Practical Guide for the Quantification of Anti-TB Medicines: Guidelines for Quantification and Supply Planning for Procurement

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About SIAPS

The goal of the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program implemented by Management Sciences for Health is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve the 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

quantification, forecasting, supply planning, anti TB medicines, TB program

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CONTENTS

ACRONYMS

ADR	adverse drug reaction
BA	bioavailability
BE	bioequivalence
BOC	Bureau Of Customs
GMP	good manufacturing practice
DSM	drug supply management
FDA	Food And Drug Administration
NTP	National TB Control Program
PNF	Philippine National Formulary
SIAPS	Systems For Improved Access To Pharmaceuticals And Services
SLD	second-line anti TB drugs
SOH	stock on hand
STG	standard treatment guideline
WHO	World Health Organization

PURPOSE OF THE GUIDE

This guide is intended to serve as a reference for national-level quanitification, forecasting, and supply planning to inform the procurement of anti-tuberculosis (TB) medicines in the Philippines.

It provides practical guidance for program managers, technical staff, and other key personnel, outlining common considerations and best practices for quantification, and highlighting different methods. It also includes specific guidance for the collection, review, and analysis of data, as well as for building forecast assumptions.

To aid in completing quantification exercises, this guide also includes instructions for using QuanTB—an electronic quantification and early warning system designed by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program to improve procurement processes, ordering, and supply planning for TB treatment.

INTRODUCTION

Ensuring the availability of quality-assured TB medicines at service delivery points is an important element for the success of the National TB Control Program (NTP). If medicines are unavailable, patients will not be properly treated, and TB cases will inevitably worsen—and possibly spread. Proper quantification and forecasting is critical to ensuring the availability of anti-TB medicines.

Quantification is the first step in the procurement cycle, and is intended to determine the quantity of products needed. This process directly contributes to ensuring an uninterrupted supply of medicines. Forecasting is the process of analyzing data and building assumptions to predict the status of medicines availability in the future.

While this guide focuses on quantification and forecasting for procurement, these exercises have many other applications. Quantification and forecasting are also utilized in estimating budget requirements, developing procurement quantities for new programs, developing procurement quantities for program scale-up, quantifying requirements for medicines funded by the government or foreign donors, estimating pharmaceutical requirements for emergency relief situations, and comparing actual medicine consumption with theoretical need.

Quantification and forecasting should be carried out by the program manager and key technical staff with collaborative efforts from other government agencies and stakeholders. Quantification and forecasting exercises produce outputs based on estimates, and should therefore be regularly reviewed and updated to reflect current needs and projections.

CONSIDERATIONS IN QUANTIFICATION AND FORECASTING

As quantification and forecasting exercises must often work with incomplete data, assumptions must be made. The person responsible for the activity should consider a number of key factors to achieve an accurate forecast with the lowest possible margin of error. The following are key considerations in the context of the National TB Program of the Philippines:

1. Characteristics of medicines (e.g. availability, acceptability and shelf-life)
2. Quality
3. Program target
4. In-country procedures
5. Lead time
6. Consumption trends
7. Duration of treatment
8. On-going patients
9. Programmatic decisions and trends
10. Reporting
11. Budget
12. Other inventory management aspects

Characteristics of Medicines (e.g. Availability, Acceptability, and Shelf Life)

Ensuring the effective and efficient use of medicines is a significant concern for resource-constrained settings like the Philippines. Medicines and pharmaceutical products have unique characteristics that can affect the quantities to be ordered, as well as planning for the whole supply chain.

Medicines

- Are life-saving, if used appropriately
- Can be expensive
- Have product quality requirements and limited shelf-life
- Have unique handling and storage requirements
- Regulated by national authorities
- Require appropriately trained personnel for product handling

Anti-TB drugs and recommended anti-TB regimens in particular present additional complications, which warrant careful attention and planning for program managers, technical staff, experts, and other key personnel involved in the NTP.

Anti-TB medicines

- Have a short shelf life
- May not be available locally, increasing the chance of procurement delays
- May cause complicated adverse drug reactions, which may lead to a decrease in patient compliance
- Need special storage considerations (e.g. cold chain storage for injectables)
- Are prescribed in regimens with a very long treatment duration and complicated combinations

The short shelf life of anti-TB medicines means that added care is needed in quantification to minimize stock-outs and expiry. A short shelf life may contribute to higher levels of product wastage and expiry, which will decrease the quantities currently available, and increase the risk of stock-outs. Anti-TB medications which are not locally available should be monitored carefully because of the longer lead time needed to procure from international sources which may lead to more delays in procurement. The probability of adverse drug reactions (ADRs) must also be taken into account, as this may lead to a decrease in patient compliance and a subsequent decrease in movement of stocks and higher risk of product expiry. Anti-TB medicines in injectable form also require special and strict storage requirements.

Anti-TB treatment regimens are also very complex. Most regimens require patients to take their medications multiple times a week continuously for a long span of time, with some treatments extending to 18 months or more. There is also a need to consider the quantities of ancillary drugs taken by the patients during their treatment plan. Most importantly, patients must have access to an uninterrupted and continuous supply of anti-TB medications as patient compliance is a critical factor to prevent the spread of antimicrobial resistance and the overall success of the TB program.

Accounting for the characteristics of medicines—and specifically of anti-TB regimens—ensures that the pharmaceutical supply chain is working and a continuous supply of high-quality medicines are made available for patients.

Quality

Quality is a major consideration in quantification and procurement. The assumption is that products being quantified are already of appropriate quality and can pass required standards.

Problems with medicine quality can be a danger for patients, may be associated with a higher risk of product damage or wastage, and can even lead to product recalls. Quality issues can significantly decrease the stocks of medicines available for use, which will increase the risk of stock-outs.

Program Target

The targets set by the program must be clear prior to the quantification and forecasting activity. Program targets identify the current commitment or agenda expected to be delivered by the program and the Department of Health.

Care should be taken to ensure that program targets are aligned with the current capacity to deliver. The program may target a higher number of patients than what is realistically possible based on the quantification. In this situation, there is a need to align the targets or the capacity of the program to be able to reach such targets.

Program targets may also show the future direction of the program. This may include plans to either increase or decrease the number of program beneficiaries, implementation changes, and advocacy initiatives that will have an impact in the uptake of patients and consumption of medicines, all of which should be considered during quantification and forecasting.

In-Country Procedures

The amount of time it takes to facilitate in-country procedures should be taken into account during the forecasting activity. Delays in procedures should be avoided as much as possible by considering and thoroughly preparing for the requirements and processes of in-country procedures.

Examples of in-country procedures to consider

- Requirements of the Food And Drug Administration (e.g. drug registration, GMP certification, BA/BE testing, ADR reporting)
- Import and clearance requirements of the Bureau of Customs (BOC)
- Requirements for inclusion in the Philippine National Formulary (PNF)

For example, a delay in the clearance of the BOC due to incomplete documentary requirements may lead to the BOC not releasing the products on time. This will cause further delays in lead time and increase the risk of stock-outs.

Lead Time

The lead time is the amount of time between when an order is placed and when the drug is received at the site. When the lead time is not considered during the quantification activity, there is a high risk of the access site running out of stocks before the delivery comes in. This may also cause a delivery to arrive too early, when the storage area is not yet ready to accept new stocks.

The procurement of medicines and diagnostic supplies for the NTP at the national and local level follows the Republic Act 9184 or the “Government Procurement Act”. Within the current system, there are three main lead times that should be considered: lead time for procurement; lead time for the supplier; and lead time for distribution.

The lead time for procurement is the amount of time it takes for the bids and awards committee to process all requirements for procurement and award the bid. This largely depends on the product, as well as the availability of suppliers. The lead time for the supplier is the amount of

time it takes for the supplier to deliver the products to the national office. This lead time is especially important for anti-TB medicines procured from an international partner, who will often need a large amount of time to process the request and deliver the products. Lastly, the lead time for distribution is the amount of time that it will take for the national office to distribute products from the warehouse to the access site.

Consumption Trends

Aside from the standard treatment guidelines (STGs)—which identify the medicines that will be prescribed to the majority of patients and are a major factor in determining consumption trends—there are other factors to consider when performing quantification and forecasting.

The occurrence of adverse drug reactions (ADRs) is a major reason for patients to shift from one treatment regimen to another. For example, reactions to the anti-TB medicine kanamycin, which is known to cause ototoxicity, may push physicians to prescribe a different treatment. Quantification should be able to account for these situations, to either ensure that such a drug being replaced can be redistributed to other sites to avoid expiry, or that drug alternatives will not run out.

Site performance and advocacy campaigns should also be considered. A site that is not performing well may suddenly have an increase in enrollment due to better performance or the recent launch of advocacy campaigns. Such an increase should be accounted for during quantification as this may cause a sudden increase in consumption rates.

Ongoing Patients

The long duration of anti-TB regimen warrants the need to consider patients in ongoing treatment. Factors which may increase treatment duration of patients include delay in start of treatment, delay in release of diagnostic results, changes in treatment regimen and patient non-compliance.

When performing quantification and forecasting, both new patients as well as ongoing patients must be considered to ensure that facilities have sufficient stock levels. Current trends in consumption patterns of ongoing patients should be continuously monitored.

Programmatic Decisions and Trends

Treatment strategies and recommendations for treating TB are continuously changing, and these should be accounted for.

The World Health Organization (WHO), together with other leading organizations that fight TB, consistently releases new guidelines and updates that will lead to changes in the conduct of program implementation for NTP. The implementation of the nine-month treatment regimen for

the Programmatic Managament of Drug-Resistant TB (PMDT) as the standard shorter treatment regimen is one current example. The most significant change in this regimen is the reduction of the treatment from 18 months to nine months. This presents a significant decrease in consumption of medicine stocks during treatment, which should be considered during quantification. New medicines may also be recommended, as well as new program strategies.

One should consider these changes or take a look at the global direction in the fight against TB to ensure that what is being quantified and procured is aligned with international guidelines, and to avoid procuring drugs or products that will not be used by the program.

Reporting

Reporting rates and data quality are critical when using consumption data to forecast. If reporting rates are low, assumptions must be made during quantification to account for non-reporting sites. If report data are questionable or dubious, efforts should be given to validate such data prior to using them for quantification. Low quality data or data with too many assumptions may lead to inaccurate quantification and forecasting.

Budget

After quantification and forecasting, the final quantities must be checked against the approved or available budget, and any funding gaps between should be addressed. There may be a need to either increase funding to address funding gaps, or to go back to the quantification and make changes in the assumptions. If addressing funding gaps is not possible, management must prioritize program targets and try to maximize the limited budget.

PARTIES INVOLVED IN QUANTIFICATION

Quantification involves a number of key personnel and stakeholders. It is therefore important that the roles and involvement of each involved party is clearly identified. The figure below presents the process of quantification with the key roles of each personnel and partners.

Program Manager

The job of the program manager is to provide overall supervision on the quantification process, including relevant inputs and information needed for quantification preparation. The program manager also reviews and validates the forecasts generated by the process.

DSM Unit

The DSM Unit is responsible for gathering data and information in preparation for quantification, and for leading the quantification exercise. It also leads and facilitates DSM working group meetings, generates forecasts based on comments and inputs from the working group, and coordinates with the NTP Manager, DSM working group members, and the Procurement Unit on issues regarding the quantification.

DSM Working Group

The DSM Working Group must provide relevant inputs and information needed for the quantification preparation. It also helps in reviewing, providing commentary on, and approving and endorsing the forecast, quantification and supply plan. The Working Group also carries out regular review and updates to forecasting procedures.

Procurement Unit

The Procurement Unit utilizes the forecasting and supply plan for ordering, and communicates with suppliers on supply plan adjustments based on the regular review and updating of the forecast.

METHODS OF QUANTIFICATION

Quantification methods used may vary based on the application it is intended for and the resources and information available.

There are four general methods of quantification:

- Consumption
- Morbidity
- Proxy consumption
- Service-level projection of budget requirements

Consumption Method

The consumption method of quantification uses records of past consumption of individual medicines (adjusted for stockouts and projected changes in medicine use) to project future program needs. In the consumption method, a list is prepared of all medicines eligible for procurement, and the most accurate inventory records of past consumption are used to calculate the quantities needed for each medicine.

Morbidity Method

The morbidity method estimates the need for specific medicines based on the expected number of attendances, the incidence of common diseases, and standard treatment patterns. The morbidity method uses patient data (attendances at health facilities) and morbidity data (the frequency of common health problems) to project the need for medicines based on assumptions about how the problems will be treated.

Proxy Consumption Method

The proxy consumption method uses data on disease incidence, medicine consumption, demand, or use, and/or pharmacetical expenditures from a "standard" supply system to extrapolate the consumption or use rates to the target supply system. This is based on population coverage or service level to be provided. The proxy consumption method uses known consumption data from one system, called the standard, to estimate the medicine needs in a similar or expanded system, known as the target. This method can be population-based (defining medicine use per 1,000 population) or service-based (defining medicine use per specified patient case, inpatient admission or rural health center).

Service-Level Projection of Budget Requirements

Service-level projection of budget requirements uses the average medicine cost per attendance or bed-day in different types of health facilities in a standard system to project medicine costs in

similar types of facilities in the target system. This method is used to estimate financial requirements—not specific medicine quantities—for pharmaceutical procurement on the basis of costs per patient treated at various levels of the same health system.

Table 1. Comparison of Quantification Methods

Method	Uses	Essential data	Limitations
Consumption	• First choice for procurement quantifications, given reliable data • Most reliable predictor of future consumption	• Reliable inventory records • Records of supplier lead time • Projected pharmaceutical costs	• Must have accurate consumption data • Can perpetuate irrational use
Morbidity	• Estimating need in new and scaling-up programs or disaster assistance • Comparing use with theoretical needs • Developing and justifying budgets	• Population and patient attendances • Actual or projected incidence of health problems • Standard treatments (ideal, actual) • Records of supplier lead time • Projected pharmaceutical costs	• Morbidity data not available for all disease • Standard treatments may not really be used • Accurate attendance difficult to predict
Proxy consumption	• Procurement quantification when other methods are unreliable • Comparing use with other supply systems	• Comparison area or system with good per capita data on consumption, patient attendance, service levels, and morbidity • Number of local health facilities by category • Estimates of local user population broken down by age	• Questionable comparability of patient populations, morbidity, and treatment practices
Service-level projection of budget requirements	• Estimating budget needs	• Use by service levels and facility type • Average medicine cost per attendance	• Variable facility use, attendance, treatment patterns, supply system efficiency

Source: Management Sciences for Health. MDS-3: Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health; 2012

PREPARATION

Step No.	Steps	Responsibility	Timeline	Possible sources
Review program information				
1	Determine the changes in program implementation	DSM working group members	Quarterly	Current information
2	Determine the period and scope of the forecast and quantification	DSM working group members	Quarterly	Current information
3	Determine the ongoing patients and target patients to enroll	DSM unit	Quarterly	Funder, NTP manager, DSM report
4	Determine regimen and duration of treatment	DSM unit	Monthly	DSM report
5	Determine actual consumption	DSM unit	Monthly	DSM report
6	Determine projected consumption	DSM unit	Monthly	DSM report
7	Budget	NTP manager/ funder	Annual	NTP manager/ funder
Supply management information review				
1	Shelf life	DSM unit	Quarterly	Manufacturer, Supplier
2	Stock on hand (considering the expiration dates)	DSM unit	Monthly	DSM report
3	Pending deliveries (stock on order or pipeline)	DSM unit	Monthly	Supplier, Procurement unit
4	Lead time (procurement, delivery, distribution)	DSM unit, Procurement unit	Quarterly	Supplier, Procurement unit
5	Storage capacity	DSM unit, Warehouse	Quarterly	Current information
6	Buffer stock	NTP manager, DSM unit	Quarterly	Current information

Review of Program Information

A thorough review of program implementation information should be gathered as the first step of preparation for quantification. Mechanisms and structures should be in place to gather this information on a regular basis. Data quality management should be maintained to ensure the use of reliable information in the quantification and forecasting process.

1. Determine Changes in the Program Implementation

Consider incoming or foreseen changes in program implementation that could affect the treatment of patients. Changes or decisions should be considered to ensure that medicines supply will not be compromised. Forecast and quantification output should be reviewed and updated depending on the urgency and timeline of changes to occur.

Country experience

In 2010, the Programmatic Management of Drug-resistant TB program of the Philippines adopted the use of a standardized shorter 9-month treatment regimen.

Possible challenges

- For new regimens,there maybe no data for consumption available. In this case, careful planning and assumptions should be considered based on morbidity data or data from other previous regimen.
- Forecast and quantification should consider the amount of products required to implement the new standard treatment regimen, as well as the decrease in consumption of the other products to be phased out during the transition period.
- Initially, a gradual increase in utilization can be considered based on the expansion plan, and close monitoring should follow.

2. Determine the Period and Scope of the Forecast and Quantification

The specific period of forecast and quantification should be identified. In principle, a forecast which covers a broader time period tends to be more inaccurate and needs more assumptions relative to a forecast with a shorter time period of scope. Forecast and quantification covering a broader period may need to be reviewed and updated regularly as changes, variables, and assumptions continue to rise overtime.

One recommendation is to perform a forecast covering both a broader time period and shorter time period. A forecast which covers a longer period of time may show hints on the current direction of the program useful for long-term planning, while a forecast for a shorter, more current period may show new trends that can be considered. Both provide different insights and may be compared with each other for a more meaningful assessment.

3. Determine the Ongoing Patients and Target Patients to Enroll

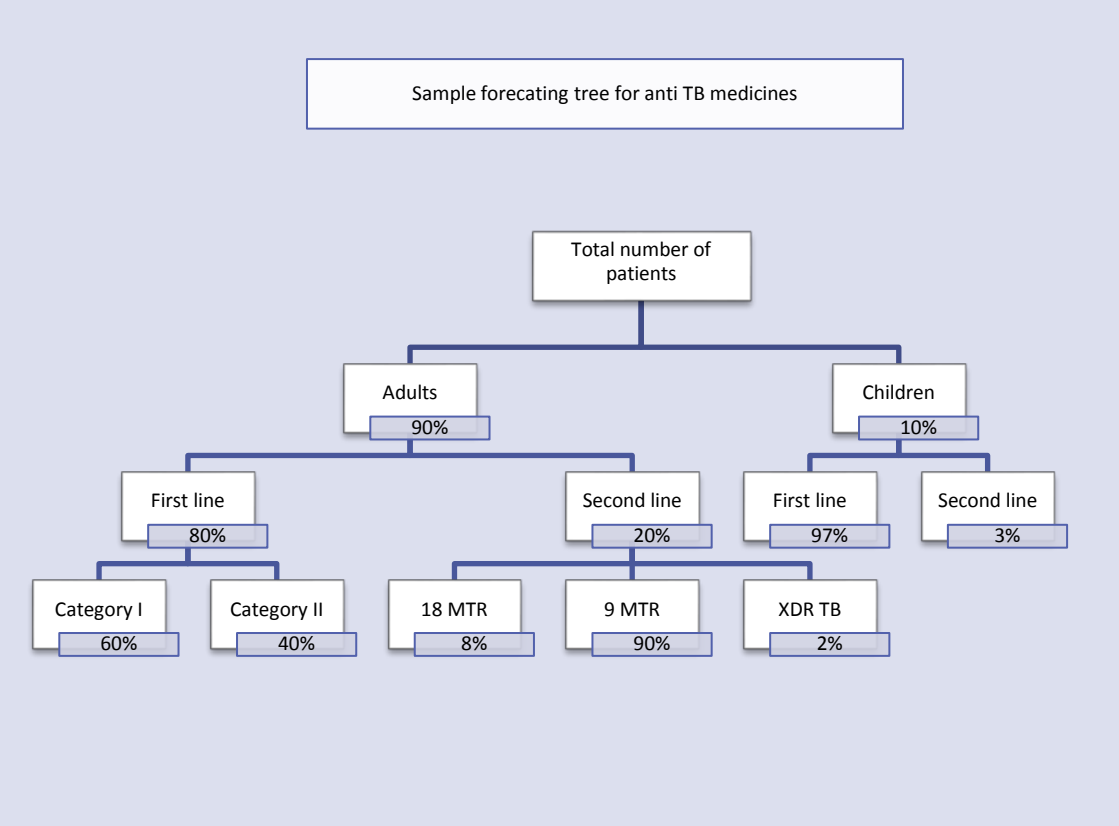
For programs that have been in existence for several years and already have patients on treatment, it is important to consider the number of ongoing patients for the purposes of quantification and forecasting. This is especially necessary for patients who are on treatment for longer durations, such as those being treated for MDR-TB.

To ensure that all patients in need of treatment will be provided with the necessary medicines, target patients for enrollment should be identified and considered in the forecast. Furthermore, changes in the number of target patients to enroll should be monitored closely. If the program does not reach the target number of patients, due to lagging or unexpected problems during implementation, consumption will decrease, and there is a higher risk of expiry. If the program enrolls more patients than what is the actual target, consumption will increase, and there is a higher risk of stock-outs. The forecast and quantification output should be adjusted accordingly.

4. Determine Regimen and Duration of Treatment

A standard list of medicines and treatment regimens selected for program use should be identified. If a new medicine or treatment regimen is introduced, all necessary information

should be gathered, such as duration of use, average daily dose, shelf life, and other relevant characteristics. It would be helpful to build a forecasting tree in which each patient is separated into treatment categories.



5. Determine Actual Consumption

For programs continuing implementation, determining actual consumption levels is essential. Actual consumption refers to the definite quantities of medicines used by enrolled patients on treatment. This data is incorporated in quantification and forecasting to project future needs of ongoing enrolled patients until they finish their treatment. This can be obtained from reports of consumption of health facilities reflecting the ongoing patients and the medicines they are currently using.

6. Determine Projected Consumption

This data refers to the foreseen percentage rate of utilization of each medicines for the target number of patient to be enrolledwhich can be obtained from health facility reports. The projected consumption for target patients to enroll can be based on actual consumption, with consideration of other variables, such as programmatic decisions and consumption trends. Specific variables to determine the projected consumption are: percentage utilization of each medicine, average dose,

and duration of treatment. In-depth expertise and background on the clinical management of TB, as well as current standard treatment guidelines, is required to make such assumptions.

7. Budget Approval

As discussed, ensuring that there is no funding gap between the forecasting and quantification output versus the actual budget available is critical to ensure the success of program implementation. Approval of the necessary resources required is important prior to performing actual procurement.

Supply Management Information Review

Aside from information related to program implementation, relevant information on supply management is fundamental for the quantification and forecasting of medicines.

1. Shelf Life

Review the shelf life of each product and consider this in planning for the time and quantities for delivery.

2. Stock on Hand (Considering the Expiration Dates)

Review the current stock on hand at all levels to avoid overstocking. Consider the expiration dates of stocks. Stocks that will reach their expiration within the period of the forecast should not be counted as part of the inventory.

3. Pending Deliveries (Stock on Order or Pipeline)

Stock on order should be considered as part of the stock on hand. The scheduled delivery of orders should also be considered in planning for delivery schedules.

4. Lead Time (Procurement, Delivery, Distribution)

Lead time of procurement, delivery and distribution should be considered in forecasting and quantification as it requires orders to be placed on a timeline that considers lead time.

5. Storage Capacity

Capacity of warehouses for storage should be considered. There might be a need to schedule more frequent deliveries if storage capacity is insufficient.

6. Buffer Stock

Buffer stock or safety stock of medicines should be determined and considered in forecasting and quantification.

7. Sources of Data

It is important to note where programmatic information can be sourced, and the program should have its own mechanism to regularly collect and ensure that this information will be accessible. A mechanism to monitor data sources should also be present to ensure the validity of data collected.

Sample Sources of Data

- Program Management: Changes in program implementation, updates to recommended Standard Treatment Guidelines, new program policies and strategies, change in budget allocation, change in program targets
- Laboratory: Drug Susceptibility Test data, possible lead time of enrollment, increase in diagnostic capacity
- Treatment facilities: Consumption data, patients adherence data, stock on hand, stock out and expiration experiences
- Warehouses: Stock on hand, expiration date, distribution lead time, storage capacity, buffer level
- Procurement unit: Procurement method, lead time, suppliers, delivery details

FORECASTING

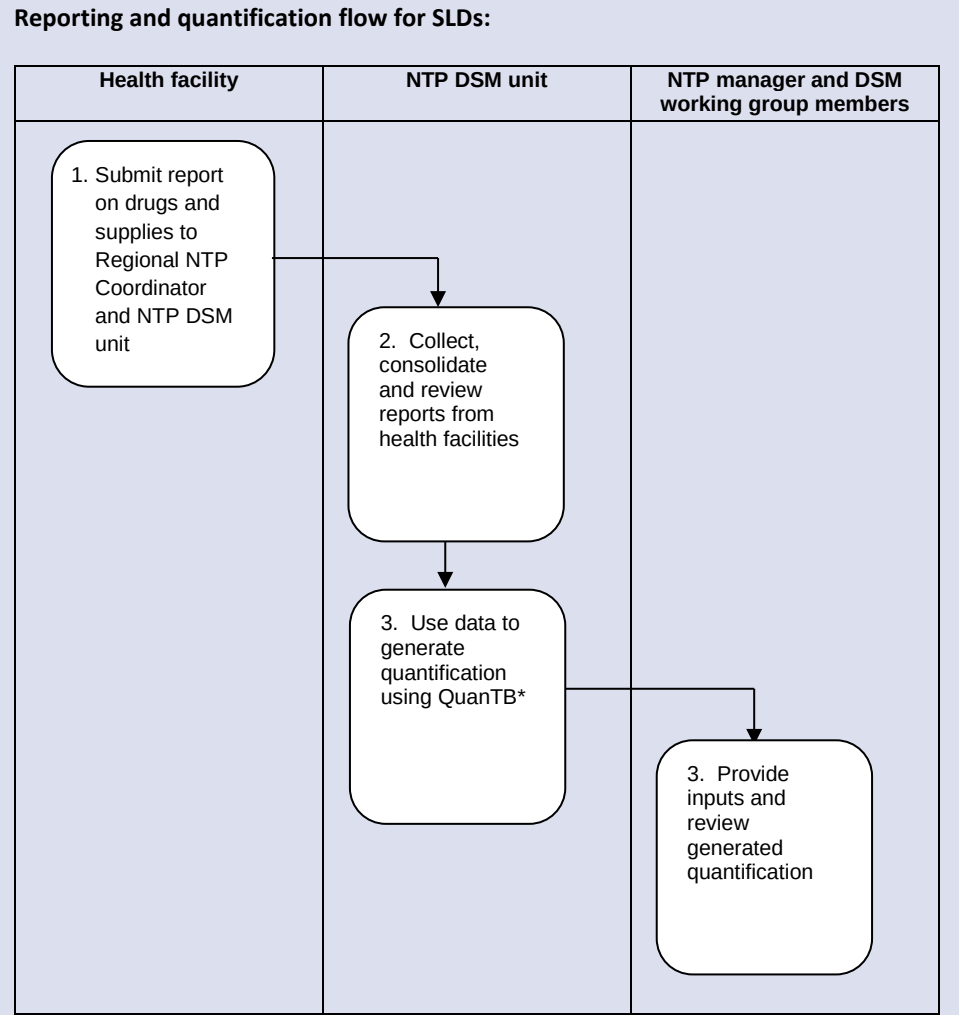
Steps	Responsibility	Timeline	Possible sources
Analyze prepared data	DSM unit	Quarterly	DSM report, data gathered
Choose method to be used	DSM unit	Quarterly	N/a
Develop forecasting assumptions	DSM working group members	Quarterly	DSM report, data gathered
calculate quantities needed	DSM unit	Quarterly	DSM report, data gathered

Analyze Prepared Data

The consolidated data from health facilities is very important for forecasting. The more data available, the greater potential there is for better analysis of the output.

Some of the considerations in analyzing data are the following:

- Completeness of data
- The period of data collection
- Quality of data reported
- Timeliness of data collected



*QuanTB is a quantification tool developed by SIAPS. For details on how to use the tool refer to the QuanTB User's Guide, citation found in the reference page

Choose Method to be Used

Depending on the status of implementation and available data, the program may choose which method would be most appropriate to use. The different methods are stated in the previous chapter.

Develop Forecasting Assumptions

It is vital to gather accurate and reliable data for use in building assumptions. The program needs to establish good coordination with health facilities, warehouses and partners to collect relevant necessary information.

It is best practice to document all assumptions made by the team. These assumptions should be presented clearly, and in an organized manner. Reviewing the forecast and quantification output

will also mean rechecking the assumptions as these will have a major effect on the output. Further, clearly documented assumptions will also help guide the next forecasting and quantification activities.

COUNTRY EXPERIENCE: Sample of assumptions used for forecasting and quantification

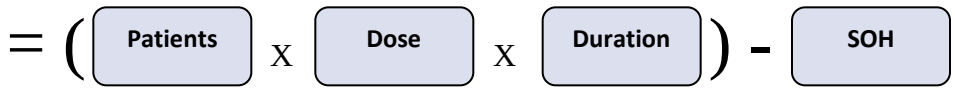
The following are sample assumptions used in creating the forecast for the National Tuberculosis Program (NTP) of the Department of Health (DOH) Philippines.

Assumptions for February 2016 forecast

1. Data used are from the following reports:
   a. **Actual and projected utilization and ongoing patients:** DSM report of January 2016 for the consumption data. 8 Facilities did not submit their reports
   b. **Stock on hand report:** as of Feb 9, 2016 from treatment facilities and in warehouses
   c. **Pending orders:** From Order Management System of GDF as of Feb 2016
2. Treatment duration: 20 months (8 months intensive; 12 months continuation)
3. Target patients to enroll for July 2015 forecast with 9MTR:
   a. 2016: Target **5177** or 431 patients/month
4. Percent utilization
   a. Utilization of Cfz is increasing based on consumption trends. For enrolled patients in Jan 2016 percentage utilization is at 5.67% (21/370). This was used for the projection of utilization for the expected cases
   b. Utilization of Cm is expected to decrease due to the issuance of memo regarding the use of Km as injection of choice for new enrolled patients. 15% utilization for Cm was assumed for new cases to be enrolled.
   c. Utilization of Pto is increasing based on consumption trends. For enrolled patients in Jan 2016 percentage utilization is at 95.40% (353/355 patients). This was assumed for expected cases to be enrolled.
   d. Utilization of PAS has decreased based on actual consumption. For enrolled patients in Jan 2016 percentage utilization is at 7.02% (26/370). This was used for the projection of utilization for the expected cases
5. All pending deliveries for Y2 2015 request will be delivered on February 2016.
6. Forecast used QuanTB tool version 3.0

Calculate Quantities Needed

To calculate for the required quantities, the following formula can be used to quantify the needs for ongoing patients and target patients to enroll:



Patients	Dose	Duration	SOH
# of patients needing the drug (ongoing+ future)	# of units/day as daily dose per patient with average weight	= # of dosing days x # of months per treatment	Rational SOH
% Utilization			Pending orders (medicines in the pipeline)

Sample computation for target patients

Medicine	Patients		Dose	Duration	Quantity need for target patients
	Estimated number of cases to treat (A)	% utilization (B)	Average daily dose (C)	Duration of treatment in days (D)	Quantity for full regimen (E) = A x B x C x D
Kanamycin 1 g	200	95%	1 vial	26dx8mo	39,520
Prothionamide 250 mg	200	95%	2 tabs	26dx20mo	197,600

Sample computation for ongoing and target patients total quantity need

Medicine	Patients		Dose	Duration	Quantity need for target patients	Ongoing patients	SOH	Total quantity need
	Estimated number of cases to treat (A)	% utilization (B)	Average daily dose (C)	Duration of treatment in days (D)	Quantity for full regimen (E) = A x B x C x D	Consumption of ongoing patients (F)	SOH (G)	Total quantity to request H= (E+F) - G
Kanamycin 1 g	200	95%	1 vial	26dx8mo	39,520	3 patients x 1 vial/day x 26 d x 4 months =312 vials	800	39,032
Prothionamide 250 mg	200	95%	2 tabs	26dx20mo	197,600	3 patients x 2 tabs/day x 26 d x 16 months =2,496 tablets	50.000	150,096

Notes:
Treatment duration of ongoing patients shoud be included in the assumptions
Orders in the pipeline should be included in the SOH
Expiration of medicines should be monitored. Medicines that will be expired should not be included in the SOH

SUPPLY PLANNING

Steps	Responsibility	Timeline	Possible sources
Determine minimum and maximum stock level	NTP manager, DSM working group members, DSM unitt	Quarterly	Current information
Determine factors affecting supply planning		Quarterly	Data gathered
Determine delivery schedule	DSM unit	Quarterly	Quantification output generated

Determine the Minimum and Maximum Stock Levels

The set minimum and maximum stock levels serve as the borderline in scheduling the arrival of deliveries and in placing orders. Determination of the minimum and maximum level is based on several factors such as lead time, consumption rates, and storage space available.

Orders should be placed to ensure that stock levels do not go under the set minimum stock level. Stock levels going below may mean that inventory is already at critical levels, and that there is already a high risk for experiencing stock-outs. On the other hand, orders received going beyond the maximum stock level also poses different problems, such as unavailability of storage space. Having too much stock also increases the risk of experiencing product expiry.

Determine Factors Affecting Supply Planning

Planning the delivery schedule of orders is needed to ensure an uninterrupted supply of medicines. Information on full consumption requirements of products, current stocks-on-hand (SOH), and stocks on order is needed to plan the delivery schedule appropriately.

Factors to be considered in scheduling deliveries are as follows:

Lead Time in Procurement Delivery and Distribution

In placing orders for procurement, procurement and distribution lead time should be considered to make sure that orders will arrive on time and according to plan.

Some specific considerations to note are:

- Feasibility of performing staggered deliveries to ensure fresh batch of stocks will be delivered
- Lead time of six months, for GDF/suppliers
- Local shipment lead time
- Additional lead time for customs approval, for products from international sources

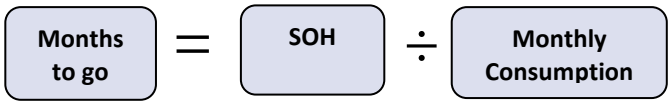
Shelf Life of Medicines

Some medicines have shorter shelf life than others. Orders and deliveries should be scheduled to ensure that the quantities to be delivered will be consumed within the shelf life of medicines. Clearly coordinate with the supplier the shelf life requirement of the products ordered. Usually the products should have a shelf life of one to two years, depending on the product itself. The shelf life requirement should be included in the procurement contract with the supplier.

There are cases where the supplier will not be able to follow the required shelf life of the products, especially when there is a manufacturer issue. For these specific batches, approval to receive these products should be carefully evaluated and done on a case-to-case basis. If the products are urgently needed by the program, and there is data to support that the products will be consumed before its expiry date, then accepting these batches are justified. Complete documentation of these cases is recommended.

Stock on Hand Status (Months to Go of Stocks)

Monitoring of inventory status versus the consumption determines until when the current stock on hand will be available and can be consumed. It will also enable the program to identify medicines that will expire before they are consumed. This will give a clear idea as to the when the medicines should be replenished. The formula below is used to determine the "months to go" of stocks:



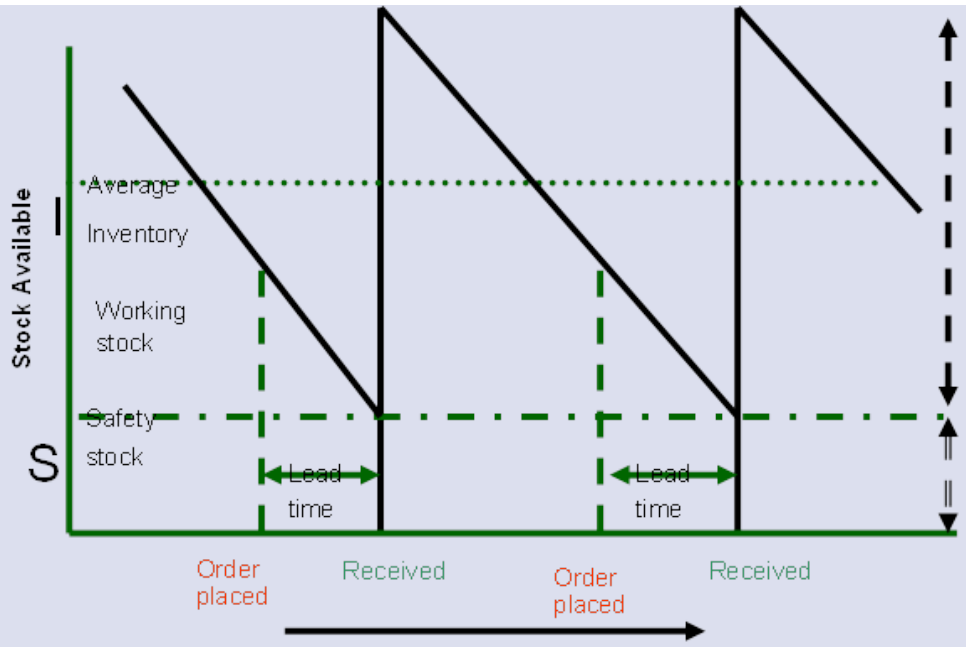
Sample of monitoring stock on hand status

Medicine	SOH (A)	Monthly Consumption (B)	Stock status or "months to go" (A÷B)
Kanamycin 1 g	800 vials	Ongoing: 3 patients x 26 days = 78 Future: (20 patients x 80% x 1 vial/day x 26d/mo) = 416 vials TOTAL = 494 vials	1.6 months (if not enrolling new patients, 10 months)
Prothionamide 250 mg	50,000 tabs	Ongoing: 468 tablets/mo Future: (20 patients x 100% x 2 tablets/day x 26d/mo) = 1040 tablets TOTAL = 1508 tablets	33 months

Determine Delivery Schedule

Once the stock status is determined, this should be related to the lead time and minimum stock level. Ideally, if a certain medicine will reach its minimum stock level based on calculated stock

status, an order should be placed in advance, giving consideration to the lead time. Upon arrival of the delivery, the stocks should reach its maximum stock level and medicines should be consumed within its shelf life.



The Ideal Inventory Management Model. This is followed by most inventory items inside the health facility. This is the Ideal Model because there are certain assumptions made for the inventory control model to follow this visual representation. The assumptions are:

- Pharmaceuticals are issued in response to demand
- Stock on hand steadily declines until a point when orders need to be placed
- Suppliers performs according to plan
- Shipments arrive on time
- Quantity ordered received
- Inventory level comes back to its starting maximum point
- No shortages
- Lead times are constant

For this model, note that:

- The y-axis of the graph shows the stock available while the x-axis shows the time period.
- As time goes on, the stock levels of the drug will go down until an order is placed.
- When an order is placed, the stocks will not increase immediately because of the lead time.
- After the lead time, the facility will receive the orders which will cause stock levels to rise until the maximum levels set.
- The safety stock level is determined to protect the inventory from sudden changes in demand during normal consumption of stocks.
- All are important to be able to manage inventory appropriately.

USING QUANTB

QuanTB is a tool that offers user-friendly features such as accurate quantification projections, customizable and adaptable platform, early warning system, models for different scenarios and full cost of orders. The tool was created by the USAID funded Systems for Improved Access to Pharmaceutical and Services (SIAPS) Program to help TB programs in improving the process of forecasting, planning and management of medicines.

Detailed instructions on how to use QuanTB can be found in the QuanTB user guide, which can be downloaded at: http://siapsprogram.org/publication/quantb-user-guide/

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