Analyzing Options for Strengthening Pharmaceutical Systems

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Analyzing Options for Strengthening Pharmaceutical Systems

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About SIAPS

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

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Key Words

Options analysis, supply chain management, technical assistance, technical assistance approach, analysis of options, options analysis framework, options analysis definition, pharmaceutical systems, pharmaceutical systems strengthening.

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INTRODUCTION

Health and pharmaceutical systems are continually evolving and changing in response to social, economic, and political factors, and the introduction of novel technologies. System architects are striving for equity, efficiency, sustainability, and universal health coverage, and systems must adapt to achieve these goals and others set by the global health agenda. Events such as the Ebola epidemic in Western Africa in 2014–2015 highlight weaknesses in health systems and prompt cycles of assessment and improvement.

In general, most planned health system reforms consider similar approaches including decentralization, outsourcing of services and functions to the private sector, separation of functions, and increased stakeholder engagement. In pharmaceutical systems, supply chain configurations, regional (or global) regulatory arrangements and harmonization efforts, and other basic pharmaceutical system structures have become relatively standardized, with reformers and technical assistance providers selecting from an increasingly defined basket of standard interventions. However, as systems strengthening approaches strive to address the complex relationships between identified issues in pharmaceutical system functions and the settings in which they operate, technical assistance strategies must adapt to increase stakeholder engagement and incorporate system context, while promoting country ownership and engagement.

The options analysis approach has evolved from early technical assistance practices that typically entailed an informal expert assessment accompanied by recommendations. These evaluations were largely qualitative in nature and were generally performed by consulting technical experts. In the 1990s, greater attention was paid to quantitative results and reporting on global health, and the indicator-based assessment became the gold standard in baseline assessments and monitoring and evaluation of interventions. Validated indicator-based assessments provide better evidence for determining problems and evaluating interventions. However, given the pressure that systems are under to adjust to changing demands, interventions and improvements do not always benefit from a thorough analysis of alternative options for action, given the specific problems faced and the country context. Furthermore, indicator-based assessments do not automatically establish the underlying causes of problems, which require a more qualitative analysis.

The options analysis is the next step in this technical assistance progression. Initially developed as an approach for selecting among defined supply chain configurations, the options analysis engages stakeholders from the beginning of the process through decision making. It accounts for the specific country context and compares options for intervention in terms of pre-defined criteria. Rather than issuing recommendations, the options analysis team presents stakeholders with elaborated intervention alternatives, including factual arguments that would help them to determine the best option or options for implementation and future steps.

To promote informed decision making in selecting appropriate interventions to address complex issues faced by health and pharmaceutical systems, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program has prepared this guidance document for technical assistance providers, policymakers, and key stakeholders in pharmaceutical systems to use as they consider system improvements and intervention alternatives. This approach involves active

engagement of relevant stakeholders throughout a systematic assessment and comparison of options based on current system considerations, viability of potential interventions in view of their operational characteristics, existing legal and regulatory frameworks, and potential cost implications.

This paper describes an evidence-based approach for the critical and systematic analysis of intervention options in pharmaceutical systems, supported by practical examples and technical annexes that the reader may use to tailor the approach to a variety of technical areas and problems.

The advent of priority public health disease programs biased interventions toward those that increased access to program-specific pharmaceutical products through support for procurement and supply management only, decreasing the focus on holistic pharmaceutical systems strengthening. The global health community has been confronting this issue for the past few decades, and recent health crises as well as the development of the sustainable development goals have emphasized the importance of a systems strengthening approach. As a result, efforts to increase accessibility and availability of quality, affordable medicines and other health technologies must expand in scope beyond interventions targeted at supply chains. As more attention is paid to non-supply chain elements to pharmaceutical systems, strategies for pharmaceutical system strengthening, including the options analysis approach, must expand to areas beyond supply chain management as well.

The SIAPS program advocates for a holistic view of pharmaceutical systems, and works to make sustainable contributions to pharmaceutical system governance; human resources; information; financing; service delivery; and medical product availability, accessibility, quality, and use. Figure 1 illustrates this approach. The technical materials that accompany this paper are grouped according to these technical areas, so that the options analysis approach may be applied to a wide range of pharmaceutical system challenges.

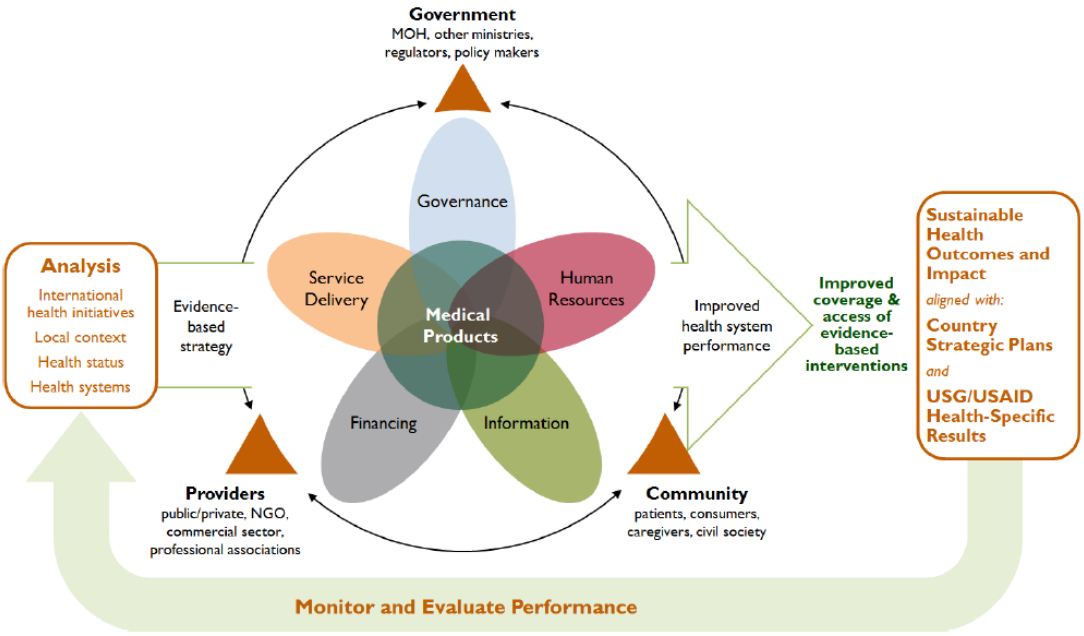

Figure 1. SIAPS framework for pharmaceutical systems strengthening

Within the SIAPS framework for pharmaceutical systems strengthening, the options analysis approach is represented to the left of the diagram. This approach takes place in the Analysis section of the framework, and contributes to the development of evidence-based strategies tailored to the identified problem, while accounting for context.

What Is an Options Analysis?

An options analysis is an explicit and transparent comparison of alternative ways to address underlying causes of a specific problem or problems. Internal stakeholder or external technical assistance providers may perform the options analysis for the organization or system requiring the analysis." This approach can be used across a variety of technical areas in the pharmaceutical system and is meant as a guided means to address problems in a systematic and transparent way.

The process involves:

- Engagement of stakeholders from the beginning of the process through decision making and selection of options
- Examination of the current system, including problems and underlying causal factors
- Identification of alternatives or options for consideration
- Analysis of enablers and barriers to each option based on consideration of defined variables for decision making
- A decision-making process that could also build consensus in selecting one or more options

Figure 2 illustrates how these processes relate to one another. In general, an options analysis takes a step-wise approach from examination of the current system and context through to decision making and commitment to implementation and mapping of next steps. The notable exception is stakeholder engagement. Stakeholders should be involved through the entire process, including the implementation of selected options, and measurement of progress and outcomes.

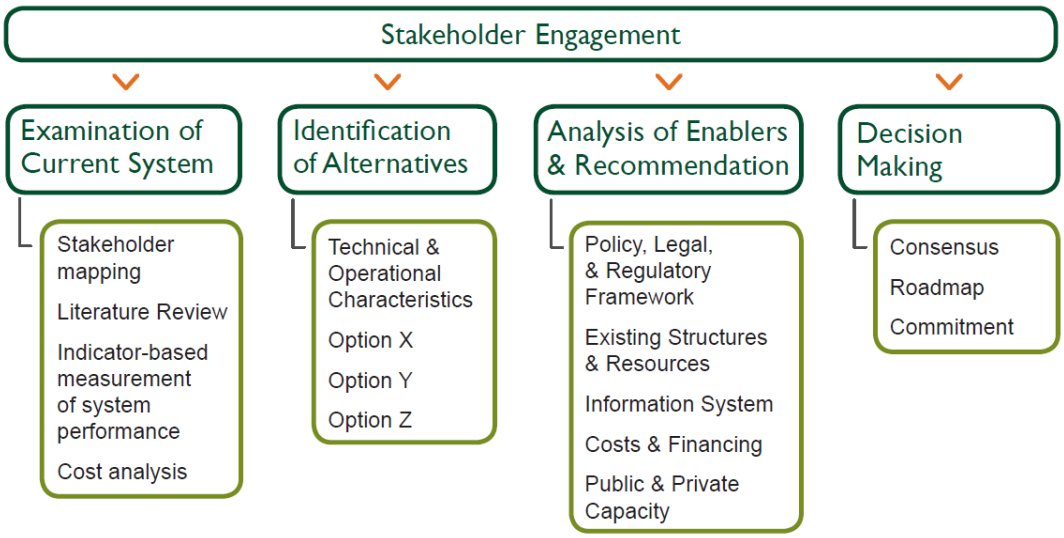

Figure 2. Framework for options analysis

When Is an Options Analysis Appropriate?

Since the options analysis is resource-intensive, the approach is best suited to high- level problems. Issues requiring system-level interventions should be approached methodically, and alternatives should be weighed with input from relevant stakeholders.

Box 1. Problems, Underlying Factors,* and Interventions

Problems are usually quite broad—
Health facilities are regularly stocked out of family planning commodities

Problems can usually be broken down into more specific issues upon initial analysis—

- *Insufficient procurement of commodities*
- *Poor distribution practices*
- *Lack of inventory management capacity at health facility level*

Underlying factors are identified once the extent of the problem has been examined upon further analysis—

- Insufficient procurement of commodities is due to:
  - *Inadequate funding*
  - *Lack of reliable demand and need data for determining purchase order quantities*
- Poor distribution practices are due to:
  - *Lack of delivery infrastructure leading to unscheduled pickups*
  - *Inadequate staffing levels at warehouses for accurate record keeping*
- Lack of inventory management capacity at health facility level is due to:
  - *Inadequate staffing levels to complete labor intensive record keeping*
  - *Lack of procedures for ordering and pickups allows for unplanned, fragmented procurement*

Interventions should be developed to address the identified underlying factors— possible interventions include:

- *Restructured information systems to better improve quantification and inventory management*
- *Increased investment in transportation infrastructure,* and
- *Supportive supervision in inventory management at health facility level*

*Please note that "underlying factors," "determinants," and "root causes" may be used interchangeably to describe system elements that contribute to the identified problem.

Please note that the framework for this approach does not include problem identification. Options analyses must be conducted after the problem under investigation has already been clearly identified or broadly perceived. For example, widespread stock-out of tuberculosis medicines, inappropriate use of antimalarial medicines, shortage of trained pharmacy staff, lack of available information for decision making at the Ministry of Health, or insufficient funds to procure needed commodities are all problems that might merit an options analysis. The extent of the problem is investigated to identify the underlying factors that contribute to the problem such as an examination of how the stakeholders in the current system are mapped, literature review, indicator-based assessment, and cost analysis. Only when the problem and its underlying factors are well understood can the analysis proceed to identify alternative options for intervention and select the most appropriate course of action.

STAKEHOLDER ENGAGEMENT

Engagement of stakeholders should occur continuously throughout the options analysis process, from initiation of the analysis to the decision making process. Stakeholder engagement is a key differentiator between a true options analysis and an assessment with recommendations. Focusing on keeping system participants, beneficiaries, and decision-makers involved throughout the process increases their investment in the ultimate course of action and facilitates that stakeholders will accept, implement, support, and sustain the selected option. Stakeholders should actively participate in each step of the analysis process, including problem definition, assessment of the current system and its context, identification of potential options, analysis of enablers and barriers to each option, and ultimately option selection.

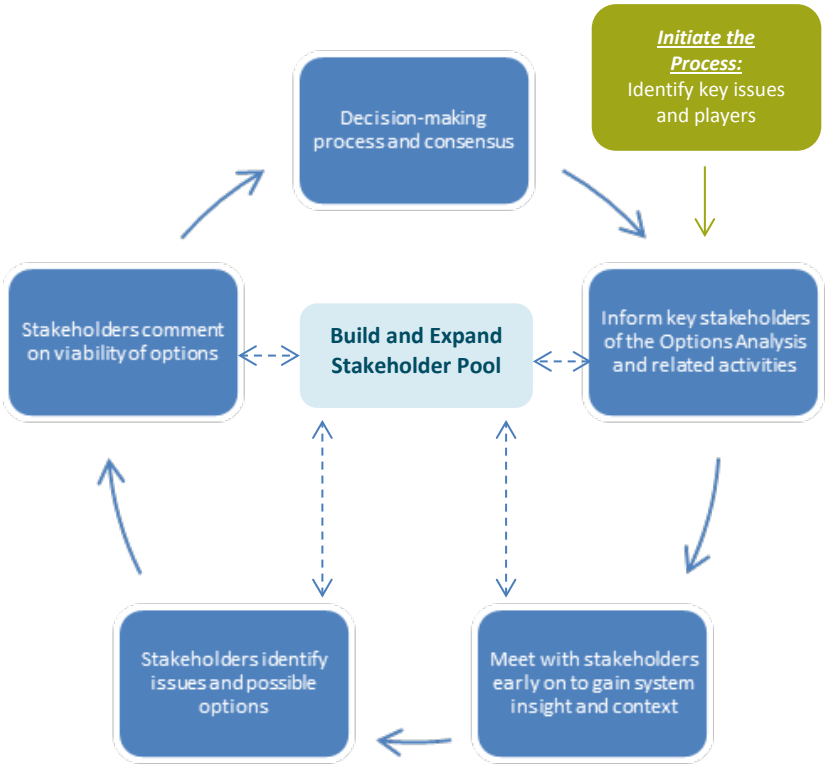

Figure 3. Stakeholder engagement process[1]

Figure 3 shows the complete process of stakeholder engagement. At each step, stakeholder interviews may identify more stakeholders to follow up with, ensuring that the stakeholder pool expands as the analysis progresses.

[1] Adapted from: Management Sciences for Health. 2011. *Building Local Coalitions for Containing Drug Resistance: A Guide*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

The process begins with **identification of key issues and players**. Ostensibly, the agency that initiates the options analysis and related activities is a primary stakeholder. The request may come from a donor agency, health program, the ministry of health, health departments, geographic region, etc. It is important to note that options analyses may vary in scale, and the initiating stakeholder plays a key role in setting the scope and identifying other early stakeholders for consultation. A preliminary literature review concerning the problem or area under investigation and mapping of the current system should turn up more leads.

Once stakeholders are identified, the analysis team may need to **inform stakeholders of the options analysis and related activities**. Beyond the initiating stakeholder, major players may be unaware of the analysis and its potential implications. Ensuring that stakeholders are on the same page at the beginning of the process will facilitate their cooperation and may increase stakeholder buy-in of outcomes if they are brought in at the outset of the analysis. These initial meetings may also provide an opportunity for the analysis team to gauge stakeholder support for change and in many cases can generate further leads and provide current system context.

Box 2. Identifying Stakeholders[1]

When working in health systems and pharmaceutical systems, stakeholders generally fall into these broad categories:

1. Government sector (includes ministries of health, health programs, regulatory authorities)
2. Political sector
3. Funders (includes lenders, donors, insurers)
4. Global partnerships
5. NGOs/other private philanthropic organizations (local or international)
6. Health care providers (public and private sector)
7. Laboratory services
8. Logistics providers and distributors (may be public or private)
9. Educators and trainers
10. Commercial sector (includes suppliers and manufacturers)
11. General public (includes consumer, special interest groups, and vulnerable populations)
12. News media and journalists

Not every problem will involve stakeholders from each category, but it may be helpful to organize identified stakeholders from interviews or a review of the literature according to these or similar categories. This allows the analysis team to group stakeholders by interest area and highlight categories where they may want to engage more stakeholders. Please refer to annex A for a stakeholder identification worksheet with examples of stakeholders for each category.

Stakeholder meetings are essential to **gain system insight and context**. Use these interviews to ask questions about perceived problems, the political environment in which these issues take place, and contributing factors to these problems. Key stakeholders may provide historical background of the system, recent changes, its current state, observed trends, and where they think the system is headed. Much of this information may not be readily available in the literature review portion of the analysis and may have major implications for the viability of certain options later in the analysis.

During these meetings, stakeholders may be able to contribute ideas that **identify specific issues and potential intervention options**. Consulting a wide variety of stakeholders at varying levels of the system will maximize this potential, as different perspectives will yield alternative insight on a specific problem. Speaking with stakeholders can also help to make options under consideration more specific to the country context or may result in options that the analysis team had not previously considered. For example, stakeholders suggest that the TB program consider implementing a recent outsourcing of logistics services model that was used in the family planning program, of which the options analysis team would have otherwise been unaware.

Once potential options are identified, discussions may become more focused on their **viability** given the context and stakeholders' opinions regarding the alternatives. As the options are analyzed in terms of objective criteria (such as cost or private sector capacity) the opinions of key stakeholders provides additional insight as to the reception of options when they are presented for consideration. For example, a particular option under development involves a reduction in staff. Stakeholders consulted early in the process have alerted the options analysis team to the fact that this may be politically contentious so that they may consider this when presenting the option for consideration later in the process. It is important to account for deep-seated political resistance, as negative political or public perception of potential interventions may prevent acceptance regardless of the supporting evidence in favor of the intervention. Implementers of the options analysis approach must be aware of how terms used and proposed options are perceived, and fall back on objective measures that support the recommended options.

In the end, **decision making and consensus** may be carried out through a relatively small group of key stakeholders, or may be a more inclusive process involving a large group.

Annex A contains worksheets and resources to help identify and organize stakeholders.

EXAMINATION OF THE CURRENT SYSTEM

To develop practical interventions and options, a comprehensive understanding of the system as it exists is essential. There are a variety of tools and methodologies to achieve this. Familiarity with system components and published knowledge of the perceived problem will inform the types of options that should be considered and is a necessary starting point for the options analysis approach. Triangulation of interview data, indicator-based assessment results, and documentation is required for a fuller understanding of the particular factors underlying poor performance. Commonly, problems are caused by multiple, complex factors, so alternative solutions should aim to address all of the factors involved, which requires a thorough understanding of the problem being analyzed.

Stakeholder Mapping

Mapping of stakeholders is necessary for broadening stakeholder engagement. Though it is likely that most stakeholders will be identified through early interviews, preliminary research and literature reviews can identify key agencies and organizations involved in the system and connected with the problem that the analysis team is examining. When mapping stakeholders, be sure to note their interests and levels of influence to assess whether additional advocacy is needed to promote reform, or if there are issues of conflict of interest at play. Refer to annex A for a stakeholder identification worksheet, which organizes stakeholders into groups based on how they interact with the problem under investigation.

Literature Review

Literature reviews serve to identify new stakeholders, communication channels, and organizations, programs, and initiatives involved in relevant activities. Documents provide insight into the policy and legal framework of the area under investigation, and the processes of selection, procurement, distribution, and use of health commodities along with management support practices, and training and education efforts. The literature may describe the pervasiveness of the problem and trends, and provides a benchmark about the extent of public knowledge of the problem based on the availability of relevant information.

Relevant documents may include policies and legislation, regulations, published and unpublished reports and articles, previous assessments, curricula, media articles, presentations. Grey literature may be found through publicly accessible databases and search engines, or through the websites or archives of identified stakeholder organizations such as The World Bank, World Health Organization, donors, or partnership organizations.

Not only does a review of the literature provide context for the current system, it can also identify enablers and barriers for options under consideration. Please refer to annex B for a sample worksheet to guide the literature review process.

Indicator-Based Measurement of System Performance

Structured assessments are critical to accurately diagnose emergent problems and analyze options for improvement. In the context of an options analysis, the general nature of problems may be evident in many cases, but the underlying causes may not be clearly known or understood. Options analyses are typically undertaken in situations where there is a commonly acknowledged problem but different approaches to address it. In these instances, assessments must be done quickly, while still producing a thorough understanding of where various elements of the system are performing well and where they are not, the underlying factors, and the types of interventions that might be appropriate to address these problems. Conventional indicator-based assessments gather information from the various levels of the pharmaceutical system, and multiple types of information are collected from document and records reviews, interviews, and observation. Survey instruments are standardized and comprehensive and may be tailored to a specific assessment or adapted from manuals. Refer to annex C for a list of indicator-based assessments.

Cost Analysis and Costing Methodologies

The costing analysis performed for the current system provides the foundation for costing of options later in the analysis. Components are usually added to or subtracted from the current system cost to compute the cost of each option for comparison, so it is important to thoroughly analyze the system at baseline. Once cost elements are identified, the appropriate cost data may be collected.

It is imperative that data are collected on the system's costs prior to analyzing options while the assessment of the current system is underway because costing is much easier if necessary data are collected while the assessment team is in the field, as they will already be speaking with many of the stakeholders who can provide this information. To facilitate data collection in this regard, the analysis team should structure their costing tool ahead of time, so that they have a good idea of the type of information that will need to be collected and potential sources of information. The pre-fabricated costing tool will likely change as information is added and stakeholders are consulted—new components may need to be accounted for or processes in practice may differ from what was expected. Nevertheless, organizing the costing tool ahead of time and incorporating costing into the assessment process helps to ensure that costing is systematic and costing data is collected more easily.

There are a variety of costing methodologies and approaches to choose from. The most appropriate methodology will depend on the system parameters—what is the nature of the problem being analyzed and what system elements must be included to effectively cost the system. Methodology will also depend on the information that is available to the analysis team—the accuracy and level of detail of this analysis is highly dependent on the type and quantity of information the analysis team has access to.

The first step in developing a cost analysis tool is to determine the major components that need to be included. For supply systems, this usually includes pharmaceutical acquisition costs such as cost of procurement; inventory holding costs that are associated with storage and distribution; purchasing costs that include administrative costs of the procurement process; and shortage costs incurred in the event of stock-out. These are the major categories employed in a total cost analysis, which is

an approach that compiles information on variable pharmaceutical costs to provide a pharmaceutical system-level picture of expenditure. This approach readily allows managers to compare various system configurations to evaluate their impact on projected cost.

Table 1. Baseline TB Supply Chain Costs, Philippines

Cost Component	Cost (Philippine pesos–PHP)
A. Storage Cost, National Level	**224,077.80**
Area of MMD Warehouse	909.61
Duration in Warehouse	1
Utilities Multiplier	225.48
Number of Staff Persons	1
Staff Time	5.6
Staff Cost	99.675
Number of Deliveries	2
B. Transport Cost, Central to Regions	**1,278,180.02**
Volume of Delivery	682.21
Cost of Transport - Land	Varies*
Cost of Transport - Sea	Varies*
Cost of Transport - Air	Varies*
Number of Deliveries per Year	4.00
C. Storage Cost, Regional Level	**79,862.97**
Total Area of Regional Warehouses	227.40
Utilities Multiplier	225.48
Number of Staff Persons	3
Staff Time	2.00
Staff Cost	11,211.00
Number of Deliveries per Year	4
D. Transport Cost, Regions to Provinces	**1,064,692.77**
Number of Provinces	82
Frequency of Delivery	4
Transport Cost	Varies*
Number of Staff Persons	2
Staff Time	8
Staff Cost	60
Staff Per Diem	250
E. Storage Cost, Provincial Level	**205,099.68**
Number of Provinces	82
Area of Provincial Warehouse	Varies*
Utilities Multiplier	225.48
F. Transport Cost, Provinces to DOTS	**1,934,400.00**
Number of DOTS Facilities	2,418
Frequency of Delivery	4
Cost of Pick-up	200.00
Total Estimated Cost:	**4,786,313.23**

☐ Computed or Assumed Value ☐ Based on interviews and available data

*This was computed for each region and varied widely; for national level calculations, this was done for each region or province and then totaled to produce the values for D and E.

Alternatively, when analyzing the costs of other system components that do not easily fall into these categories, think broadly about the system parameters to determine the major drivers of cost. It may be helpful to use the levels of the system being analyzed in the indicator-based assessment to guide the selection of these components, since they will likely correspond. For example, if the system being costed spans central, regional, provincial, and health facility levels, you could structure your analysis to account for costs incurred at each of these levels, (table 1). Note that this costing example has the available information organized by system level, but includes costing data required for a total cost analysis as well. Recall that the choice of structure for the costing tool is partially dependent on the information available. In this case, information was recorded and housed at the varying system levels, so this structure was best suited to the available information.

In addition to the total cost analysis, several other approaches and specific costing tools are available to perform the required analysis. These include VEN analysis, ABC analysis, price comparison analysis, lead-time analysis, expiry-date analysis, and hidden-cost analysis for interventions and structures that involve the movement of products, while activity-based costing and service costing are more generic and apply to operations that do not move products (box 4). These may be used in combination or separately to analyze the identified problem within the specified system parameters. Specific costing tools for analyzing health programs or defined system levels have been developed by a variety of organizations for a variety of purposes. See annex D for a list of costing tools to guide your analysis.

Once the preliminary costing tool is developed, data collectors may begin collecting or locating cost information. Depending on the costing method, the data required for analysis may already exist in records or financial statements. For costing methods that require data collection, stakeholders may not be able to disclose data regarding system costs if procurement or payment information is particularly sensitive.

Data collectors may need to get creative to locate missing data or fill in blanks based on available information. Relevant data may be found in publicly posted tender documents or awarded contracts, or information available in a similar setting or based on industry standard rates may be substituted. For example, storage costs may not be available for the particular commodities included in the analysis; however, storage costs may either be calculated based on similar commodities in the same facility or based on commodity storage rates in a similar facility, depending on what data is accessible to the analysis team.

Box 4.Costing Methodologies[2]

The following approaches may be used in conjunction with a total cost analysis or separately to evaluate specific costs and expenditures associated with certain aspects of pharmaceutical systems.

1. **Total Cost Analysis:** compiles information on variable costs associated with purchasing and inventory management to help managers consider options for change in terms of their impact on total costs
2. **VEN Analysis:** categorizes pharmaceuticals by their relative public health value - useful in setting purchasing priorities, determining safety stock levels and pharmaceutical sales prices, and directing staff activities
3. **ABC Analysis:** examines the annual consumption of medicines and expenditures for procurement by dividing consumed medicines into defined categories
4. **Price Comparison Analysis:** compares pharmaceutical prices paid by different supply systems as a measure of procurement efficiency
5. **Lead-Time Analysis:** tracks procurement lead times to determine where lead time may be reduced – usually evaluates safety stock and payment time
6. **Expiry-Date Analysis:** examines levels of stock on hand and their expiry dates compared to consumption to project wastage
7. **Hidden-Cost Analysis:** examines supplier performance to identify hidden costs incurred due to problems including delayed delivery and short shipments.
8. **Activity-Based Costing:** is a method that is useful for non-product based problems. It involved assigning overhead costs proportionally to the items that use them.
9. **Service Costing:** also lends itself to non-product based processes. Total costs of providing a specific service are divided by the number of services rendered. For example, clinic operating costs (staff, utilities, medicines costs) can be divided over hours in operation or number of patients seen.

Please refer to **Chapter 40 of the MDS-3** for a complete explanation of each costing methodology listed here, and see **annex D** for a listing of additional costing tools.

If costs need to be calculated or are pulled from alternative sources, be sure to explicitly state any assumptions made and be consistent when costing the options so that costs may be compared later. For example, in a recent supply chain options analysis for TB commodities in the Philippines (table 1), reliable costing information was only available for one region of the country so assumptions had to be made to scale up the cost for the entire country (18 regions). This was done by scaling the costs based on the number of TB-DOTS accredited facilities in each region compared to the number in the index region. This assumption was carried through the costing analysis for each option as well, so that the costs could be compared to one another to evaluate savings or cost increases for each relative to the baseline cost. See annex 4 for a list of costing tools that may be adapted for options analysis costing activities. For further guidance on costing methodologies, consult Chapter 40 of the Managing Drug Supply-3.

[2] Adapted from: Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies – Chapter 41 Section 4: Costing.* Sterling, VA: Kumarian Press.

IDENTIFICATION OF ALTERNATIVE OPTIONS FOR INTERVENTION

Once the current system assessment is complete and the problem is well-understood, the analysis team should begin developing options for intervention to address identified issues.

Identify Possible Solutions

It is important to develop several alternative solutions for stakeholders to consider. Each option needs to be specific and detailed, so that they may be thoroughly costed (as far as possible) and compared during the analysis phase. Options must be specific enough that they may be described in terms of their technical and operational characteristics. While developing options, always be mindful of country context.

Consider Stakeholder Inputs

Stakeholder interviews can generate potential options and can provide a venue for preliminary feedback early on in the process. Stakeholders may be aware of previous models or interventions that have been successful or unsuccessful in the past, and have insight into current political trends.

Consider Interventions from the Literature

When designing options, draw upon relevant literature to shape potential interventions. Pharmaceutical system strengthening and health system reform are not new, many of the problems prompting options analyses have been dealt with before, and the literature contains well-documented interventions and strategies for addressing these problems. Use these examples as a starting point to develop defined options for analysis and implementation. Box 5 demonstrates the options under consideration in Jordan to address issues with appropriate use of medicines and pharmaceutical expenditures.

Box 5. Strategies to Improve Medicine Use in Jordan[3]

The Problem: Inefficient pharmaceutical selection and procurement, and inappropriate prescribing were perceived to adversely affect appropriate spending and use of medicines. USAID was interested in providing limited and one time technical assistance to address this problem.

The Goal: Improve the selection and use of medicines.

Possible Options:

1. Revise the Rational Drug List

- Work with MeTA and key stakeholders to develop pragmatic, yet rigorous, strategy to revise the RDL
- Capacitate the pharmacy and therapeutics committee and other relevant hospital departments to work together
- Produce results and reports that document the impact of the RDL on antibiotic use and spending

2. Improve the prescribing and use of antibiotics in obstetrics

- Incorporate an antibiotic prophylaxis protocol as part of standard procedures during obstetric surgery
- Capacitate the pharmacy and therapeutics committee and relevant hospital departments to work together to improve antibiotics use at hospital level (obstetrics department)
- Produce results and reports that document the impact of the intervention on antibiotic use and spending
- Monitor parallel trends in bacterial susceptibility and clinical outcomes

Note that the options are relatively broad, but that each one involves a series of very specific steps. This facilitates costing and consideration of technical and operational characteristics.

Since issues that prompt options analyses tend to be high-level or structural in nature, or involve issues pertaining to processes, competing models or configurations are usually the types of options under consideration. For example, if the current supply system exhibits issues with several operational levels, an options analysis may be appropriate to examine and compare varying supply chain configurations (central medical store, vendor managed inventory, private supply chain etc.). Refer to box 6 for a list of common pharmaceutical supply chain configurations. Annex E contains common system models for reference across a variety of technical areas that may form the basis of options during this phase of the analysis.

[3] Adapted from: Lee D. 2010. *From Policy to Practice: Options for USAID Technical Support to Jordan's Pharmaceutical System.* Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health

Box 6. Common Supply Chain Configurations[4]

Although many variations exist, supply systems generally fall into five basic models.

1. **Central Medical Store**
Medicines are financed, procured, and distributed by the government, which owns, funds, and manages the entire supply system.
2. **Autonomous Supply Agency**
Often established under the ministry of health or as independent organizations to combine the benefits of private management with adequate public sector supervision.
3. **Direct Delivery**
Government contracts to establish suppliers and prices, suppliers deliver directly to individual regional/district stores or health facilities.
4. **Primary Distributor**
Central government contracts to establish suppliers and prices, and enters second contract with a primary distributor. The suppliers deliver to the primary distributor, which then delivers to warehouses/medical stores and health facilities.
5. **Private System**
Commercial pharmacies provide all medicines. Governments may contract with pharmacies to provide essential medicines to public sector patients, and pharmacies may be established in public facilities

When designing options for improve supply systems, each of these models may form the basis of an option for intervention. Given the problem, one of these configurations may be a better fit for the country context than the current supply model. For system configurations and intervention categories relating to a variety of technical areas, refer to annex E.

[4] Adapted from: Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies – Chapter 8: Pharmaceutical Supply Strategies*. Sterling, VA: Kumarian Press.

ANALYSIS OF ENABLERS AND BARRIERS

Once options are developed, they must be compared methodically in terms of appropriate criteria, including cost. The characteristics under comparison will vary based on the nature of the identified problem and the options being considered. In general, the following criteria can be adapted to analyze most alternatives. Information should be organized to allow for straightforward comparison across options. Annex F contains several examples of options matrices with theoretical options and criteria for sample problems.

At its core, the analysis of enablers and barriers serves to demonstrate how well each option is expected to work to solve or improve upon identified issues. The baseline assessments from the beginning of the options analysis process should shape this section of the analysis. If several barriers were identified during the assessment, state how each proposed option is expected to impact these barriers. It is possible that options may improve upon certain aspects of the problem, but may exacerbate others. There may not be a perfect option so it is important to analyze options as completely as possible and present stakeholders with all potential outcomes of the interventions under consideration.

Alignment with Policy, Legal, and Regulatory Framework

Consider whether each option aligns or conflicts with existing policies, planned reforms, relevant trends, and priorities. Is option A proposing a decentralized model where current policies favor centralization? Does option B encourage self-regulation and oversight in a context where hierarchical oversight is the norm? These are the types of questions that should be asked when evaluating options in terms of their social and political congruence. Regardless of the technical area or the types of options being analyzed, each must be weighed in terms of political alignment and viability, stakeholder support and opposition, and acceptability to decision makers, funders, managers, and end users and beneficiaries.

In most cases, options will require new or modification of existing policies and may entail changes in the legal and regulatory framework. Evaluate if changes are needed, and if so, what types of changes (for example, development of new or revision of existing policies or legislation, creation of new regulatory or oversight bodies) and the implications of these reforms for implementation (training considerations, length of time required to make changes, approval procedures). Policy and legal reforms usually require the involvement of multiple ministries and government bodies, and take a long time to implement.

Availability of Existing Structures and Resources

These criteria will vary widely depending on the type of problem and the identified options. For example, private sector capacity for supply chain interventions may be assessed and compared based on ISO certification, number and visibility of clients, transportation infrastructure, whether storage facilities have temperature controls, and reporting infrastructure, while interventions for

regulatory systems may consider the available laboratory infrastructure, accreditation schemes for premises or personnel, and inspection criteria.

Information System Requirements

With all interventions, regardless of which pharmaceutical system component is being analyzed, it is important to evaluate options in terms of their impact on information systems. This includes new or changed reporting requirements, information sharing structures, and related responsibilities and functions. It is crucial to consider the reasons why information systems are underdeveloped or underused in the existing system prior to implementing changes or improvements. For example, if a new pharmaceutical workforce cadre is created, their responsibilities must be clearly defined, including who they report to and how they collect and report data to higher levels. Previous staff concerns regarding the reporting requirements in the last configuration should be addressed at this time to increase acceptability and promote effective information system utilization. System alterations are opportunities to increase the availability and quality of information, and this important function of all systems should not be overlooked in their redesign.

Costs and Financing

When analyzing costs for each option, repeat the same costing process used to analyze the current system to compare the costs of different options to one another and to the current system costs. Be careful to consider the perspective of the payer when identifying costs; it is important to distinguish between costs to a specific program, costs to the government health budget, and costs to end users or patients.

Modifying or introducing a government program may save money for the government, but may also shift costs to consumers, potentially creating unintended and undesirable effects. These considerations are important when weighing options, as cost is just one component of the analysis. In addition to projected cost of each option, the source of funds to finance the identified options should be identified and presented, where possible. Identifying possible financing avenues to stakeholders can enhance the perceived viability of options, particularly if the analysis includes practical means to implement them.

Considering Value

Comparing options on the basis of anticipated costs alone can be misleading. While it is important to analyze, anticipate, and present the costs of different options, it’s critical to consider value.

Where two (or more) options are likely to produce similar outcomes by different mechanisms, then comparing costs to find the most efficient path is essential. But where both costs and outcomes of various options differ, it is important to try to identify the option that is most cost effective.

There are various techniques for assessing value, including cost benefit analysis (where costs and benefits can be readily monetized); cost utility analysis (where the anticipated outcomes of the different options under consideration may be measured in terms of improvement in duration and quality of life); or cost consequences analysis (where comparing outcomes that are non- health related or difficult to quantify, including distributional [equity] considerations). Refer to box 7 for more information on these methods.

Box 7. Methods to Analyze Value[5,6]

Many methodologies exist to analyze value, below is a selection of methods that lend themselves well to analyzing health system interventions –

Cost Benefit Analysis
Compares the cost and benefits of an intervention by translating the health benefits into a monetary value, so that both costs and benefits are measured in the same unit

Cost Utility Analysis
Measures both costs and benefits of alternatives to find the strategy with the best ratio of benefits, measured in units of "utility" (results are usually compared using cost per QALY or DALY)

Cost Consequences Analysis
Does not pull costs and benefits into the same unit, rather it reflects that benefit types differ and not all may be compared or measured using the same units. This distinguishes it from cost-effectiveness analysis, where the units of outcome must be the same for the interventions being compared. The assumption is that in making decisions based on a CCA, different decision makers will place their own weights on the different benefits and costs, implicitly if not explicitly. CCA is sometimes referred to as a disaggregated approach, because the benefits and costs are not combined into a single indicator such as net benefit or a cost-effectiveness ratio.

For more information, refer to MDS-3 Chapter 10.7 and Drummond et al

Public and Private Capacity

When designing options, outsourcing key functions to the private sector should be considered where appropriate. Even if outsourcing is not politically or financially viable, it is useful to examine how other players in the country operate. This may include networks of non-governmental organizations, other public programs, or the private sector. These comparisons may highlight why the system under analysis is failing to achieve objectives or deliver services effectively.

[5] Adapted from: Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies – Chapter 10.7: Economic Evaluation of Pharmaceutical Products.* Sterling, VA: Kumarian Press.
[6] Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the economic evaluation of health care programmes.* Oxford university press; 2015 Sep 24.

During the analysis of enablers and barriers, thoroughly examine the capacity of the private and public sectors to perform the proposed tasks. There may be instances where functions that are performed in the public sector should be outsourced and others where third-party performance of functions should be retained in the public sector (for example, regulatory or oversight functions require careful consideration when outsourcing is proposed). Metrics to evaluate public and private capacity may include staffing levels, certifications, number and visibility of clients, and geographic reach.

Sustainability

Sustainability is a key factor to consider when evaluating options. Something that is effective in the short term may not be the most efficient or sustainable, once resources are exhausted. However, given resource constraints or the capacity of the system, it may not be possible to implement sweeping reforms and instead require short term or temporary interventions as a preliminary step to sustained improvements. For example, if a country faces a shortage of pharmacists, creating a new pharmacy technician cadre is a sustainable option, but would take time to implement. In the immediate term, importing foreign health workers to fill the existing gap may be a requisite first step before larger, longer term reforms can be realized. Such observations should be presented in the analysis conclusions and should be mindful of country context. Presenting a mix of options that represent both immediate improvements and long-term goals can help decision makers implement needed changes at present and set future targets.

When evaluating sustainability of options, the following questions can guide the analysis:

- Are the options under consideration long-term solutions or short-term measures?
- Are the costs associated with them sustained over long periods (or indefinitely) or one time payments?
- Do options depend on donor support or other resources that may diminish over time?
- Does the system have the technical capacity to maintain the interventions or will this require prolonged technical assistance?
- Can capacity be built into the system to promote country ownership and sustainability and, if so, what are the implications in terms of resources and time?

DECISION MAKING AND CONSENSUS

Box 8. Decision Making Support in El Salvador[7]

The Problem: Stock-outs of formulary medicines despite sufficient funding for product procurement

The Goal: Improve institutional supply chain performance

Options:
1. Strengthen current in-house supply chain operations
2. Contract with suppliers for direct delivery
3. Contact third party logistics services
4. Use retail pharmacies for dispensing

Key Stakeholders Engaged:
- Social Security Chief Executive Officer
- Social Security health and supply system managers
- Social Security board members

Decision Making Support:
- Presentation of analysis to decision makers
- Facilitation of the discussion of the way forward
- Held small and large group meetings with senior managers and board members to develop an action plan

Once options are developed and analyzed, the results of the analysis should be disseminated to stakeholders so that they may evaluate the findings and convene to select options and develop an action plan. Decision making may occur in a variety of settings, ranging from a small, closed-door meeting to a series of public workshops. The form of the decision making or consensus building process will depend on the country context, and whether key stakeholders prefer to keep the process small in scope or open it up to a wider audience.

Decision making should involve a discussion of all of the presented options and debate regarding the advantages and limitations of each. Ideally, stakeholders should move toward consensus in terms of favored options while weighing the findings of the analysis. Keep in mind that the options analyzed may be hybridized to form a final solution to the issue at hand, as decision-makers may pick aspects of multiple options to combine. An example of decision making support provided for an options analysis performed in El Salvador can be found in box 8.

Not all stakeholders have the same goals and there may be strong resistance to proposed interventions due to vested interests. To manage this contingency, it is important to thoroughly map stakeholders so that the analysis team and other partners or stakeholders are aware of the interests in play. Advocacy for reform is also key before and during the options analysis process to promote change and build support. The options analysis process itself can be an opportunity to promote reform by demonstrating savings or benefits associated with interventions. For example, one country shifted procurement to the Global Drug Facility mechanism against the preference

[7] Adapted from: Lee D. et al. 2000. *Reforma del Sistema de Suministro de Medicamentos: Análisis de Sistemas Alternativos.* Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus (RPM Plus) Program. Arlington, VA: Management Sciences for Health.

of the national procurement body because the benefits of the switch were presented to higher level officials who did not have a vested interest in this process.

With politically fraught areas of intervention, such as governance, the options analysis process may not proceed directly to decision making and consensus but instead move more slowly and carefully toward a transparent decision-making process. Consider available entry points to engage with decision makers and identify opportunities for progress toward decision making and consensus. It is possible that before larger options be considered, the context requires smaller, incremental changes to prepare. Examples include initiatives to increase transparency, developing supportive policies, laws, and standards, developing standard operating procedures for the decision making process, or strengthening the capacity of oversight bodies to monitor the process.

Building Consensus[8]

Consensus is defined as "agreement among all participating stakeholders."[8] In the options analysis approach, it is strongly recommended that consensus should be achieved; however, it should not be required to make a decision and move forward. Groups that seek consensus but do not achieve it should acknowledge dissent respectfully and should have ground rules in place in advance that allow them to select options that are supported by the vast majority of stakeholders represented. In some cases, one stakeholder or smaller group will have final authority to make the decision, depending on the country context. In these cases, it is still important to strive for consensus among representative stakeholders, as this can increase support for the final decision and promote acceptance.

Consensus can be built through advocacy for reform prior to the decision making and consensus building process. Once selected stakeholders are convened, options and evidence should be presented and discussed. In discussions, ensure that each stakeholder or group is permitted to share their opinions and voice their support or misgivings. Acknowledging dissent is an important first step to address a potential impasse.

Once support begins to build for a particular option or set of options, re-engage stakeholders that are withholding their support to understand their reservations. Details of the intervention package may need to be clarified or changed to garner their endorsement. Revision of details may be all that is needed to achieve unanimous support. Another way to increase support for presented options is to clarify goals and aspirations. Certain stakeholders may not be willing to compromise on incremental reform, which may be impractical given the context. If stakeholders can agree on a reasonable endpoint, unrealistic expectations can be managed and stakeholders may be more willing to work with the proposed options for intervention. Detailed contingency planning may address uncertainties about the selection of options. For example, – certain groups may not want to endorse a given option because they are unsure about the ramifications if

[8] Susskind, L., KcKearnan, S., Thomas-Larmer, J. 1999. *The Consensus Building Handbook.* The Consensus Building Institute. SAGE Publications: Thousand Oaks, CA. ISBN 0-7619-0844-7

implementation does not go as expected. In these situations, developing a contingency plan can put stakeholders' minds at ease, enabling them to select an option or options and move forward.

If these conflict resolution techniques do not succeed, and further improvements to the options cannot break an impasse, stakeholders should make a decision that satisfies a great majority of stakeholders, and should carefully consider how to present dissenting views on the final selection without alienating opposing groups or undermining support for the final decision.[8]

Roadmap and Commitment

Once the option or options are selected, stakeholders should begin to develop their chosen option(s) into actionable interventions. This includes breaking the solution down into progressive steps, refining projected costs in an intervention budget, selection of indicators to monitor intervention progress and outcomes, and allocating tasks, timelines, and benchmarks to specific departments or technical partners.

Stakeholders may not be able to complete the planning process within the scope of a single decision making meeting, but it is important to continue engaging stakeholders and encouraging road mapping and planning for implementation. Without operationalizing the options with continued stakeholder support, the outcome of the options analysis is a largely theoretical intervention that may never be put into action in the absence of thorough planning, budgeting, and assignation of responsibilities and next steps.[9] Some common elements to consider in implementation planning include:

- Building in referenda – allowing constituents to vote on proposed changes to build in sustainability so that political will is expressed across changes in political leadership
- Developing implementation working groups to maintain momentum and monitor progress and outcomes
- Partnering across organizations and sectors to spread ownership of the process and encourage coordination

Refer to annex G for a sample stakeholder commitment plan.

[9] WHO and Stop TB Partnership. 2008. *Engaging Stakeholders for Retooling TB Control*. Geneva: WHO. Available from: http://www.stoptb.org/assets/documents/global/retooling/Retooling_Stakeholders.pdf

CONCLUSIONS

The options analysis approach is designed to account for the specific context of the country setting and the problem to be solved. Rather than provide technical assistance through qualitative expert assessment accompanied by a series of recommendations, the options analysis methodology is based on an engaged understanding of the current system and a thorough investigation of the problem in question through indicator-based assessment tools and qualitative techniques to identify alternative solutions to address the problem and its underlying factors.

Stakeholder engagement is the hallmark of an effective options analysis. Stakeholders should be involved from the beginning of the process to its conclusion, informing everything from the development of the assessment tool to the vetting of options. They should be informed as the analysis progresses to ensure transparency and to promote their ownership of the assessment results and their support of the selected option for implementation.

Through the application of this approach, technical assistance providers, policymakers, and key stakeholders in pharmaceutical systems can support informed decision making and sustainable system strengthening. Expanded stakeholder involvement in the technical assistance process promotes country ownership and follow through, and can increase the likelihood that interventions will be embraced by the people who will carry out and be impacted by proposed changes.

A NOTE ON THE ANNEXES

The remainder of this text contains reference materials for conducting an options analysis. These resources are a combination of cross-cutting (references and further reading, annex A, annex B, annex D, annex G) and technical area-specific tools (Annexes C, E, and F). They are intended to structure the analysis and provide specific considerations and examples that pertain to each technical area discussed in the paper. These tools may be adapted to suit varying options analysis contexts and scenarios.

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69. Management Sciences for Health. 2011. *Building Local Coalitions for Containing Drug Resistance: A Guide.* Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.
70. Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies – Chapters 27-35.* Sterling, VA: Kumarian Press.
71. Systems for Improved Access to Pharmaceuticals and Services Project. 2015. *Developing, Implementing, and Monitoring the Use of Standard Treatment Guidelines: A SIAPS How-to Manual*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health. This document can be downloaded at: www.siapsprogram.org/publication/stg-how-to-manual
72. World Health Organization. 1993. *How to investigate drug use in health facilities: selected drug use indicators.* EDM Research Series No. 007. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js2289e/
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74. World Health Organization. 2015. *Global Action Plan on Antimicrobial Resistance.* Geneva: WHO. Available from: http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1

Other Resources

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76. Lee D. et al. 2000. *Reforma del Sistema de Suministro de Medicamentos: Análisis de Sistemas Alternativos*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus (RPM Plus) Program. Arlington, VA: Management Sciences for Health.
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78. Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies – Chapter 41 Section 4: Costing*. Sterling, VA: Kumarian Press.
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81. World Health Organization. 2010. *Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies*. Geneva: World Health Organization. http://www.who.int/healthinfo/systems/monitoring/en/
82. World Health Organization and Stop TB Partnership. 2008. *Engaging Stakeholders for Retooling TB Control.* Geneva: WHO. Available from: http://www.stoptb.org/assets/documents/global/retooling/Retooling_Stakeholders.pdf

ANNEX A. STAKEHOLDER IDENTIFICATION WORKSHEET

Use this worksheet to identify and map stakeholders. The first two columns help to organize stakeholders, and the Underlying Factors section allows the user to mark how the identified stakeholder intersects with the identified problem and its underlying factors. Begin with the first two columns of the worksheet at the beginning of the stakeholder engagement process. As the options analysis progresses and underlying factors are identified, complete the Underlying Factors section. Once existing stakeholders have been mapped against underlying factors, you may need to identify additional stakeholders to fill in gaps.

Note: The forms have been reformatted somewhat to fit on the page.

Sample Form[10]

Name of Stakeholder (Organization, group or individual at national, regional or local level)	**Stakeholder Description** (Primary purpose, affiliation, funding)	**Underlying Factors**				
		Underlying Factor A	**Underlying Factor B**	**Underlying Factor C**	**Underlying Factor D**	**Underlying Factor E**
Government Sector						
Ministry of health (various departments)						
Ministry of finance (health budgets)						
Political Sector						
National policy-maker						
Municipality						

[10] Adapted from: Management Sciences for Health. 2011. *Building Local Coalitions for Containing Drug Resistance: A Guide*. Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.
And WHO and Stop TB Partnership. 2008. *Engaging Stakeholders for Retooling TB Control*. Geneva: WHO. Available from: http://www.stoptb.org/assets/documents/global/retooling/Retooling_Stakeholders.pdf

Name of Stakeholder (Organization, group or individual at national, regional or local level)	**Stakeholder Description** (Primary purpose, affiliation, funding)	**Underlying Factors**				
		Underlying Factor A	**Underlying Factor B**	**Underlying Factor C**	**Underlying Factor D**	**Underlying Factor E**
Funders						
Donor						
Insurer						
Regional Bank/ World Bank						
Global/Regional partnerships						
Stop TB						
Roll Back Malaria						
World Health Organization						
NGOs/other private philanthropic organizations						
Local						
International						
Faith-based						
Health care providers						
Professional organizations						
Specialists						
Primary care physicians						
Laboratory Services						
National reference laboratory						
Academic institutions						

Name of Stakeholder (Organization, group or individual at national, regional or local level)	**Stakeholder Description** (Primary purpose, affiliation, funding)	**Underlying Factors**				
		Underlying Factor A	**Underlying Factor B**	**Underlying Factor C**	**Underlying Factor D**	**Underlying Factor E**
Logistic Providers and Distributors						
Public						
Private						
Educators and Trainers						
Professional training institutions and councils						
Research institutions						
Commercial Sector						
Suppliers						
Manufacturers						
General Public						
Consumer groups						
Special interest groups/ vulnerable populations						
News media and journalists						
Foreign correspondents						
Health reporters						
Radio, TV stations						

Example of a Completed Form

Sample problem: Antimicrobial resistance to artemisinin-based combination therapies
Sample underlying factors: Low availability of combination therapies, inappropriate use, inappropriate prescribing, data on antimicrobial resistance patterns is unavailable, poor inventory management at health facility levels

Note: the form has been reformatted somewhat to fit on the page.

Name of Stakeholder (Organization, group or individual at national, regional or local level)	Stakeholder Description (Primary purpose, affiliation, funding)	Underlying Factor				
		Irregular Supply Chain and Medicine Availability	Poor Availability and Use of Information	Poor Inventory Management	Inappropriate Use	Suboptimal Service Delivery
Government Sector						
Ministry of Health National Malaria Program	Department that steers and directs malaria program implementation and spearheads malaria treatment introduction and protocols	✓	✓	✓	✓	✓
National Essential Medicines List Committee	Group of technical experts who evaluate and approve new medicines or treatment regimens for use in the public sector	✓				
National Medicines Regulatory Authority	Agency that evaluates, approves and licenses new medicines and treatment regimens	✓				
Ministry of Finance (health budgets)	Agency that facilitates development and review of budget and provides public funds	✓	✓	✓		✓
Political Sector						
National policy-maker	Individuals who mobilize high-level political will Individuals who ensure appropriate financing	✓	✓	✓	✓	✓
Municipality	Local government unit that ensures appropriate financing for health care	✓	✓	✓	✓	✓

Name of Stakeholder (Organization, group or individual at national, regional or local level)	Stakeholder Description (Primary purpose, affiliation, funding)	Underlying Factor				
		Irregular Supply Chain and Medicine Availability	Poor Availability and Use of Information	Poor Inventory Management	Inappropriate Use	Suboptimal Service Delivery
Funders						
Global Fund to Fight AIDS, Tuberculosis and Malaria	International donor organization that provides grants for the purchase of malaria related commodities	✓				
USAID	United States Agency that funds technical assistance related to health in select countries	✓	✓	✓	✓	✓
President's Malaria Initiative	American initiative that funds technical assistance related to malaria prevention and control, and procures malaria related commodities for donation	✓	✓	✓	✓	✓
Global/Regional Partnerships						
Roll Back Malaria	Global partnership that seeks to scale up malaria-control efforts at country level, coordinating partner activities to avoid duplication and fragmentation, and to ensure optimal use of resources.	✓	✓	✓	✓	✓
WHO group for Emergency Response to Artemisinin Resistance (ERAR) in the Greater Mekong Sub-Region		✓	✓	✓	✓	✓
NGOs/Other Private Philanthropic Organizations						
Local	Organization that may provide primary care services, donate or distribute malaria commodities	✓		✓	✓	✓
International	Organization that may provide primary care services, donate or distribute malaria commodities	✓		✓	✓	✓

Name of Stakeholder (Organization, group or individual at national, regional or local level)	Stakeholder Description (Primary purpose, affiliation, funding)	Underlying Factor				
		Irregular Supply Chain and Medicine Availability	Poor Availability and Use of Information	Poor Inventory Management	Inappropriate Use	Suboptimal Service Delivery
Health Care Providers						
National Medical Association	Professional organization for physicians. May set professional guidelines and train on SOPs, STGs, etc.		✓	✓	✓	✓
Specialists	Heads of relevant medical departments in key hospitals, researchers, disease or topic experts		✓			
National Coalition of Primary Care Nurses	Professional group for primary care nurses. May set professional guidelines and train on SOPs, STGs, etc.		✓	✓	✓	✓
National Pharmacists' Association	Professional group for pharmacists. May set professional guidelines and train on SOPs, STGs, etc.	✓	✓	✓	✓	✓
Community Health Workers	Support malaria diagnostics and treatment through community case management	✓	✓	✓	✓	✓
Laboratory Services						
National Reference Laboratory	Performs central level surveillance testing of antimicrobial resistance. Sets norms and standards for diagnostic testing at peripheral levels		✓			
Logistic Providers and Distributors						
Public	Department that manages distribution functions, and administrative aspects of logistic services	✓	✓			
Private	Private organizations that currently distribute malaria commodities and/or manage logistics, or could possibly perform this function in the future	✓	✓			

Name of Stakeholder (Organization, group or individual at national, regional or local level)	Stakeholder Description (Primary purpose, affiliation, funding)	Underlying Factor				
		Irregular Supply Chain and Medicine Availability	Poor Availability and Use of Information	Poor Inventory Management	Inappropriate Use	Suboptimal Service Delivery
Educators and Trainers						
Professional training institutions and councils	Provide training and generate and/or disseminate educational materials regarding malaria, malaria prevention, and appropriate treatments			✓	✓	✓
Research institutions	Generate information that may be used to educate patients, health providers, and other decision makers		✓			
Commercial Sector						
Suppliers	Include wholesalers and other entities that sell antimalarials and other malaria commodities (diagnostic tests, bed nets, etc.)	✓				
Manufacturers	Produce malaria commodities	✓				
General Public						
Consumer groups	Patient safety and advocacy groups		✓		✓	
Special interest groups/vulnerable populations	Malaria patient support groups		✓		✓	
News Media and Journalists						
Foreign correspondents	May disseminate information about malaria (background information, outbreak reporting, trends)		✓			
Health reporters	May disseminate information about malaria (background information, outbreak reporting, trends)		✓			
Local news media	Includes radio stations and newspapers that may be used to disseminate messages targeting patients, health providers, or policy makers		✓		✓	✓

ANNEX B. DOCUMENT REVIEW WORKSHEET

Keyword(s) used in search	**Full Reference** (Including link, where applicable)	**Key information areas** (Medicines policy, regulation, selection, procurement, distribution, use, quality, availability, management support, education/training, surveillance, advocacy, media, etc.)	**Enablers** (to access, of appropriate use, of GMP etc.)	**Barriers**	**Other Relevant Information**	**Comments/ Notes**
Example: Philippines, tuberculosis, medicine, stock-out	Islam, T., van Weezenbeek, C., Vianzon, R., Garfin, A. M. C. G., Hiatt, T., Lew, W. J., & Tisocki, K. (2013). Market size and sales pattern of tuberculosis drugs in the Philippines. *Public Health Action,* 3(4), 337-341. http://www.ingentaconnect.com/content/iuatld/pha/2013/00000003/00000004/art00017	Availability, medicines policy, regulation, access	**Identified enablers of access to TB medicines in the Philippines**: - Public procurement of TB treatment kits (first line) for category I and category III kits (both used for new cases of TB) was sufficient to cover all reported new cases of TB for the study period (2008-2011), with substantial buffer stock	- Public Procurement of category II (for retreatment cases of TB) TB treatment kits was irregular, not always centralized, and insufficient to meet needs during the study period (2008-2011) - 38 TB drug formulations of 28 different strengths available in the private sector in 2011 (variability in treatment protocols, efficacy. - Does not adhere to recommended best practices for TB treatment, WHO guidelines) - No built in mechanism in government data collection system to capture TB cases outside of the NTP	Contains diagram of public sector TB medicine flow from suppliers to distribution channels	What is the best way to engage the private sector in TB treatment? Public-private mix model was initiated early in the Philippines, but mixed coverage is limited, TB treatment = immense out of pocket expenditure for many

ANNEX C. LIST OF INDICATOR-BASED ASSESSMENT TOOLS

Pharmaceutical Systems

1. MSH/RPM (Management Sciences for Health/Rational Pharmaceutical Management Project). 1995. *Rapid Pharmaceutical Management Assessment: An Indicator-Based Approach.* Arlington, Va.: MSH/RPM. http://erc.msh.org/newpages/english/toolkit/rpma.pdf
2. World Health Organization. 2007. WHO Operational Package for Assessing, Monitoring and Evaluating Country Pharmaceutical Situations: Guide for Coordinators and Data Collectors. Geneva: WHO. http://www.who.int/medicines/publications/WHO_TCM_2007.2.pdf
3. World Health Organization. 2006. Using Indicators to Measure Country Pharmaceutical Situations: Fact Book on WHO Level I and Level II Monitoring Indicators. Geneva: WHO. http://www.who.int/medicines/publications/WHOTCM2006.2A.pdf
4. World Health Organization/WHO AIDS Medicines and Diagnostics Service. Developed 2007, continuously updated. *The Procurement and Supply Management Toolbox.* [Internet] Available from: http://www.psmtoolbox.org/en/tools.php

Supply Chain Management

5. World Health Organization. 2012. *Tools for mapping financial flows for medicines procurement and distribution, and for rapid assessment of medicines supply management systems*. Geneva: WHO. http://www.who.int/medicines/areas/access/tata_tool_24Aug2012.pdf?ua=1

Regulatory Systems

6. Management Sciences for Health. Draft as of February 2016. *Regulatory Systems Assessment Tool.*
7. Pan American Health Organization. Revised 2009. *Manual para la evaluación de autoridades nacionales para medicamentos y productos biológicos.* Available from: http://www.paho.org/HQ/index.php?option=com_content&view=article&id=1615%3A2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&catid=1267%3Aquality-drug-regulation&Itemid=1179&lang=en
8. Strengthening Pharmaceutical Systems (SPS) Program. 2009. *Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries.* Submitted to the U.S. Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health.
9. U.S. Pharmacopeia – Drug Quality and Information Program. March 2007. *Rapid Assessment of Medicines Quality Assurance and Medicines Quality Control.* Available from: http://www.usp.org/sites/default/files/usp_pdf/EN/dqi/rapidAssessmentTool.pdf
10. World Health Organization. WHO Regulatory Package. Updated July 2014. Available from: http://infocollections.org/medregpack/interface/home.htm

11. World Health Organization. 2012. *Assessment Criteria for National Blood Regulatory Systems.* Available from: http://www.who.int/bloodproducts/NationalBloodRegSystems.pdf
12. World Health Organization. 2011. *Harmonized NRA assessment tool – for vaccines.* Available from: http://www.who.int/immunization_standards/national_regulatory_authorities/tools_revision_2014/en/
13. World Health Organization. 2007. *WHO data collection tool for the review of drug regulatory systems & Practical Guidance for Conducting a Review*. Geneva: WHO. Available from: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en/

Financial Management

14. Management Sciences for Health. 2010. The Financial Management Assessment Tool (FinMAT). Cambridge, MA: MSH. Available from: http://www.msh.org/resources/financial-management-assessment-tool-finmat?keywords=&field_resource_type[0]=Tool&page=1
15. World Health Organization. *OASIS:* http://www.who.int/health_financing/tools (Organizational Assessment for Improving & Strengthening Health Financing – to analyze performance of a health financing system by assessing key design issues and implementation, identify bottlenecks in the way institutions and organizations function and help in finding institutional and organizational alternatives.)

Governance

16. WHO. (2009). Measuring transparency in the public pharmaceutical sector. Assessment instrument. Geneva: World Health Organization. http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspENG.PDF
17. Brudon, P., Rainhorn, J. D., Reich, M. R. (1999). Indicators for monitoring national drug policies: a practical manual. Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf

Human Resource Management

18. Management Sciences for Health. 2012. Human Resource Management Rapid Assessment Tool for Health Organizations: A Guide for Strengthening HRM Systems. 3rd Edition. Cambridge, MA: MSH. Available from: https://www.msh.org/sites/msh.org/files/hrm_tool_version_3_2012_final_webv.pdf
19. Human Resources Management Rapid Assessment Tool for HIV/AIDS Environments: A Guide for Strengthening HRM Systems http://erc.msh.org/newpages/english/toolkit/hr_hiv_assessment_tool.pdf
20. Human Resources Management Rapid Assessment Tool for Private- and Public-Sector Health Organizations: A Guide for Strengthening HRM Systems http://erc.msh.org/newpages/english/toolkit/hrd.pdf

21. Management Sciences for Health. 1998. *The Health and Family Planning Manager's Toolkit: Supervisor Competency Self-Assessment Inventory*. Boston: MSH. Available from: http://erc.msh.org/newpages/english/toolkit/supervis.pdf
22. Management Sciences for Health. 2003 – Updated 2005. *Workgroup Climate Assessment (WCA) Tool and Guide for Facilitators*. Available from: https://www.msh.org/resources/workgroup-climate-assessment-wca-tool-and-guide-for-facilitators

Information Systems

23. Management Sciences for Health. 1997. *Warehouse Information System Assessment Tool.* Boston, MA: MSH. Available from: http://www.msh.org/resources/warehouse-information-system-assessment?field_resource_type[0]=Tool
24. WHO/WPRO (World Health Organization/Regional Office for the Western Pacific). Developing Health Management Information Systems: A Practical Guide for Developing Countries. Geneva: WHO. Available from: http://www.wpro.who.int/health_services/documents/developing_health_management_information_systems.pdf
25. Reynolds, J. 1993. "Assessing Information Needs" (User's Guide, Module 1). In Primary Health Care Management Advancement Programme. Geneva: Aga Khan Foundation. Available from: https://pglibrary-publichealth.wikispaces.com/file/view/Module+1+Assessing+Information+Needs+(Facilitator's+Guide).pdf

Appropriate Medicines Use

26. World Health Organization. 2003. Introduction to Drug Utilization Research. Geneva: WHO. Available from: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Drug%20utilization%20research.pdf
27. Strengthening Pharmaceutical Systems. How to Investigate Antimicrobial Use in Hospitals: Selected Indicators. Published for the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health. (February 2012). Available from: http://apps.who.int/medicinedocs/en/d/Js21031en/
28. Management Sciences for Health, Center for Pharmaceutical Management. Antimicrobial Resistance Module for Population-Based Surveys. Submitted to the U.S. Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health. (2008). Available from: http://projects.msh.org/projects/rpmplus/Documents/upload/AMR_Mod_8_5_8_FINAL.pdf
29. World Health Organization. (2009). Medicines use in primary care in developing and transitional countries – Fact Book summarizing results from studies reported between 1990 and 2006. Geneva: World Health Organization. Available from: http://www.who.int/medicines/publications/who_emp_2009.3/en/

ANNEX D. LIST OF COSTING TOOLS

For additional guidance on costing methodology, please refer to Chapter 41, Section 4, of the MDS-3.[11]

1. Marginal Budgeting for Bottlenecks Toolkit Developed by UNICEF and World Bank – Version 5.6 (2011) Available from: http://www.devinfolive.info/mbb/mbbsupport/index.php
    - Helps users design, plan, and budget health programs related to maternal and child health.

2. Integrated Healthcare Technology Package (iHTP) Simulation Tool developed by WHO and the Medical Research Council of South Africa – Version 2.1.8 (2015) Available from: http://www.ihtp.info/
    - Helps users determine which health services and interventions are necessary based on target population demographics, disease profiles and cost-effectiveness. Incorporates intervention and service costing and can indicate whether all required resources for a defined set of interventions are available.

3. OneHealth Tool developed by the International Health Partnership – Version 4.32 (July 2015) Available from: http://www.avenirhealth.org/software-onehealth
    - Used for supporting the costing, budgeting, financing and national strategies development of the health sector in developing countries with a focus on integrated planning and strengthening health systems. Allows for program specific costing as well as health system component costing.

4. Planning, Costing and Budgeting Framework developed by Management Sciences for Health – (August 2007) Available from: http://erc.msh.org/mainpage.cfm?file=9.33.htm&module=toolkit&language=English
    - Allows users to clearly identify the linkages between all elements of a plan – the activities, strategies, objectives and goals, and the budget that would be required to achieve these goals and objectives.

5. HOSPICAL: A Tool for Allocating Hospital Costs developed by Management Sciences for Health. Available from: http://erc.msh.org/mainpage.cfm?file=5.15.htm&module=toolkit&language=English
    - Helps users to improve hospital performance and make decisions about resource allocation within or among hospitals.

6. Community Health Services Costing Tool developed by Management Sciences for Health – Available from: http://www.msh.org/resources/community-health-services-costing-tool

[11] Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies – Chapter 41 Section 4: Costing.* Sterling, VA: Kumarian Press.

- Helps users estimate the costs of providing health services at the community level. It can be used for individual community services, packages of services, or for all community services. It can be used to calculate the current costs and/or the costs of starting a new program or scaling up an existing one.

7. TB Service Delivery Costing Tool developed by Management Sciences for Health. Available from: http://www.msh.org/resources/tb-service-delivery-cost-tool
    - Helps users gain a better understanding of the current and future cost of TB programs to help identify where greater efficiency and cost-effectiveness can be achieved and to help advocate for the provision of adequate funding.

8. TB Economic Burden Analysis Tool developed by Management Sciences for Health.Available from: http://www.tbcare1.org/publications/toolbox/costing/
    - Helps users to assess the economic burden of TB on society at national and subnational levels. Although the tool was developed for TB services, it could be adapted for other vertical programs, such as malaria and HIV/AIDS. **Please note that other TB-specific costing tools are also available through the link above.**

9. Integrated Community Case Management (iCCM) Costing and Financing Tool developed by Management Sciences for Health – Version 1.0 (October 2013) Available from: http://www.msh.org/resources/integrated-community-case-management-costing-financing-tool
    - Results and analysis provide evidence-based data for implementing, scaling-up, and maintaining iCCM activities that enable funding advocacy, conducting feasibility/sustainability studies, assessment of cost-effectiveness, and planning financing strategies and mechanisms.

10. Cost Revenue Analysis Tool Plus (CORE Plus) developed by Management Sciences for Health – Available from: http://erc.msh.org/toolkit/Tool.cfm?lang=1&CID=3&TID=113
    - Helps managers and planners estimate the costs of individual services and packages of services in primary health care facilities as well as total costs for the facilities.

11. Goals Model Developed (Part of Spectrum) developed by Constella Futures/Futures Institute – Version 5.32 (July 2015) and Resource Needs Model (also part of Spectrum) Both available from: http://www.avenirhealth.org/software-spectrum.php
    - The Goals Model helps efforts to respond to the HIV/AIDS epidemic by showing how the amount and allocation of funding is related to the achievement of national goals, such as reduction of HIV prevalence and expansion of care and support.
    - The Resource Needs Model estimates the costs of implementing an HIV/AIDS program, including costs for care and treatment, prevention programs, and policy and program support.

12. cMYP Costing and Financing Tool developed by WHO, Version 3.8 (March 2015) Available from:
    http://www.who.int/immunization/programmes_systems/financing/tools/cmyp/en/
    - Enables users to plan costing and financing aspects of national immunization programs. Part of the WHO-UNICEF guidelines for developing a comprehensive multi-year plan for immunization.

13. Integrated Health Model Developed by the United Nations Development Programme, Version 3.0 (July 2009) Available from:
    http://www.undp.org/content/dam/undp/library/Poverty%20Reduction/MDG%20Needs%20Assessment%20Tools/Copy%20of%20Integrated_HealthTool.xls
    - Assists countries to estimate required resources to meet health-related MDGs. Uses multiple vertical costing models for various health programs combined within the greater health system.

14. Planning & Budgeting for TB Control Developed by WHO, Version 6 (January 2015) Available from: http://www.who.int/tb/dots/planning_budgeting_tool/download/en/
    - This tool is designed to help countries develop plans and budgets for TB control at national and sub-national level within the framework provided by the Global Plan and the Stop TB Strategy. These plans can be used as the basis for resource mobilization from national governments and donor agencies.

15. Malaria Cost Estimation Tool (part of CHOICE) developed by WHO. Available from: http://www.rollbackmalaria.org/toolbox/tool-search#!/23/view
    - The Malaria Costing Tool estimates the resource requirements of proven malaria interventions over a period of time. The tool is based on a review of costing studies and an extensive consultation with malaria experts.

16. Child Health Cost Estimation Tool (part of CHOICE) developed by WHO. – Available from: http://www.who.int/maternal_child_adolescent/news_events/news/2010/05_10/en/
    - The tool allows managers and planners to determine the financial requirements associated with scenarios for scaling up health interventions provided to children under five years, over a period of time (1-10 years).

ANNEX E. SYSTEM MODELS AND CONFIGURATIONS

This annex contains common models and configurations for the major pharmaceutical system components identified in the paper. Models are proposed for supply chain systems, pharmaceutical regulatory systems, and information systems. Configurations for financing systems for pharmaceuticals under universal health coverage and pharmaceutical human resources are also proposed below.

Appropriate use of medicines and good governance are determined by behaviors of actors within pharmaceutical systems, and existing system constructs. Governance concerns the process of decision making and how these decisions are implemented at all levels of the pharmaceutical system, and therefore is crosscutting in pharmaceutical systems. Appropriate use is defined by a cluster of behaviors, and, like governance, is inherently non-structural, unlike the aforementioned pharmaceutical system components. Literature regarding governance and appropriate use of medicines aims to identify principles and set out best practices and strategies for improving adherence to these principles and practices. In general, a combination of selected strategies should be employed to improve adherence to principles and practices of good governance and appropriate medicines use. The tables for these components are organized by categories of intervention rather than presenting alternatives for models or configurations. Frequently, interventions that promote good governance or appropriate use of medicines are embedded within options for other system components. For example, supply chain improvements can make procurement processes less vulnerable to interference, and improved regulatory capacity at the national medicines regulatory authority can promote adherence to regulated prescribing and dispensing practices.

Use these tables to develop alternative options for analysis. The options analysis approach is typically used at high levels of the pharmaceutical system, and oftentimes options will involve reconfiguring system components. The proposed models, configurations, and categories of interventions for these components are intended as a starting point for the development of specific options that account for country context.

Supply Chain Models

This table identifies several common pharmaceutical supply system models. Selected advantages and limitations for each model are included for illustrative purposes only, as these are principally dependent on system context and the identified problem. Note that many supply systems represent hybrids of these models, but they are presented here to shape options for analysis when evaluating models for pharmaceutical supply chains.

Supply Chain Model	Advantages	Limitations
Central Medical Store • Traditional public sector pharmaceutical supply system • Medicines are procured and distributed by a centralized government unit • Contracting of suppliers and storage/delivery are the responsibility of the central medical store, medicine monitoring and quality are the responsibility of the central medical store and the national regulatory authority	• Maintains government control over entire system • Is easy to monitor	• High capital cost for offices, storage, and transport facilities • Recurrent cost of staff, transport, other operating costs • Limited incentive for efficiency • Open to political and other interference
Autonomous Supply Agency • Bulk procurement, storage, and distribution managed by autonomous or semi-autonomous agency • Contracting of suppliers and storage/delivery are the responsibility of the autonomous agency, monitoring of medicine quality is the shared responsibility of the pharmaceutical procurement office, autonomous supply agency, and the national regulatory authority	• Maintains advantages of centralized system • Flexibility in personnel and management systems may improve efficiency • Is less open to interference • Separate finances facilitate revolving drug funds	• Cost and effort of establishing supply agency • May retain some constraints of central medical store model • Limited competitive pressure for efficiency if operated as monopoly
Direct Delivery System • Decentralized approach; tenders establish the supplier and price for each item; medicines delivered directly by supplier to districts and major facilities • Contracting suppliers is the responsibility of the pharmaceutical procurement office, storage and delivery are the responsibility of the suppliers, and monitoring of medicine quality is the responsibility of the pharmaceutical procurement office and the national regulatory authority	• Eliminates cost of government-operated storage and distribution • Decentralized order quantities and delivery help adjust to variations in seasonal and local demand • Maintains price benefits of centralized tendering • Reduces inventory costs and expiration for high-cost, low-volume medicines	• Coordination and monitoring of deliveries, payments, and quality are demanding • Feasible only where adequate private infrastructure exists • Suppliers limited to those able to ensure local distribution (may reduce competition, increase cost) • Direct delivery by multiple suppliers (especially to remote areas) is inefficient, may raise costs

Supply Chain Model	Advantages	Limitations
Primary Distributor (Prime Vendor) System • PPO establishes contracts with pharmaceutical suppliers and separate contract with a single primary distributor, which warehouses and distributes medicines to districts and major facilities • Contracting of suppliers is the responsibility of the pharmaceutical procurement office, storage and delivery are the responsibility of the primary distributor, and monitoring of medicine quality is the shared responsibility of the pharmaceutical procurement office and the primary distributor	• Maintains advantages of single distribution system • Potential primary distributors compete on service level and cost	• Monitoring of service level and pharmaceutical quality is demanding • Competition depends on well developed private distribution system
Primarily Private Supply • Private sector manages all aspects of pharmaceutical supply • Contracting of suppliers, and storage and distribution are the responsibility of the suppliers and the private enterprises that dispense medicines; monitoring of medicine quality is the responsibility of the national regulatory authority	• Least demanding and lowest cost for the government	• Does not ensure equity of access for poor, medically needy, or other target groups • Medicine quality is more difficult to monitor

Regulatory System Models

Regulatory systems should perform many, if not all, of the following core functions:[12]

- Licensing (of manufacturing, importation, wholesale and/or retail pharmacies and dispensing outlets, pharmacy personnel, etc.)
- Product evaluation and registration
- Inspection (of manufacturing, distribution channels, dispensing facilities, etc.)
- Import control
- Quality control of products
- Control of medicines promotion and advertising
- Pharmacovigilance

These functions may also include:

- Price control
- Control of prescribing and dispensing practices

These functions may vary depending on country context and the legal mandate of the entity.

The following proposed models present different arrangements of these functions that vary in their location within regulatory systems and who performs them. Many regulatory systems represent hybrids of these models, shown here with potential advantages and limitations of each. Note that these are for illustrative purposes only, as advantages and limitations of each model are principally dependent on the system context.

Regulatory System Model	Advantages	Limitations
Ministry of Health Regulatory Department or Unit • Regulatory functions are fully integrated into the central Ministry of Health	• Maintains government control over entire system function Facilitates government monitoring and oversight • Offers efficiencies in fixed costs – low capital investment • Maintains regulatory functions in systems that otherwise are not self-sustaining financially • Provides opportunity for better coordination with other departments or units of the Ministry of Health • Recurrent cost of staff, transport, other operating costs paid by government	• May lose some efficiencies as budget is tied to central government funding allocation, rather than regulatory activities and functions – operating costs may not match fee structure • Open to political and other interference in decision making • Scope for redirection of staffing or funding as political priorities change

[12] Adapted from: Ratanawijitrasin, S., Wondemagegnehu, E. 2002. *Effective drug regulation: a multicountry study*. Geneva: WHO. Available from: http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf

Regulatory System Model	Advantages	Limitations
Semi-Autonomous Regulatory Authority • The regulatory authority is not fully integrated into the central Ministry of Health • Regulatory has autonomy in some but not all respects	**Decision making autonomy:** Has autonomy from Ministry of Health in terms of decision making, with national budget as main source of funding	
	• Reduces likelihood of political or other interference with regulatory functions • Government funding maintains efficiencies in structural costs • Maintains regulatory function in systems that otherwise are not self-sustaining financially	• May decrease oversight, transparency • Government must clearly delegate regulatory authority to the agency • Must ensure government commitment to enforcement and cooperation • Recurrent cost of staff, transport, other operating costs paid by government
	Funding Autonomy: Remains within Ministry organizational structure, with revenue generated by cost recovery, either through direct collection of fees and charges by regulatory entity or through hypothecated central collection of fees and charges	
	• Maintains government control over entire system • Facilitates government monitoring and oversight • Promotes regulatory efficiency to generate revenue	• Open to political and other interference • Not viable in small systems that do not carry out sufficient revenue-generating activities to sustain functions • • Economic incentives may distort regulatory priorities
Autonomous Regulatory Authority • Regulatory authority is a stand-alone agency and has independent organizational structure; independent in terms of both decision making and funding	• Maintains advantages of centralized system • Flexibility in personnel and management systems may improve efficiency • Potentially less prone to political interference • • Separate finances facilitate funding sustained by fees for regulatory operations	• Resources needed to establish separate agency • May retain some constraints of centralized system • Duplication of support functions—agency must manage own human resources, information systems, finances, etc. • Government oversight and transparency to the public may be limited • May be more exposed to sectoral influence

Within these three defined categories, there may also be separate functional entities, where specific regulatory functions are located independently from the national medicines regulatory authority. Examples include regulatory boards and committees who meet to grant product registrations or pharmacovigilance centers housed at a university.

Advantages for these structures include:

- Flexibility in staffing and participation—allows for specialists to participate in regulatory functions
- Generally less bureaucratic

- Less costly—board members unlikely to be employees, less infrastructure, and personnel
- Generally more streamlined in terms of processes due to singular purpose/function
- Usually affiliated with research institutions or universities attracts skilled participants and encourages knowledge sharing
- Separates functions to allow for increased decision making autonomy
- Outsources some costs

And potential limitations include:

- Committee selection may lack transparency
- May meet infrequently
- Limited incentive for efficiency
- Conflicts of interest may be difficult to assess and manage
- Processes may not be well defined and standards may be applied inconsistently
- Structure may not be stable; possible interruption in function due to inconsistent participation or other changes
- Separation of functions may decrease communication and transparency across the regulatory authority as a whole
- Separation of funding may result in certain functions becoming under-resourced
- External resources may be subject to conflicts of interest, coercion, or influence from special interest groups

Configurations for Pharmaceutical Financing Under Universal Health Coverage

Financing systems for pharmaceuticals consist of revenue sources, revenue collectors, intermediaries and revenue managers, and purchasers, and end users. This table identifies several configurations for pharmaceutical financing with the aim of expanding access to pharmaceuticals or managing medicines benefits under universal health coverage schemes, and characterizes several potential advantages and limitations of each.

Note that many financing systems represent hybrids of these configurations, but they are presented here to shape options for analysis when evaluating choices for determining how to expand population coverage for pharmaceuticals. Within each configuration, decisions regarding the scope of coverage, reimbursement options, medicines purchasing strategies, and management of benefits will need to be made. Advantages and limitations of each are presented for illustrative purposes only, as these are principally dependent on system context and the identified problem.

Financing System Configuration	Advantages	Limitations
Ministry of Health Programs • Increased funding to Ministry of Health and health programs intended to expand coverage of medicines for the population • Ministry or health program purchases medicines and distributes them to end user free of charge • May be for specific diseases, medicines, target populations and others depending on implementation • - Typically administered by public health facilities	• Mechanism is straightforward—specific commodities are provided free of charge or are subsidized through individual programs • Ministry of Health maintains control of funds • Uses existing centralized structures for procurement, distribution, and administration to the end user	• Programs may not be well integrated with each other; difficult overarching management of benefits and communication between departments or programs • May be inefficient in terms of duplication of efforts and processes with multiple departments or programs

<table>
<tr><th>Financing System Configuration</th><th>Advantages</th><th>Limitations</th></tr>
<tr><td>Other Government Agencies
Population coverage for pharmaceuticals and related services is achieved through a combination of government programs designed to serve specific populations
Examples include programs that provide pharmaceuticals and services to prisoners, public employees, the elderly, the poor, women and children, etc.
May be within facilities operated by the program or through separate health facilities/providers</td><td>Mechanism is straightforward—specific commodities are provided free of charge or are subsidized through individual programs
Uses existing centralized structures for procurement, distribution, and administration to the end user</td><td>Programs may not be well integrated with each other—difficult overarching management of benefits and communication between departments or programs
May be inefficient in terms of duplication of efforts and processes with multiple departments or programs
Difficult to achieve population coverage through fragmented or specialized programs</td></tr>
<tr><td rowspan="3">Health Insurance
Population coverage is achieved through a risk pooling mechanism that involves regular payment of insurance premiums to protect users from having to pay the full cost of catastrophic illness
Health insurance schemes generally fall into one of four categories: national, social, community-based, or private</td><td colspan="2">National Health Insurance: Plans are implemented by the national government. Funded primarily through tax revenue, with employer/employee contributions and premiums. Coverage up to nationwide. Services are provided by accredited public or private sector facilities</td></tr>
<tr><td>Can base cost to consumer on employment status, income, age etc.
Large risk pool that may mitigate effects of skimming or adverse selection</td><td>Benefits and funding may be subject to political interference
May be difficult to raise sufficient revenue without large tax increases or levying significant premiums on all or some of the population
Generally cannot cover the entire population without significant taxpayer contributions (usually for the elderly, the poor, women and children etc.)</td></tr>
<tr><td colspan="2">Social Health Insurance (Social Security): Semi- or fully autonomous government agency administers the plan. Funded through payroll deductions. Typically formal sector workers are covered. Services are administered by program-specific providers with some services contracted out</td></tr>
</table>

Financing System Configuration	Advantages	Limitations
	• Can achieve high levels of population coverage depending on size of formal sector	• Usually only covers formal sector workers • Informal or unemployed usually have greater need for coverage assistance and may not be included in social security schemes
	Community-Based Health Insurance: Plans are managed by non-profit community organizations**.** Funded through tax revenues and voluntary contributions**.** Covers informal workers, low income and rural groups. Services are administered by plan-approved public or private providers (or the plan may establish their own facilities)	
	• Usually targets small populations with high need for coverage that may not be covered through social or private insurance mechanisms • Coverage and benefits can be targeted to specific community needs	• May be difficult to regulate • Gaps in coverage may persist if not enough organizations provide coverage • Not effective for covering the entire population
	Private Health Insurance: Plan is managed by private companies (may be for-profit or nonprofit). Funded through member contributions, premiums, and direct payments**.** Only plan contributors are covered**.** Services are provided by in-network providers, contracted providers, or both	
	• Government does not need to devote resources to management of medicines benefits— this is handled by private insurers • Consumers can self-select benefits they want and need and how much they want to pay for health coverage	• May be prone to adverse selection or skimming behaviors and other distortions • Plans are usually run by for-profit companies— may be subject to economic distortions • Affordability may be an issue for large segments of the population • Quality of care and coverage may be unequal across the population

Governance

Governance concerns the process of decision making and the process by which these decisions are implemented.[13] Because "good governance" is a behavior rather than a structural system component, this table is structured according to categories of interventions that aim to improve adherence to good governance principles and practices instead of models or configurations for governance systems. In general, a combination of interventions from these categories is used to improve governance in pharmaceutical systems. However, budget, time constraints, and political and contextual realities are often limiting factors in implementing a comprehensive package of interventions from the start. Based on the identified problem, it may be best to focus on one level of the system, one particular agency, or one intervention category with the potential for scale up in the future. Governance initiatives can be difficult to get off the ground, particularly in challenging political contexts where governance is weak. Transparency and accountability may need to be improved before other reforms may be implemented, and advocacy for reform can take significant time and resources. It is important to distinguish which problems and solutions are appropriate to tackle first by or by the agency or which are best led by other initiatives or in-country entities.

Please note that interventions in other technical categories (supply chain management, regulatory systems, etc.) may also be considered governance interventions, particularly those that increase transparency and accountability, promote autonomy, mitigate conflicts of interest, reduce interference, or increase oversight. Because governance impacts all pharmaceutical system components, it is a necessary consideration when selecting models or configurations for those components and in some cases may be a primary concern where reducing corruption and mismanagement are primary concerns. So selection of supply chain models, regulatory systems models, financial configurations can be considered as alternatives for improving oversight, transparency, accountability to reduce corruption, improve equity, affordability, coverage, etc.

Principles of good governance include:[13]

- Strategic vision
- Participation
- Transparency
- Consensus-orientation
- Rule of law
- Equity
- Efficiency and Effectiveness
- Responsiveness
- Accountability

Advantages and limitations of implementing each category of intervention are presented for illustrative purposes only, as these are principally dependent on the country context and the specific problem identified.

[13] United Nations Development Programme. 1997. Governance for Sustainable Human Development. New York: UNDP.

Category of Governance Intervention[14]	Advantages	Limitations and Additional Considerations
Policies and Legislation • Development of policies and legislation supported by rule of law • Interventions may include assessment of compliance, development of enforceable and well-informed medicines policies, updating and strengthening existing policies, identifying best practices to inform norms and standards, facilitating participation in the legislative process	• Pharmaceuticals must be carefully regulated due to their ubiquitous use and potential danger when used incorrectly • Policies and legislation can exert influence throughout the system • Policies and legislation can regulate the in-country activities of external actors that are otherwise difficult to control (such as foreign pharmaceutical companies' advertising activities or clinical trials) • Needed to establish statutory bodies and grant regulatory oversight	• Passing new policies and legislation is a lengthy process – may take several years • Mechanisms must be in place to ensure adequate participation of civil society and relevant stakeholders, beneficiaries • Mandates need to be enforceable and adequately funded to ensure implementation • Opportunities for abuse increases when policies are not coherent, roles and responsibilities are not clearly defined, and conflicts of interest are not addressed • Must be continually updated
Strengthening Organizational Structures • Promotes appropriate decision making, authority and oversight • Interventions may include building advocacy for transparent structures with broad participation, evaluating existing structures to identify gaps, designing or reviewing committee membership, or defining criteria for member selection, terms of reference, and roles and responsibilities	• Bodies that provide oversight are essential to ensure good governance • Increasing transparency and participation in organizational structures is central to improved governance • Committees and other bodies should be independent and impartial, and should be perceived as such	• Autonomy may be difficult to achieve given existing structures and inherent dependencies built into the system • Political interference, nepotism, and corruption may be difficult to detect and address • Relevant experts may be rare in the setting—they may sit on several boards and consult for the pharmaceutical industry. Maintaining their impartiality may be difficult

[14] Adapted from: Strengthening Pharmaceutical Systems (SPS). Pharmaceuticals and the Public Interest: The Importance of Good Governance. Submitted to the U.S. Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health

Category of Governance Intervention[14]	Advantages	Limitations and Additional Considerations
Systems and Processes • Incorporating transparency, accountability, and ethical practices into standards, procedures, systems and processes • Interventions may include helping to define decision making criteria, developing formal standards or procedures, improving the availability of accurate data, improving or establishing oversight mechanisms, and developing performance metrics and targets	• Important decisions are made at each step of the pharmaceutical management cycle, so promoting good governance practices and evidence-based decision making in these processes have wide ranging impacts on patient access to quality pharmaceuticals • Standards and procedures usually take less time to develop than policies and legislation, and can be tailored to a specific process, organization, or system level • International standards already exist for many common pharmaceutical processes (Good Manufacturing Practices, Good Procurement Practices, Good Storage Practices etc. are all available from the WHO)	• Strong lobbies may influence decision making and processes for the pharmaceutical sector • Mismanagement, corruption, and unethical practices in routine pharmaceutical operations may be pervasive and difficult to change • Need to reassess since reforms may be rolled back over time and systems may adapt around new reforms • Oversight and enforcement of processes and procedures may be difficult to implement at all levels of the system • Capacity and adequate resources for audits, appeals, and other oversight processes should be built into intervention proposals • Accurate reports must be made publicly available and continually updated – when data are not available, timely, or reliable may require considerable investment to address

Category of Governance Intervention[14]	Advantages	Limitations and Additional Considerations
Human Resources • Improving human resource management to enhance performance and ethical practices • - Interventions may include assisting in the identification of human resource management gaps, building advocacy for and implementing approaches to address those gaps	• Staff in the pharmaceutical sector often handle high value products or participate in activities vulnerable to collusion, coercion and other corrupt practices – addressing human resource management issues can address these issues throughout the system • Preventing political interference or nepotism is critical in the appointment of personnel • Clear performance and job descriptions can help to address poor staff performance • The public can help to enforce human resource policies through formal complaint mechanisms at very little cost	• In many countries, ability to exercise good governance is limited by lack of human resources • Separation of key responsibilities and oversight activities may be difficult to implement regularly due to staff shortages • Low salaries, poor work conditions, and inadequate staffing can contribute to weak performance and tempt staff to engage in corrupt practices – addressing these conditions may require significant investment

Human Resource Management

The table below identifies several configurations for pharmacy staffing within health systems, and characterizes several potential advantages and limitations of each. Please note that these examples do not include other pharmaceutical staff, such as regulators, warehouse staff, or laboratory personnel. It is important to consider professional and supervision based models for the entire pharmaceutical staffing system, in addition to the prescriber/dispenser model. However, for simplicity, this matrix only pertains to pharmacy staff.

Note that many pharmaceutical human resource systems represent hybrids of these configurations, but they are presented here to shape options for analysis when evaluating choices for pharmaceutical staffing. Within each configuration, decisions regarding the roles and responsibilities of each staff level, supervision and reporting structures, rigor of training, and accreditation processes will need to be made. Advantages and limitations of each are presented for illustrative purposes only, as these are principally dependent on system context and the identified problem.

Pharmaceutical Human Resource System Configuration	Advantages	Limitations
Pharmacist-Operated System • All pharmaceutical dispensers are fully licensed pharmacists • Each outlet/facility has a pharmacist in charge of the pharmacy and pharmaceutical management processes (inventory, ordering, etc.)	• Only highly trained pharmacy staff are dispensing • Perceived higher quality of service • Due to high education level, it is likely that norms and standards are well adhered to	• May be a lack of pharmacists in country • Could result in large numbers of informal providers and dispensers (drug sellers, traditional healers, non-licensed pharmacies) filling the gap • Pharmacists expect higher salaries than less skilled workers • Many pharmaceutical management tasks (inventory, paperwork, etc.) do not require a pharmacy degree

Pharmaceutical Human Resource System Configuration	Advantages	Limitations
Pharmacy Technician Operated System (Tasking Shifting to semi-professional cadre) • Pharmacy technician (or pharmacy assistant) is in charge of pharmacy and management processes • - Less training and education required, still goes through formal accreditation process and education program	• Training pharmacy technicians is faster than training pharmacists–can fill staffing gaps more quickly • Less rigorous educational requirements will likely increase numbers of eligible pharmacy technicians vs. pharmacists • Training can ensure that staff are capable of most tasks involved in pharmaceutical management • Frees up pharmacists for more technical or skilled work, more efficient use of time	• Possible that patients may perceive a lower quality of service or products dispensed by non-pharmacists • Will take time to establish a new cadre or re-train existing workers for new job responsibilities • Oversight and reporting structures must be carefully constructed, with resources allotted for supervision and enforcement of requirements
Accredited or Licensed Non-Professional Operated System • Includes mix of nonprofessionals with professional supervision and oversight • - Licensed pharmacist is responsible for a network of dispensing facilities	• Leverages existing establishments and providers while bringing them into the formal sector • Allows pharmacists more flexibility and gives them more managerial responsibilities • Can function with very few pharmacists relative to other configurations • Training can ensure that staff are capable of most tasks involved in pharmaceutical management	• Possible that patients may perceive a lower quality of service or products dispensed by non-pharmacists • Will take time to establish a new cadre or retrain existing workers for new job responsibilities • Oversight and reporting structures must be carefully constructed, with resources allotted for supervision and enforcement of requirements • Currently operating informal providers will need to be convinced of the benefits of accreditation—resources may need to be set aside for incentives

Information Systems

Pharmaceutical management information systems (PMIS) are designed to collect, process, report, and use information for decision making. Major components of PMIS are:[15]

- Record-keeping documents (registers, ledgers, filing systems for internal use)
- Information reporting forms (status reports that transmit data to other departments or levels)
- Feedback reports (usually provided to units that collected the information)

The information needs of users at each level should form the basis of PMIS design or revision. Where possible, changes should build on existing forms, reports, and procedures. Any forms or procedures developed or modified should be designed through a participatory process and field-tested with their intended users. Within each PMIS model decisions regarding the management of the system (public or outsourced), the extent to which existing tools vs. custom tools are used, and defining the indicators and what information must be produced to facilitate informed decision making will need to be made.

Note that many pharmaceutical management information systems represent hybrids of these models, but they are presented here to shape options for analysis when evaluating choices for designing or revising a PMIS. Advantages and limitations of each model are presented for illustrative purposes only, as these are principally dependent on system context and the identified problem.

Pharmaceutical Management Information System	Advantages	Limitations
Paper Based • All information is collected using paper forms and hard copies are submitted to central level for collection and analysis	• Does not require reliable electricity, internet access, or expensive infrastructure like computers or mobile devices • Does not require computer literacy or extensive training to operate • Can be used easily in remote areas	• Forms may take time to send from peripheral to central levels • Data entered into paper based systems cannot be restricted or data validated at the entry point which may result in inconsistent data across users • Forms must be printed and distributed – as physical commodities they can also be out of stock at facilities • Forms are time consuming to analyze and process

[15] Adapted from: Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies – Chapter 49: Pharmaceutical management information systems*. Sterling, VA: Kumarian Press.

Pharmaceutical Management Information System	Advantages	Limitations
Electronic • Information is collected electronically at facility level and transmitted to central level for processing and analysis	• Data can be restricted and validated at the entry point to ensure consistency • Tools can be designed to automate the analysis and visualization processes • Data can be transmitted instantly or at scheduled intervals without delay • Electronic systems do not require printing or distribution and they can be updated from central level	• Requires reliable electricity and/or internet access, computers, mobile devices • Staff may require intensive training to use electronic systems and develop required computer skills • Infrastructure and tool development may be expensive
Hybrid • Information is collected and processed through a combination of paper based and electronic means • Usually involves paper based forms at facility level, with digitization at regional or provincial level with electronic transmission to central level for processing and analysis	• Paper based forms can be used in rural or peripheral facilities where use of electronic systems is impractical • Electronic processing of data allows for reporting flexibility and enhanced data validation • Hybrid systems are flexible in terms of where and how data are transferred from paper based to electronic forms • Systems can be tailored to fit a variety of budget constraints, and investment in new infrastructure and training can be limited to specific levels	• Issues with paper based systems persist where they are used (stock out, labor intensive to fill out, lack of consistency etc.) • Transcribing data from paper based forms to electronic systems is labor intensive and may cause delays in the availability of information

Appropriate Medicines Use

Rather than present models or configurations for promotion of appropriate use, this table is structured according to categories of intervention because "appropriate use" is a behavior rather than a structural system component. Ideally, all of these intervention categories should be implemented together to improve the use of medicines by prescribers, dispensers, and end users sustainably. However, budget and time constraints are often limiting factors in implementing such a sweeping package of interventions at one time. Based on the identified problem, it may be best to focus on one level of care, one particular actor (prescribers, dispensers, users of medicine), or one intervention category, with the potential for scale up in the future.

Advantages and limitations of implementing each category of intervention are presented for illustrative purposes only, as these are principally dependent on the country context and the specific problem identified.

Appropriate Use Intervention Category[16,17]	Advantages	Limitations and Additional Considerations
Educational Strategies *Training of prescribers* • Formal education (pre-service) • Continuing education (in-service) • Supervisory visits • Group lectures, seminars, and workshops *Printed materials* • Clinical literature and newsletters • Clinical treatment guidelines and medicine formularies • Illustrated materials (flyers, leaflets) *Approaches based on face-to-face contact* • Educational outreach • Patient education • Influencing opinion leaders through advocacy	• Effectively increases knowledge • Continuing education and re-certification can refresh providers on appropriate prescribing and dispensing practices, and can ensure that providers are up to date with recent changes in recommendations and best practices for prescribing and/or dispensing • Effective pre-service education of prescribers is essential for promoting rational use of medicines • Highly cost effective • System strengthening intervention—pre-service educational interventions are sustainable as knowledge persists after cessation of intervention or technical support	• Resource intensive • Limited sustainability (except for pre-service education, which is generally considered a sustainable intervention) • Do not often alter behavior when implemented individually without other supporting interventions • Often need to be combined with managerial and regulatory interventions to be effective • Requires refreshers and continuous repetition and investment

[16] Adapted from: Quick, J. D., R. O. Laing, and D. Ross-Degnan. 1991.*Intervention Research to Promote Clinically Effective and Economically Efficient Use of Pharmaceuticals: The International Network for Rational Use of Drugs*. Journal of Clinical Epidemiology 44(Suppl. 2):57–65.

[17] Adapted from: Management Sciences for Health. 2011. *MDS-3: Managing Access to Medicines and Health Technologies – Chapters 27-35*.Sterling, VA: Kumarian Press.

Appropriate Use Intervention Category[16,17]	Advantages	Limitations and Additional Considerations
Managerial Strategies *Monitoring, supervising, and feedback* • Hospital drug and therapeutics committees • District health teams • Government inspectorate • Professional organizations • Self-assessment *Selection, procurement, and distribution* • Essential medicines lists or other limited procurement lists • Drug use audit and feedback • Drug use evaluation • Hospital and regional drug committees • Cost information *Prescribing and dispensing approaches* • Structured medicine order forms • Standard diagnostic and treatment guidelines • Course-of-therapy packaging	• Can produce a sustained impact with limited risk of adverse or unexpected results • Monitoring and supervision that is conducted in-person and is supportive is generally well accepted by prescribers – particularly prescription audit and feedback • Selection, procurement, and distribution activities can be effective in reducing the number of inappropriate medicines in use and can maintain the quality of procured medicines • Pre-printed pharmaceutical order forms are relatively simple to implement and have been shown to increase cost-effective prescribing • Pre-printed or stamped labels can help clarify dosing instructions that may otherwise be forgotten by patients • Course-of-therapy prepackaging makes distribution of medicines safer, easier, and faster which frees the dispenser from routine counting and simplifies multidrug dispensing to improve adherence to recommended regimes and increases accuracy of inventory recording of supplies	• Typically require considerable effort to initiate and maintain • Labeling requires supplies and infrastructure – may be difficult to maintain stocks and ensure compliance with labeling requirements • Labeling may not be effective where rates of illiteracy are high – effective pictures or symbols will need to be developed and pre-printed, which can be costly • Prepackaging of medicines is technically a manufacturingprocess, which must be done under strict controls reflecting good manufacturing practices • Prepackaging is repackaging, and the legal responsibility for the quality and labeling of the newly packed medicine is transferred from the original manufacturer to the re-packager • Repackaging of medicines may compromise the original manufacturer's expiry date, and generally an expiry date of six months, or the original expiry date if less, is given to repackaged medicines. The quality of the product must be checked before and after prepacking. • Package seals must also be checked on a regular basis to ensure that they close tightly and will protect the prepackaged medicine adequately

Appropriate Use Intervention Category[16,17]	Advantages	Limitations and Additional Considerations
Economic Strategies • May include price setting, capitation-based budgeting (budgeting per patient rather than for each service or medicine provided), reimbursement, user fees, and insurance	• Financial incentives—if executed properly, can strongly affect medicines use in a positive way • Cost recovery programs can be effective at promoting appropriate use of medicines by selling essential medicines below their actual costs, while offsetting the lower price by charging extra for non-essential medicines	• If financial incentives are not executed properly, medicines use may be negatively distorted • More expensive medicines may become under-prescribed, even where their use is appropriate and indicated if economic incentives are not implemented carefully • If health workers receive profits or payment based on medicine sales there may be an enticement to overprescribe and prescribe more expensive medicines
Regulatory Strategies • May include limited medicines lists, restrictions on prescribing and dispensing • Medicines registration and enforcement of regulations can reduce the number of sub-standard and inappropriate medicines on the market	• Effective registration processes and restrictions on pharmaceutical sales help keep dangerous and ineffective medicines off the market • Health authorities may restrict paramedical staff to a limited number of medicines on the essential medicines list to reduce waste and inappropriate use of expensive medicines • Health facilities may restrict prescribing of certain medicines to more experienced prescribers or specialists	• May have unexpected or unintended outcomes, which may result in extra costs or adverse patient consequences • Resources are required to maintain the effectiveness of regulatory authorities • Regulatory capacity is strained in many low-income countries due to lack of adequate human resources • When safe but relatively ineffective medicines are withdrawn from the market, they may be replaced with effective medicines used inappropriately • Restrictions on the number of medicines prescribed to a single patient are easily sidestepped by issuing separate prescriptions • Limitations on dispensing may have adverse effects on patients—those with chronic diseases may be required to visit health facilities more often to pick up smaller amounts of their medication. When setting restrictions on treatment duration or dispensing quantities, exceptions must be built in for chronic diseases and exceptional cases

ANNEX F. OPTIONS MATRIX WITH EXAMPLES

Once options are developed and costed, they should be compared to one another using defined criteria. As discussed previously, options should be evaluated according to their alignment with the current policy, legal, and regulatory framework; existing structures and resources; information system requirements; costs and financing; public and private capacity; and sustainability. These categories may change slightly to suit the specific problem under investigation and the proposed options. Note that the current system should be evaluated alongside the options, so that improvements and alterations to the current system within each alternative are clear. Additionally, costs can be compared to the current system cost so that their costs are more meaningful. The options matrix is a valuable tool to quickly compare alternative strategies for intervention, but does not comprise the options analysis by itself. This matrix should be used to present findings visually, but should be supported by a report or paper that contains the assessment results, methodology, thorough costing information, and a write up of the complete analysis, along with proposed next steps for stakeholders.

Several example matrices are included below with sample options following this blank template:

Options Matrix Template

Analysis Criteria	Current System [Description]	Option A [Description]	Option B [Description]	Option C [Description]	Option D [Description]
Alignment with Policy, Legal, and Regulatory Framework					
Existing Structures and Resources					
Information System Requirements					
Costs and Financing					
Public and Private Capacity					
Sustainability					

Example 1. Supply Chain Management

Sample problem: Stock-out of HIV medicines at health facilities, in spite of adequate purchase of supplies at central level

Sample underlying factors:

- Lack of warehouse space at central level to receive semi-annual shipments leads to backup of supplies in supplier storage
- Inaccurate stock recording at facilities leads to unexpected shortages, inappropriate distribution of stock
- Irregular delivery between central, regional, provincial warehouses, and to health facilities leads to unpredictable stock levels on hand at all levels
- Lack of reporting between levels leads to inaccurate quantification

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	HIV program oversees supply chain. Medicines are delivered 2x per year from supplier to central medical store (where quality testing occurs), then distributed to regional then provincial warehouses for sporadic pickup by health facilities	**Current system remains largely intact with changes to the delivery schedule at all levels of the system – supplier delivers to central medical store 4x per year, deliveries to peripheral warehouses 4x per year, health facilities pick up 4x per year with more frequent pickups available upon request**	**Outsourced distribution and reporting to third party logistics provider (3PL). Suppliers deliver HIV commodities to central warehouse for product quality testing followed by 3PL pickup and distribution directly to health facilities 4x per year. When 3PL makes deliveries, they make note of stock levels and amounts delivered to report to central level.**	**[Description]**	**[Description]**
Alignment with Policy, Legal, and Regulatory Framework	FDA product quality testing required at central level upon receipt of product. National government is outsourcing more services, looking to decrease investment in nationally-held warehouse space	No change from current system in this respect	Aligns with policy of outsourcing and decreasing government-held warehouse space requirements		
Existing Structures and Resources	Requires warehouses at central, regional, and provincial level. Distribution infrastructure is greatly reduced due to recent natural disaster – health facilities must use own transport to pick up supplies	Reduces bottleneck at central level for supplies due to space restrictions – more frequent shipments reduce the shipment size and space requirements	Eliminates need for transport/pickup within the public sector. Some buffer stock should be available at peripheral levels for health facilities to access between scheduled deliveries, if necessary.		

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	HIV program oversees supply chain. Medicines are delivered 2x per year from supplier to central medical store (where quality testing occurs), then distributed to regional then provincial warehouses for sporadic pickup by health facilities	**Current system remains largely intact with changes to the delivery schedule at all levels of the system – supplier delivers to central medical store 4x per year, deliveries to peripheral warehouses 4x per year, health facilities pick up 4x per year with more frequent pickups available upon request**	**Outsourced distribution and reporting to third party logistics provider (3PL). Suppliers deliver HIV commodities to central warehouse for product quality testing followed by 3PL pickup and distribution directly to health facilities 4x per year. When 3PL makes deliveries, they make note of stock levels and amounts delivered to report to central level.**	**[Description]**	**[Description]**
Information System Requirements	Reporting is done through paper stock cards and is completed irregularly at all levels of the system	With regularly scheduled deliveries and pickups, reporting should be more regular and consistent – predictions of stock levels and requirements should improve	Reporting and collection of data are outsourced to the 3PL. Reporting requirements need to be carefully laid out in the contract with them, along with accountability and oversight for data quality and timeliness.		
Costs and Financing	$10 million USD per year for transport, storage, procurement costs etc.	$10.5 million USD per year for additional transportation costs for increased deliveries and pick ups	$13.5 million USD per year		
Public and Private Capacity	Currently limited distribution, reporting, inventory management capacity in the public sector	Limitations with transportation infrastructure persist. Private suppliers have capacity to increase frequency of deliveries.	3PL providers operate on a large scale in the country, there are several with appropriate certifications and the capacity to perform this function		
Sustainability	Impractical to continue to procure increasing buffer stocks to mitigate system inefficiencies. Each time HIV commodities are out of stock it generates bad press and the HIV program comes under fire.	Can reduce need for excess buffer stock if products flow through system levels efficiently. Reporting issues may persist. No change to system transportation infrastructure.	Sustainable in perpetuity, so long as resources are available to renew contracts. Decreased administrative burden on health care providers and infrastructure requirements for the system should generate efficiencies and cost savings in the long run if assets (warehouses, delivery trucks) may be sold		

Example 2. Regulatory Systems

Sample problem: Substandard and falsified medicines are known to be in the market, leading to adverse outcomes and increased morbidity and mortality.

Sample underlying factors: Limited capacity of national regulatory authority to inspect manufacturing sites, pharmacies, and drug outlets for violations; inefficiencies at the national laboratory and ineffective sampling strategy; weaknesses in the product registration/marketing authorization process; large informal sector for sale and purchase of medicines, weak pharmacovigilance system for reporting and communicating medicine safety and quality concerns.

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	National regulatory authority exists but has limited staff and resources to perform essential functions. Open borders with neighboring countries allow for easy smuggling of counterfeit and substandard medicines. The regulatory authority does not perform site inspections of drug dispensing outlets. There are large numbers of informal drug sellers operating in the country.	**Identify and remove substandard and falsified medicines by implementing decentralized spot testing products at medicine dispensing outlets through use of community inspectors (using MiniLab or similar kits) and development of protocols for removal of substandard products and procedures for notification. Aims to remove substandard products already in the market, for sale to the public.**	**Develop an accreditation program for informal drug dispensing outlets. Accredited outlets have access to subsidized medicines and trainings to grow their businesses, while agreeing to operate within restrictions set by the national regulatory authority. Accredited drug dispensing outlets are registered and inspected regularly. Aims to prevent substandard products in the market from being sold to the public.**	**Strengthen licensing and inspection of wholesalers to prevent substandard products from entry into dispensing points.**	**[Description]**
Alignment with Policy, Legal, and Regulatory Framework	Regulations exist that restrict the import of medicines and prohibits the purchase or sale of counterfeit medicines in the country, but there are no resources available to fund enforcement efforts.	Would need to certify community inspectors to perform inspections on behalf of the national regulatory authority. Must develop and disseminate testing protocol, protocol for removal of substandard products, procedures for notification.	National regulatory authority has not previously made contact with the informal sector. Accreditation scheme will need to be developed, along with rules of engagement to outline the agreement between dispensing outlets and the national regulatory authority to ensure that accredited drug dispensing outlets may only purchase from licensed and approved wholesalers. Requires development of appropriate incentives and sanctions.	Requires development of sanctions and strengthened licensing capacity at the national regulatory authority. Would need to train and certify additional inspectors.	

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	National regulatory authority exists but has limited staff and resources to perform essential functions. Open borders with neighboring countries allow for easy smuggling of counterfeit and substandard medicines. The regulatory authority does not perform site inspections of drug dispensing outlets. There are large numbers of informal drug sellers operating in the country.	**Identify and remove substandard and falsified medicines by implementing decentralized spot testing products at medicine dispensing outlets through use of community inspectors (using MiniLab or similar kits) and development of protocols for removal of substandard products and procedures for notification. Aims to remove substandard products already in the market, for sale to the public.**	**Develop an accreditation program for informal drug dispensing outlets. Accredited outlets have access to subsidized medicines and trainings to grow their businesses, while agreeing to operate within restrictions set by the national regulatory authority. Accredited drug dispensing outlets are registered and inspected regularly. Aims to prevent substandard products in the market from being sold to the public.**	**Strengthen licensing and inspection of wholesalers to prevent substandard products from entry into dispensing points.**	**[Description]**
Existing Structures and Resources	National regulatory authority has 10 employees, who are mainly occupied with administrative tasks including medicines registration	MiniLab kits are relatively low cost and come with training materials. Resources would be required to pay community inspectors and conduct trainings, purchase kits and reagents, and to take action in the event of detection of substandard or counterfeit medicines.	Accredited drug dispensing outlet programs have been used in several countries. These programs can be replicated and adapted to suit the country's needs. Resources will be required for trainings, inspections, enforcements, and distribution of materials and infrastructure to outlets in the program.	Inspectorate already visits wholesalers, however frequency and rigor of inspections will need to increase. Inspector retraining will be required and funding will be needed to pay for additional inspectors.	
Information System Requirements	There is no registry of authorized medicine dispensing outlets or any guidance on recognition of common counterfeit drugs	Community inspectors should report to the national medicines regulatory authority when violations are detected, and a register of infractions should be developed. Repeat offenders should be sanctioned and shut down, if possible. Must have communication channels in place to notify the public or service providers of a recall or communicate risk.	Accredited outlets should report inventory, sales figures, supplier information, and data on notifiable diseases to the national regulatory authority. Forms will need to be developed.	Inspectors should report to the national medicines regulatory authority when violations are detected, and a register of infractions should be developed. Repeat offenders should be sanctioned and shut down, if possible. Must have communication channels in place to notify the public or service providers of a recall or communicate risk.	

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	National regulatory authority exists but has limited staff and resources to perform essential functions. Open borders with neighboring countries allow for easy smuggling of counterfeit and substandard medicines. The regulatory authority does not perform site inspections of drug dispensing outlets. There are large numbers of informal drug sellers operating in the country.	**Identify and remove substandard and falsified medicines by implementing decentralized spot testing products at medicine dispensing outlets through use of community inspectors (using MiniLab or similar kits) and development of protocols for removal of substandard products and procedures for notification. Aims to remove substandard products already in the market, for sale to the public.**	**Develop an accreditation program for informal drug dispensing outlets. Accredited outlets have access to subsidized medicines and trainings to grow their businesses, while agreeing to operate within restrictions set by the national regulatory authority. Accredited drug dispensing outlets are registered and inspected regularly. Aims to prevent substandard products in the market from being sold to the public.**	**Strengthen licensing and inspection of wholesalers to prevent substandard products from entry into dispensing points.**	**[Description]**
Costs and Financing	Costs $1.2 million USD per year currently, plus unknown health care costs associated with increased morbidity	Costs $3.6 million USD per year for reagents and kits for 15 inspectors, including the cost of maintaining the current system. Suggest beginning in the capital city with later scale up. Some costs may be offset through charging of fees or penalties	Depends on the level of subsidization of medicines for sale through outlets, and the form of incentives for drug sellers to participate. Estimated cost of $3.8 million USD per year to accredit and inspect facilities, and maintain the program. Some costs may be offset through charging of fees or penalties	Costs $2 million USD per year, including cost of maintaining current system for development of protocols, training, and additional inspectors. Fewer inspectors are required than for option A since there are fewer wholesalers than dispensing outlets in the country.	
Public and Private Capacity	Public capacity is limited for performance of inspections and quality checks at current levels of investment. Closing the border is impractical in the short term due to geographical and resource constraints.	Training for use of MiniLabs is fairly straightforward – pharmacy technicians and those with less education can be trained to use the kits and test for counterfeit and substandard drugs with the system.	Informal private sector exists, capacity for training must be developed to formalize informal facilities and drug sellers. Public capacity to inspect and enforce must be developed and maintained.	Public capacity is limited for performance of inspections and quality checks at current levels of investment. With additional funding, development of protocols could be supported by a technical assistance partner, and additional inspectors could be hired and trained.	

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	National regulatory authority exists but has limited staff and resources to perform essential functions. Open borders with neighboring countries allow for easy smuggling of counterfeit and substandard medicines. The regulatory authority does not perform site inspections of drug dispensing outlets. There are large numbers of informal drug sellers operating in the country.	**Identify and remove substandard and falsified medicines by implementing decentralized spot testing products at medicine dispensing outlets through use of community inspectors (using MiniLab or similar kits) and development of protocols for removal of substandard products and procedures for notification. Aims to remove substandard products already in the market, for sale to the public.**	**Develop an accreditation program for informal drug dispensing outlets. Accredited outlets have access to subsidized medicines and trainings to grow their businesses, while agreeing to operate within restrictions set by the national regulatory authority. Accredited drug dispensing outlets are registered and inspected regularly. Aims to prevent substandard products in the market from being sold to the public.**	**Strengthen licensing and inspection of wholesalers to prevent substandard products from entry into dispensing points.**	**[Description]**
Sustainability	With no change, the quality of medicines available for sale will continue to deteriorate. Costs to patients for health care and continued treatment following purchase of substandard medicines will continue to escalate.	The MiniLab system is a short term solution. Eventually a national reference laboratory should be established to test all drugs imported in the country. This solution does not address the open borders or the influx of counterfeit and substandard medicines; it only detects them once they are already on the market and removes them from sale.	System should be sustainable with sustained investment in inspection and training. Reduces the market for substandard and counterfeit medicines as informal sector becomes more legitimate. Over time this may help alleviate the influx of these drugs. Regular inspection and increased data availability should remove substandard and counterfeit medicines from the market, while promoting informed decision making at central and peripheral levels.	System should be sustainable with sustained investment in inspection and training. Prevents the proliferation of substandard and falsified medicines from the wholesaler to dispensing outlets – recalls can be more directed and need for inspection at community level is reduced.	

Example 3. Financial Management

Sample problem: Patients pay out of pocket for many essential medicines

Sample underlying factors: Many medicines are not available for free through the public sector due to lack of funds. There are not enough public sector facilities that dispense medicines to cover the entire population. Chronic diseases and neglected tropical diseases do not currently have their own programs, so though medicines to treat these diseases are on the essential medicines list, they are not included in any program budgets.

Analysis Criteria	Current System **Vertical programs have their own budgets to procure medicines for program-specific diseases. Many basic medicines are not covered in this scheme, and program budgets are sufficient only to supply medicines to disease-specific treatment centers. Many patients in rural areas cannot access public facilities and pay out of pocket for medicines from private providers**	Option A **Seek donor assistance to procure medicines for vertical programs**	Option B **Establish national health insurance that includes coverage for essential medicines. Private providers may become accredited for reimbursement by the insurance scheme for professional services and provision of essential medicines and other supplies.**	Option C **[Description]**	Option D **[Description]**
Alignment with Policy, Legal, and Regulatory Framework	The constitution states that essential medicines should be available free of charge, but the public sector does not currently cover all medicines or the whole population	Maintains the current structure, but medicines are procured through international mechanisms using donor funding. Exemptions to current laws requiring domestic procurement will need to be made.	Establishes entirely new financing mechanism. Policies, laws and regulations will need to be updated to establish this scheme. Decisions concerning how the mechanism will be funded and administered must be made by relevant stakeholders, including service providers, funders, patient groups etc.		

Analysis Criteria	Current System **Vertical programs have their own budgets to procure medicines for program-specific diseases. Many basic medicines are not covered in this scheme, and program budgets are sufficient only to supply medicines to disease-specific treatment centers. Many patients in rural areas cannot access public facilities and pay out of pocket for medicines from private providers**	Option A **Seek donor assistance to procure medicines for vertical programs**	Option B **Establish national health insurance that includes coverage for essential medicines. Private providers may become accredited for reimbursement by the insurance scheme for professional services and provision of essential medicines and other supplies.**	Option C **[Description]**	Option D **[Description]**
Existing Structures and Resources	Health programs are limited in their coverage both geographically and in terms of the quantities of medicines they can afford to procure. Chronic diseases and neglected tropical diseases do not currently have their own programs, so though medicines to treat these diseases are on the essential medicines list, they are not included in any program budgets.	The Global Fund can provide assistance for the procurement of medicines for HIV/AIDS, malaria, and TB. UNICEF can assist with funding for and procurement of vaccines and medicines to treat children, the Global Financing Facility is available to support program needs for reproductive, maternal, and child health. Many pharmaceutical companies have donation programs for medicines to treat neglected tropical diseases. Programs would need to be restructured to allocate funding to filling gaps left by donor funding.	The plan may be administered through the existing social security agency, with increased investment to expand coverage to those who are not already included in this scheme. The formulary should be expanded to include all essential medicines, and private health facilities should be accredited to participate in the plan so that geographic coverage is maximized.		
Information System Requirements	Transactions that occur in the private sector are not reported. There is no data available on the prices paid, the treatments offered, the number of patients accessing services in the private sector, or the diseases being treated there.	Donor coordination will require good quality information. Many donation programs also have specific reporting requirements. If not covered in donated funding, resources will need to be allocated to increased quality of data in order to generate reports and reduce wastage and overlap of efforts.	All included providers will be required to report on numbers of patients, services and products provided, and diseases treated. Since the public has a large population of indigent and informally employed people, increased investment in birth registration and assignation of social security numbers is required to provide coverage to these populations.		

Analysis Criteria	Current System **Vertical programs have their own budgets to procure medicines for program-specific diseases. Many basic medicines are not covered in this scheme, and program budgets are sufficient only to supply medicines to disease-specific treatment centers. Many patients in rural areas cannot access public facilities and pay out of pocket for medicines from private providers**	Option A **Seek donor assistance to procure medicines for vertical programs**	Option B **Establish national health insurance that includes coverage for essential medicines. Private providers may become accredited for reimbursement by the insurance scheme for professional services and provision of essential medicines and other supplies.**	Option C **[Description]**	Option D **[Description]**
Costs and Financing	HIV, TB, Maternal and Child Health, and Malaria programs each have a budget of $1 million USD per year to purchase commodities, including diagnostics, medicines, and other products. = $4 million USD/year	Many procurement costs are removed from the public sector and are covered by donors. Cost associated with monitoring and evaluation, reporting, supply chain management, etc. will remain in the public sector. Budgets allocated to health programs should remain the same or increase if possible, so that quality of services increases and resources are better utilized. Investments from donors should be used to expand coverage of essential medicines free of charge. $4 million USD per year plus unknown increased investment	Projected annual cost is $35 million USD per year, though this is offset through tax revenue and payroll deductions. Donor financing may be able to supplement procurement costs of medicines through the national health insurance scheme. Initial investments to establish reporting mechanisms, train administrators and providers, expand the social security administration, and accredit private health facilities will be required. Total startup costs are projected at $20 million USD over 5 years.		
Public and Private Capacity	Private sector for health care and sale of medicines is large, but public sector capacity to subsidize or reimburse essential medicine sales does not exist.	Many NGOs and technical assistance providers are available to help structure programs that meet donor requirements, and can leverage donor funds to increase coverage and the impact of required interventions.	The private sector is already providing a great many health services to the population. The public sector needs to build capacity to accredit and monitor private provider participation in the national health insurance scheme. The social security administration is an existing entity, but investment will need to increase significantly in order to expand coverage and absorb the procurement and supply management functions currently performed by health programs		

Analysis Criteria	Current System **Vertical programs have their own budgets to procure medicines for program-specific diseases. Many basic medicines are not covered in this scheme, and program budgets are sufficient only to supply medicines to disease-specific treatment centers. Many patients in rural areas cannot access public facilities and pay out of pocket for medicines from private providers**	Option A **Seek donor assistance to procure medicines for vertical programs**	Option B **Establish national health insurance that includes coverage for essential medicines. Private providers may become accredited for reimbursement by the insurance scheme for professional services and provision of essential medicines and other supplies.**	Option C **[Description]**	Option D **[Description]**
Sustainability	Current levels of out of pocket expenditure are not sustainable. Lawsuits suing for true coverage of essential medicine under the constitution are likely.	Reliance on donor funding is not sustainable, however this step may be needed initially in order to reduce out of pocket spending by the public on essential medicines. Once appropriate structures are in place and the system is stronger, donor funding can be slowly decreased and supplemented with other revenue sources to increase system resilience and sustainability.	Once national health insurance is established, it can be sustained through user fees, taxes, and payroll deductions. The key will be determining the appropriate level of investment, and putting proper controls on expenditure and reimbursement in place. Decisions must be made regarding inclusion of the informal sector, controlling utilization, formulary selection, pricing, etc. In theory, if the entire population is included in a single coverage mechanism, unified data, reporting, and formularies should create sustainable efficiencies.		

Example 4. Governance

Sample problem: The central medical stores often pay prices for medical products that are higher than expected.

Sample underlying factors: Processes for tendering and awarding bids do not comply with international best practices. Procurement procedures and prices paid are not made available to the public. The audit committee for the central medical stores (CMS) is underfunded and performs audits infrequently, without formal audit procedures or clear performance standards.

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	The Central Medical Stores (CMS) are tasked with procurement, distribution, and inventory management for medicines in the public sector. The procurement committee consists of 3 people and meets infrequently. There is a committee tasked with auditing the CMS, but they lack the resources to perform regular audits, and they do not have an auditing procedure or clear performance standards and metrics.	**Establish multiple departments to separate procurement functions and reduce the opportunity for corruption or collusion in the procurement process.**	**Increase available resources for the existing auditing committee and require quarterly audits with reports. Work with partners to develop procedures for auditing, performance indicators and standards that comply with international best practices.**	**[Description]**	**[Description]**
Alignment with Policy, Legal, and Regulatory Framework	Policies and laws require competitive bidding for procurement, and give preferential treatment to domestic suppliers. Structures exist for auditing of the CMS, but they are under-resourced	Not aligned with current regulatory and legal framework. Departments will need to be established by legal decree	Works within currently established entities to improve processes and implement defined standards and procedures.		
Existing Structures and Resources	Appropriate structures are in place to carry out procurement processes, however, investment is inadequate and standards and procedures for processes are lacking	New structures will need to be established to separate functions, including office infrastructure and increased staffing levels	Requires increased investment, no new structures or entities need to be created. The audit committee will require resources to function – mobile technology, space to meet, etc.		
Information System Requirements	There is a lack of transparency in procurement processes and the performance of the CMS due to absence of performance standards and metrics, and the fact that available information is not publicly posted	Lines of communication will need to be open between different departments in order to coordinate activities involved in the procurement process.	Availability and quality of data should increase. Reporting system for audits, performance reports, procurement processes and prices paid should be developed and made publicly available. Can use the existing Ministry of Health website for publication.		
Costs and Financing	Current investment levels in procurement processes and the audit committee total $500,000 USD per year	Startup cost of $1.3 million USD spread over 3 years initially, plus $950,000 USD per year	Requires $825,000 USD per year to expand the capacity of the audit committee and maintain the reporting structure. Development of standards and procedures and their update can be facilitated through donor funding.		

Analysis Criteria	Current System **The Central Medical Stores (CMS) are tasked with procurement, distribution, and inventory management for medicines in the public sector. The procurement committee consists of 3 people and meets infrequently. There is a committee tasked with auditing the CMS, but they lack the resources to perform regular audits, and they do not have an auditing procedure or clear performance standards and metrics.**	Option A **Establish multiple departments to separate procurement functions and reduce the opportunity for corruption or collusion in the procurement process.**	Option B **Increase available resources for the existing auditing committee and require quarterly audits with reports. Work with partners to develop procedures for auditing, performance indicators and standards that comply with international best practices.**	Option C **[Description]**	Option D **[Description]**
Public and Private Capacity	There is inadequate capacity in place within the system to perform essential functions while promoting good governance principles at current funding and staffing levels. Standards and procedures are largely absent for the measurement of the performance of the CMS, procurement monitoring, and the completion of audits.	Capacity within the public system is adequate to perform these functions so long as adequate resources are available.	Capacity in the public system is adequate to perform these functions so long as adequate resources are available.		
Sustainability	The current situation is unsustainable in terms of the overages paid for medicines and the lack of appropriate governance procedures in place. The situation will likely continue to deteriorate if left unchecked, and product quality, availability, and spending are likely to be impacted in the future.	The system is sustainable so long as adequate funding can be found to sustain these changes and investments. Does not immediately address price issues or performance measurement unless implemented with other interventions.	Addresses identified issues with the current system. Works congruently with existing structures and expands on them to rationalize practices and processes. Funding will need to be allocated to sustain these improvements		

Example 5. Human Resource Management

Sample problem: The number of licensed pharmacists working in the public sector is inadequate to meet the needs of the system. Patients frequently purchase medicines from informal drug sellers or private facilities to access essential medicines.

Sample underlying factors: There is a legal requirement that public pharmacies must be staffed by a licensed pharmacist at all times. Pharmacists are drawn to the private sector due to higher pay and better working conditions with more opportunities for advancement. The pharmacy school at the national university graduates classes of approximately 25 pharmacists per year.

Analysis Criteria	Current System **There is a large informal sector selling essential medicines to the public. These medicines are offered free of charge in the public sector, however, the requirement that each public pharmacy be staffed by a licensed pharmacist at all times has resulted in very few public sector pharmacies, which limits access to these medicines free of charge.**	Option A **Expand the pharmacy school at the national university to increase the number of graduating pharmacists each year**	Option B **Change regulations to allow pharmacy technicians to staff and manage public pharmacies as part of small pharmacy networks under the supervision of licensed pharmacists**	Option C **[Description]**	Option D **[Description]**
Alignment with Policy, Legal, and Regulatory Framework	Public sector pharmacies are required to be staffed by licensed pharmacists at all times by law.	Maintains existing requirement that public pharmacies are staffed by licensed pharmacists	Laws and regulations will need to be altered to permit pharmacy technicians to staff public pharmacies.		
Existing Structures and Resources	Only one university in the country has a pharmacy school, the program graduates approximately 25 pharmacists per year.	The pharmacy school is already in place, however significant investment in staffing and classroom space are required in order to increase the graduating class size sufficiently to expand the available pool of pharmacists in the public sector	New training will need to be developed to acquaint staff with new roles and responsibilities. Additional pharmacies can be established relatively quickly, requiring startup investment to establish them and continued investment to staff them.		
Information System Requirements	Pharmacists are required to perform inventory management and produce stock status reports in addition to dispense medicines.	No change	Supervision and reporting systems are critical when task shifting work to lower technical levels. Since each pharmacist will manage a network of several pharmacies, they must receive and generate regular reports on their activities, inventory status, etc.		

Analysis Criteria	Current System There is a large informal sector selling essential medicines to the public. These medicines are offered free of charge in the public sector, however, the requirement that each public pharmacy be staffed by a licensed pharmacist at all times has resulted in very few public sector pharmacies, which limits access to these medicines free of charge.	Option A Expand the pharmacy school at the national university to increase the number of graduating pharmacists each year	Option B Change regulations to allow pharmacy technicians to staff and manage public pharmacies as part of small pharmacy networks under the supervision of licensed pharmacists	Option C [Description]	Option D [Description]
Costs and Financing	Salaries for existing staff at existing public pharmacies = $1 million USD per year	Current system costs ($1 million USD per year) + annual subsidies to retain additional teaching staff at pharmacy school = $300,000 USD per year + $3 million USD initial investment to expand the school. Initial investment of $20,000 USD to establish each additional public sector pharmacy plus $60,000 per year in salaries and other annual costs per pharmacy.	Maintains the same number of pharmacists as the current system ($1 million USD per year) + $30,000 USD per year per pharmacy technician for salary and initial investment of $20,000 USD for each additional public pharmacy. The training for pharmacy technicians should be relatively short, so the program can pilot quickly then scale up to increase geographic coverage as resources allow.		
Public and Private Capacity	The private sector has a high concentration of qualified pharmacists and private pharmacies are numerous.	The appeal of the private sector pharmacy environment to pharmacists persists in the system. High capacity of the private sector to deliver services remains.	This model may generate increased interest in working in the public sector, since individuals do not need to complete a rigorous pharmacist training program to work in a pharmacy. This significantly expands the pool of qualified workers. Additionally, pharmacists do not need to spend effort doing menial counting or inventory tasks, and instead advance to more managerial roles quickly.		
Sustainability	The current situation is not sustainable – patients are paying high prices for medicines that are provided free of charge in the public sector. The public sector is decreasing in size as staff flock to the private sector. Public sector services are important to rationalize prescribing and dispensing behaviors, promote appropriate use of medicines, regulate the quality of goods and services, and provide free access to essential medicines.	Increasing the number of graduates from the pharmacy program does not guarantee that they will work in the public sector. Additionally, it takes time to graduate new classes of pharmacists, so benefits will not be seen for approximately 5 years (depends on the length of the program).	Resources must be available to support the increased number of pharmacies in the public sector. Sustainability in terms of staffing should increase due to the expanded worker pool and the reduced barrier to entry into the pharmaceutical workforce in the public sector. Salaries for non-pharmacists are less than for pharmacists, and staff can be trained to replace turnover relatively quickly and cheaply.		

Example 6. Information Systems

Sample problem: Information on cases of TB and stock status of needed supplies is collected inconsistently across the country. Lack of information at central level leads to inaccurate quantification and stock-outs of needed supplies at peripheral levels.

Sample underlying factors: Paper forms are labor intensive for health facility staff to fill out. Forms must be kept in stock at facilities and physically transported to higher levels for consolidation and analysis. Health facility staff members do not have time to take regular inventory and request stock far enough in advance to avert stock-outs.

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	Paper based stock cards are used to manage inventories at central and peripheral system levels. The cards are frequently out of stock, or aren't filled out completely or frequently. Currently, laboratories report laboratory-confirmed cases of TB directly to the TB program at central level, but this underestimates the cases in treatment by a large margin, since many patients suspected of having TB are enrolled onto treatment without laboratory confirmation, particularly children.	**Establish a completely digital system using mobile devices for health facility reporting, and computer-based systems for inventory management at warehouses. Add data collection categories for TB suspects enrolled on treatment and build in system reminders to improve timeliness and completion of data entry.**	**Maintain paper-based system at health facilities that lack computers with internet access. Paper forms will be turned in at peripheral warehouses when supplies are picked up. Health centers with existing computers and internet access may use an online portal to enter data. Warehouses will use a computer-based system to enter inventory and stock management data.**	**[Description]**	**[Description]**
Alignment with Policy, Legal, and Regulatory Framework	Collection of data is built into the existing system, however there are no checks in place to ensure that data entry is complete and timely, and no consequences for incomplete data entry.	Builds in increased accountability for data entry, due to the ability to set reminders and requirements in a digital system.	Builds in increased accountability for data entry, due to the ability to set reminders and requirements in a digital system, and information transfer requirements at distribution points.		
Existing Structures and Resources	Paper based forms are in place, however, they are frequently out of stock or aren't collected on a regular basis.	Major investments in infrastructure will be required. Mobile networks are available and widespread in the country, but devices will need to be distributed and data entry systems must be developed.	Does not require significant expansion of digital infrastructure at health facilities. Warehouse improvements may be required to support computerized data collection. Note that the system at warehouse level should be used for all commodities, not just for TB in order to increase efficiency.		

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	Paper based stock cards are used to manage inventories at central and peripheral system levels. The cards are frequently out of stock, or aren't filled out completely or frequently. Currently, laboratories report laboratory-confirmed cases of TB directly to the TB program at central level, but this underestimates the cases in treatment by a large margin, since many patients suspected of having TB are enrolled onto treatment without laboratory confirmation, particularly children.	**Establish a completely digital system using mobile devices for health facility reporting, and computer-based systems for inventory management at warehouses. Add data collection categories for TB suspects enrolled on treatment and build in system reminders to improve timeliness and completion of data entry.**	**Maintain paper-based system at health facilities that lack computers with internet access. Paper forms will be turned in at peripheral warehouses when supplies are picked up. Health centers with existing computers and internet access may use an online portal to enter data. Warehouses will use a computer-based system to enter inventory and stock management data.**	**[Description]**	**[Description]**
Information System Requirements	Data must be tabulated from paper based forms at central level, which is labor-intensive. The TB program lacks resources to hire full time data entry staff, so temps are hired when resources are available to sporadically enter data into the system. Available information at central level often lags months behind the situation on the ground, so there are major delays at central level in addressing stock outs.	Investment in computers, mobile devices, new data entry systems, training, and system maintenance will be required.	Investment in computers, new data entry systems, re-designed stock cards, training, and system maintenance will be required.		
Costs and Financing	Printing and distribution of paper based forms = $500,000 USD per year, plus $75,000 USD per year in temporary staff for data entry	Initial investment of $3 million USD to purchase mobile devices and computers and establish internet connections, $500,000 investment in data entry system design, $500,000 investment for training development and implementation. $1 million USD per year to pay for mobile data and internet connections. $50,000 per year for 1 full time data management staff member at central level, $25,000 USD per year for re-training after year 1.	Initial investment of $27,000 USD to purchase computers and establish internet connections for warehouses. $500,000 investment in data entry system design, $500,000 investment for training development and implementation. $300,000 per year to print and distribute stock cards. $25,000 per year for internet connections at warehouses. $50,000 per year for 1 full time data management staff member at central level, $25,000 USD per year for re-training after year 1.		
Public and Private Capacity	Capacity for data entry and management exists within the system but is under-resourced and has limited time to perform these functions	Capacity for data entry and management exists within the system. System and infrastructure maintenance can be managed by private sector	Capacity for data entry and management exists within the system. System and infrastructure maintenance can be managed by private sector		

Analysis Criteria	Current System	Option A	Option B	Option C	Option D
	Paper based stock cards are used to manage inventories at central and peripheral system levels. The cards are frequently out of stock, or aren't filled out completely or frequently. Currently, laboratories report laboratory-confirmed cases of TB directly to the TB program at central level, but this underestimates the cases in treatment by a large margin, since many patients suspected of having TB are enrolled onto treatment without laboratory confirmation, particularly children.	**Establish a completely digital system using mobile devices for health facility reporting, and computer-based systems for inventory management at warehouses. Add data collection categories for TB suspects enrolled on treatment and build in system reminders to improve timeliness and completion of data entry.**	**Maintain paper-based system at health facilities that lack computers with internet access. Paper forms will be turned in at peripheral warehouses when supplies are picked up. Health centers with existing computers and internet access may use an online portal to enter data. Warehouses will use a computer-based system to enter inventory and stock management data.**	**[Description]**	**[Description]**
Sustainability	The system is not sustainable due to persistent supply and management issues caused by low data availability at all levels of the system. Stock outs and other problems damage system credibility and increase morbidity and mortality.	The system is sustainable so long as adequate resources are continually invested. The system can be updated centrally, though retraining may be required each time.	The system is sustainable so long as adequate resources are continually invested. The system can be updated centrally, though retraining may be required each time. Requires less investment initially and to maintain than a fully digital system, and is more feasible in terms of phased implementation. Paper-based forms persist, but with increased accountability and data management tasks are spread over several levels of the system, rather than all at central level.		

Example 7. Promotion of Appropriate Use

Sample problem: Antimalarial medicines are given for a variety of conditions without proper confirmation of diagnosis. The malaria control program is concerned about the emergence of resistance to available treatment regimens and the wastage of expensive treatments on non-malaria patients.

Sample underlying factors: Providers presume that any patient presenting with a headache should be treated for malaria. This is exacerbated by patient requests for antimalarial treatment for undiagnosed illnesses, as antimalarials are provided free of charge and are perceived as the most effective treatment for most ailments. Lack of regulation and enforcement regarding prescribers and dispensers allows for informal and unqualified personnel prescribing and dispensing medicines.

Analysis Criteria	Current System **High number of informal providers prescribing and dispensing antimalarials inappropriately. Even formal providers are over-prescribing due to patient demand and availability of free antimalarial medicines.**	Option A **Increase restrictions on who may prescribe and dispense antimalarial medicines and require proper diagnosis**	Option B **Use a series of public education campaigns to decrease inappropriate demand for antimalarial medicines**	Option C **[Description]**	Option D **[Description]**
Alignment with Policy, Legal, and Regulatory Framework	Existing regulations restricting sale and use of antimalarials are outdated and not enforced.	New regulations will need to be developed, and resources must be allocated for enforcement	No change from current system		
Existing Structures and Resources	The malaria control program has adequate resources from the government and donor programs to procure large amounts of antimalarial medicines. However, donors have begun to question the large procurement volumes requested and the amounts wasted on non-malarial patients.	Increased investment in diagnostics will be required. Works within existing health and dispensing facilities to restrict prescribing and dispensing. Additional public facilities or clear referral mechanisms may need to be established to maintain geographic coverage and accessibility under new restrictions.	Uses existing mass media (radio, television, billboards) to target patient behaviors		
Information System Requirements	Currently, providers mark how much medicine is prescribed and/or dispensed and fill out requests for new stock. There is no requirement that cases of malaria be confirmed through diagnostic testing in order to justify stock requests.	Restrictions built into stock request systems so that unauthorized providers may not request or receive antimalarial shipments. Monitoring and evaluation of antimalarial use at all levels of health system to track effectiveness of the intervention.	Monitoring and evaluation of antimalarial use at all levels of health system to track effectiveness of the intervention		

Analysis Criteria	Current System **High number of informal providers prescribing and dispensing antimalarials inappropriately. Even formal providers are over-prescribing due to patient demand and availability of free antimalarial medicines.**	Option A **Increase restrictions on who may prescribe and dispense antimalarial medicines and require proper diagnosis**	Option B **Use a series of public education campaigns to decrease inappropriate demand for antimalarial medicines**	Option C **[Description]**	Option D **[Description]**
Costs and Financing	The malaria control program procures $10 millionworth of antimalarial medicines each year.	Initial investment of $500,000 to develop restrictions plus $750,000 on system restructuring – referral system design, training, etc. Additional $1 million per year in diagnostic kit purchases, with projected $4 million per year savings on antimalarial medicines. $100,000 per year for monitoring and evaluation.	Annual investment of $300,000 USD for development and dissemination of new educational messaging and materials for patients regarding inappropriate use of antimalarial medicines. $100,000 per year for monitoring and evaluation. Projected savings of $1.5 million per year on procurement of antimalarial medicines.		
Public and Private Capacity	Both public and private sector prescribers and dispensers are misusing antimalarial medicines	The private sector will likely push back against these restrictions and requirements of referral. Enforcement of restrictions must be continual in order to sanction violations. Careful monitoring of the intervention outcome is essential to ensure that access is not over-restricted.	Local advertisers in the private sector can be used to disseminate messages to the public. Technical assistance providers and stakeholders should be consulted to help develop messages and materials.		
Sustainability	The current system is unsustainable due to high levels of waste and mismanagement of products. If the situation is not corrected, donors may withdraw support and resistance to current regimens will increase morbidity, mortality, and treatment costs.	Investments in oversight and enforcement are offset by cost savings on the medicines themselves, however it is possible that cases of untreated malaria will rise without monitoring and appropriate adjustment of restrictions. Work with the private sector is key to ensure buy in of private providers, otherwise violations of restrictions may be widespread and benefit will be reduced.	Educational interventions are rarely effective and sustainable by themselves. May require additional actions in order to produce significant and sustained improvements in use of antimalarials.		

ANNEX G. STAKEHOLDER COMMITMENT WORKSHEET

Please note that this is an example and not all fields may be relevant for each options analysis. The stakeholders included here may not be the same stakeholders as those included in Annex A.

Name of Stakeholder[18] (Organization, group or individual at national, regional or local level)	Role in Intervention	Level of Knowledge and Implementation Capacity	Available Resources	Timeline of Involvement	Deliverables
Government Sector					
Ministry of health (various departments)					
Ministry of finance (health budgets)					
Political Sector					
National policy-maker					
Municipality					
Funders					
Donor					
Insurer					
Regional Bank					
Global partnerships					
Stop TB					
Roll Back Malaria					
NGOs/other private philanthropic organizations					
Local					
International					
Faith-based					

[18] Adapted from: WHO and Stop TB Partnership. 2008. *Engaging Stakeholders for Retooling TB Control*. Geneva: WHO. Available from: http://www.stoptb.org/assets/documents/global/retooling/Retooling_Stakeholders.pdf

Name of Stakeholder[18] (Organization, group or individual at national, regional or local level)	Role in Intervention	Level of Knowledge and Implementation Capacity	Available Resources	Timeline of Involvement	Deliverables
Health care providers					
Professional organizations					
Specialists					
Primary care physicians					
Laboratory Services					
National reference laboratory					
Academic institutions					
Logistic Providers and Distributors					
Public					
Private					
Educators and Trainers					
Professional training institutions and councils					
Research institutions					
Commercial Sector					
Suppliers					
Manufacturers					
General Public					
Consumer groups					
Special interest groups/vulnerable populations					
News Media and Journalists					
Foreign correspondents					
Health reporters					
Radio stations					