the treatment report Drafting the epidemiological data report Developing the annual work plan Validating drug request forms Submitting the form through the WHO ES-PEN portal Following up the drug request	NTDs program coordinator	10 to 11 months prior to the MDA campaign
2	Shipping notification and green light	Release of the shipping notice Anticipated preparation for customs clearance and removal of drugs Anticipated preparation of the delivery of drugs Acceptance of the shipment by the NTDs program coordinator and approval of the "green light"	NTDs program WHO Donor	4 months prior to the MDA campaign

3	Customs clearance and delivery	Customs clearance Removal of drugs Delivery of drugs Receipt of drugs at the national drug store PNA	NTDs program WHO National drug store (PNA)	3 months prior to the MDA campaign
4	Transport	Transport from central level to regions Transport from regions to districts Transport from districts to service delivery points	NTDs program National drug store (PNA) District health officer	15 to 30 days prior to the MDA campaign
5	Inventory management	Drug storage Physical inventory Removal of drugs from the warehouse Management of drugs with a near expiration date Management of damaged or expired drugs	Pharmacists and managers in charge of stores at all levels (e.g., national, regional, districts, peripheral health facilities)	Between 15 to 60 days prior to the campaign depending on the level
6	Storage	Storage of drugs at central level Storage of drugs at regional and district level	Pharmacists and managers in charge of stores at all levels	Between 15 to 30 days prior to the campaign depending on the level
7	First expired, first out	Improving the visibility of expiration dates	Pharmacists and managers in charge of stores at all levels	Upon reception of new drugs

8	Reverse logistics	Planning of reverse logistics at central level Collection, transfer, and processing	Pharmacists and managers in charge of stores at all levels and district health officer	One month after the campaign
9	Removing expired and unserviceable drugs	Identification Separation Recording/ documenting/ reporting	Pharmacists and managers in charge of stores at national and regional levels	1 to 2 months after the campaign
10	Waste management	Centralization of waste Destruction	Regional pharmacist Regional hygiene unit	15 days after the campaign
11	Forecast and quantification of NTD drug needs	Forecasting and quantification	NTDs program	11 months prior to the MDA campaign
12	Pharmacovigilance	Notification and reporting of adverse events	Health workers	During the MDA campaign

Table 1: Areas and steps of the operational manual of procedures.

Abbreviations: ESPEN: Expanded Special Project for Elimination of Neglected Tropical Diseases; MDA: Mass Drug Administration; NTDs: Neglected Tropical Diseases; PNA: Pharmacie Nationale d'Approvisionnement; WHO: World Health Organization.

The manual was partly piloted, and proved to be crucial, during an MDA campaign in 2020 targeting schistosomiasis, lymphatic filariasis, onchocerciasis, and helminthiasis in 47 health districts in Senegal. It will be fully implemented during the 2021 MDA campaign, and it is expected to improve efficiency and availability of medicines in health facilities during the campaign, and to contribute to reaching coverage targets countrywide. Over time there will be significant savings and reductions in drug wastage, which is increasingly essential in resource-scarce settings.

Lessons learned

A Well-planned process

The process was guided by a framework proposed by WHO with strong recommendations and timelines. This approach facilitated

the review and adaptation of the procedures to the country context but also the documentation of the main comments and corrections that were shared with WHO through the evaluation questionnaire.

Involvement of all stakeholders

The involvement of stakeholders throughout the process ensured the effective participation of all actors and the production of a manual that meets the country's needs and addresses the current challenges of the NTDs supply chain at each level of the health system. Indeed, policymakers, drug supply chain specialists, program managers, implementing partners, and users reviewed and adapted the procedures proposed by WHO. In addition, pharmacovigilance was included as an important component of the manual.

Building on previous experiences

The planning of key steps was based on the process generally followed for the development and validation of policy and strategy documents within the Ministry of Health.

In addition, the national manual of procedures for the management of essential medicines was used as a reference for the development of the NTD drugs SOPs, which is specific to NTD drug management during campaign in opposition to routine drugs delivery. Furthermore, the national pharmacovigilance guidelines served as a reference for the integration of the twelfth component of the SOP's manual.

Moving forward

Developing a manual of procedures is not enough; it must be operationalized. There are still steps to be taken to complete the process. These include developing management tools and training manuals, training stakeholders, and disseminating SOPs at all levels of the health system to optimize its uptake during the next campaign in 2021.

Conclusion

Developing SOPs for NTDs drug supply chain management was a major step toward ensuring availability of high-quality drugs in target areas across the country during MDA. However, the process needs to be completed and the SOPs fully tested during the next MDA campaign. Data and lessons learned should be systematically collected during each campaign to support regular revision and update of the manual.

Furthermore, additional guidelines are required to guarantee availability of needed drugs in the last mile. Indeed, guidelines or SOPs for drug distributors are required and training organized to ensure safe distribution of drugs at the community level. Drug distributors need a complete and simple procedure to successfully conduct an MDA campaign. Community drug distributors are crucial for NTD campaigns to reach all eligible people, but they need training to distribute drugs in a safe and adequate manner. Specific SOPs for such actors are urgently needed to complete the excellent work performed by the NTD program and its partner in Senegal. This will help to address gaps identified in the drug supply chain process and enable rational use of medicines during mass drug administration for NTDs.

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Conflict of Interest

The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

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