Impact of the Introduction of Sputum-Smear Bacilloscopy Kits for Diagnosing Tuberculosis in the Dominican Republic

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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CONTENTS

ACRONYMS AND ABBREVIATIONS

BK	bacilloscopy
GDF	Global Drug Facility
LARNER	National Respiratory Illness Reference Laboratory
MOPH	Ministry of Public Health
MSH	Management Sciences for Health
NTPC	National Tuberculosis Control Program
SPS	Strengthening Pharmaceutical Systems
SSMIL	Laboratory Materials and Medicine Supply System (Sistema de Suministro de Medicamentos e Insumos)
TB	tuberculosis
USD	U.S. dollar
USAID	United States Agency for International Development
WHO	World Health Organization

BACKGROUND

Since 2005, Management Sciences for Health's Strengthening Pharmaceutical Systems Program (MSH/SPS), financed by the U.S. Agency for International Development (USAID), has provided technical assistance to the National Tuberculosis Control Program (NTCP) of the Dominican Republic. In 2007, the NTCP had yet to incorporate management of diagnostic materials in the NTCP's Laboratory Materials and Medicine Supply System (Sistema de Suministro de Medicamentos e Insumos; SSMIL). From February to April 2008, with funds from USAID, SPS/MSH documented supply chain disruptions on all levels of the laboratory network and a lack of standardized procedures, which contributed to periodic stock-outs. Interruptions were recorded in the processing and reading of sputum-smear bacilloscopies (BKs) and cultures, leading to delays in the delivery of results and start of treatment for patients diagnosed. A high cost of lyophilized supplies (presentation in grams) was also documented, caused by the limited forms of these reagents available on the local market. This scarcity led to several procurement processes being conducted per year for reagents and some fungible materials (microscope slides and filter paper, among others), which increased procurement costs. Other factors that contributed to the stock-outs were deficiencies in transportation from the central level to the peripheral facilities[1] and the shortage of containers for distribution.

Based on these findings, MSH/SPS supported interventions from June to September 2008 aimed at improving the management of laboratory supplies, which included—

- Establishing standard procedures for managing laboratory supplies and training on their use
- Creating tables of calculation factors for estimating needs for reagents, materials, and supplies used for BK diagnosis and cultures
- Establishing standard procedures for international procurement of laboratory supplies
- Introducing a laboratory network supervision tool
- Organizing a single system of laboratory supply and medicine management information

Six months after the inventions described were implemented, an assessment of the progress was made, which showed improvements in components of the laboratory materials supply chain.[2]

[1] C. Valdez and E. Barillas. 2008. *Estudio de Línea Basal de la Situación de la Gestión de Suministro de Insumos de Laboratorio del PNCT en República Dominicana* [Baseline study of the laboratory supply management situation of the NTCP in the Dominican Republic]. Presented to the U.S. Agency for International Development by the Program. Arlington, VA: MSH.

[2] C. Valdez and E. Barillas. 2009. *Informe de progreso sobre la implementación de los procedimientos operativos del Suministro de Insumos de Laboratorios del PNCT en la República Dominicana* [Progress report on the implementation of operating procedures for the supply management in NTCP laboratories of the Dominican Republic]. Presented to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS). Arlington, VA: Management Sciences for Health.

In addition to these interventions, MSH/SPS supported the completion of an analysis that compared the prices of lyophilized products and basic consumables on the local market with reagents and basic consumables acquired in the form of kits through the Global Drug Facility (GDF). Savings to the Ministry of Public Health (MOPH) were estimated at approximately 150,000 U.S. dollars (USD) for the purchase of these supplies through the GDF[3] (see appendix 1). Based on this analysis and the aforementioned study, the MOPH passed Ministerial Resolution No. 0000007 on July 2, 2008, which establishes and supports the procurement of BK diagnosis supplies in the form of kits solely through the GDF. In September 2009, 100,000 BK tests arrived in the country in the form of 55 basic kits, 100 consumables kits (see appendixes 2 and 3 for the contents of the kits), 100,000 containers for sputum samples, and 25 microscopes. From that point, distribution to the entire network of laboratories began.

To support strengthening the laboratory supply management component, MSH/SPS proposed performing an evaluation six months after the introduction of the kits at national scale. This report includes the methodology used, presents the findings revealed in interviews of key players, and combines analysis of the impact of the process and recommendations for the future in the final section.

[3] Ibid.

OBJECTIVE

To document the process of introducing BK kits and assess their use and impact on supply management in the NTCP of the Dominican Republic.

METHODOLOGY

The proposed study was descriptive-exploratory in nature with a combined quantitative-qualitative methodology. Face-to-face interviews were conducted using a structured instrument that included six modules aimed at documenting variation in the indicators previously measured in the baseline study:[4] order and delivery, availability, level of service, information system, quality of supervision and use of the consumables and basic BK kits. To learn about the introduction process for the kits, interviews were conducted using a question guide, which was semi-structured by key themes related to the introduction of the kits. The study included a review of the BK records and inventory cards of the facilities in the NTCP laboratory netework.

The sample was selected in two or three steps. A selection was made from the updated list of laboratories in the network, taking into account the following criteria:

- Membership in the NTCP laboratory network
- A mix of 50 percent urban and 50 percent rural
- A mix of 50 percent of provinces with high tuberculosis (TB) detection rates and 50 percent of provinces with low detection rates
- Different levels within the structure of the network (regional, intermediate, local)
- A mix of 50 percent geographically easy to access and 50 percent remote, with difficult access of provinces

Based on these criteria, 18 laboratories were selected, with a total of 38 bioanalysts interviewed (10 percent of all laboratories on the national level) with a monthly BK production corresponding to 35 percent of the total BKs reported in a month on the national level. The sample included one national reference laboratory, five regional laboratories, five intermediate laboratories, and seven local laboratories.

The information was collected from May 2010 to June 2010 by a multidisciplinary field team, under the coordination of MSH. To analyze the data, a database was created in Access where all the variables codified previously from the structured questionnaire were tabulated. The results were converted into tables of simple frequencies, and variables were cross tabulated. For the qualitative analysis of the face-to-face interviews, a list was made of key themes, and the responses were tabulated, assigning response codes to the answers.

[4] Ibid.

FINDINGS

Kit Introduction Process: Supply Management on the Central Level

A total of 203 laboratories are now part of the NTCP laboratory network.[5] The structure of the network of laboratories that perform BK diagnosis is organized into three levels according to their complexity. At the top is the National Respiratory Illness Reference Laboratory (Laboratorio de Referencia Nacional de Enfermedades Respiratorias; LARNER), Level III, the governing unit on the national level for network laboratories that perform TB testing. Its functions include logistics for laboratory materials and supplies to the regional laboratories, training, supervision, evaluation and implementation of internal and external quality control for the regional laboratories. LARNER performs tests to identify *Mycobacterium* and sensitivity to anti-TB medicine. The regional and intermediate laboratories, Level II, carry out the logistics for the supplies to the local laboratories and do BKs and cultures as well as quality control tests for the laboratories in their micro network. There are 8 regional laboratories and 40 intermediate laboratories for BK testing. Local laboratories, Level I, diagnose TB through BK samples received at their own laboratories and those the Sample Collection Units send or refer. There are a total of 154 local laboratories.

In the interview with the director of the national network of laboratories, she said that the NTCP selects the testing supplies. The NTCP rules and protocols describe the supplies required and technical specifications for doing BKs and cultures.

On the central level, the NTCP reports that supplies in lyophilized form and fungible materials are procured through suppliers on the local market. For 2008, the estimated cost of a BK test with lyophilized products and basic fungible materials was approximately USD 1.029, whereas for the same year, the cost of a BK test using the basic and consumables BK kits purchased through the GDF was USD 0.236.[6] These data were corroborated and updated in this study: the 2010 cost of a BK, including lyophilized reagents and fungible materials purchased on the local market[7] was USD 1.97, whereas with the kits it was USD 0.33, including the reagents and fungible materials. Considering that 167,000 total BKs were processed in 2010, the estimated savings for purchasing these supplies through the GDF was USD 227,200 (figure 1 and table 1).

The staff dedicated to preparing large volumes of reagents spent about six to eight hours per week at a cost of USD 180.00 per month (a quarter of the salary of a laboratory worker at the

[5] Under Secretary of Quality/SESPAS, component of laboratory network. 2009. *Informe de la Situación de la Red de laboratorio a nivel nacional en RD* [Report on the status of the laboratory network on the national level in the DR].

[6] E. Barillas and C. Valdez. 2009. *Informe técnico: Análisis de la gestión del suministro de medicamentos e insumos de salud del sector público en República Dominicana* [Technical report: Analysis of the management of medicines and health supplies of the public sector in the Dominican Republic]. Presented to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems Program (SPS). Arlington, VA: Management Sciences for Health.

[7] In the months of May to August 2010, lyophilized products and materials had to be purchased on the local market because of delays in the purchase of kits through the GDF.

MOPH). Therefore, the opportunity cost of the staff that could be assigned other tasks at LARNER must be added to the savings already described.

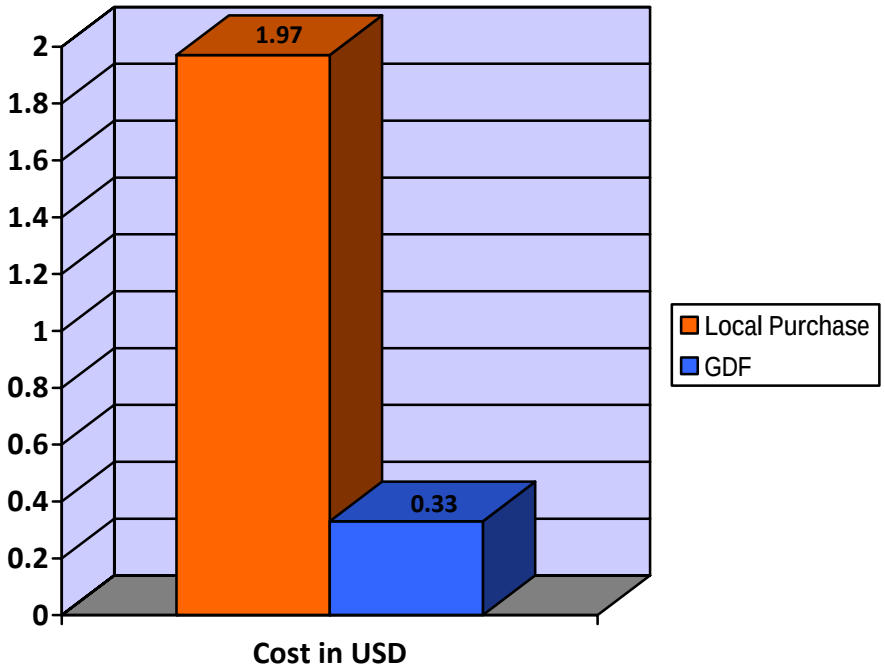


Figure 1. Comparison of the cost of a BK using purchase prices of reagents on the local market in the Dominican Republic and the procurement of reagents through the GDF, 2010

Table 1. Comparison of the Costs of Acquiring Reagents and Basic Materials on the Local Market in the Dominican Republic with the Acquisition of Reagents and Basic Materials through the GDF, 2008–2010

			2008			2010		
Product	**Form**	**Requirement for One BK**	**MOPH Price per Product (USD)**	**MOPH Price per BK (USD)**	**GDF Cost per BK (USD)**	**MOPH Price per Product (USD)**	**Cost per BK (USD)**	**GDF Cost per BK (USD)**
Plastic container	Unit	1	0.458	0.458	**0.056**	0.00	0.00	**0**
Microscope slide	Box of 72 units	1	6.47	0.09		9.71	0.13	
Wooden applicator	Package of 1,000 units	1	9.74	0.010		14.61	0.01	
Immersion oil (cc)	100 mL	0.04	14.95	0.006		22.57	0.23	
Basic fuchsin (cc)	1 kg bottle	0.5	1,893.57	0.001		2,840.35	0.03	
Crystallized phenol (g)	400 g bottle	0.2	46.51	0.001		69.77	0.17	
95º Alcohol (cc)	Gallon	7.8	41.26	0.110	**0.18**	61.89	0.02	**0.33**
Hydrochloric acid	Gallon	0.5	57.77	0.010		86.66	0.03	
Methylene blue (cc)	500 g bottle	0.3	304.05	0.001		456.08	0.91	
Sodium hypochlorite	400 g bottle	0.2	3.46	0.000		5.19	0.01	
Filter paper (cm)	Box of 100 units	1	33.19	0.341		43.15	0.43	
Distilled water	Gallon	1	2.44	0.001		2.93	0.00	
			2008 total cost per BK	**1.029**	**0.236**	**2010 total cost per BK**	**1.97**	**0.33**

The initial purchase of kits was made with funds from the "National Tuberculosis Response" project of PROFAMILIA/Global Fund in 2009. Before procurement of the kit from the GDF, lyophilized supplies were purchased on the local market with MOPH funds. The lead time (from request until receipt at the warehouse) was six to eight months, and most of the time supplies were delivered in partial lots because of their limited availability on the local market. The lead

time (from the transfer of funds to GTZ[8]—the German Technical Cooperation Agency—until receipt at the warehouse) for purchases from GDF was four months. The customs clearance process took 10 business days and was carried out by the MOPH through its customs department. LARNER ensured the national-level distribution.

Three types of kits, described in table 2, were acquired.

Table 2. Description of the Kits Acquired through the GDF[9]

Kit	Contents
Basic materials kit	Contains the materials necessary to equip a new BK unit or update an existing one (see appendix 2)
Consumables kit	Contains reagent solutions (minimum expiration term three years) and other consumable material (microscope slides, filter paper, immersion oil, etc.) necessary to prepare 1,000 BKs (see appendix 3)
Microscope and accessories	Contains a high-quality Olympus CX21 microscope for biological samples, as well as a mirror, external illumination lamp bracket, rechargeable battery, and charger (see appendix 5).

The lyophilized supplies were stored at LARNER in a space too small for large volumes and were distributed in light-colored 3,000 mL bottles with no quality controls, no safety measures for staff exposed to toxic materials, and no policies for preservation or protection from exposure to light.[10] The director said that prior to the arrival of the kits, lyophilized products were reconstituted at LARNER and then transported to the network of laboratories. Waste occurred in the lyophilized product reconstitution process because they had no standard calculation factors with exact units for dilution in large volumes. For example, stain reagents were diluted in 100,000 mL demijohns, and the laboratory did not have containers for their storage and subsequent distribution. Therefore, they were bottled in 100 mL demijohns until their dispatch, which could be postponed for a long time, during which the concentration was lost.

In the process of preservation and transportation to the peripheral facilities, losses occurred because the stain reagents were transported in light-colored plastic bottles (recycled water, alcohol, or Coca-Cola soft drink bottles) in violation of NTCP and World Health Organization (WHO) recommendations to ensure their preservation and purity. With the introduction of BK kits from the GDF, LARNER omitted the conversion of lyophilized products to stain reagents because the basic kit contains ready-to-use reagents in the exact concentration and in dark or amber bottles appropriate for their preservation and consistent with WHO quality standards.

[8] Intermediary for purchase in the Dominican Republic.
[9] Order form and technical agreement for the acquisition of diagnosis kits. Global Drug Facility. www.stoptb.org/gdf/dp/order/form.
[10] C. Valdez and E. Barillas. 2009. *Informe de progreso sobre la implementación de los procedimientos operativos del Suministro de Insumos de Laboratorios del PNCT en la República Dominicana.* Presented to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems Program (SPS). Arlington, VA: Management Sciences for Health.

The director said that receiving the kits has streamlined the storage process and distribution to the peripheral facilities, thereby enabling better management of the inventory and efficient dispatch.

LARNER established a plan for distributing the kits to the facilities in the network. For laboratories with low productivity, the contents of the kit were divided, sending only half their contents and keeping the original bottles. Laboratories with higher demand received the full kit to carry out 1,000 tests.

Outer packaging of the kits

Internal contents of the kits

Use at the NTCP Laboratory Network Level

LARNER/Central-Level Network

Among the advantages of using the kits, mentioned by the staff interviewed on the central level were the standardized forms and units of measurement of the materials, supplies, reagents, and equipment. The quality of the reagents, and consequently of the smears, was reported as superior compared with the methods and supplies used previously. In a test conducted by LARNER comparing both types of reagents, the clarity and intensity of the stain in the samples processed with reagents from the kits were superior to those prepared using empirical methods at LARNER. This was a qualitative assessment made by the laboratory workers; this evaluation did not include a double-blind test for comparison. An average shelf life of six months is reported for stain reagents prepared using empirical methods at LARNER, whereas the average shelf life of the stain reagents from the consumables kit is three years.[11]

The disadvantages reported by LARNER include the English instructions on the contents of the kit and their use. These documents had to be translated and reproduced prior to their distribution. A rash was reported by the staff members who transported the kits from customs to LARNER, which was attributed to a spill of the 5 percent phenol disinfectant (Lysol) from one of the boxes.

The contents guidelines and technical and use specifications are consistent with the procedures used by the country, with the exception of the following—

- The use of 5 percent phenol (Lysol) as a disinfectant instead of 1 percent bleach
- The staining time of the fuchsin stain, for which the national protocol establishes 5 minutes and the kit 12 minutes
- Acid alcohol 2 minutes according to the national protocol and 5 minutes with the kits
- The LARNER staff reported that 95 percent alcohol was not used by any laboratory because of the burners used with propane gas (see table 1).

Regional and Local-Level Network

Requisitions and Deliveries

At 94 percent (17) of the laboratories evaluated, the procedures for placing requisitions are standardized, and order forms are used on the regional level. The average lead time for facilities in the network between the request for and receipt of reagents prepared at LARNER with lyophilized products was eight days (median of three)[12]; whereas with the kits, it was three days (median of

[11] Order form and technical agreement for purchasing diagnostic kits. Global Drug Facility. www.stoptb.org/gdf/dp/order/form.

[12] C. Valdez y E. Barillas. 2009. *Informe de progreso sobre la implementación de los procedimientos operativos del Suministro de Insumos de Laboratorios del PNCT en la República Dominicana.*

two days). With the kits, a reduced lead time was confirmed for delivery of the supplies because of streamlined distribution logistics and dispatch from the central level to the facilities. This is because the supplies are ready to use, they do not go through any advance preparation or packaging processes, and the availability of all the materials and staining reagents is guaranteed at the time they are picked up by the staff of the facilities. The interviewees reported that with the method of reconstitution from lyophilized products, dispatch to the facilities was usually delayed because of insufficient quantities prepared by LARNER each week, a lack of bottles or jars for packaging and delivery, the lack of one or more basic fungible materials (filter paper, microscope slides, applicators, etc.), and staff not available for the delivery.

Eighteen (100 percent) of the laboratories received the complete kit with the supplies requested and on the date scheduled, whereas with the earlier method, less than 65 percent received the supplies requested.[13] At 61.1 percent (11) of the laboratories, the kits were picked up at the higher level using vehicles or resources of the institution or health facility. The baseline study reported, however, that at 30 percent of the laboratories, reagents were picked up by the laboratory workers, frequently paying out of pocket for the transportation.

Level of Service: Use

Of the laboratories, 88 percent confirmed higher quality and improved sharpness of image in microscopic reading after using the kits. Ninety-four percent reported improved sharpness of image and intensity in the coloration, and 83 percent reported faster reading when using the kits compared with the previous method. One laboratory worker said, “With the kit, the stain method is a clean process. Before, we observed precipitation of the fuchsin, foreign matter in the reading (pieces of gauze), dark and opaque coloration, making it more difficult to identify the bacilli and requiring more of our time.” With regard to the procedures for using the kits, 100 percent of the interviewees thought they were “easy to understand.” The study found that 77 percent of the laboratory workers performed all the steps recommended by the GDF for the stain. The remaining 23 percent used fuchsin for 5 minutes instead of the 12 minutes the kit recommends, and this despite the fact that they all said that they received verbal and written directions from LARNER on the new stain procedure.

Following the delivery of the kits, the study documented that the laboratories evaluated are processing and reading an average of 13 BKs per day (average work day of six hours), while they reported 10 BKs per day with the previous method. This could be attributed to the fact that the introduction of the kits guarantees the availability of all the materials and stain reagents required to carry out a BK. Previous studies documented that the shortage of supplies caused the BK diagnosis to be suspended at least one or two days per quarter in each laboratory.[14] In addition, the staff said that although the staining process is longer with the kit, the smears are observed with improved sharpness of image and intensity, leading to a higher number of slides read per hour, enabling easier and faster determination of the number of acid-alcohol resistant bacilli by field.[15]

[13] Ibid.
[14] Ibid.
[15] This result is supported by the guidelines of the Pan American Health Organization (PAHO), which establish: “If the smear and stain are good, this enables faster BAAR/field reading; otherwise, repeat the microscopy.” PAHO.

As mentioned, the average staining time with fuchsin, using the empirical method and reagents prepared by LARNER, was 5 minutes, whereas the kit directions recommend staining for 12 minutes. Of the laboratories evaluated, 77.8 percent (12) reported using fuchsin for 12 minutes as established in the kit directions. The use time for methylene blue established by the kit is the same as that recommended in the national protocols used previously, but the acid alcohol must be used for 3 minutes longer than the time established in the protocols LARNER used previously. Table 3 summarizes the differences between the procedures.

Table 3. Procedures for Ziehl-Neelsen Stain before and after the Kit

	Procedure Used by the NTCP for Ziehl-Neelsen Stain	Procedure Recommended by the Kit for Ziehl-Neelsen stain
1	Filter the carbolized fuchsin before using it. If a precipitate is detected after filtering, discard the reagent.	Cover the smears with filtered strong carbol fuchsin stain.
2	Cover the slide with filtered fuchsin.	With a cotton swab moistened with alcohol, heat the stain until vapor just begins to rise. Do not reheat.
3	Heat until vapor is released three times in 5 minutes.	Allow the heated stain to remain on the slide for 10–15 minutes.
4	Wash with clean water.	Wash the slide with clean water.
5	Cover with decolorizer for 2 minutes (acid alcohol).	Cover the smear with 3% v/v acid alcohol for 5 minutes or until the smear is sufficiently decolorized, i.e. pale pink.
6	Wash with water.	Wash well with clean water.
7	Cover with methylene blue for 1 minute.	Cover the smear with methylene blue stain for 1–2 minutes.
8	Wash with water and air dry.	Wash well with clean water. Wipe the back of the slide and place it in a draining rack for the smear to air dry.

The disinfection method used most before the introduction of the kits was 1 percent bleach and 5 percent phenol. The study reported that 54.85 percent (7) of the laboratories evaluated used 1 percent bleach as a disinfectant before the introduction of the kits, as the national protocols establish. The disinfectant used in the kit is 5 percent phenol (Lysol). The study reported that 61.5 percent (11) of the laboratories use Lysol as a disinfectant; the others use other methods. According to the findings, 66.7 percent (12) reported a good quality for the disinfectant. Suspected allergies were reported among the disadvantages by the interviewees from the use of Lysol. They reported that it has a strong odor, which limits its use in some facilities, and because of its high concentration, the staff in some laboratories dilutes it to lower concentrations.

2008. *Manual for the Bacteriological Diagnosis of Tuberculosis: Standards and Technical Guidelines—Part 1, Smear Tests*.

Availability

The availability of 14 supplies that should be permanently available in the kits for doing BKs was assessed (stain reagents and basic consumable materials). At the time of the visit, all 14 supplies (100 percent) were available, compared with 67 percent availability reported in the study conducted by MSH/SPS in 2008, before introduction of the kits. In 100 percent of the laboratories evaluated, it was corroborated through observation that the consumption of reagents and materials corresponded to the number of tests performed at the time of the visit. Only 95 percent alcohol is reported as having a surplus or being unused.

The study did not report the suspension of BK diagnosis caused by a lack of supplies during the preceding three months at any of the 18 laboratories evaluated, whereas the baseline study conducted by MSH/SPS in 2008 reported at least a one-day suspension during the preceding three months at 59 percent (N = 27) of the laboratories evaluated.[16]

Before introduction of the kits, the containers for storing reagents were plastic bottles, unprotected from exposure to light and with no expiration date. In the study, kits were found in all the laboratories with dark bottles for preservation and with expiration dates, consistent with NTCP standards and WHO guidelines.

Inventory Control

When the physical inventories were conducted, the study showed that 100 percent of the laboratories store the supplies from the kits in the laboratory where stock is monitored. The laboratory director is the person who prepares the estimates and reagent requests based on historic consumption. In 81 percent of the laboratories, it was reported that it is easier to estimate the needs with the kits than with reagents prepared empirically, using the kit for 1,000 tests as the basic inventory unit (for requisition and delivery purposes). Inventories are conducted monthly in 100 percent of the laboratories, and 53 percent of the facilities reported that the LARNER has never conducted inventories.

Information System

With the support of MSH/SPS, the NTCP developed a manual to standardize SSMIL procedures, which includes the forms that must be completed for requests and deliveries. This manual was available in only 6 of the total 18 laboratories visited. The laboratories reported that they had the forms established in the manual for requests and deliveries, but they do not update them.

[16] C. Valdez and E. Barillas. 2008. *Estudio de Línea Basal de la Situación de la Gestión de Suministro de Insumos de Laboratorio del PNCT en República Dominicana*. Presented to the United States Agency for International Development by the SPS Program. Arlington, VA: MSH.

Table 4. Comparison of the Supply Chain Process before and after the Introduction of the Kits

	Before Introduction of the Kits	After Introduction of the Kits
Lead time for receipt after the order is placed	6–8 months	4 months
Staff hours per month dedicated to preparing reagents and organizing distribution to the peripheral facilities	6 hours	1 hour
Cost per BK in 2010	USD 1.97	USD 0.33
Percentage of laboratories that receive the total quantity of supplies requested	65	100
Percentage of consistency	95	97
Cost of the estimated losses caused by expiration or in the reconstitution process (for each 100,000 tests)	Short shelf life (6 months); no expiration controls, products used after expiration, and estimated cost due to loss unknown	Shelf life extended to 3 years and expiration dates
Percentage of availability of BK staining materials and supplies	67	100
Percentage of laboratories that reported suspending BK because of lack of supplies and reagents at least one day in the preceding three months	59	0

ANALYSIS

Introduction of the basic and consumables BK kits from the GDF for diagnosis of TB helped eliminate the problems of regular supply stock-outs in the NTCP national laboratory network in the Dominican Republic, a situation which limited the population's access to diagnosis. The study showed 100 percent availability of reagents and materials in all the facilities evaluated after the kits were introduced. In addition, the introduction of the kits permitted savings of person-hours in the preparation of stain reagents, savings on the cost of each test carried out, and significant improvements in the logistics chain, thereby enabling more streamlined and efficient management of storage and distribution from the central level to the peripheral facilities, and better organization of deliveries, leading to savings on fuel and per diems paid to the staff. A secondary benefit was the improved motivation of the laboratory technicians and professionals who use the kits, in particular those in remotely located laboratories (Haiti–Dominican Republic border). In general, the laboratory staff is very satisfied with the use of the kits, especially because they improve the working conditions of bioanalysts.

Because of MOPH administrative problems in the management of international purchases, to date the funds to purchase the kits have been provided by the Global Fund/PROFAMILIA project. These problems should be corrected so that the MOPH can permanently assume this recurring expense.

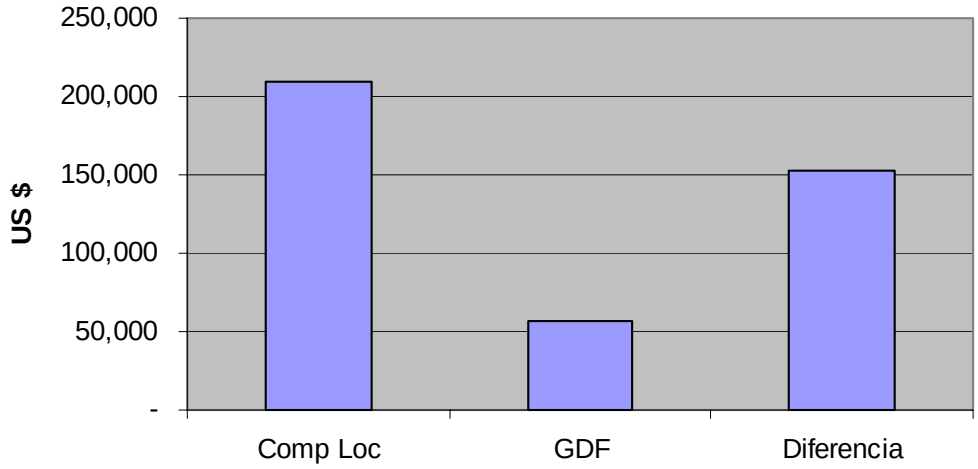
The study suggests that the quality of the stain with the kit is superior to the empirical method used previously, and this is attributed to the fact that the concentration of the reagents is preestablished in each bottle according to WHO quality standards. Similarly, the study showed that although the staining process is longer with the kits, the staff interviewed reported greater image sharpness and increased speed in reading the slides. However, this study did not include a double-blind test to support these observations probabilistically. The NTCP reports a 95 percent to 97 percent consistency before and after the kits.

Use of the kits can be optimized in future if the GDF ensures that the instructions for their use and specifications for each of the kits (basic and consumables) are in Spanish. The GDF could also consider designing kits for a smaller number of tests (500, for example). These would be useful for low-productivity laboratories. Alternatively, the kit for 1,000 tests can be divided into secondary packages with 500 tests each.

The Dominican Republic's experience can be used for countries with high incidence rates of TB, because the continuous supply of kits can help mitigate the shortage of microscopes, laboratory equipment, and supplies necessary for sputum smears. In countries with weak and fragmented supply systems, BK kits are transformed into a strategy for improving the availability of these materials, contributing to greater detection and more streamlined and timely diagnosis.

ANNEXES

Annex 1. Comparison of the Purchase Prices of Reagents in the Local Market in the Dominican Republic with the Purchase of Reagents through the GDF, 2008



Source: Barillas, E., and C. Valdez. 2009. *Informe técnico: Análisis de la gestión del suministro de medicamentos e insumos de salud del sector público en República Dominicana.*

Annex 2. Description of the Basic Kit

Product	Quantity per Kit
WHO publications: *Laboratory Services in Tuberculosis Control: Part 1 Organization and Management* and *Part 2 Microscopy*	1 copy of each book
Precipitate beaker	2
Filter funnel, large	1
Filter funnel, medium	1
Filter funnel,small	2
Wash bottles	6
Wire loop holder with heat-resistant handle	2
Nichrome-wire inoculating loops	75
Spirit lamps	2
Roll of cotton wick for spirit lamp	1
Microscope slide storage boxes	6
Microscope slide drying racks	2
Diamond-point microscope slide marker	1
Slide-holding forceps, 15 cm	2
Adjustable-length staining racks	2
Timer	1
Inventory list	2 copies
Packing list from the supplier and product specifications	1

Annex 3. Description of the Consumables Kit

Contains enough material to prepare and stain 1,000 microscopy tests.

Product	Quantity per Kit
Strong carbol fuchsin	5 × 1 liter
Methylene blue (3 g/L)	5 × 1 liter
Acid alcohol 3% v/v	7 × 1 liter
Industrialized methylated spirit	1 × 2.5 liters
Immersion oil	5 × 20 ml
Lysol, 5% solution (phenolic disinfectant)	5 × 1 liter
Microscope slides	20 boxes of 50 microscope slides
Filter paper	1 box with 100 round filters
Lens cleaning tissue	2 packages of 100
Waterproof marker pens	2
Gloves	3 boxes of 100 gloves
Instructions book	1
Material Safety Data Sheet	1 for Box 1 y 1 for Box 2
Inventory list	2 copies

Annex 4. Description of the Sputum Collection Containers

Item	Quantity per Kit
Screw-capped, leak-proof, single use/disposable sputum collection container, made of combustible material, translucent with easily labeled wall panel. Wide mouth at least 45mm in diameter. Volume = 50 ml, minimum.	1,000 containers
Inventory list	2 copies

Annex 5. Description of the Microscope and Accessories

Product	Quantity
Olympus CX21 binocular microscope	1
Eyepieces	2
Objectives	4
Nosepiece	1
Condenser	1
Dust cover	1
Illumination	1
Instruction manual	1
Voltage protection device	1
12 V battery	1
Charger	1
External illumination lamp to use with battery	1
Mirror	1
Replacement bulbs for halogen quartz lamp for microscope	9
Replacement bulbs for the external light source	10
Storage box	1
Self-indicating silica gel	1 × 100 g sachet
Microscope user's manual	1
Inventory list	In duplicate
* International adapter, as required	1