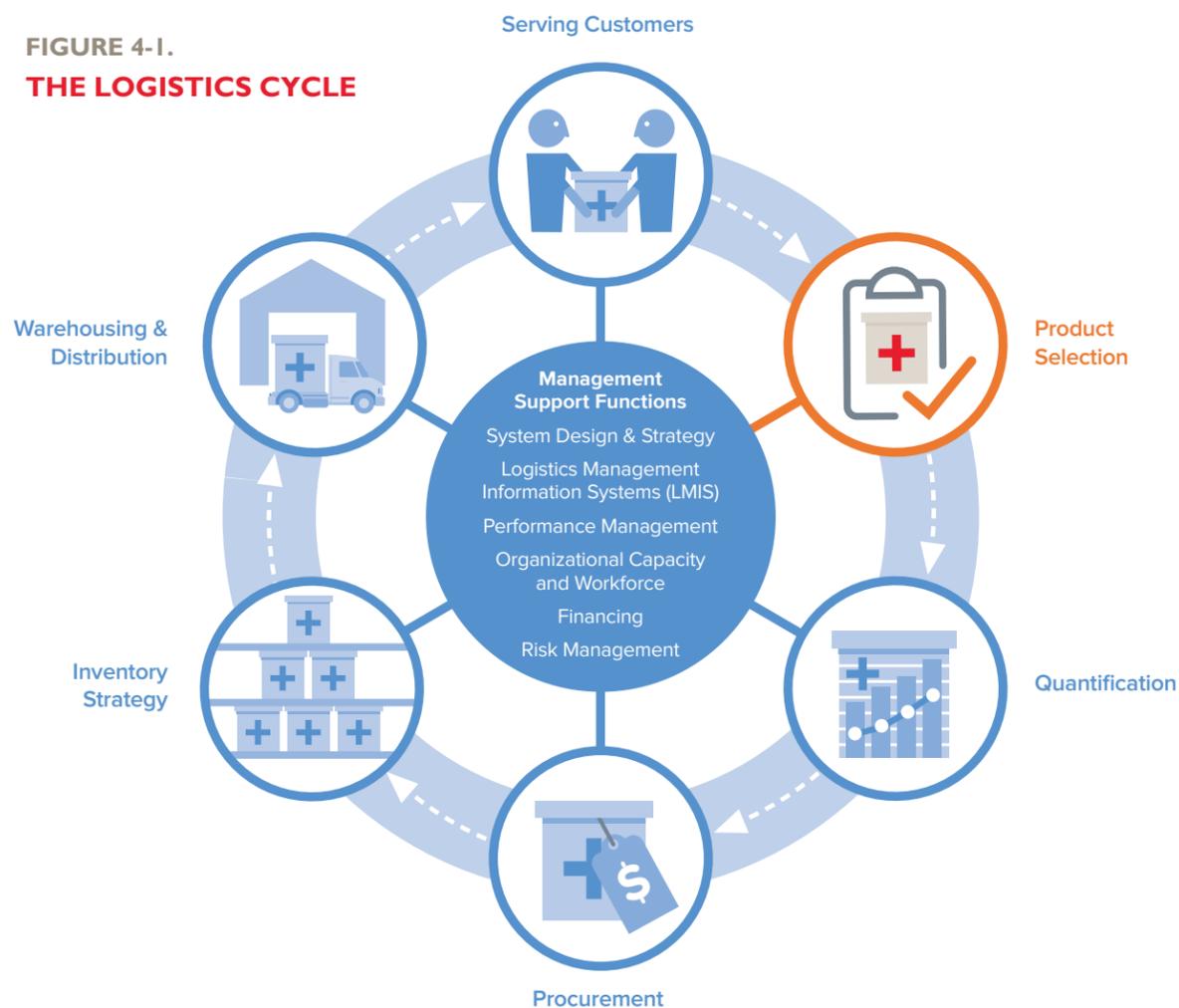




FIGURE 4-1.
THE LOGISTICS CYCLE



WHAT A SUPPLY CHAIN MANAGER NEEDS TO KNOW:

The supply chain manager needs to know the following about product selection, which are covered in this chapter.

- The impact of product selection in strengthening procurement, supply chain management, and health service delivery
- The role of national Essential Medicines Lists (EMLs), Standard Treatment Guidelines (SDGs), and product registration in product selection
- Particular considerations for standardization of laboratory equipment and supplies for product selection.

4.1 PURPOSE OF PRODUCT SELECTION

Product selection refers to the process by which health programs, as a whole, select, evaluate and ultimately procure the products that will be used and consumed in service delivery. A key element of the logistics cycle, product selection is directly linked to serving customers by defining what products are procured and used in the health system and the range of products that a customer can receive (see figure 4-1). One of the key elements of product selection is standardization, which enables programs to make decisions regarding several aspects of the products in question leading to the achievement of best value and the avoidance or proliferation of similar products and SKUs in its supply chain and program. Limiting the variety of products that are used and available at public sector facilities can make the supply chain more manageable.

The product selection process hinges on collaborative decision making between several actors in the supply chain. In many cases, the process involves the use of an interdisciplinary committee using clear terms of reference, governance structures, policies and procedures, and selection criteria for the development of an approved list of products, the output of which is a designated list of items. With a designated list of products, the staff at the central warehouse can become more familiar with the products, ensure that they meet the needs of the program, and monitor and maintain stock levels of all products throughout the system.

The ability to select products enables the development and implementation of a national coordinated logistics system, and allows for the redistribution of products throughout the system. Prioritizing particular products can be a tool for supply chain managers to ensure availability of those products. Product selection can provide economies of scale, thereby facilitating reduction of cost for some supplies and access to more affordable commodities. Selecting products is a prerequisite to quantification since it identifies the products that should be quantified.

Selection is an integral part of the application of the concept of value analysis. Value analysis is the systematic and organized application of recognized techniques and criteria to identify the benefits derived from the use of a specific product (or service). The process seeks to enhance the benefit by providing the performance needed at the lowest overall cost. Product selection therefore leads to the efficient use of resources, reduces the opportunity for error, and increases patient-centered outcomes.



DEFINING A PRODUCT— WHAT'S IN A STOCK KEEPING UNIT (SKU)?

Products are assigned an identification number or SKU, based on their characteristics, such as medicine, brand, size, color, etc., which facilitates their management. For example, paracetamol will be given a unique manufacturer SKU based on its form, dosage and pack size. The information needed to identify a unique product is —

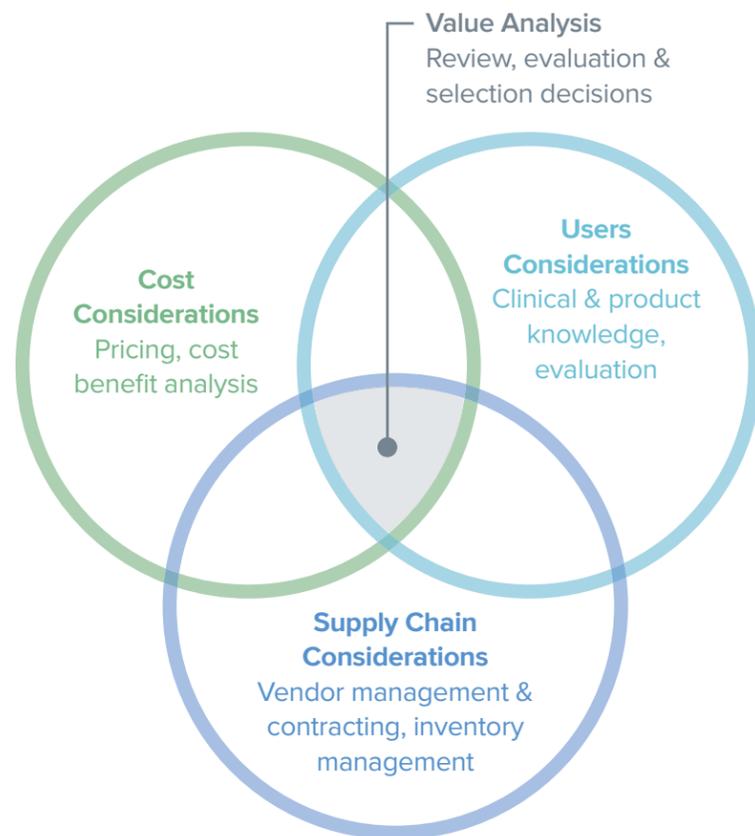
Product name + dosage + form + unit size.

For example:

Paracetamol 500 mg tablet 1,000/bottle

The unit should be stated in the smallest form issued to the facility; even if bottles of 1,000 tablets come in packs of 10, the SKU would represent one bottle and the facility would request 10 bottles rather than one pack of 10 bottles.

FIGURE 4-2.
APPLYING VALUE ANALYSIS IN PRODUCT SELECTION



In general, when building a product list, it is best to keep the number of stockkeeping units to as few as possible while still providing an acceptable level of service. Fewer products enhance the agility, manageability, and efficiency of a supply chain. It means fewer items to store, distribute, and track. Dealing with a reduced number of options is also easier for health care providers. It means they have fewer products to learn about and have more experience with those with which they work.

Fewer SKUs may also have a financial benefit. Managing fewer products requires less effort in stockkeeping and information management, and may have an impact on warehousing and distribution costs as well. Savings can also be realized in the procurement process—buying fewer products, but in greater quantities, could result in reduced unit price.

The product selection process is informed by local policies and guidelines as well as procedure guides and protocols. Pharmaceutical products are selected from or become part of a national essential medicines list (EML) and are based on standard treatment guidelines (STGs); products must be registered for overall use in-country. The next section discusses product selection for each of these components.

4.2 NATIONAL ESSENTIAL MEDICINES LIST

A national EML describes the medicines that satisfy the priority health care needs of a population, and are approved for use throughout the country. Often, as part of the development of the national EMLs, countries define at which levels of care in the health system each product will be used, based on disease patterns and complications commonly treated at each level. For example, not all disease conditions are treated at every facility in the country. Second-line antiretroviral treatment may not be provided in the rural health center, but may be available at the district hospitals and higher levels.

The essential medicines list specifies the medicines to be used to treat different conditions. Countries normally apply an evidenced-based approach to determine medicines that will be included on the national EML. Often a product should be:

- Relevant to the local disease patterns
- Proven to be of good quality, effective, and safe
- Cost-effective when considering total treatment cost



For a detailed look at drug selection, see Management Sciences for Health's MDS-3: Managing Access to Medicines and Health Technologies (*Virginia: Management Sciences for Health, 2012*).

The committee that develops the national EML may be primarily comprised of doctors, pharmacists, and ministry officials. Including a supply chain manager on this committee adds a needed perspective on how their selections could impact the supply chain and, eventually, product availability. Often the need to make informed choices and tradeoffs arise in the selection process. For example, product characteristics, such as packaging and cold chain requirements, have significant supply chain implications. If the most ideal product requires cold chain, and most facilities do not have a reliable cold chain, then an alternative product may be included on the list. Supply chain managers must ensure that products procured and distributed in the public sector health system are included on the national EML.

WHO publishes a model list of essential medicines that individual countries can adapt and use to develop their own national EML. Ministries of health should also consider the local context and disease patterns when finalizing this list. It should be updated regularly to address any new products on the market or shifts in disease patterns.



WHAT'S IN A NAME?—INTERNATIONAL NON-PROPRIETARY, BRAND, GENERIC, AND INNOVATOR NAMES

Program managers are encouraged to refer to their products using the international non-proprietary name (INN). An INN is given to pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property.

For marketing purposes, brand names are associated with a particular manufacturer, but there should be no difference in chemical composition with reference to the active pharmaceutical ingredient (API) content from one brand to the next. All branded products will also carry the INN. Branded products can be produced by either generic manufacturer or innovator companies.

An innovator medicine is the name of the product produced by the

manufacturer that initially developed the product. These products are usually given patent protection for 20 years from the date the patent was submitted. This provides protection for the innovator of the medicines to recover the initial costs incurred in research development and marketing expenses.

A generic drug is a pharmaceutical that is produced and distributed without patent protection. It has the same active pharmaceutical ingredients as the innovator medicine.

For supply chain purposes, using the INN enables you to purchase products from multiple suppliers, whether branded or generic, and manage them as the same product.

4.3 REGISTRATION OF PHARMACEUTICAL PRODUCTS

In most countries, pharmaceutical products require prior evaluation and approval from a regulatory body, often called the national drug regulatory authority (NDRA). Products should be proven to be effective, safe, and of good quality before they are registered. Some countries also consider the cost of the product, or whether it is needed. Because the quality of the medications is checked as part of the registration process, each brand (produced by different manufacturers and locations) is registered independently. In most cases, not only the product, but also the packaging, and labeling and use information is registered.

Many pharmaceutical products registered for use in a country may not be on the national EML, or on the standard treatment guidelines. Products are registered if their efficacy, safety, and quality

are acceptable to the regulatory authority. While they may not be on the EML, they may be used by the private sector and, in some cases, even used by public sector practitioners on rare occasions.

Failure to follow the pharmaceutical registration protocol could lead to products being held up by customs when they enter the country. Not only does this delay the delivery of important health care products, but it wastes time, costs money, and risks spoilage or expiry of products while at customs.

The registration of products is the responsibility of the manufacturer, not the Ministry of Health or supply chain managers. However, supply chain managers must ensure that the products they are responsible for procuring and distributing are registered, as required.

4.4 STANDARD TREATMENT GUIDELINES

Standard treatment guidelines (STGs) are suggested treatment protocols for the most optimal treatment outcomes of a specific clinical problem, in a given setting, based on the consensus of experts. The treatments for specific clinical issues are selected based on common diseases in the area; they may vary based on the level of the treatment facility and the severity of the condition. Products chosen to be available at a particular facility, or level of facilities, should be based on STGs.

Adhering to STGs has significant supply chain management benefits. If health practitioners adhere to suggested treatment protocols, a smaller range of products need to be available at each facility; and, as stated earlier, fewer SKUs are easier to manage. The STGs are developed based on the most effective and cost-effective treatment. If treatment providers prescribe the same product for the same condition, product demand is more predictable, facilitating more accurate forecasts. Clear, well-defined STGs are, in fact, a prerequisite for conducting morbidity-based forecasts; they form the basis for the assumptions around forecasting. If clinicians do not follow the STGs, large stockouts and/or expiries of unused medicines may result.

Each time STGs or products change, the supply chain must adapt. Service providers must be trained in prescribing and dispensing new treatment regimens and products. New products must be incorporated into logistics management procedures for ordering, stock monitoring, and reporting on consumption and stock levels.

Key activities for preparing the supply chain to introduce new products, or changes in treatment guidelines, include:

- Government approval and registration of new products
- Disseminating new guidelines and provider training in prescribing and dispensing of new treatment regimens and products

- Ensuring appropriate storage conditions and space to accommodate new products in storage and transport
- Transition plan for replacement and/or discontinuation of products to facilitate use of existing stocks before expiry
- Incorporating new products and treatment regimens into existing LMIS forms
- Updating quantifications to reflect expected changes in product consumption and stock levels
- Adjusting the timing of procurement and supplier delivery schedules to ensure continuous supply
- Recalculating funding requirements and mobilizing additional funding, if needed



HOW TO MANAGE SUBSTITUTIONS

For some items, you may be willing to accept a substitute when your first choice is not available. For example, if you need ballpoint pens, although you may want blue ink pens, you may be willing to accept black ink. What if, however, you urgently need a blue pen? Would you accept a low-quality blue pen, or pay a higher price for a blue pen somewhere else? Although substitution of one product for another may work for ballpoint pens, it may not always work for health commodities. A family planning client may not want to

switch to pills if an injectable contraceptive is not available. When product substitution is discussed, it is important to substitute products with the same active pharmaceutical ingredient, say, a generic for a brand or vice versa. However, in the case of essential medicines, one antibiotic with a similar activity profile may be substituted for another in some circumstances. The difference between a pen and a person's health is obvious. To be effective, a health system must fulfill all six rights.

4.5 FUNDER REQUIREMENTS

Some funders will require that if you use their funds to purchase products, they must meet certain criteria. Some may request that you use a particular procurement agent. Or, often they require that products be on the WHO prequalified list. However, if these products are not on the country's EML, registered, included in the STGs, and included in the pre-service trainings to ensure clinicians know how to use it, the products may be underutilized. Receipt of the products may be delayed during customs clearance while waiting to be registered, or products sit in a warehouse while clinicians are trained how to use them. When selecting products based on funder requirements, be sure they meet the other key criteria for product selection.

4.6 LABORATORY SUPPLIES AND EQUIPMENT STANDARDIZATION

Laboratory equipment and supplies can be extremely challenging to manage because of the variety and quantity of products. Some countries have product lists with several thousand products associated with the laboratories alone. As a product selection strategy, standardizing laboratory equipment and supplies can contribute significantly to better management of the supply chain.

Laboratory equipment primarily includes durable equipment, such as autoclaves and x-ray machines. Not only is this type of equipment expensive, but to run properly, it also requires ongoing maintenance and supplies. Thus, when selecting laboratory equipment, the following should be considered:

- Availability of staff trained in operating and repairing equipment
- Availability of supplies necessary for the equipment to function
- Appropriateness to the setting—e.g., disease patterns, use at the appropriate levels of the system, voltage systems in the country, and gauges in the correct unit of measure

For the equipment to function dependably, the supplies associated with this equipment, including replacement parts and products required to run tests, must be available. Laboratory equipment often requires reagents which may be unique to the specific equipment. Laboratory equipment may be classified as “closed systems”—requiring brand specific reagents and consumables which might be available only from the original manufacturer or authorized agents, or “open systems”—which require reagents and consumables which may be openly sourced. Such compatibility considerations are critical in the selection of laboratory equipment.

Laboratory supplies include consumables, primarily disposable items, such as syringes, bandages, cotton dressings, catheters, and sutures; reagents, which are the



WHAT ARE THE KEY CRITERIA FOR SUPPLY

CHAIN MANAGERS TO CONSIDER WHEN MAKING PRODUCT SELECTION DECISIONS?

Pharmaceuticals that are selected for procurement and national distribution in the public sector health system should typically meet four criteria:

- Included on the national essential medicines list
- Registered for use in-country
- Included in the standard treatment guidelines
- Meet all funder requirements for products purchased with donor funds



Photo courtesy of A. Makulec, Ethiopia

biological or chemical components active in testing; and durables, other than equipment, such as glassware, stands and holders, and other items that do not necessarily require routine resupply. These products are often in large supply, and may not be included on paper-based LMIS forms. Their management can be challenging because many of these products come in multiple pack sizes and variations. Each pack size is considered a different SKU, which can mean a very extensive product list.

Every effort should be made to standardize the list of laboratory supplies that are procured and managed through the public health supply chain. Although some health workers prefer a wider selection, it is less expensive and more efficient to narrow the product selection down to one or two pack sizes or types that will be appropriate for most situations. With a standardized list of laboratory supplies, quantification will be much simpler.

FOLLOW THESE STEPS WHEN STANDARDIZING LABORATORY PROGRAMS:

- 1 SET TEST MENUS.** In collaboration with a wide range of stakeholders, decide which laboratory tests should be provided at each level of the system.
- 2 DECIDE ON TEST TECHNIQUES.** A smaller, more technical group should decide which techniques to use for the selected tasks.
- 3 SELECT EQUIPMENT.** After you select the techniques, choose the appropriate equipment to carry out these tests and techniques.

When implemented effectively, standardized testing menus and test techniques for laboratory services offer advantages to patients (facilitates understanding of disease progression and treatment benefits), providers (gives an opportunity to develop and monitor quality of care standards), and supply chain managers (makes demand more predictable).



Many types of laboratory equipment and the products associated with them are available; a large number of them are complicated to use. Standardizing the equipment and their associated products can greatly ease the process of managing its supply chain.

For example, in Kenya, after laboratory standardization, the list of products to procure was reduced from small quantities of 3,000 products, to larger quantities of 300 supplies. With larger orders, they were able to obtain their laboratory products at a lower price.



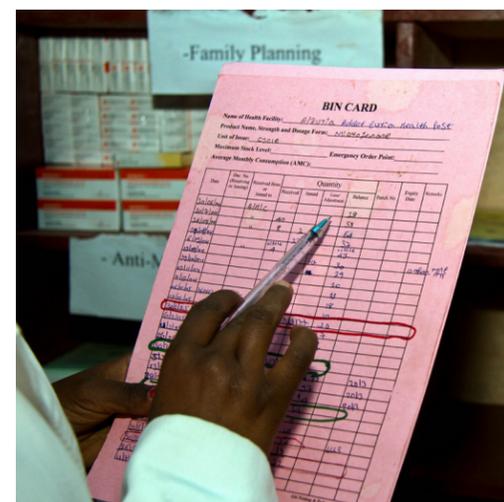
QUALITY MONITORING IN PRODUCT SELECTION

Customers deserve quality products. Even after products have been distributed to customers, programs should strive to continue to monitor quality. Programs must know how customers feel about the quality of the products and whether they are satisfied with the product and service they received. Health workers must adhere to standard treatment guidelines (STGs) (which outline the quality of treatment to be given) when serving clients.

Quality monitoring of both the product and the service is critical to the success of efforts to promote the appropriate use of products—vaccines, or other essential medicines. Customers should be counseled to correctly use the products they receive. The results of monitoring customer satisfaction can be used to inform/guide decisionmakers on patient preferences and about changes in product selection and use for the next procurement cycle. Remember, serving customers is at the top of the logistics

cycle and entails getting the right goods to those customers.

To monitor the quality process between product selection and quantification, you can determine if the products to be quantified are on the NEML, approved, and registered for use in-country; if STGs exist and are up-to-date; and if service providers have been trained in proper use. As described elsewhere in this chapter, these are key elements in the product selection phase. To help ensure the quality of procurement decisions, it is important to examine guidelines, prescribing practices, and registration status during product selection to avoid delays and procurement of inappropriate products. Furthermore, you should compare prices of substitutable products, ensuring that they are equally medically appropriate and in line with country-specific requirements. Quality monitoring plays an important in quantifying and procuring the right products at the right price, based on appropriate product selection and use.



Photos courtesy of IAPHL