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COMMODITY SECURITY FOR ESSENTIAL MEDICINES

CHALLENGES AND OPPORTUNITIES

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Abstract
Commodity security exists when clients can obtain and use essential health commodities when and where they need them. This concept is an extension of earlier frameworks that were first developed for family planning and reproductive health commodities and later for HIV/AIDS commodities. The systems, functions, and policies identified in these frameworks—necessary for reproductive health or HIV/AIDS commodity security—are also at the center of the World Health Organizations' (WHO) essential medicines strategy. Commodity security (and its program-specific antecedents) and the WHO essential medicines strategy is a starting point from which to shape coordinated and integrated approaches to improve the availability of essential health supplies. By reviewing the program-specific approaches that have been used to date, many lessons can be learned to improve availability and access. The integration of distribution systems, health services, financing sources, and policy frameworks can also be a useful strategy to strengthen commodity security for multiple categories of essential medicines. The solution, however, is not *all or none*. Programs can strengthen commodity security by integrating one, some, or all these functions. Advantages and disadvantages exist to both product-specific (i.e., vertical) and integrated approaches. However, global and country-level trends are pointing toward a systems view of health services, which tends to support a multi-product category, integrated approach to commodity security.

Cover Photo: Stocked supply shelves in Eritrea pharmacy. From the Improving Health Care Delivery Systems in Eritrea (TASC) project. Photographer: Rene Salgado.

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ACRONYMS

ACT	artemisinin-based combination therapy
ART	antiretroviral therapy
CMH	Commission on Macroeconomics and Health
CS	commodity security
CYP	couple-years of protection
EMCS	essential medicines commodity security
EML	Essential Medicines List
GDF	Global Drug Facility
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
HACS	HIV/AIDS commodity security
IEC	information, education, and communication
LDC	least-developed country
LMIS	logistics management information system
MDDBS	multi-donor direct budget support
MDR-TB	multidrug-resistant tuberculosis
NDC	non-drug consumable
NPS	National Population Strategy (Jordan)
OI	opportunistic infection
PEPFAR	President's Emergency Plan for AIDS Relief
RBM	Roll Back Malaria (Partnership)
RH	reproductive health
RHCS	reproductive health commodity security
STI	sexually transmitted infection
SWAp	sector wide approach
TASO	AIDS Support Organization
TB	tuberculosis
UN	United Nations
UNFPA	United Nations Population Fund
WHO	World Health Organization

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1.0 INTRODUCTION

The World Health Organization (WHO) has developed and supports the concept of essential medicines, which includes pharmaceutical products that address the priority health care needs of the greatest number of people in a given country. WHO implements the concept with a model Essential Medicines List (EML) and through the support of country specific lists and a Medicines Access Strategy. Achieving access to essential medicines is also defined by the concept of commodity security (CS), which is described as the ability of clients or end users to obtain and use health commodities when and where they need them. Variations of this concept include contraceptive security, where the right to *choose* among different family planning methods is introduced as part of ensuring that individual needs are met. A broader variation of CS, reproductive health commodity security (RHCS), includes contraceptives in its definition, as well as other essential commodities for reproductive health, such as medicines for maternal and perinatal use, products to prevent and treat sexually transmitted infections (STI), and supplies for safe delivery. The CS concept has been further applied to HIV/AIDS commodities to improve routine availability and to help rationalize the selection and use of hundreds of essential health products for HIV prevention, treatment, and care. These CS approaches and WHO's essential medicines access strategy can be seen as similar, comprehensive approaches to the broad challenges of medicine supply availability.

Each concept is based on an expansive strategic framework that describes the various systems, programs, financing requirements, policies, and contextual environments that need to be in place to strengthen CS for the specific categories of medicines. For example, a common approach is the idea that well functioning distribution systems or sufficient commodity financing cannot, alone, ensure CS without the adequate functioning of other components (e.g., service delivery, supportive policies, and adequate human resources). The frameworks examined in this paper assert that this comprehensive, multi-sectoral approach is fundamental to findings solutions for essential medicines commodity security (EMCS).

1.1 PURPOSE AND OBJECTIVES

Many lessons to improve the availability of and access to essential medicines can be learned from a review of program specific, vertical approaches to commodity security for reproductive health (RH), family planning, and HIV/AIDS. These approaches have been implemented in part by focusing on a (relatively) limited number of products in their operational frameworks; in some circumstances, integrating certain components (e.g., distribution systems) across programs (Rao 2008). The integration is reinforced by recent policy positions and financing approaches by global institutions, including the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), UNITAID, and the President's Emergency Plan for AIDS Relief (PEPFAR). These and other organizations with global reach are increasing support to a health systems approach to ensure an adequate supply of commodities linked to essential health packages (EHP) which cross-cut vertical programming. The health systems approach supported by these groups is also consistent with WHO's long-standing Primary Health Care (PHC) strategy, comprising eight components; among them, access to essential medicines.

The benefits of a program-specific approach and the trend toward integration may seem confusing or even contradictory, but they are not. In fact, the central argument of this paper is that they should be understood and leveraged because—

- practitioners and advocates should and are recognizing that a *comprehensive view* of health programs, policies, and systems is necessary to improve CS
- within this broad view, each separate category of essential medicines have *unique requirements*— such as varied supply chain considerations, financing requirements, and interest group support—that must be addressed to successfully operationalize CS strategies
- Opportunities exist *to integrate programs and functions* between and within essential medicine categories; if accomplished, these can increase the sustainability and capacity of supply programs and thereby improve overall commodity security.

This concept paper was written to begin, but certainly not to end, a discussion among organizations and individuals concerned with health commodity supply about ways to draw on some of these concepts, practices, and lessons to improve CS.

To do this, this paper will—

- define what commodity security is by reviewing and comparing existing CS concepts and frameworks (section 2.0)
- use select examples to show that although different categories of essential medicines (e.g., contraceptives, antimalarials, antiretrovirals, and vaccines) have their own requirements and stakeholder groups, a common CS approach can be successfully adapted (section 3.0)
- review the challenges, benefits, underlying assumptions, and global trends influencing integrated approaches to commodity security (section 4.0).
- determine the essential requirements for CS (sections 4.0 and 5.0) and the differences between a broad, integrated approach and a category-specific approach.
- identify opportunities to establish common thinking, strategic approaches, and implementation of commodity security for all essential medicines (section 5.0).

1.2 BACKGROUND

The essential medicines concept was first introduced by the WHO in 1977 when they published the Model EML (WHO 1977). WHO's definition of essential medicines is—

> *Those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility* (WHO 2002).

The Model EML was created to support countries when they developed their national EMLs; countries use the list to address the primary health care requirements of their populations. The creation of EMLs was supported to limit the large numbers of ineffective and non-essential drugs in the markets of many

developing countries (Vian 2003). Defining essential medicines has helped countries rationalize selection and procurement decisions; this process has also been a precursor to develop systems and policies to ensure regular access to medicines (WHO 2007a). By 2007, 156 of 193 sovereign countries had developed national EMLs; many of these countries have routinely revised their national lists to account for the availability of new medicines and changing disease patterns. The model and national lists are developed through an evidence-based process with regard to public health impact, quality, safety, efficacy, and cost-effectiveness (WHO 2007a).

As defined by WHO and the member states that have undertaken the national EML process, essential medicines should be routinely available to clients, in adequate stock at health centers, of assured quality, and affordable (especially for the very poor) (WHO 2004). This is not very different from the way commodity security has been applied for RH, family planning, and HIV/AIDS commodities. For example, at a meeting in Istanbul in May 2001, stakeholders defined regular access to RH commodities through the reproductive health commodity security (RHCS) concept; it stated that RHCS exists *when every person is able to choose, obtain, and use quality contraceptives and other essential reproductive health products whenever s/he needs them* (IWG 2001).[1]

WHO's 2007 Model EML (WHO 2007b), as well as many national EMLs, includes contraceptives and medicines for RH. Additional RH medicines are listed on the *Interagency List of Essential Medicines for Reproductive Health,* which .was developed through a collaborative process that included WHO, the United Nations Population Fund (UNFPA), and technical partners. It represents an international consensus on what should be defined as essential RH commodities (WHO/UNFPA 2006). However, not all RH medicines on the Interagency list are included on the 2007 WHO Model EML,[2] nor have all found their way onto national EMLs, despite their importance for the maternal health and family planning needs in many, if not all, countries. There is also a United Nations (UN) approved list of essential medicines for humanitarian disasters that is considered a subset of the Model EML; it includes 85 products that were developed specifically for emergency and refugee situations (WHO 2002).

1.2.1 A UNIVERSAL DEFINITION AND APPLICATION

While the WHO Model EML and national EMLs are developed with regard to public health impact, quality, safety, efficacy, and cost-effectiveness, opinions vary as to what products are essential, and therefore, how the stakeholders might apply the CS concept. This is one challenge to a universal definition and application of CS for essential medicines. A second, practical matter, are the numerous other program and policy issues that must be considered to ensure CS for essential medicines, other than simply including them on one of several essential lists. Third, is the significant difference between stating that there *should* be commodity security for all essential medicines and actually putting the concept into operation. Generally, what countries consider essential is defined by the hundreds of products on their national EMLs. Stating that financing, provider training, or even the supply chain, is the sole issue or solution to CS for all medicines ignores the impact that these have on each other and on the commodities. Commodity security for any health product requires adequate financing, logistics systems, program coordination, and other factors that make up the enabling environment that supports access and use. For example, current global medicine strategies supported by USAID, WHO, UNFPA, and others—whether for contraceptives, a broader set of RH products, or essential medicines—all assert that broad, systemic solutions are required (e.g., adequate capacity to finance and distribute

[1] To reach the goals implicit in each of these definitions, a number of operational variables—the availability of health workers, effective distribution systems, client outreach programs, adequate financing, and so on—need to be addressed. This paper explains them in more detail them in sections 2.1–2.3.

[2] It could also be reasonably argued that all of the RH products on the Interagency list are considered essential by WHO because it is considered a sub-list of WHO's Model EML.

medicines, a supportive policy environment, and regular coordination). Operationalizing this approach may require category or program-specific approaches that consider specific characteristics, such as public health impact and cost, available financing, political and donor commitment, and so on.

Nonetheless, the broad, common assumptions about the programs, systems, and policies that make up commodity security and access to medicines is a starting point from which to shape coordinated approaches and to take advantage of opportunities to integrate functions. What is equally useful is an understanding of the unique characteristics of the different categories of essential medicines, which will help create more specific solutions in countries where CS practices are applied.

2.0 DEFINING COMMODITY SECURITY CONCEPTS AND FRAMEWORKS

The Public Health Challenge: Why Access to Medicines Is Important

Strategic approaches to ensure access to essential health commodities was a direct response to the impact of medicines on public health. In 2001, the Commission on Macroeconomics and Health (CMH) estimated that 10.5 million lives per year could be saved by the year 2015 by scaling up access to existing health interventions to prevent or treat infectious diseases, maternal and perinatal conditions, reproductive health needs (see box), childhood diseases, and non-communicable diseases (WHO 2001). Most of these interventions depend on the routine supply of essential medicines and consumables.

In 2003, there were almost 6 million deaths from HIV/AIDS, tuberculosis, and malaria combined (GFATM 2007). Children under five in sub-Saharan Africa accounted for the majority of the more than 1 million deaths. Additionally, WHO estimates that in 2002 more than 2 million children in developing countries died from perinatal conditions; 4 million died from just three diseases: pneumonia, measles, and diarrhea (WHO 2004). Furthermore, heart disease, cancer, and other chronic diseases cause most of the deaths in middle-income countries; they are becoming an increasing problem in low-income countries. In all these cases, medicines and non-drug consumables (NDC) that are essential for prevention and treatment exist, but regular access to them remains one of the central challenges to health systems.

Family Planning Saves Lives

More than 200 million women have an unmet need for safe and effective family planning. If these women were able to access safe, effective, and affordable contraceptive supplies, more than 100,000 maternal deaths—one-fifth of the world's total—could be avoided each year. Further, being able to time and space their pregnancies empowers women, enables them to choose their family size, and often leads to more prosperous lives (UNFPA 2005). Yet, supply chains are increasingly challenged, and, too often, failing to ensure a reliable supply of contraceptives for current users, much less for the more than 200 million additional women with unmet need.

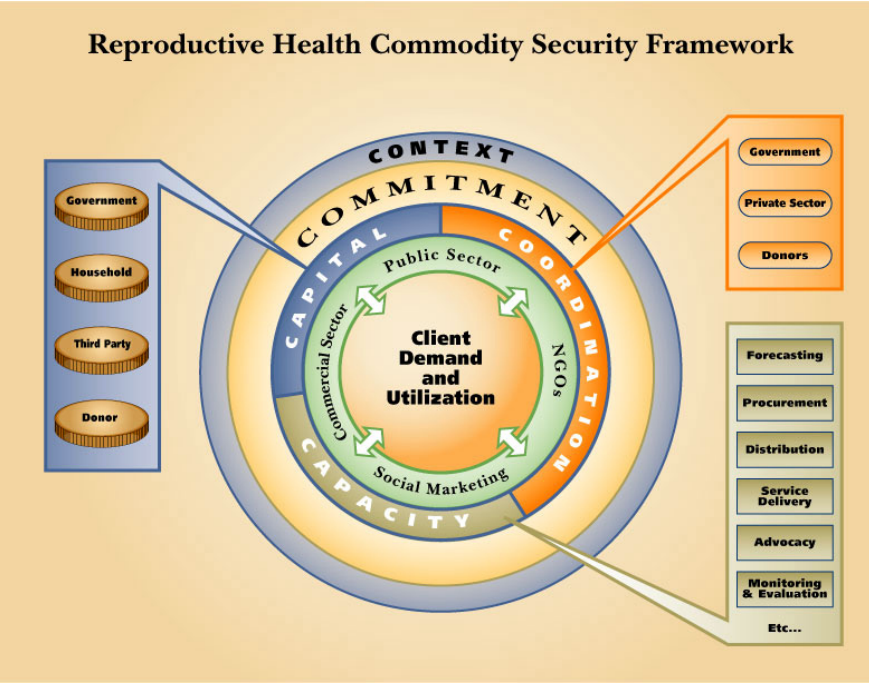
Basic to the development of commodity security and medicines access frameworks is recognizing how important it is to ensure regular access to essential health commodities to prevent and treat diseases and to provide primary health care services. Common to each is a shared understanding of how a holistic model that includes the supply chain, policies for medicines, service delivery, the pricing environment, intellectual property issues, and health financing all affect the access to and the availability of medicines. In the following sections, we review these frameworks.

2.1 REPRODUCTIVE HEALTH COMMODITY SECURITY

Definition and Objective: *People are able to choose, obtain, and use the reproductive health supplies they want* (Hare et al. 2004).

The RHCS framework, first published in 2004, describes the elements that are involved in securing RH supplies. At the center of the framework is the *client*—the ultimate beneficiary of RHCS. In every country or region, there is a *context* that both affects and is affected by RHCS. This is made up of national policies and regulations that directly or indirectly affect access to contraceptives and RH commodities. The context also includes socioeconomic conditions, political and religious norms, and competing national priorities that may be beyond the sphere of influence of RH stakeholders, but nonetheless shape RH supply outcomes. Within this context, the policymakers and public and private health care workers *commitment* to policies, programs, and systems is fundamental to ensure ownership and sustainability. It forms the basis from which stakeholders (government, donors, and consumers) will invest the necessary *capital* to procure supplies and finance the necessary distribution and health service systems for RHCS (Hare et al 2004).

Figure 1. Reproductive Health Commodity Security Framework

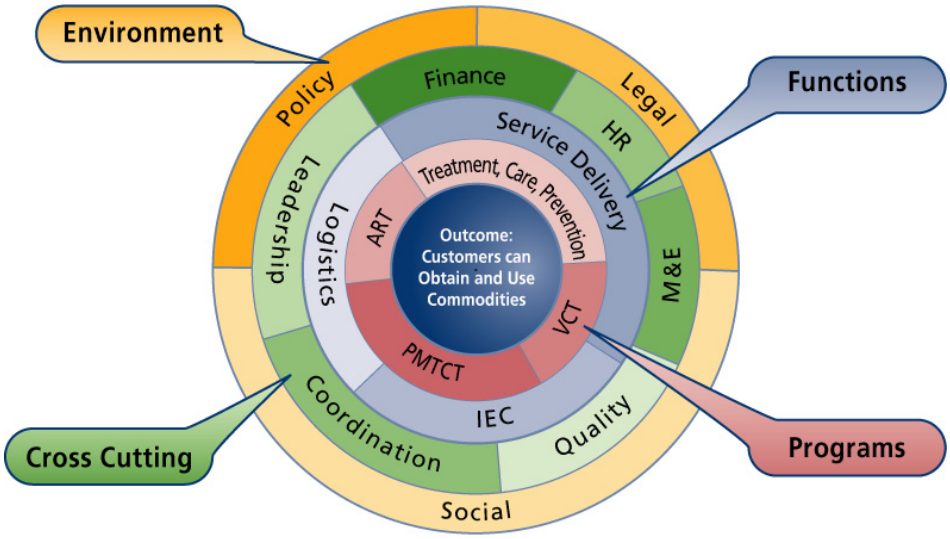


Households, third parties (e.g., employers and insurers), governments, and donors are all possible sources of capital. Due to the variety of important stakeholders in RHCS—including government, donors, and the private sector—interagency *coordination* is required to ensure the effective allocation of resources, strategy development, and joint programming. *Capacities* must exist for a range of functions—policy development and implementation; commodity forecasting and procurement, and distribution; service delivery; and monitoring and evaluating progress. Capital, coordination, and capacities are the basis for the public and private RH supply channels to efficiently meet the needs of the total market of client demand—from those who need subsidized products to those who are able to pay.

2.2 HIV/AIDS COMMODITY SECURITY

Definition and objective: *When patients and service providers can choose, obtain, and use medicines and other health commodities when and where they need them for prevention, treatment, and care of HIV/AIDS and related illnesses* (Dowling 2006).

Figure 2. HIV/AIDS Commodity Security Framework
(Dowling et al. 2006)



The HIV/AIDS commodity security (HACS) framework (see figure 1) was adapted from the RHCS framework (see figure 2); it shares much of the same conceptual underpinning. The ability of *customers* to obtain and use commodities is also at the center of the framework. The customers range from those taking antiretroviral therapy (ART), to those using condoms to prevent infection, to individuals receiving care in the form of nutritional supplements, and to those using antibiotics to cure opportunistic infections (OI), or fighting tuberculosis (TB) co-infections. Service providers are also customers; they include a variety of clinical and program personnel (e.g., laboratory staff, counselors, and physicians) who depend on a routine supply of health commodities to make HIV/AIDS programs work.

The framework suggests that ensuring CS for the different categories of HIV commodities requires a comprehensive, multi-programmatic effort. These programs require antiretroviral (ARV) drugs; drugs to treat OIs; HIV test kits; laboratory reagents; medical consumables, such as syringes and gloves; and information, education, and communication (IEC) materials to support adherence and increase uptake. The framework also identifies functions, including logistics and service delivery that are needed to make these programs work, it emphasizes that cross-cutting issues exist at every level of the programs and functions, including leadership, human resources, financing, and the quality of products and services at all levels (Dowling 2006).

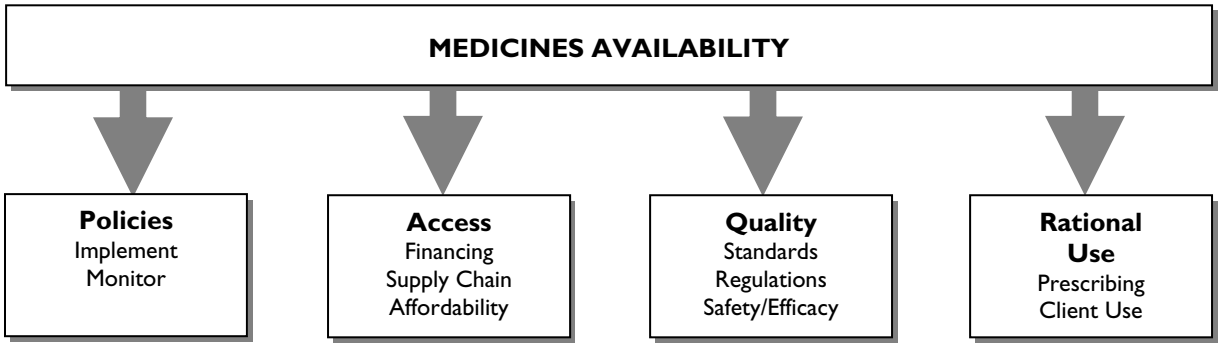
Commodity security for the people who use HIV/AIDS products and services rests on the capacity to coordinate within and between the functions and systems and to improve the policy, legal, and social environment in which they operate. The HACS model framework brings all of these elements together to illustrate how they must be addressed when shaping a strategic response to commodity security for HIV/AIDS programs.

2.3 WORLD HEALTH ORGANIZATION'S ESSENTIAL MEDICINES STRATEGY

Definition and Objective[3]: *(To) help save lives and improve health by ensuring the quality, efficacy, safety and rational use of medicines, including traditional medicines, and by promoting equitable and sustainable access to essential medicines, particularly for the poor and disadvantaged* (WHO 2004).

The World Health Organization's Medicines Strategy (see figure 3) comprises four broad objectives: (1) promote the formulation, implementation, and monitoring of national medicines **policies**, (2) expand **access** to essential medicines (by improving financing and supply systems), (3) improve the **quality** and safety of medicines, and (4) promote the **rational use** of medicines by health workers and consumers in the public and private sectors (WHO 2004).

Figure 3. WHO's Medicines Access Strategy



The strategy is not limited to just one or a few categories of essential medicines. All countries and stakeholders seeking to secure essential health commodities need to adopt the strategy. It is much broader in scope and does not include program specific components, such as those in the RHCS and HACS frameworks. However, the four objectives are divided again into seven components that broadly reflect what is needed to achieve product availability. These components are similar to the components in the other frameworks. The WHO framework can be applied to formulate strategies in the absence of or in coordination with other category specific CS approaches (see table 1).

[3] WHO is publishing a new medicines strategy for 2008–2013, which may include a revised framework and descriptive language.

Table 1. WHO Medicines Strategy Components

Objectives						
Policy		***Access***		***Quality & Safety***		***Rational Use***
Components						
Implement and Monitor Policies	Traditional Medicines Policy	Fair financing mechanisms and affordability of essential medicines	Medicines supply systems	Norms and standards for pharmaceuticals	Medicines regulation and quality assurance systems	Rational use by health professionals and consumers
Advocate and support the implementation and monitoring of medicines policies (e.g., develop and monitor trade policies supportive of medicines access).	Adequate support provided to countries to promote the safety, efficacy, quality, and sound use of traditional medicines.	Financing the supply and increasing the affordability of essential medicines in the public and private sectors.	Efficient and secure systems for medicines supply in the public and private sectors.	Strengthened global norms, standards, and guidelines for the quality, safety, and efficacy of medicines.	Improved capacity of medicines/ drug regulatory authorities and quality assurance strengthened.	Cost-effective and rational use of medicines by consumers and providers.

2.4 OTHER APPROACHES

The frameworks discussed in this section do not represent an exhaustive list of all the approaches to commodity security. They are multi-programmatic, comprehensive frameworks that underscore the position that a range of systems, functions, and policies are necessary to improve product availability. Other commodity initiatives have been based on WHO's Medicines Access strategy; they are focused primarily on distribution, financing, and global advocacy. These include more narrowly defined program-based approaches, for example, the Roll Back Malaria (RBM) Partnership, which focuses on commodities for malaria prevention and treatment, including artemisinin-based combination therapy (ACT), insecticide treated bed nets, and rapid diagnostic tests (RBM 2008). Similarly, the Stop TB Partnership and the Global Drug Facility (GDF) focus on access to antibiotic medicines to treat TB infections. While these partnerships have provided significant support for the diseases they support, the models often encourage fragmentation of funding resources and supply systems. Nonetheless, each of these organizations bases the selection of products that they focus on, at least partly, on the WHO Model EML and on what they consider essential to their mission.

3.0 CHARACTERISTICS OF ESSENTIAL MEDICINES: ADAPTING CS APPROACHES

Category-specific approaches to commodity security have proven successful in being able to diagnose gaps in access to commodities and, subsequently, to develop strategic plans to address them. While implementation remains a challenge, a focus on a limited range of medicines enables policymakers and implementors to better understand, evaluate, and design solutions based on the unique characteristics of the commodities. As the number of products under consideration grows, the solutions grow more complex because each category of commodities—often each individual product—have unique requirements that must be addressed. This section highlights the significant differences among the categories of essential medicines; stakeholders must consider them as they decide if and how to limit or expand the medicines they are trying to secure.

Despite inclusion on the WHO Model EML of medicines that should be considered essential, ultimately each country is responsible for determining which health commodities are best suited for the primary health care needs of its population. Strategies that attempt to secure the availability of and access to essential medicines need to establish, with a high degree of specificity, the products they want to target, the unique characteristics of those products, and the challenges and opportunities those characteristics will present for achieving CS objectives. For example, in the area of RHCS, many countries have purposefully limited their focus on contraceptives because the financial and capacity requirements of securing several hundred essential RH medicines are substantially different than those for the relatively few contraceptive commodities. In other countries, RHCS stakeholders agreed that a distinction within the category of essential RH products is inherently biased against users of non-focus products; CS efforts should extend to the range of maternal, obstetric, antenatal, and family planning commodities (Rao and Dick 2007).

Table 1 lists some of the unique characteristics of different categories of essential medicines. It illustrates the range of product requirements and unique challenges that must be considered when developing CS approaches. The categories in table 1 were chosen because, together, they represent a significant portion of the health and disease burden in many least-developed countries (LDC). (A complete list would require an examination of hundreds of products under 27 categories of essential medicines, ranging from anesthetics to vitamins and minerals in the Model EML.) The ability to achieve commodity security in these areas will have a considerable impact on public health. Table 3.0 also identifies many characteristics relevant to procurement and selection decisions, as well as potential financing sources—an essential requirement for commodity security. Within certain essential medicine categories—reproductive health, tuberculosis, and vaccines—the defined characteristics typically apply to most or all commodities in the category; in others—particularly HIV/AIDS and malaria—the characteristics are specific to a specific commodity (ARVs and ACTs, respectively).[4]

[4] For more information on the listed products (and those not listed), see the *WHO Model Formulary 2006*. Geneva: World Health Organization. 2006.

Table 2 clearly shows that, while it is necessary to include the broad systems, functions, and policy components, CS implementation strategies at the country level will be category-specific, and sometimes, commodity-specific, and will include a range of different partners, resources, and supply chains. For example, commodity security for vaccines, because of its highly specialized supply chain requirements and distribution methods, will probably require its own approach to address these unique characteristics. Conversely, a CS strategy to ensure the supply of ARVs may consider including TB medicines because of the high incidence of co-infection. See sections 4 and 5 for a more detailed discussion on this subject.

The list is not exhaustive. It illustrates the range of product requirements and unique challenges that must be considered when developing CS approaches for any or all of the categories.

Table 2 shows clearly that, while it is necessary to include the broad systems, functions, and policy components in each of the commodity frameworks, CS implementation strategies at the country level will be category-specific and sometimes commodity-specific, and will include a range of different partners, resources, and supply chains. Commodity security for vaccines, for example, due to its highly specialized supply chain requirements and distribution methods, will likely require its own approach to address these unique characteristics. Conversely, a CS strategy to ensure the supply of HIV/AIDS products or ARVs, may consider including TB medicines because of the high incidence of co-infection. See sections 4 and 5 for a more detailed discussion on this subject.

Table 2. Characteristics of Select Essential Medicines

Category	Commodity/Clinical Use	Characteristics
HIV/AIDS	**Chronic Treatment**	
	Antiretrovirals (ARVs)	• Requires long-term supply commitment, as cure does not yet exist • Requires > 90% adherence to ensure efficacy and reduce resistance • Requires complex clinical component for monitoring • Scale of needed financing substantial, despite price reductions • Potential social stigma associated with use • Substantial global financing sources available for procurement
Malaria	**Acute Treatment**	
	Artemisinin-based combination therapy (ACT)	• Unit costs reduced in last several years (~$U.S.1.00 landed cost in-country as tablets in blister packs per adult treatment (MMV 2005) • Fixed dose combination, which is effective against existing drug resistant strains • Have no negative pharmacological interactions, are well-tolerated, and show acceptable toxicity • Suitable for use in children and pregnant women • Short shelf life, resulting in the need for a short logistics pipeline • Substantial global financing sources available for procurement

Category	Commodity/Clinical Use	Characteristics
Reproductive Health	**Chronic Treatment**	
	Contraceptives	• Ability of clients to choose among a variety of methods important for use and adherence • Limited range of available products • Wide range of couple-years of protection (CYP) costs between methods • Wide range of side effects among methods • Potential social and political stigma associated with use • Growing demand for modern contraception • Limited global financing available for procurement
Tuberculosis	**Semi-chronic Treatment**	
	Treatment Antibiotics	• Infection resistant to standard drug treatment (multidrug-resistant tuberculosis (MDR-TB) may result in need for multiple products • More effective medicines are coming through the research and development pipeline • Current treatment course of 6 months leads to low adherence and fosters development of drug resistance • Complex laboratory and monitoring component • Limited global financing sources available for procurement (Stop TB 2005)
Vaccines[5]	**Semi-chronic Treatment**	
		• Sensitivity to heat, humidity, and fluctuations in temperature require cold chain supply management • Packaging of newer vaccines (e.g., bulky, single dose) present challenges to existing storage and cold chain capacity in LDCs[6] • Predictable demand forecasting for routine immunizations • Substantial global financing (e.g., UNICEF, PAHO, GAVI) available for procurement • High cost effectiveness when comparing price and health impact • User fees may be barrier to uptake (i.e., routine immunization, preventative, not curative) (WHO 2001) • Limited private sector market in low-income countries • Limited number of producers

[5] Many of the characteristics are taken from Milstein 2005.

[6] From written correspondence with Robert Steinglass, January 2008.

4.0 INTEGRATED APPROACH TO COMMODITY SECURITY

4.1 THE CHALLENGES

To take an integrated approach to commodity security for all essential medicines requires a substantially greater level of program coordination, collaboration, and political will than it would for any one specific category. For example, mobilizing country stakeholders to develop and implement contraceptive security strategies limited to a relatively small number of family planning methods (e.g., oral pills, male and female condoms, injectables, etc..), distributed through a vertical supply chain, free of charge to the consumers, is probably more workable in the short-term. When several hundred or even dozens of additional medicines with unique supply chain requirements (e.g., short shelf life, cold chain, limited suppliers, etc.), are added, the varying financing methods and a larger group of stakeholders and interests present much more of challenge. The management and coordination of the different health programs becomes more complex as a larger variety of medicines need to be selected, purchased, distributed, and tracked through a logistics management information system (LMIS). This may, as proponents of vertical systems may argue, reduce the efficiency of the distribution system by concentrating too many of the functions centrally in a system that does not have the capacity to manage multiple categories of products.

For contraceptive security strategies developed in Ghana and Jordan, the countries took these factors into account when they considered whether or not to integrate a larger number of RH products in the operational definition of their respective strategies. Both countries narrowed the products to the sub-category of contraceptives. Ghana made its decision because family planning supporters were able to demonstrate a critical funding gap and a high unmet need for contraceptives (Ghana MOH 2004). For Jordan, access and the availability of contraceptives was seen as an essential element of the National Population Strategy (NPS), which was explicitly developed in response to a critical need for a "proactive approach for reducing the annual growth of its population" (POLICY Project 2006). By contrast, in Zambia, HIV/AIDS stakeholders decided not to limit the wide range of essential medicines needed for prevention, treatment, and care when they developed their HACS strategy. While it avoided the difficult politics of prioritizing HIV medicines among a diverse set of programs and stakeholders, some saw the CS strategy that resulted as unmanageable because it cut across many programs and involved dozens of organizations.

4.2 HOW IT CAN WORK

Integration of commodity security approaches is not *all or none*. Commodity security comprises many components—logistics, policies, financing, service delivery, and several other functions noted in each of the frameworks in section 2.0. Integrating one or a few of these components can help support improved availability for essential medicines. The following examples show how what has already been accomplished.

4.2.1 POLICIES AND MANAGEMENT

Successful integration can also take place at the *policy* level. In 2007, to address the supply management challenges between RH and HIV/AIDS commodities, the Zambian MOH paused to review its commodity security policies for program coordination, supply chain, procurement, and financing. Currently, they are managing separate RHCS and HACS processes. However, the MOH realized that a significant overlap in system strengthening is needed to improve the availability of these and other medicines managed by the public sector. Their current view is to allow each process to *mature*, then review and consolidate interventions in each of the strategies that will form the basis of a CS approach for all essential medicines and consumables on the national EML (Rao and Dik 2007). This example shows how leadership and clear policy direction from MOH policymakers can set an agenda that incrementally builds to a broader, long-term view of CS for all essential health products.

4.2.2 FINANCING

Decision makers are also beginning to see the value of integrating procurement *financing*. Health sector basket funding arrangements—mechanisms where donors, the World Bank, and recipient governments pool their funding, then jointly identify priorities—are being implemented in many countries. Instead of program-specific allocations made by individual donors and recipient governments for certain health commodities, the funds are integrated in one *basket*, then allocated for procurement based on the product supply needs. Basket funds in Ghana, for example, support contraceptives, vaccines, and other categories of essential medicines. In Nepal, the flexibility of this approach has allowed the country to increase needed support for contraceptives, from U.S.$126,000 in 2006 to nearly $1.9 million in 2007[7] (GON 2006). These pooled, or integrated, approaches encourage more rationale decisions regarding the selection and procurement quantities of essential health commodities because they take a comprehensive view of supply needs and involve more stakeholders in the decisions.

4.2.3 THE SUPPLY CHAIN

In 2002, Bolivia took steps to integrate specific aspects of the *supply chain*. Over the years, it had developed a strong vertical distribution and information management system for contraceptives. This capacity influenced the decision by the MOH to integrate some commodities for maternal and child health, and then additional essential medicines, into the contraceptive supply system—in effect creating an integrated supply chain for essential medicines (Dowling 2008). Category-specific CS approaches, in this case for family planning, can be a starting point to build infrastructure and capacity to support further integration of CS functions for additional categories of essential medicines. This approach extends to other systems where opportunities have been identified to reduce duplication of services. For many years, countries have distributed vitamin A during routine immunization programs to complement and strengthen health prevention services and to take advantage of the capacity already in place in vertical vaccination programs (WHO 1998). In the late 1990s, Mali integrated contraceptives into its essential medicines supply chain. This initially led to decreased availability of product consumption data when the systems were merged; however, instead of returning to a separate supply system for contraceptives, the MOH improved LMIS reporting forms and practices for all essential medicines in the system, thereby strengthening logistics data management for multiple categories of medicines (Dowling 2008).

[7] The funds were combined contributions to the basket fund by the World Bank, DFID, and the government of Nepal.

4.2.4 SERVICE DELIVERY

The provision of essential medicines can also be integrated as part of comprehensive *health service delivery*. The prevalence of the HIV infection among patients in TB treatment clinics can be 80 percent or higher in some countries (Sharma, Mohan, and Kadhiravan 2005). It is one of the most common OI for those infected with HIV. As a result, many HIV and TB programs have been integrated at the service delivery level by providing essential health commodities to treat and diagnose TB and HIV at one service delivery site. In Uganda, for example, The AIDS Support Organization (TASO) is providing clinical and home-based care for TB/HIV co-infection (PEPFAR 2008). Other programs like these gain efficiencies and improve services by training health workers in both TB and HIV interventions, thus, reducing the number of commodity distribution sites without compromising care.

4.3 UNDERLYING ASSUMPTIONS SUPPORTING THE INTEGRATED APPROACH

Country-level policymakers and global commodity funding organizations have become more interested in using an integrated approach to commodity security and access to essential medicines. From the country perspective, the argument has been that all categories of essential medicines are important. It is difficult to support one more forcefully than others because all essential medicines address basic, critical public health concerns; influential interest groups—rightly so—have been built around concerns that champion the routine availability of those medicines. Global organizations are more frequently approaching integration through proposed investments in health systems, which they argue improves access to all categories of essential medicines by strengthening the underlying systems and programs that deliver them. While programming for category specific medicines—vaccines and those delivered in emergency situations and through seasonal campaigns—will continue, donors and recipient governments seem to be taking a broader view where the reliable availability of essential medicines is only one key aspect of meeting health sector goals.

Factors behind these trends include—

- *The health systems approach:* Strengthening the health system—the organizations, service delivery capacity, infrastructure, people, and resources—can improve the environment for commodity security for all essential medicines in the system. For example, a health system approach that addresses the shortage of health care workers can help identify unnecessary duplication in supply systems in countries that cannot afford to fully maintain separate systems for different commodity groups.
- *Improve use of current capacity:* This approach aims to obtain greater performance from existing resources, as contrasted with additional resources for strengthening health systems (above). Separate procurement and logistics systems, overlapping product selection and forecasting functions, and separate budget processes increase the management burden for MOHs and create additional costs. For example, warehousing and transporting products in vertical programs leads to higher fixed costs, which could be divided between multiple product categories.[8]
- *Health impact across medicine categories:* Many health interventions and medicines traditionally used and referenced as belonging to one category, can produce desired health outcomes for other programs. For instance, the use of male condoms for family planning has reduced the transmission of HIV and other STIs. Likewise, male condoms meant to increase HIV prevention, can help meet the

[8] Very little documentation exists on the cost of in-country supply chains. A cost comparison of vertical and integrated supply chains and their performance will help inform discussions by quantifying the benefits and drawbacks of integrated distribution systems.

unmet need for contraception (Fleischman 2006). Moreover, medicines used to treat STIs in HIV-positive patients have broad applicability for use as an antibiotic for scores of other acute and chronic infections.

- *Common assumptions about commodity security:* Each of the conceptual frameworks discussed in this paper conclude that, despite the unique characteristics of different product categories, the same components (e.g., financing, logistics, policy commitment, coordination, and capacity) must be addressed to ensure CS. Country-level interventions in any one of these components, even if developed for a particular product category, will probably have spill-over effects for other commodities. For example, improvements to stock management practices at central medical stores, completed as part of a contraceptive security strategy will improve the management of all commodities stored at the warehouse. Likewise, increasing the organizational capacity of the public sector procurement agency to manage tenders for ARVs will no doubt leave them more receptive to initiating tenders for purchases of other commodities.

4.4 GLOBAL TRENDS

4.4.1 GLOBAL FINANCING

Global-level commodity financing institutions have started operating from a broader view of commodity security. The GFATM and UNITAID[9] have indicated that they are, in some measure, willing to finance dual or multi-purpose use products, such as male condoms used for family planning and antibiotics and co-trimoxazole, which is used as part of some HIV treatment regimens and in reproductive health. However, global funding mechanisms like GFATM, PEPFAR, the GAVI Alliance, the Global Drug Facility of the Stop TB Partnership, and other institutions with significant resources remain largely focused on disease-specific targets that require support for a limited range of commodities (Druce 2006). Yet, it is becoming clear that broad health system improvements and support for additional categories of medicines impact their core targets. Ultimately, the direction and scope of this broader funding rests largely with the countries that request it and can demonstrate these linkages.

4.4.2 COUNTRY FINANCING

Major donors and international lending institutions have started to move away from project and program funding to multi-donor direct budget support (MDDBS) and basket funding for health sector wide approaches (SWAp). These financing mechanisms give policymakers more flexibility to address funding gaps for priority health services, including a broader range of essential medicines on their national EMLs. SWAp evolved, at least in part, in response to the proliferation of project or *earmarked* funding, which can be difficult to coordinate and often favor more visible, politically popular programs at the expense of other health sector priorities. The SWAp is intended to promote more rational resource allocation decisions—including those for funding essential medicines—by matching health resources to (consensus-based) priority health interventions (Vian 2003).

4.4.3 PREQUALIFICATION OF ESSENTIAL MEDICINES

The expansion of the WHO Prequalification Programme is further evidence that global institutions are implementing programs that promote a more holistic view of the essential medicines model. The WHO program, established in 2001, prequalifies manufacturers of medicines and their products based on

[9] Comments from the Executive Director at a public meeting at UNITAID headquarters in Geneva, October 2007.

Good Manufacturing Practices and other criteria for product standards, including quality, safety, and efficacy for HIV, malaria, and TB. The program was initially set up to prequalify products that the United Nations (UN) procurement agencies, like UNICEF, could procure and distribute for these three categories. The list of prequalified medicines has grown and is now used in selection and procurement decisions by GFATM, UNITAID, and country procurement agents. The program helps operationalize one of the four components (Quality and Safety) in the WHO Medicines Strategy; it is also an important tool that supports commodity security objectives for an expanding number of essential medicines. In 2006, the program expanded to include RH medicines, starting with oral and injectable contraceptives, and products for the prevention and treatment of postpartum hemorrhage and ecalmpsia. The program has more recently added influenza-specific antiviral medicines. As the program continues to grow, both in the number of products under each of the current categories and, in additional categories, it will facilitate the access of countries and global organizations to a wider range of essential medicines.

5.0 CONCLUSIONS: OPPORTUNITIES FOR UNIFIED ACTION

Will EMCS require a radical change in the way we view drug distribution? Has the old way of segmenting and setting up vertical commodity distribution systems, financing, and planning led to fragmentation and missed opportunities to improve efficiencies, and thus the availability of the essential medicines that make primary health care interventions possible? The answer to these questions and the future for commodity security approaches, is not yet clear. However, recent global trends and in-country practices do show movement toward more investments in health systems, in particular for supply chains that seek to manage a broader array of essential medicines.

> Vertical programs are easier to manage and enable program managers to focus efforts on a limited number of targets. Vertical programs also provide a platform from which to advocate for neglected diseases.

Nonetheless, there are also benefits to programming by specific product categories. Consequently, category specific CS approaches (e.g., RHCS and HACS) were developed to respond to this reality. Limiting commodity security strategies to certain products can lead to programs that are more focused, more feasible, and likely to show results. The key advantage to this approach is that targets become relatively easier to achieve than in an integrated CS approach that requires the performance of multiple programs. So-called vertical approaches also provide platforms from which to advocate for important, sometime neglected, health issues.

On the other hand, category-specific programs can distort financing for essential medicines in ways that are disproportionate to disease patterns. Rwanda, for example, a country with a just over 8 million residents and a 3 percent HIV prevalence rate, receives approximately $47 million in annual HIV/AIDS funding, compared to just $1 million in funding for childhood diseases (Foster 2006), which have a much higher mortality rate. Further, countries run the risk of creating parallel, overlapping, and fragmented commodity security programs that may not be sustainable and can exacerbate the human resource gaps faced by almost all low-income countries in the health sector.

> An integrated approach takes advantage of opportunities to use capacity efficiently and to improve systems for many categories of essential medicines.

5.1 MOVING ESSENTIAL MEDICINES COMMODITY SECURITY FORWARD

A Universal Approach Exists

The broad components (e.g., financing, logistics, policy commitment, coordination, and capacity) that the multiple frameworks share, and described in this paper, are necessary when framing any commodity security strategy, whether for multiple categories or a single category of medicines. These frameworks have in common a shared understanding of how policies, the mix of service delivery channels and programs, client and provider behavior, and distribution systems work together to form the constituent parts of commodity security. The universality of these essential components makes it possible to have integrated strategic approaches to commodity security.

Integration Is a Tool to Improve CS for Essential Medicines

An *integrated* approach to commodity security is one that addresses commodity-specific considerations—such as available sources of financing, the desired mix of public and private provision, need for related services and consumable supplies, and supply chain considerations—for commodities from distinct programs. A successful approach would consider the capacity of the CS systems; its strengths and weaknesses; and the specific financing, distribution, and handling requirements of different essential medicines. An integrated approach takes advantages of opportunities to use current capacity efficiently and tries to improve systems with additional resources to support multiple categories of essential medicines. The approach can best be characterized as managing broadly but acting specifically. The benefits of an integrated approach should be tangible and measurable.

Integration Requires Characteristics of Essential Medicines to be Considered Carefully

An integrated approach is distinct from a *generic*, broad-based solution because the latter does not accommodate program and product requirements and does not consider the effects those specific policies may have on programs and systems for other commodities. Initial evidence shows that integrated strategies (though challenging) can succeed, while generic strategies are certain to fail.

One Size Does Fit All

Taking an integrated approach to commodity security does not mean that all components of commodity security (financing, procurement, warehousing, LMIS, service delivery, etc.) must be integrated. Rather, a thoughtful and strategic analysis is required to determine which components are amenable to integration, across which product categories, and where commodity or program requirements dictate that components should remain independent.

The prospects for the success of a commodity security strategy – whether for a few or many product categories – will be maximized by (1) identifying and addressing the different characteristics of the medicines that it seeks to secure; and (2) taking advantage of opportunities to achieve overall system efficiencies and reduce redundancies.

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