

DEFINING AND MEASURING PHARMACEUTICAL SYSTEMS STRENGTHENING

Report of the SIAPS Partners' Consultative Meeting
September 11-12, 2014



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to Pharmaceuticals and Services

Defining and Measuring Pharmaceutical Systems Strengthening: Report of the SIAPS Partners' Consultative Meeting

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Defining and Measuring Pharmaceutical Systems Strengthening: Partners' Meeting Report

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This report should be read in conjunction with the associated background discussion paper as revised after the meeting (page 18).

Contributors and Reviewers

Tamara Hafner, SIAPS consultant and Helena Walkowiak, SIAPS Principal Technical Advisor prepared this meeting report and the background discussion paper.

The background discussion paper reflects the contributions of David Lee, CPM/MSH Director, Technical Strategy and Quality. Veronika Wirtz and Richard Laing, both from the Department of Global Health at Boston University School of Public Health, contributed to the section on composite indicators. This section was revised after the meeting to reflect their contribution.

Richard Laing and the following SIAPS and MSH staff reviewed the draft of the background discussion paper: Francis (Kofi) Aboagye-Nyame, Michael Cohen, Ruth Musila, Sue Putter, and Maura Soucy.

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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Systems for Improved Access to Pharmaceuticals and Services
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Website: www.siapsprogram.org

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Acronyms

AOR	Agreement Officer's Representative [USAID]
CPM	Center for Pharmaceutical Management [MSH]
HSAA	Health System Assessment Approach
DFID	Department for International Development
HDI	Human Development Index
HTA	Health Technology Assessment
IHP+	The International Health Partnership
JSI	John Snow International
MSH	Management Sciences for Health
OECD	Organisation for Economic Co-operation and Development
PAHO	Pan American Health Organization
RPM Plus	Rational Pharmaceutical Management Plus Program
SIAPS	Systems for Improved Access to Pharmaceuticals and Services Program
SPS	Strengthening Pharmaceutical Systems Program
USAID	US Agency for International Development
WHO	World Health Organization

Executive Summary

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program convened a consultative meeting of its partners to identify definitions of a pharmaceutical system and pharmaceutical systems strengthening and components to be included in a measurement framework for systems strengthening. The meeting held on September 11-12, 2014, brought together SIAPS core and resource partners, experts from the US Agency for International Development (USAID), the Pan American Health Organization (PAHO) (representing the World Health Organization), and Boston University School of Public Health. The discussions were guided by a background discussion paper prepared by SIAPS staff (page 18) and presentations given at the beginning of each session.

More than 30 participants, who represented 13 different organizations working to improve access and use of pharmaceuticals in low- and middle-income countries, agreed on the following working definitions of a pharmaceutical system and pharmaceutical systems strengthening:

- A *pharmaceutical system* consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.
- *Pharmaceutical systems strengthening* is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to enhance responsive and resilient system performance for achieving better health outcomes. The critical components of a pharmaceutical system are its core functions, structures, the supporting health system resources, and an enabling policy, legal, and governance framework.

Participants also identified the pharmaceutical system components to be included as part of a measurement framework for systems strengthening: policy, law and governance; regulatory systems; pharmaceutical products and services; human resources; financing; information; innovation, research and development, manufacturing, and trade. In addition, for each of these system components, participants proposed critical elements to guide SIAPS in the selection of indicators for a measurement framework. Recommendations were also made to inform the use of composite indicators as an approach for measuring and ranking the performance of national pharmaceutical systems.

Key next steps include developing the measurement framework for pharmaceutical systems strengthening. In addition, indicators and tools to measure progress made in strengthening systems must be identified and piloted. The framework and indicators will help guide health system planners and donors that are considering investing scarce resources in ways that will have lasting results.

Background

In 2012, the US Agency for International Development (USAID) awarded the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program¹ to promote and utilize a systems strengthening approach to improve access to pharmaceutical products and services consistent with the US Government's Global Health Initiative objectives of improved and sustainable health impact. Although the impact of investments in strengthening health systems must be effectively captured and communicated, there is no standardized approach for measuring progress toward stronger, more sustainable pharmaceutical systems. Furthermore, there is no widely accepted definition of what constitutes a pharmaceutical system, or its strengthening. In the absence of clear definitions and generally accepted reliable measures, countries and donors lack information to direct interventions and investments to address weaknesses and ascertain that these investments are resulting in stronger, more resilient pharmaceutical systems. To address this need, SIAPS is working with partners to develop a measurement framework with clearly linked metrics to enable stakeholders to objectively measure the performance of pharmaceutical systems and changes thereof, and use this information for intervention design and evaluation to enhance the delivery of pharmaceutical services.

A literature review was undertaken as a first step to gain conceptual clarity on what a pharmaceutical system is and what strengthening the system entails. The resulting report (page 18) was the background discussion paper and basis for discussions at the SIAPS Partner Consultative Meeting held at the Management Sciences for Health (MSH) offices in Arlington, Virginia, on September 11-12, 2014. The participants (page 14) brought a wealth of expertise in an array of pharmaceutical management technical areas to the meeting.

¹ The USAID-funded SIAPS Program is implemented by MSH with core partners Accreditation Council for Pharmacy Education, Harvard University, Logistics Management Institute, and University of Washington and specialized resource partners African Medical and Research Foundation, Ecumenical Pharmaceutical Network, Results for Development, IMPERIAL Health Sciences, VillageReach, and William Davidson Institute

Meeting Objectives

The objectives of the meeting were to:

1. Agree on working definitions of what constitutes a *pharmaceutical system* and *pharmaceutical systems strengthening*.
2. Based on these definitions, identify the key elements that must be operationalized and turned into indicators and discuss potential sources of data.
3. Agree on next steps for selecting or developing appropriate indicators for measuring pharmaceutical systems strengthening outcomes.

The meeting was structured around four sessions that centered on addressing the meeting objectives. The first session focused on deriving definitions of a pharmaceutical system and pharmaceutical systems strengthening. In the second and third sessions, meeting participants discussed and identified the system components to be included in the measurement framework and the key elements of each component that should guide the selection of indicators. The final session focused on discussing next steps for identifying appropriate indicators for measuring pharmaceutical systems strengthening outcomes, including approaches and challenges to using composite indicators. The meeting agenda can be found on page 15.

Each session began with a presentation that summarized relevant background information and findings from the literature review, which were summarized in the background discussion paper distributed to participants prior to the meeting. Participants then engaged in small-group deliberations to address the session objectives and presented the results in plenary. A list of the members in each group can be found on page 17. Each session concluded with a plenary discussion to review the results of the group work and, where appropriate, reach agreement on the session outputs and recommendations. Professor Richard Laing of Boston University facilitated the meeting.

Welcome and Introductory Remarks

Douglas Keene, Vice President of the MSH Center for Pharmaceutical Management (CPM)

Dr. Keene welcomed the participants, wished them a successful meeting, and highlighted the importance of the meeting outcomes for CPM's programs.

Tony Boni, USAID Agreement Officer's Representative (AOR) for the SIAPS Program

In his introductory remarks, Mr. Boni noted that the SIAPS Program was designed to test the theory that a systems approach to pharmaceutical systems strengthening would yield sustainable, country-owned, resilient systems by focusing on the intersections between the medical products building block and the other health systems components of governance, financing, human resources, information systems, and service delivery, all of which have their own interactions. The hypothesis was that pharmaceutical systems strengthening interventions need to be deliberately designed, planned, implemented, and monitored, with systematic consideration of all health systems components. This approach would be more likely to engender sustainable systems improvements.

He stressed that an expected key result of the SIAPS Program was the development and validation of a framework and metrics for pharmaceutical systems strengthening. USAID intended that SIAPS should be able to demonstrate that USAID contributions are making a difference and contributing to the development of stronger systems that can help countries achieve expected health outcomes. USAID and other donors need information to guide them on what to target and invest in as well as metrics to assess whether these investments are resulting in stronger, more resilient pharmaceutical systems. The challenge is to justify investments in pharmaceutical system strengthening and show value for money, as reflected by improved access to and appropriate use of medicines.

This meeting was an important step in thinking through technical issues as we seek to develop robust measures that can gauge the impact of interventions in promoting sustainability and stronger, more resilient pharmaceutical systems.

Mr. Boni also highlighted the need to distinguish between *support to the health system* and *health system strengthening*. Returning to the metrics issue, he noted that there is often a lack of recognition that performance of the health system is not necessarily indicative of the sustainability and strength of the system. It is essential to determine the factors that strengthen pharmaceutical systems and clearly identify confounding factors such as unsustainable donor support that temporarily improves system performance, but does not actually strengthen systems in a sustainable manner. The bottom line is that metrics to determine when a system has been strengthened are lacking.

He concluded his remarks by saying that this meeting was an important step in thinking through technical issues as we seek to develop robust measures that can gauge the impact of interventions in promoting sustainability and stronger, more resilient pharmaceutical systems.

Francis (Kofi) Aboagye-Nyame, SIAPS Program Director

Mr. Aboagye-Nyame welcomed the meeting participants and introduced Professor Richard Laing, the meeting facilitator. He reminded participants of the SIAPS Program objective—to promote and use a systems strengthening approach consistent with the Global Health Initiative that will result in positive and sustainable health impact—and provided an overview of the pharmaceutical systems strengthening framework that SIAPS uses to guide its work. As noted by Mr. Boni, a key deliverable for the SIAPS Program is the development of a framework with clearly linked indicators to enable stakeholders to objectively measure progress toward stronger, more sustainable systems.

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The work is now underway to develop this framework and related metrics, which will also help differentiate between interventions that strengthen a system and those that support it. This information will enable health planners and donors to more effectively design and select interventions and direct scarce resources to address critical weaknesses. The metrics will also provide a means for SIAPS to validate that the program's systems strengthening approach is resulting in stronger pharmaceutical systems. SIAPS has convened this meeting of its partners and other experts with knowledge and experience in an array of pharmaceutical management technical areas in low- and middle-income countries as a first step in developing a measurement framework and testable indicators. He concluded by presenting the meeting objectives and thanking the participants for their inputs.

Summary of Presentations and Discussions

Defining a Pharmaceutical System and Pharmaceutical Systems Strengthening

The objective of this session was to reach agreement on working definitions of pharmaceutical system and pharmaceutical systems strengthening.

The session began with a presentation by Tamara Hafner, SIAPS Consultant, reviewing the key findings of the literature review as summarized in the background discussion paper (page 18). She highlighted the three explicit definitions of a pharmaceutical system identified which provide a useful starting point. Two definitions related to pharmaceutical management and eight frameworks that were also identified provided further insight into understanding the goals and scopes of a pharmaceutical system. Based on a review of the identified definitions and frameworks, a pharmaceutical system can include structures/organizations, individuals/people, resources, and functions. The system is often defined in terms of its functions, subsystems, or decision points along the medicine chain. With respect to system goals, a consistent theme is improved access and use. It may be access to medicines, pharmaceuticals, medical products, vaccines, and technologies; these terms were not clearly defined and often used interchangeably.

No explicit definitions of pharmaceutical systems strengthening were found, however, three definitions of health systems strengthening exist which provide some guidance and draw attention to two major themes: improving performance (efficiency and quality) and improving resilience or capacity to address future health challenges and sustain improvements.

SIAPS used these various definitions and frameworks to develop definitions of a pharmaceutical system and pharmaceutical systems strengthening, which were presented as a starting point for group discussions. The proposed definitions were:

- *A pharmaceutical system* consists of all organizations, individuals, resources, and actions and their interactions that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use.
- *Pharmaceutical systems strengthening* is the process of identifying and implementing strategies and actions that achieve sustainable changes in one or more critical components of a pharmaceutical system to improve system performance and capacity, to address future health and system challenges, and to contribute to better health outcomes through equitable improvements in access, quality, coverage, and use of pharmaceutical products and related services. (Note that the critical components of a pharmaceutical system are its core functions, structures, and the supporting health system resources and an enabling policy, legal, and governance framework.)

The five groups were asked to use these proposed definitions as the basis for their discussions and propose working definitions. None of the five groups proposed entirely new definitions, however, all the groups suggested some modifications.

The groups made the following points on the proposed definition of a pharmaceutical system:

- There was general agreement with the goals of the system as described.
- The definition needs to link the pharmaceutical system in some way to health outcomes and situate it in the context of the broader health system. Although strengthening pharmaceutical systems contributes to improving health outcomes, it is difficult to directly attribute improvements in health outcomes to improvements in system performance, particularly given the many determinants of (ill) health. In the plenary discussion, the participants agreed that appending “towards improving health outcomes” or some variation thereof to the proposed definition would address this issue.
- Several groups suggested that stakeholders in the system may include households or entire communities, and not just individuals. The participants agreed to replace the term *individuals* with *people* to account for communities as stakeholders.
- With regard to the question of “access to what?” – all groups discussed whether *pharmaceutical products* is a sufficiently inclusive term and the use of *health technologies* as an alternate. Noting that *health technologies* is a very broad term that goes beyond medicines and other pharmaceutical products, the participants decided that *pharmaceutical product* was more appropriate as it helped to delineate a clear boundary for the scope of a pharmaceutical system.

The group work feedback regarding the proposed definition of pharmaceutical systems strengthening focused on two main themes:

- The definition should convey a sense of coordination, because without coordination, the various processes and actions are unlikely to lead to a strengthened system.
- The proposed definition does not adequately address the goal of improving system resilience and responsiveness. The participants agreed in the plenary discussion that this goal should be stated explicitly in the definition.

Lastly, the participants agreed that to avoid overly lengthy definitions, a glossary defining terms such as access, pharmaceutical products, resources, and processes should be developed to accompany the definitions.

These and other minor suggestions yielded the following two agreed-upon definitions:

- *A pharmaceutical system* consists of all structures, people, resources, processes, and their interactions within the broader health system that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use to improve health outcomes.
- *Pharmaceutical systems strengthening* is the process of identifying and implementing strategies and actions that achieve coordinated and sustainable improvements in the critical components of a pharmaceutical system to enhance responsive and resilient system performance for achieving better health outcomes. The critical components of a pharmaceutical system are its core functions, structures, the supporting health system resources, and an enabling policy, legal, and governance framework.

Key Components of the Pharmaceutical System

The objective of this session was to identify the key components of a pharmaceutical system to inform the development of a framework for measurement of pharmaceutical systems strengthening.

Helena Walkowiak, Principal Technical Advisor, CPM, opened this session with a presentation of the pharmaceutical system components compiled from a review of the 8 frameworks and 44 assessment tools discussed in the background discussion paper (page 18). Although none of the frameworks explicitly depict a pharmaceutical system, they provide a useful starting point for identifying the key components of a pharmaceutical system. The compilation of these framework elements, presented in table 2 of the background discussion paper, includes the following:

- Functions (subsystems; “medicine chain”): selection; procurement; distribution; use; research, and development; clinical trials; regulation; manufacturing; and packaging
- “Building blocks” (policy and legal framework, management support systems, resources/inputs): service delivery; [leadership and] governance; policies, law, and regulation (supported by good governance); medical products, vaccines, health technologies; human resources; information; financing [pricing; price setting/negotiation]; infrastructure; organization
- Environment: market forces, innovation, transparency, donors’ agenda, and funding

Ms. Walkowiak explained that, due to the scarcity of explicit definitions and frameworks for a pharmaceutical system, the literature review had also sought to identify tools and indicator sets that have focused on assessing a pharmaceutical system or measuring its performance. Many such tools exist and much of the thinking on and knowledge of pharmaceutical systems and their assessment have been incorporated into the development and refinement of these tools over time.

Of the 53 assessment tools identified in the literature review, 44 were reviewed and the categories of indicators and survey questions compiled to further inform the process on identifying key pharmaceutical system components (summarized in table 3 of the background discussion paper).

The meeting participants discussed the system components identified from the frameworks and assessment tools in their assigned groups and proposed key components of a pharmaceutical system for inclusion in a measurement framework (table 1). Participants agreed that the challenge lay in distilling the most critical components to avoid a list so exhaustive that the resulting measurement framework becomes impractical. In the plenary discussion, the participants focused on the commonalities across the various lists from the group discussions. As an illustration, for leadership and governance, groups 1 and 3 identified these as one component, group 2 listed them as two separate components, and group 5 identified a legal framework with governance and transparency as part of that component. The participants agreed to have policy, laws and governance as a system component to capture these themes.

These and other plenary deliberations yielded the following list of components for the measurement framework:

1. Policy, laws and governance
2. Regulatory systems
3. Pharmaceutical services
4. Human resources
5. Financing
6. Information
7. Innovation, research and development, manufacturing, trade

Group 4 also identified several cross-cutting themes which the meeting participants agreed could further inform this work. They include sustainability, equity, financial protection and health, resilience, efficiency, country ownership, and evidence-based decision making.

Key Elements for Selecting Indicators

The objective of this session was to identify important elements within each of the agreed upon system components that SIAPS can use as the basis for selecting indicators.

Each group was assigned one or two of the system components (page 17) and worked to identify the most important elements within each of the assigned components for which associated indicators should be later selected to track pharmaceutical systems strengthening. The group discussions yielded the elements presented in table 2.

Table 1. Key Pharmaceutical System Components Proposed by the Five Groups

Group 1	Group 2	Group 3	Group 4	Group 5
<p>Service delivery</p> <ul style="list-style-type: none"> • Use <p>Leadership and governance (policy, law, governance)</p> <ul style="list-style-type: none"> • Regulation • Pharmacovigilance <p>Pharmaceuticals and diagnostics</p> <ul style="list-style-type: none"> • Selection • Procurement • Distribution • Manufacturing <p>Information</p> <ul style="list-style-type: none"> • Information technology • Research and development • Operational research <p>Financing</p> <ul style="list-style-type: none"> • Pricing <p>Human resources</p>	<p>Financing</p> <p>Payment</p> <p>Governance</p> <p>Leadership</p> <p>Information systems</p> <p>Human resources</p> <p>Management(?)</p> <p>Organization</p> <p>Regulation</p> <ul style="list-style-type: none"> • Pricing • Registration • Licensing and inspection • Research and development • Marketing • Pharmacovigilance • Safety • Quality control <p>Policies and legislation</p> <p>Pharmaceutical service delivery</p> <ul style="list-style-type: none"> • Distribution • Procurement • Selection • Use 	<p>Policies, legislation and regulation (includes quality assurance)</p> <p>Manufacturing, industry, trade, research and development</p> <p>Financing</p> <p>Governance and leadership</p> <p>Organization and management (includes information systems and human resources)</p> <p>Service delivery</p> <ul style="list-style-type: none"> • Selection • Procurement • Distribution • Use • Patient safety 	<p>Inputs</p> <ul style="list-style-type: none"> • Manufacturing • Procurement • Research and development • Selection • Human Resources • Financing <p>Processes</p> <ul style="list-style-type: none"> • Distribution • Human resource education • Information management • Service delivery <p>Outcomes</p> <ul style="list-style-type: none"> • Access • Use • Quality • Safety <p>Cross-cutting</p> <ul style="list-style-type: none"> • Affordability • Evidence-based decision making • Sustainability • Equity • Financial protection and health • Resilience • Efficiency • Country ownership 	<p>Legal framework</p> <ul style="list-style-type: none"> • International intellectual property rights policies • Policy and laws • Pharmaceutical sector structure • Governance/transparency <p>Pharmaceutical services</p> <ul style="list-style-type: none"> • Selection • Procurement • Distribution • Use <p>Human resources</p> <ul style="list-style-type: none"> • Pre-service and continuing training • Numbers and distribution <p>Regulatory systems</p> <ul style="list-style-type: none"> • Products (registration) • People • Facilities • Quality assurance <p>Management support</p> <ul style="list-style-type: none"> • Information systems • Pricing information • Forecasting • Budgeting • Quantification <p>Financing</p> <ul style="list-style-type: none"> • Supply and demand • Resource mobilizations • Costing/purchasing • Financial protection • Expenditure analysis <p>Innovation, research and development, manufacturing, and trade</p> <p>Access and use listed as outcomes</p>

Table 2. Suggested Elements to Inform the Selection of Pharmaceutical Systems Strengthening Indicators

System Component	Elements
Policy and legal framework	<ul style="list-style-type: none"> • Policies and laws <ul style="list-style-type: none"> ○ Availability, safety, quality, manufacturing, trade, and promotion of pharmaceutical products ○ Standards of practice and accreditation of facilities ○ Drug information ○ Pricing and insurance coverage • Governance <ul style="list-style-type: none"> ○ Structures and mechanisms to ensure accountability and transparency ○ Engagement and participation of civil society • High-level strategic planning
Regulatory systems	<ul style="list-style-type: none"> • Quality control • Licensing and accreditation (people, products, and education) • Medicines registration • Inspection and enforcement • Pharmacovigilance • Regulation of clinical trials • Advertising, promotion, and marketing
Pharmaceutical services	<ul style="list-style-type: none"> • Pharmaceutical supply <ul style="list-style-type: none"> ○ Product selection ○ Procurement ○ Inventory management and distribution ○ Quality assurance (including quality control) ○ Repackaging • Safe, appropriate, cost-effective prescribing and use • Dispensing and supply to individuals • Health promotion and disease prevention
Human resources	<ul style="list-style-type: none"> • Human resources policy • Human resources planning/management <ul style="list-style-type: none"> ○ Workforce analysis ○ Workforce strategy ○ “Rational use of human resources”- equitable allocation ○ Recruitment/job descriptions/performance appraisals • Human resources development <ul style="list-style-type: none"> ○ Pre-service ○ Career path/retention ○ Training/mentoring/supervision • Professionalization
Financing	<ul style="list-style-type: none"> • Resource mobilization and allocation • Costing and pricing • Financial protection mechanisms for medicines and services • Expenditure tracking
Information	<ul style="list-style-type: none"> • Data standards/standardization • Country-appropriate information systems • Data transparency/access/feedback (and accountability) • Data analysis and use (data for decision making) • Coordination and accountability • Evaluation system (operational research)

System Component	Elements
Innovation, research and development, manufacturing, and trade	<ul style="list-style-type: none">• Manufacturing capacity<ul style="list-style-type: none">○ Rated on a spectrum from low to high, with low meaning packaging capability alone and high meaning development of novel active pharmaceutical ingredients• Research, development, and innovation<ul style="list-style-type: none">○ Clinical trials○ Ethical oversight○ Research priority setting (based on health need)○ Technology transfer• Trade<ul style="list-style-type: none">○ Interaction with global and bilateral trade agreements○ TRIPS/TRIPS Plus• Import/export duties and restrictions

Discussion on Composite Indicators

USAID is interested in approaches for ranking the performance of national pharmaceutical systems. Given the multi-dimensional nature of the pharmaceutical sector, composite indicators may be a suitable measure of overall performance of a pharmaceutical system or other aspects such as its maturity. The objective of this session was to obtain participants' inputs on the merits and disadvantages of composite indicators to help inform the selection and/or development of appropriate indicators to measure the strengthening of a pharmaceutical system.

To frame the discussion, Professor Veronika J. Wirtz of Boston University presented a review of the advantages and disadvantages associated with composite indicators (included in the background discussion paper as table 4). She also reviewed the development and structure of the Access to Medicine Index² to illustrate the potential usefulness of such indicators and the process and resources needed to produce robust composite indicators.

Meeting participants were then asked to review the advantages and disadvantages presented in the slides and background discussion paper. They were asked to discuss whether SIAPS should consider developing composite indicators for pharmaceutical systems strengthening and under what conditions. There was general agreement that composite indicators could provide tremendous value by allowing for comparisons across countries and over time in the dimensions being measured. Further, if the composite indicators are developed in such a way to allow for comparison in the various technical component areas (as with the Access to Medicine Index), then these indicators could potentially be useful for ranking countries and identifying where investments are needed. However, the meeting participants, both in the working groups and the broader plenary discussion, acknowledged that composite indicators presented substantial challenges, both in terms of the resources needed and some practical methodological issues.

² The Access to Medicine Index ranks the efforts of pharmaceutical companies to improve access to medicine in low- and middle-income countries. The Index is produced by the Access to Medicine Foundation and the reports are available at www.accesstomedicineindex.org.

The major concerns included:

- Understanding the causal pathway of the phenomenon being measured in order to derive appropriate weights and develop a valid composite indicator. Some meeting participants wondered if there is a clear enough understanding of the causal pathways that affect any given change or output in the pharmaceutical system.
- The feasibility of gathering quality and comparable data that are sensitive to change. There was a discussion about who would fund these efforts in a sustainable manner and an acknowledgment that SIAPS' clients and stakeholders would need to be willing to pay for this endeavor.
- Incentives for countries to participate in data collection efforts, especially if the results are used to rank their performance in some dimension. These indicators would clearly be useful to donors, but it is unclear what the utility would be for the countries. With the Access to Medicines Index, there is a clear benefit for pharmaceutical companies to participate (even if they are ranked low on the index)—their willingness to participate provides reputational gains. Some participants noted that the process of discussing results with the countries involved could itself be part of systems strengthening. Further, if the composite indicator(s) is aligned with the interests of the countries, they would have an incentive to participate.

The discussions were concluded with an acknowledgement of some of the potential advantages of using composite indicators but given the challenges, the need for ongoing discussion and assessment of their utility for SIAPS. Participants' recommendations will be used to inform decisions on the use of composite indicators as SIAPS moves forward with developing a measurement framework for pharmaceutical system strengthening and identifying associated indicators.

Close of the Meeting

The meeting was closed with brief remarks by Mr. Kofi Aboagye-Nyame who noted that the meeting objectives had been met and thanked the participants and organizers, particularly acknowledging the efforts of Dr. Richard Laing as the meeting facilitator. He outlined the next steps for developing the measurement framework and metrics and expressed the hope that the meeting participants would continue to provide inputs in the development process. Mr. Boni also thanked the meeting participants for their contributions on behalf of USAID.

Next Steps

SIAPS will continue to work with its partners and other experts to develop the framework for measurement of pharmaceutical systems strengthening, identify associated metrics, and check the feasibility of obtaining data to routinely generate them.

The key next steps for SIAPS include:

- Disseminating the meeting report and developing the background discussion paper and meeting outcomes into a paper for peer-reviewed publication.
- Developing a framework for measurement based on agreements reached on the definitions of a pharmaceutical system and pharmaceutical systems strengthening, and the components of a pharmaceutical system. The resulting framework will be shared with the partners for comment.
- Using the elements proposed in this meeting to identify associated indicators and implementing a process to get input from SIAPS partners on the selection of appropriate indicators for piloting.

A follow up meeting is anticipated for the end of 2015 or early in 2016.

Meeting Participants

Name	Organization	Email
Francis (Kofi) Aboagye-Nyame	MSH/CPM	fnyame@msh.org
Emily Bancroft	Village Reach	emily.bancroft@villagereach.org
Edgar Barillas	MSH/CPM	ebarillas@msh.org
Tony Boni	USAID	aboni@usaid.gov
Diana Bowser	Harvard University School of Public Health	dbowser@hsph.harvard.edu
Gege Buki	MSH/CPM	gbuki@msh.org
Tobey Busch	MSH/CPM	tbusch@msh.org
Michael Cohen	MSH/CPM	mcohen@msh.org
Chuck Daniels	Accreditation Council for Pharmacy Education	cdaniels@ucsd.edu
Clinton DeSouza	IMPERIAL Health Sciences	cdesouza@ihs.za.com
Kwesi Eghan	MSH/CPM	keghan@msh.org
Tamara Hafner	MSH/SIAPS Consultant	tamara.hafner@gmail.com
Peter Hobby	MSH/CPM	phobby@msh.org
Brittany Johnson	William Davidson Institute	bgjohn@umich.edu
Michael Johnson	Logistics Management Institute	MGJohnson@lmi.org
Mohan Joshi	MSH/CPM	mjoshi@msh.org
Douglas Keene	MSH/CPM	dkeene@msh.org
Niranjan Konduri	MSH/CPM	nkonduri@msh.org
David Lee Chin	MSH/CPM	dlee@msh.org
Richard Laing	Boston University School of Public Health	richardl@bu.edu
Lisa Ludeman	USAID	eludeman@usaid.gov
David Mabirizi	MSH/CPM	dmabirizi@msh.org
Kidwell Matshotyana	MSH/CPM	kmatshotyana@msh.org
Dumebi Mordi	MSH/CPM	dmordi@msh.org
Mirfin Mpundu	Ecumenical Pharmaceutical Network	Mmpundu@epnetwork.org
Kate Onyejekwe	MSH/CPM	konyejekwe@msh.org
Patricia Paredes	MSH/CPM	pparedes@msh.org
Analia Porras	PAHO	porrasan@paho.org
Sameh Saleeb	MSH/CPM	ssaleeb@msh.org
Maura Soucy	MSH/CPM	msoucy@msh.org
Andy Stergachis	University of Washington	stergach@u.washington.edu
Abeba Taddese	Results for Development	ataddese@r4d.org
Michele Teitelbaum	MSH/Center for Health Services	mteitelbaum@msh.org
Reshma Trasi	MSH/Center for Leadership and Management	rtrasi@msh.org
Eme Unanaowo	IMPERIAL Health Sciences	eunanaowo@ihs.za.com
Catherine Vialle-Valentin	Harvard Pilgrim Health Center	catherine.vialle@post.harvard.edu
Helena Walkowiak	MSH/CPM	hwalkowiak@msh.org
Veronika Wirtz	Boston University School of Public Health	vwirtz@bu.edu
Kiley Workman	MSH/CPM	kworkman@msh.org
Linda Zackin	MSH/CPM	lzackin@msh.org

SIAPS Partner Consultative Meeting Agenda

Thursday, September 11, 2014

Time	Duration	Topic	Presenter/Facilitator
9:00-9:30	30 min	Registration and coffee/tea	
9:30-9:35	5 min	Welcoming remarks and introduction of meeting facilitator	Kofi Aboagye-Nyame (SIAPS Program Director) Richard Laing (Facilitator)
9:35-9:50	15 min	Introduction of participants	All Richard Laing (Facilitator)
9:50-9:55	5 min	Logistics	Kate Onyejekwe (Results Senior Manager, SIAPS)
9:55-10:05	10 min	Welcoming remarks	Douglas Keene (Vice President of CPM)
10:05-10:15	10 min	Welcoming remarks/introduction	Tony Boni (USAID AOR)
10:15-10:30	15 min	Introduction, meeting objectives, and overview of agenda	Kofi Aboagye-Nyame (SIAPS Program Director)
10:30-11:00	30 min	Pharmaceutical systems and pharmaceutical systems strengthening: definitions and frameworks: Overview of the literature	Tamara Hafner (SIAPS Consultant) David Lee (Director, Technical Strategy and Quality, CPM) Richard Laing (Facilitator)
11:00-11:30	30 min	Coffee/tea	
11:30-1:00	1 hr 30 min	Group work: Defining pharmaceutical system and pharmaceutical systems strengthening	Group members Richard Laing (Facilitator)
1:00-2:00	1 hr	Lunch	
2:00-2:30	30 min	Toward a framework for measuring pharmaceutical systems strengthening: Existing frameworks and approaches	Helena Walkowiak (Principal Technical Advisor, SIAPS)
2:30-3:30	1 hr	Group work: Identifying key components of a pharmaceutical system and a framework for measurement of systems strengthening	Group members Richard Laing (Facilitator)
3:30- 3:45	15 min	Coffee/tea	
3:45-4:15	30min	Group work: Identifying key components of a pharmaceutical system and a framework for measurement of systems strengthening (continued)	Group members Richard Laing (Facilitator)
4:15-4:30	15 min	Summarizing discussions for the day and comments/feedback from participants	David Lee (Director, Technical Strategy and Quality, CPM)
4:30-5:30		Opportunity for individual or group partner-SIAPS meetings	

Defining and Measuring Pharmaceutical Systems Strengthening: Partners' Meeting Report

Friday, September 12, 2014

Time	Duration	Topic	Presenter/Facilitator
8:30-8:45	15 min	Coffee/tea	
8:45-9:00	15 min	Review of day 1	David Lee (Director, Technical Strategy and Quality, CPM)
9:00-9:15	15 min	Introduction: Identifying key elements to operationalize and turn into indicators	Helena Walkowiak (Principal Technical Advisor, SIAPS)
9:15-10:45	1 hr 30 min	Group work: Identifying key elements to operationalize and turn into indicators	Richard Laing (Facilitator)
10:45-11:15	30 min	Coffee/tea	
11:15-11:45	30 min	Discussion on country-level composite index: Approaches and challenges	Veronika Wirtz (Facilitator) Richard Laing (Facilitator)
11:45-12:45	1 hr	Plenary discussion: Recommendations on the use of composite indices and methodological approaches for development and validation	All Veronika Wirtz (Facilitator) Helena Walkowiak (Principal Technical Advisor, SIAPS)
12:45-1:45	1 hr	Lunch	
1:45-2:30	45 min	Summary of discussions and deliberations	David Lee (Director, Technical Strategy and Quality, CPM) Richard Laing (Facilitator)
2:30-2:40	10 min	Closing remarks and next steps	Kofi Aboagye-Nyame (SIAPS Program Director)
2:40-2:45	5 min	Closing remarks	Tony Boni (USAID AOR)
2:45-5:30		Opportunity for individual or group partner-SIAPS meetings	

Work Group Members

Group 1	Group 2	Group 3	Group 4	Group 5
Edgar Barillas	Diana Bowser	Kofi Aboagye-Nyame	Emily Bancroft	Gege Buki
Kwesi Eghan	Chuck Daniels	Tony Boni	Tobey Busch (Rapporteur)	Tamara Hafner
Andy Stergachis	Dumebi Mordi (Rapporteur)	Peter Hobby	Michael Cohen	Brittany Johnson
Abeba Taddese	Mirfin Mpundu	Michael Johnson	Clinton DeSouza	Richard Laing
Reshma Trasi	Kate Onyejekwe	Mohan Joshi	Lisa Ludeman	David Lee
Eme Unanaowo (day 2 only)	Patricia Paredes	Niranjan Konduri (Rapporteur)	David Mabirizi	Analia Porras
Helena Walkowiak	Sameh Saleeb	Catherine Vialle-Valentin	Kidwell Matshotyana	Maura Soucy (Rapporteur)
Kiley Workman (Rapporteur)		Linda Zackin	Veronika Wirtz	Michele Teitelbaum

Identification of Elements for Each Component: Group Assignments

Component	Group
Policy and legal framework	Group 2
Regulatory systems	Group 1
Pharmaceutical services	Group 3
Human resources	Group 4
Financing	Group 1
Information	Group 4
Innovation, research and development, manufacturing, and trade	Group 5

BACKGROUND DISCUSSION PAPER

DEFINING AND MEASURING PHARMACEUTICAL SYSTEMS STRENGTHENING

Tamara Hafner
Helena Walkowiak

September 3, 2014³



USAID
FROM THE AMERICAN PEOPLE

SIAPS 
Systems for Improved Access
to Pharmaceuticals and Services

³ The background discussion paper was completed on September 3, 2014. However, the section on composite indicators was revised after the SIAPS Partner Consultative Meeting (September 11-12, 2014) to reflect contributions from Veronika Wirtz and Richard Laing, both from the Department of Global Health at Boston University School of Public Health.

Introduction

Various frameworks, indicators, and assessment tools are available to assess and monitor the performance of pharmaceutical systems. These indicators and tools tend to measure inputs, processes, outputs, and outcomes centered around key functions, namely, selection, procurement, distribution, and use of pharmaceuticals. A general theme among these various frameworks and tools is that the goal of a pharmaceutical system is to ensure timely and equitable access to and appropriate use of pharmaceuticals and/or other health technologies. However, there is no widely accepted definition of what constitutes a pharmaceutical system, nor is there a standardized approach for measuring progress toward stronger, more sustainable systems. The US Agency for International Development (USAID) and partners are calling for the development of a framework and indicators that can monitor and measure the strengthening, or weakening, of a pharmaceutical system and track whether investments in systems strengthening interventions are yielding the expected results. As such, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program⁴ aims to develop a framework with clearly linked measures to enable stakeholders to measure performance of pharmaceutical systems and changes thereof, and use this information for intervention design and evaluation to enhance the delivery of pharmaceutical services.

This paper is intended to serve as a starting point for discussions at the SIAPS Partners Meeting (September 11-12, 2014) to address the following objectives:

- Agree on working definitions of what constitutes a “pharmaceutical system” and “pharmaceutical systems strengthening”
- Based on these definitions, identify the key elements that must be operationalized and turned into indicators and discuss potential sources of data
- Agree on next steps for selecting or developing appropriate indicators for measuring pharmaceutical systems strengthening outcomes

The paper provides an overview of the literature on existing definitions and frameworks regarding pharmaceutical systems and pharmaceutical systems strengthening. It highlights some of the major issues to be considered in developing a working definition of what a pharmaceutical system is, what strengthening it entails, and for deriving a framework and metrics for measurement.

⁴ The USAID-funded SIAPS Program is implemented by Management Sciences for Health (MSH) with core partners Accreditation Council for Pharmacy Education, Harvard University, Logistics Management Institute, and University of Washington and specialized resource partners African Medical and Research Foundation, Ecumenical Pharmaceutical Network, Results for Development, IMPERIAL Health Sciences, VillageReach, and William Davidson Institute.

Methodology

Sources from the grey and academic literature and a list of search terms (Appendix 1) developed through consultation among SIAPS program staff were used for the literature search. The primary inclusion criteria were reports or studies that focused on a definition of pharmaceutical system, pharmaceutical management system, pharmaceutical systems strengthening, or health systems strengthening; a description of a framework aligned with one of these definitions; an identification of one or more components of a pharmaceutical (management) system; description of a measure of performance for such a system; description of an intervention to improve, support, or strengthen such a system; and a review or discussion of the conceptual or theoretical basis for such a system or one of its components. Assessment tools were included in the review if they were in the public domain, assess or evaluate a pharmaceutical system or an important component thereof, or were judged to add meaningfully to the conceptualization of pharmaceutical systems or pharmaceutical systems strengthening. In addition, logistics assessment tools developed for low- and middle-income country public health systems were included. Assessment tools that were simple modifications of other tools, e.g., for use in a particular country, were excluded. Various iterations of the search were done and relevant references from retrieved documents were also tracked. One limitation of the search strategy is that it was limited to academic and grey literature sources available online. It is therefore possible that we have missed internal conceptual or background papers that were not widely distributed and are the basis for the development of some of the assessment tools considered herein.

Systems Thinking in Health

Given the relationship between a pharmaceutical system and the broader health system and the interconnectedness between its components, a discussion of pharmaceutical systems strengthening must build on existing approaches aimed at understanding and strengthening health systems. There has been an emerging interest in systems thinking to understand how actors, institutions, and resources interact and operate within a health system to influence better health outcomes (de Savigny and Adam 2009; Gilson 2012). This follows a period of renewed attention on health systems, which began with the publication of the World Health Report in 2000 with health system performance as the theme. In the report, the World Health Organization (WHO) advanced a definition for health systems as “all activities whose primary purpose is to promote, restore or maintain health” (WHO 2000, p. 5) and proposed a performance measurement framework. The fundamental goals of the health system include improving the health of the population, responding to people’s expectations, and providing financial protection against the costs of ill-health. To achieve these goals, health systems must perform four basic functions: service provision, resource creation, stewardship, and mobilization and allocation of finances. This report helped to usher in a renewed focus on health systems and their strengthening and has led to a robust debate and a multiplicity of health systems and health systems strengthening frameworks (de Savigny and Adam 2009; Shakarishvili et al. 2010; van Olmen et al. 2012; WHO 2007).

WHO subsequently developed its “building blocks” framework to create a common understanding about what a health system is and what constitutes health systems strengthening. It expands the World Health Report (WHO 2000) definition of a health system to include “all organizations, people, and actions whose primary intent is to promote, restore or maintain health” (WHO 2007, p. 2). The framework identifies six essential building blocks—service delivery; health workforce; information; medical products, vaccines, and technologies; financing; leadership/governance—built around the key functions of a health system. It defines health systems strengthening as “improving these six health system building blocks and managing their interactions in ways that achieve more equitable and sustained improvements across health services and health outcomes” (WHO 2007; p. 4). It is the multiple relationships and interactions between the building blocks, more so than the blocks themselves, that define the system.

Several scholars have since applied a systems thinking approach to guide the debate on health systems and their strengthening (de Savigny and Adam 2009; van Olmen et al. 2012). Systems thinking is advocated as an approach to understand how health interventions exert their system-wide effects and to guide the design and evaluation of sustainable system-strengthening interventions (de Savigny and Adam 2009). Although the interactions between health interventions and health systems are not well understood, systems thinking brings into clear focus two basic ideas: all health interventions tend to have a system-level effect and health system processes are non-linear. Systems are dynamic; they react to the same input in different ways and generate their own behaviors. The complexity of these reactions and interactions can render the system “policy resistant [in that] seemingly obvious solutions may fail or worsen the situation” (de Savigny and Adam 2009, p. 42). Although the academic and grey literature on pharmaceutical system and pharmaceutical systems strengthening is sparse, the complexity of these reactions has long been appreciated. This is reflected in existing frameworks, such as the

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pharmaceutical systems framework developed by the Center for Pharmaceutical Management (CPM)/Management Sciences for Health (MSH) which depicts the interrelationship and interdependence of the key pharmaceutical management functions. The abundant scholarship on health systems and health systems strengthening along with existing pharmaceutical systems frameworks serve as a logical guide in working toward an understanding and agreement on what a pharmaceutical system is, its strengthening, and how to measure its performance.

Existing Definitions

Pharmaceutical System

Given the number of assessment tools for measuring various aspects of pharmaceutical system performance, we surprisingly found only three explicit definitions of pharmaceutical system. Roberts and Reich (2011) use the terms system and sector interchangeably and define the pharmaceutical system as involving eight complex subsystems: research and development, clinical trials, registration, manufacturing and packaging, procurement and importing, supply chain, dispensing, and sales/use. This definition is similar to that in the WHO transparency assessment instrument (2009). WHO, however, makes a distinction between pharmaceutical system and pharmaceutical sector defining the former as “the relationship/interactions between the various actors of the pharmaceutical sector and the way decisions are made in particular in the government” (WHO 2009; p. 1). Pharmaceutical sector is used to refer to the various actors (the government, private-for-profit organizations, private not-for-profit organizations, etc.) engaged in the “medicine chain.” The medicine chain includes research and development of new medicines; conducting clinical trials; filing patents; manufacture; registration; selection of essential medicines, medicines procurement and distribution; inspection of manufacturers and distributors; prescribing; dispensing; pharmacovigilance; and the control of medicine promotion (WHO 2009). So WHO views the pharmaceutical system as the interactions and decision-making processes among the various pharmaceutical sector actors that determine the roles and functions that they undertake to achieve the goal of medicines access and appropriate use. Kohler et al. (2014), in their paper on the need for good governance in pharmaceutical systems, also define the pharmaceutical system in terms of actors and their actions. A pharmaceutical system encompasses “the actions of public and private stakeholders as they move drugs through the supply chain from purchasing to providing to patients” (p. 3).

These definitions are a helpful starting point for conceptualizing a pharmaceutical system; however, they were generated for a specific purpose. The WHO and Kohler definitions relate to governance and transparency issues in the medicine chain. The Roberts and Reich definition is in the context of implementing pharmaceutical sector reforms and depicts the sector as a linear progression of functions. It focuses almost exclusively on policy interventions for governments to influence these functions.

Related definitions were also considered to gain further insight into understanding the goals and scopes of pharmaceutical systems. In the literature reviewed, references were commonly made to pharmaceutical management or pharmaceutical supply system. The USAID-funded Rational Pharmaceutical Management Plus (RPM Plus) Program (2005) and Miralles (2010) use the term pharmaceutical supply system, which is defined by the procedures and methods used to accomplish the four key pharmaceutical management functions—selection, procurement, distribution, and use. The Health Systems 20/20 assessment approach (HSAA) defines the management of medical products, vaccines, and technologies as “the whole set of activities aimed at ensuring the timely availability and appropriate use of safe, effective, quality medicines and related products and services in any health care setting” (Health Systems 20/20 2012, p. 242).⁵ There are earlier versions of this definition in various RPM Plus training materials and

⁵ Health Systems 20/20 Program (2006-2012) was funded by the USAID and led by Abt Associates.

Islam's (2007) edited HSAA manual, which was developed in collaboration with RPM Plus and the Quality Assurance Program.⁶

Pharmaceutical Systems Strengthening

With respect to pharmaceutical systems strengthening, no explicit definitions were found. The review included a search for definitions of systems strengthening with respect to the other five health system building blocks but no explicit statements were found. However, several definitions of health systems strengthening exist and provide some guidance. Islam (2007) defines health systems strengthening “as any array of initiatives and strategies that improves one or more of the functions of the health system and that leads to better health through improvements in access, coverage, quality, or efficiency” (p. 1-1). As mentioned previously, WHO (2007) defines health systems strengthening as “improving [the] six health system building blocks and managing their interactions in ways that achieve more equitable and sustained improvements across health services and health outcomes” (p. 3). The WHO Health Systems Strengthening Glossary (WHO 2014a) also defines health systems strengthening as “the process of identifying and implementing the changes in policy and practice in a country’s health system, so that the country can respond better to its health and health system challenges.” The latter two definitions draw attention to both performance and the capacity of the system to respond to future health and health system challenges.

⁶ The Rational Pharmaceutical Management (RPM) Program, along with the RPM Plus Program and the Strengthening Pharmaceutical Systems (SPS) Program are predecessors to the SIAPS Program, which were all funded by USAID and implemented by MSH and partners (and for RPM, in collaboration with the United States Pharmacopeia). The Quality Assurance Program was implemented by the University Research Corporation.

Existing Frameworks

Eight frameworks relevant to pharmaceutical systems were identified in the review: the pharmaceutical management system framework (RPM Plus 2005); CPM/MSH's pharmaceutical management framework (MSH 1997); John Snow International (JSI) logistics cycle (USAID | DELIVER 2009); the WHO's 'building blocks' (WHO 2007); the International Health Partnership and related initiatives (IHP+) monitoring and evaluation of health systems strengthening framework (WHO et al. 2009; WHO 2010); the access to medicines from a health system perspective framework (Bigdeli et al. 2013); the "control knobs" framework (Roberts and Reich 2011); and the SIAPS pharmaceutical systems strengthening framework (SIAPS 2013). These are a mix of conceptual and operational frameworks. Table 1 provides a summary of the key frameworks.

Table 1. Overview of Frameworks Relevant to Pharmaceutical Systems

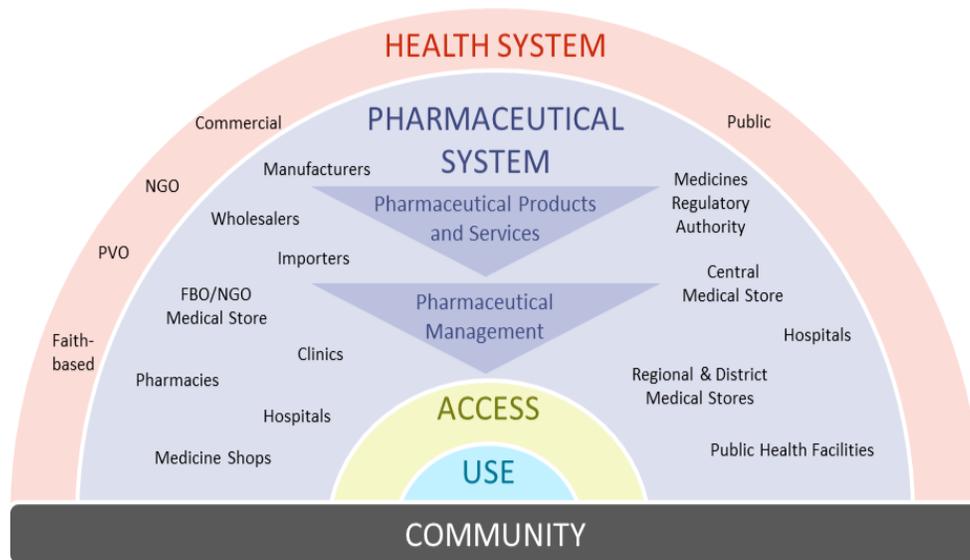
Framework	Source	Focus	Key Elements of the Framework	Goal	Overarching principles and qualifiers
Pharmaceutical management system framework	RPM Plus 2005; Miralles 2010	Relationship between health system and pharmaceutical sub-system	<ul style="list-style-type: none"> • Health system and its pharmaceutical sub-system • Institutions and stakeholders in the public and private sectors • Four interrelated core (pharmaceutical management) functions: selection, procurement, distribution, and use • Human, financial, and informational resources • Overarching policies and legislation 	<ul style="list-style-type: none"> • Access (accessibility, availability, acceptability, affordability) • Appropriate use • Access to/use of pharmaceutical products and services 	<ul style="list-style-type: none"> • Timely • Equitable • Safe, effective, quality medicines and services
Pharmaceutical management framework	MSH 1997; MSH 2012	Functions and elements of pharmaceutical management	<ul style="list-style-type: none"> • Four interrelated key functions: selection, procurement, distribution, and use • Management support systems: organization; financing; information management; and human resource management • Policy, law, and regulations supported by good governance 	<ul style="list-style-type: none"> • Access (accessibility, availability, acceptability, affordability) • Rational use • Access to/use of pharmaceutical products 	<ul style="list-style-type: none"> • Quality of products and services; specifically, product safety, quality, and cost-effectiveness
Medical products building block, WHO health systems framework	WHO 2007; WHO 2010	Core functions (building blocks) of a health system	<ul style="list-style-type: none"> • One of six interdependent building blocks: medical products, vaccines, and health technologies; service delivery; health workforce; information; financing; leadership and governance • Five requirements (to achieve goal) <ul style="list-style-type: none"> ○ National policies, standards, guidelines, and regulations ○ Market information; price setting/negotiation ○ Reliable manufacturing practices and quality assessment ○ Effective procurement, supply, storage, distribution systems ○ Support for rational use 	<ul style="list-style-type: none"> • Access • Scientifically sound and cost-effective use • Access to/use of essential medical products, vaccines and technologies 	<ul style="list-style-type: none"> • Equity • Products of assured quality, safety, efficacy, and cost-effectiveness

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Framework	Source	Focus	Key Elements of the Framework	Goal	Overarching principles and qualifiers
Control knobs framework	Roberts and Reich 2011	Means for effecting adjustments in the pharmaceutical system	<ul style="list-style-type: none"> • Five “control knobs” (adjustable independent variables): financing, payments decisions, organization of activities, regulation, and persuasion methods • Eight subsystems of pharmaceutical system: research and development; clinical trials; registration; manufacturing and packaging; procurement and importing; supply chain; dispensing; and sales/use 	<ul style="list-style-type: none"> • Intermediate performance goals: efficiency, quality, and access (physical availability and effective availability) • Ultimate performance goals: health status, financial protection, and citizen satisfaction 	<ul style="list-style-type: none"> • Reliable access • Safe, effective, affordable medicines
Conceptual framework of access to medicines from a health systems perspective	Bigdeli et al. 2013	Health systems perspective to address demand- and supply-side barriers to access to medicines	<ul style="list-style-type: none"> • Context: international, national, sub-national, local • Demand-side: individuals, households, and communities • Six building blocks and their multiple and dynamic relationships: service delivery; health sector resources—medicines, financing, information, human resources, [infrastructure]; governance (health and non-health sectors) • National and international contextual determinants: market forces, innovation, transparency, donors’ agenda, and funding 	<ul style="list-style-type: none"> • Access to medicines (accessibility, availability, acceptability, affordability, quality) • Better health outcomes 	<ul style="list-style-type: none"> • Equity • Human rights • Quality
Pharmaceutical systems strengthening framework	SIAPS 2013	Approach to strengthening pharmaceutical systems	<ul style="list-style-type: none"> • Six overlapping building blocks with medical products building block at center depicts dynamic relationships between the pharmaceutical system and health system input (human resources, information, financing), governance, and service delivery elements • Stakeholders: government, providers, and community • Analysis of local context, existing system; priority health concerns; selection and implementation of evidence-based strategies; monitoring and evaluating performance against expected outcomes 	<ul style="list-style-type: none"> • Access (accessibility, availability, acceptability, affordability) • Appropriate use • Access to/use of pharmaceutical products and services • Improved coverage and access of evidence-based interventions • [Contribute to] sustainable health outcomes 	<ul style="list-style-type: none"> • Equity • Timely • Safe, effective and quality pharmaceuticals • Evidence-based

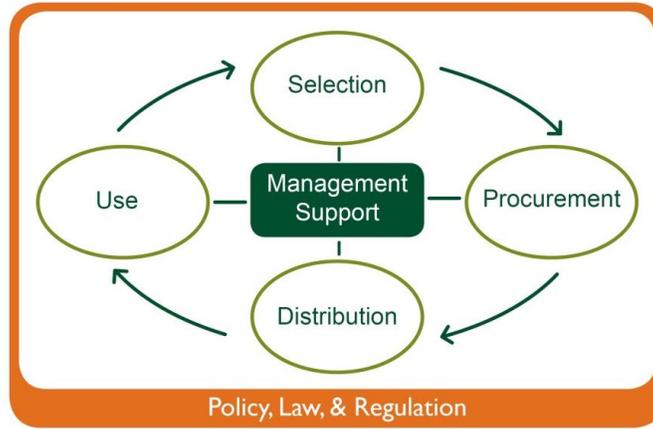
CPM/MSH Pharmaceutical Management System and Pharmaceutical Management Frameworks

The pharmaceutical management system framework (RPM Plus 2005; Miralles 2010) conceptualizes the pharmaceutical system as a subsystem of the health system (Figure 1). The pharmaceutical system includes all the institutions and stakeholders in both the public and private sectors that are involved in the procedures and methods used to accomplish the four key interdependent pharmaceutical management functions—selection, procurement, distribution, and use. Pharmaceutical management aims to ensure the timely and equitable access to and appropriate use of safe, effective, quality medicine and related products and services (Miralles 2010). The four management functions are spelled out in the CPM/MSH pharmaceutical management framework (MSH 1997; figure 2). The functions are supported by a core of management support systems: organization, financing and sustainability, information management, and human resources management. The core and support functions are enabled (and constrained) by policies, laws, and regulations and supported by good governance principles and practices that establish and sustain the public commitment to essential medicine supply (MSH 2012).



Source: Miralles 2010; RPM Plus 2005

Figure 1. Pharmaceutical management system framework

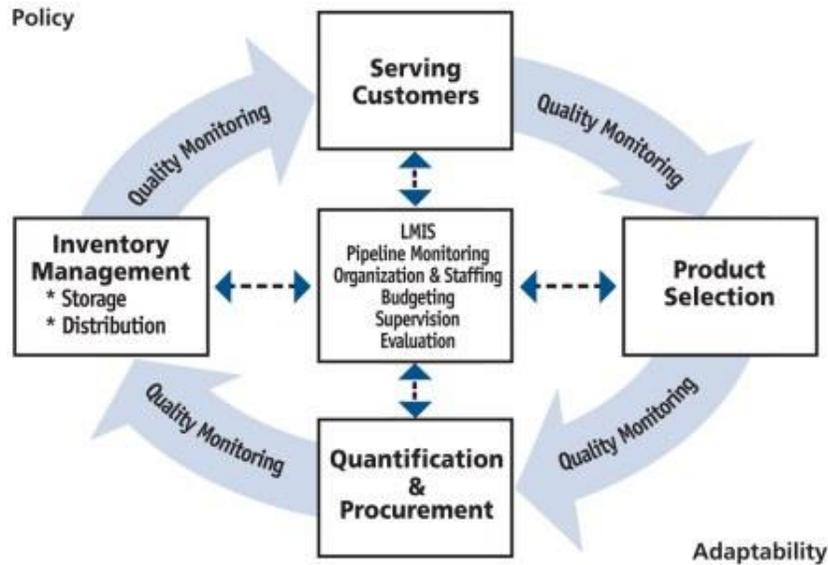


Source: SPS 2011

Figure 2. Pharmaceutical management framework

JSI Logistics Cycle

The JSI logistics cycle shares similarities with the pharmaceutical management system framework, but focuses only on aspects of the functions that relate to logistics (Figure 3). It describes logistics management as a cycle that includes serving customers, product selection, quantification, procurement, and inventory management with a set of core management support functions (USAID | DELIVER 2009; 2011).



Source: USAID | DELIVER PROJECT, Task Order 1. 2011

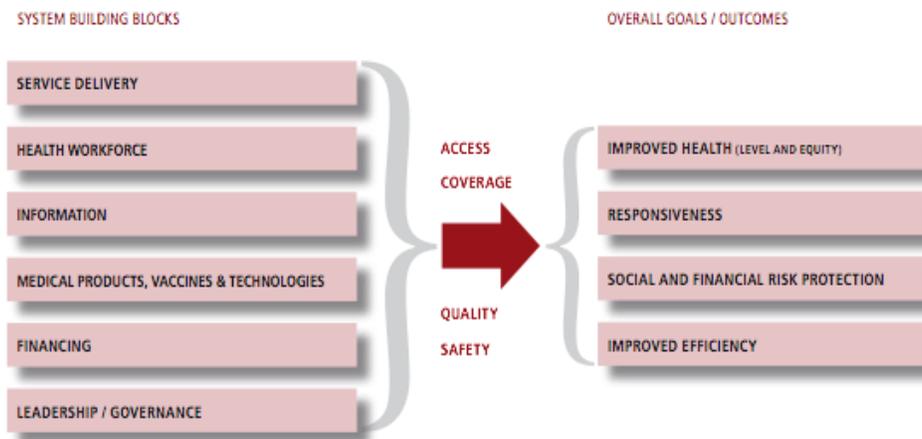
Figure 3. The logistics cycle

WHO Health Systems Building Blocks and IHP+ Monitoring and Evaluation of Health Systems Strengthening Frameworks

The WHO health systems building blocks framework (WHO 2007) does not refer to a pharmaceutical system, but rather to the provision of medical products as a core function of the health system (Figure 4). “A well-functioning health system ensures equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use” (WHO 2007, p. 3). WHO does not define the building block but identifies five requirements for achieving access and use, which are:

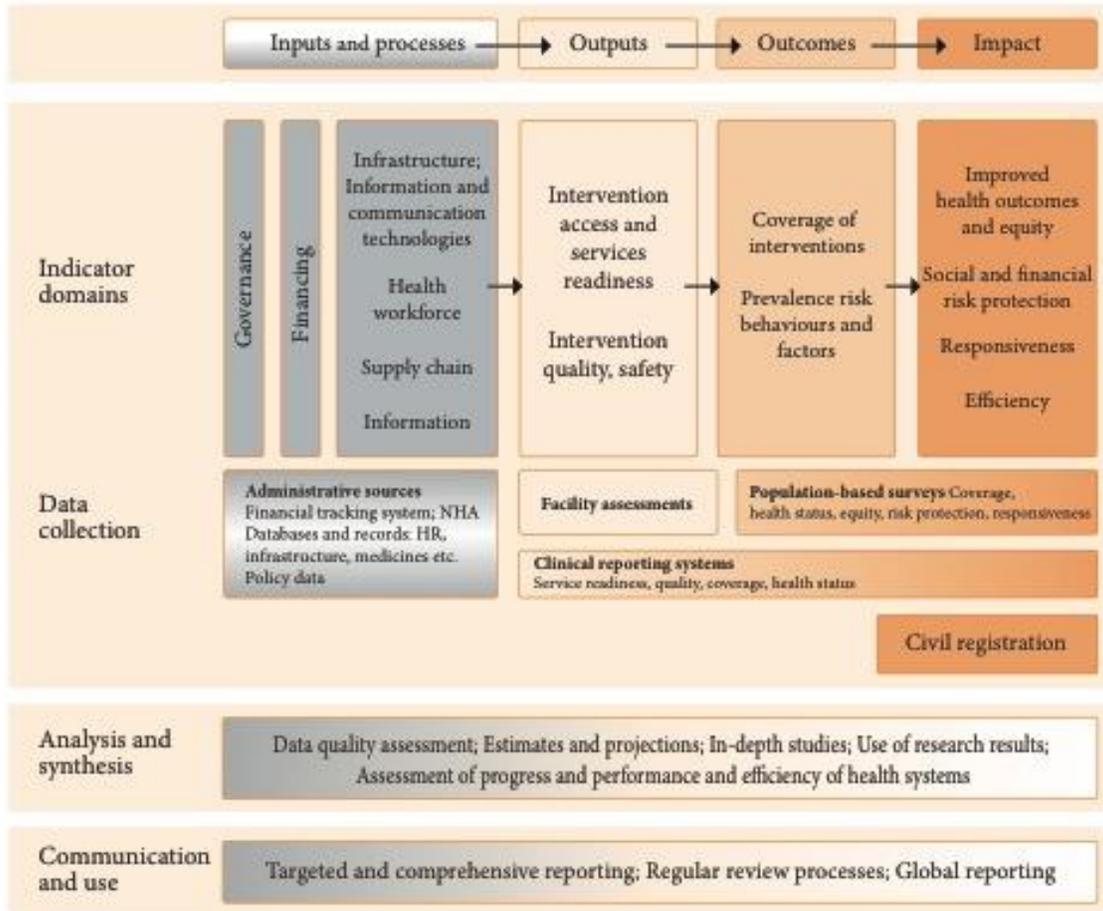
- national policies, standards, guidelines and regulations, that support policy;
- information on prices, international trade agreements, and capacity to set and negotiate prices;
- reliable manufacturing practices and quality assessment of priority products;
- procurement, supply, storage, and distribution systems that minimize leakage and other waste;
- support for rational use of essential medicines, commodities, and equipment through guidelines and strategies to assure adherence, reduce resistance, maximize patient safety, and training.

By implication, the pharmaceutical system is a subunit of the health system that aims to achieve access and rational use. The framework developed by IHP+ for monitoring and evaluating health systems strengthening (WHO et al. 2009; WHO 2010) is based on the building blocks framework (Figure 5).



Source: WHO 2007

Figure 4. WHO health system framework

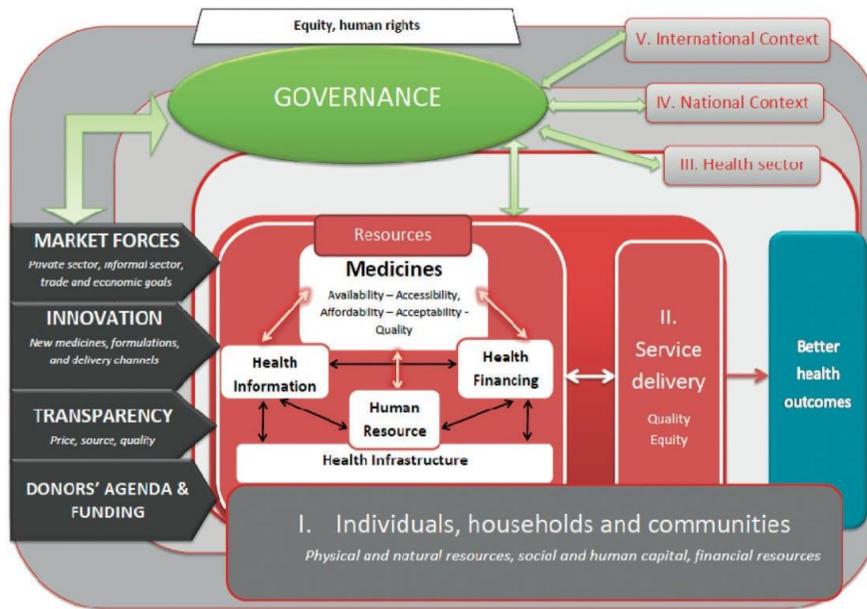


Source: WHO 2010

Figure 5. IHP+ monitoring and evaluation of health systems strengthening framework

Access to Medicines from a Health System Perspective Framework

Bigdeli et al. (2013) adapted the building blocks framework to develop a systems approach to access to medicines (Figure 6). The authors do not attempt to define a pharmaceutical system but rather to highlight the interactions between the health systems' building blocks and medicines. They identify the demand- and supply-side barriers to access and their interactions with the building blocks throughout the various levels of the health system.



Source: Bigdeli et al. 2013

Figure 6. Conceptual framework of access to medicines from a health systems perspective

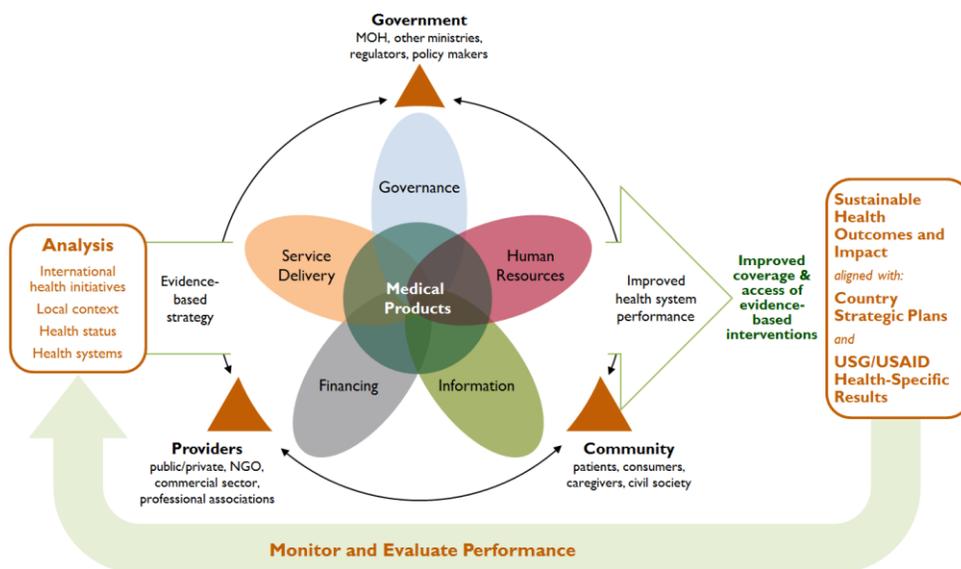
Control Knobs Framework

The Roberts and Reich (2011) control knobs framework focuses on the role of government in influencing pharmaceutical sector performance. It identifies five control knobs—financing, payment decisions, organization of activities, regulation, and persuasion efforts—as structural components of the pharmaceutical system, which can be adjusted to improve system performance. It divides the system goals into intermediate and ultimate performance goals. The intermediate performance goals—efficiency, quality, and access—are characteristics of the functioning of the system. They are intermediate between policy causes and performance effects and can be treated as a means to the ultimate performance goals, which are health status, financial protection, and citizen satisfaction. The control knobs are the adjustable, independent variables that influence the ultimate goals of the system. It should be noted that this framework was originally developed as the flagship framework for health system/sector reform (Roberts et al. 2008) and was later applied to reforming pharmaceutical systems. The authors do not make the relationship between the pharmaceutical and health systems explicitly clear. They imply that the health system is an external factor that can influence the pharmaceutical system. They also acknowledge an overlap of the various components and functions of the pharmaceutical system with those of the general health system (Roberts and Reich 2011).

SIAPS Pharmaceutical Systems Strengthening Framework

SIAPS pharmaceutical systems strengthening framework is the only one found in the review (Figure 7). The framework illustrates the proposed SIAPS approach to pharmaceutical systems strengthening, which includes analyzing and selecting appropriate interventions on the basis of

evidence, implementing, and monitoring and evaluating them against expected outcomes (SIAPS 2013). It builds on the WHO health systems framework and identifies the pharmaceutical system components, placing the medical products function at the center of the set of interacting building blocks. Also depicted are the key stakeholders categorized as government, providers, and community and the expected outcomes, as the pharmaceutical system contribution to health outcomes.



Source: SIAPS 2013

Figure 7. SIAPS pharmaceutical systems strengthening framework

What is the Goal of a Pharmaceutical System?

A consistent theme across the various definitions and frameworks is that the goal of the pharmaceutical system is to ensure access and manage use, with each of these terms being associated with some qualifier. The term access is most commonly understood in the reviewed literature as availability, affordability, (geographical) accessibility, and (cultural) acceptability of quality products and services (CPM 2003). Access may be described as timely and/or equitable. Use, explained as prescribing, dispensing or sale, and consumption by the patient, is sometimes qualified as rational, appropriate, cost-effective, timely, and/or equitable.⁷ Then there is the question of access to what? It may be access to medicines, pharmaceuticals, vaccines, pharmaceutical products, medical products, health technologies, and/or commodities, with associated qualifiers including essential, quality, safe, or effective (Health Systems 20/20 2012; WHO 2007; 2010). The various terms used for the products are not interchangeable. Pharmaceutical products, medical products, and health technologies are broad terms. For example, the health technologies assessment glossary defines health technologies as interventions that “may be used to promote health, to prevent, diagnose or treat acute or chronic

⁷ Although national medicine policies were not included in our review, it is worth noting that use has also been described as quality (Australia’s *Quality Use of Medicines*) and optimal (New Zealand Pharmaceutical Management Agency) in such policies.

disease, or for rehabilitation. [They] include pharmaceuticals, devices, procedures, and organizational systems used in health care” (HTA Glossary 2014, July 1).

Beyond access and use, there are other intermediate and ultimate system goals. According to Roberts and Reich (2011), the intermediate system performance goals—efficiency, quality, and access—are the means to improving health status, financial protection, and citizen satisfaction in the target population. This conceptualization is similar to the health system goals identified by WHO (2007) in the building blocks framework. In this case, ensuring access to and coverage for quality and safe services is the intermediate goal and the means for achieving the ultimate goals—improved health, system responsiveness, social and financial risk protection, and improved efficiency. Interestingly, the goals are comparable between the two frameworks, even though the Roberts and Reich framework refers to the pharmaceutical sector whereas the WHO building blocks framework focuses on the broader health system.

Key Stakeholders and Their Roles in the Pharmaceutical System

The health and pharmaceutical systems framework and the SIAPS pharmaceutical systems strengthening framework depict a pharmaceutical system as including all the institutions and stakeholders in the private and public sectors that are engaged in or influence pharmaceutical management functions. The Bigdeli et al. (2013) framework serves as a useful lens for examining the various stakeholders and their roles in the system. The framework assigns five levels to the health system. At the first level are individuals, households, and communities. Individual preferences, household economics, and social and cultural factors in the community influence health-seeking behavior and trigger demand in the system. The authors place the population at the center of the health system and argue that individuals and the community are more than mere passive end-users. They can help achieve better access to medicines and health services by supporting other patients and addressing some of the social and cultural barriers to access through collective networks and actions. Individuals and communities also act as stewards of the system by demanding quality service and better accountability and expressing their (dis)satisfaction with products and services (Roberts and Reich 2011; WHO 2007).

Levels 2 through 5 address the supply side of the system. Health service delivery, the second level, includes wholesalers, manufacturers, and various service providers such as hospitals, pharmacies, clinics, and medicine shops, whether public or private, formal or informal (Bigdeli et al. 2013). These actors perform their pharmaceutical management activities within the context of the policy and regulatory environment of the health sector, the third level of the health system according to Bigdeli et al. The second and third levels are analogous to the pharmaceutical system depicted in the pharmaceutical management system framework, which shows the various actors carrying out the pharmaceutical management functions to ensure access and use (Figure 1). Levels 4 and 5 refer to the national and international contexts, respectively. Cross-cutting policies and other national priorities at the national level impact the health system and hence the pharmaceutical system (Bigdeli et al. 2013; Roberts and Reich 2011). At the international level, the agenda of donor agencies and global health initiatives, and trade issues can also have supply-side effects (Bigdeli et al. 2013; Marchal et al. 2009; Roberts and Reich 2011).

Table 2 presents a compilation of the dimensions and components identified in the various frameworks reviewed above.

Table 2. Summary of Framework Elements. (The most commonly mentioned elements are in bold.)

Dimensions	Framework elements
Goals	<ul style="list-style-type: none"> • Improved access (accessibility, availability, acceptability, affordability, quality) • Better use (appropriate, rational) • Health outcomes; health status • Coverage • Efficiency • Financial protection • Satisfaction
Access to and use of what?	<ul style="list-style-type: none"> • Medicines • Pharmaceuticals • Medical products • Vaccines • Health technologies • Pharmaceutical services
Qualities of access and use	<ul style="list-style-type: none"> • Quality • Essential • Safe/safety • Effective • Cost-effectiveness
Overarching principles	<ul style="list-style-type: none"> • Equity • Timeliness • Human rights
Stakeholders	<ul style="list-style-type: none"> • Structures/institutions/organizations • Individuals/people • Government • Providers • Communities and households • Public sector • Private sector • International, national, sub-national, and local
Functions (subsystems):	<ul style="list-style-type: none"> • Selection • Procurement (procurement and importing) • Distribution (supply chain) • Use (dispensing; sales) • Research and development • Clinical trials • Regulation (including registration and licensing of individuals and facilities) • Manufacturing and packaging
“Building blocks” (policy and legal framework; management support systems; resources/inputs)	<ul style="list-style-type: none"> • Service delivery • (Leadership and) governance • Policies, law, and regulation (supported by good governance) • Resources (management support systems/inputs) <ul style="list-style-type: none"> ○ Medical products, vaccines, health technologies ○ Human resources ○ Information ○ Financing (pricing; price setting/negotiation) ○ Infrastructure ○ Organization
Environment	<ul style="list-style-type: none"> • Market forces • Innovation • Transparency • Donor’s agenda and funding

Issues to Consider in Defining Pharmaceutical Systems and Pharmaceutical Systems Strengthening

Pharmaceutical System

On account of the preceding discussion we can begin to think about what a pharmaceutical system is and what pharmaceutical systems strengthening entails. There is agreement that the goal of a pharmaceutical system is to ensure access to and rational use of pharmaceuticals. A fundamental question is what constitutes a pharmaceutical product. How do we distinguish pharmaceuticals from other medical products or health technologies? And what qualifiers, if any, should we use for access and use?

Then there is the question of what a pharmaceutical system is and how to operationalize the definition. A logical approach is to treat the pharmaceutical system as a subsystem of the broader health system. What then are the components of a pharmaceutical system? We can think of the pharmaceutical system in terms of structures/organizations (e.g., manufacturers, regulatory agencies, procurement agencies); individuals/people; resources (human, financial, information); functions/actions; or some combination thereof. How do these components contribute to the overall performance of the pharmaceutical system, the broader health system, and, ultimately to health outcomes?

Based on the reviewed definitions and frameworks presented earlier, we propose as a point of departure for further deliberation that a pharmaceutical system be defined as follows:

A pharmaceutical system consists of all organizations, individuals, resources, and actions and their interactions that aim to ensure equitable and timely access to safe, effective, quality pharmaceutical products and related services that promote their appropriate and cost-effective use.

Pharmaceutical Systems Strengthening

With regard to pharmaceutical systems strengthening, we can agree that it is about improving performance (efficiency and quality), but is that all? Systems are not static, and they need the capacity to adapt to changes in their environment. Do we also need to think of systems strengthening in terms of system maturity, sustainability, and/or resilience? There have been concerns about the resilience of health systems, particularly in light of changing disease patterns, natural disasters, and the recent global financial crisis (DFID 2014; European Commission 2014; Hou et al. 2013; Thomas et al. 2013; WHO 2014b). We can think of resilience as “the capacity of a system to absorb disturbance and reorganize while undergoing change so as to still retain essentially the same function, structure, identity, and feedbacks” (Walker et al. 2004, p. 2). So should pharmaceutical systems strengthening seek to build resilience or capacity to address challenges and sustain improvements? If so, what characterizes system resilience? How do we capture this resilience both in our definition of pharmaceutical systems strengthening and some operational measure? And what is the target or endpoint for pharmaceutical systems strengthening? In other words, what does a strengthened and resilient system look like?

Pharmaceutical systems strengthening also needs to be distinguished from other pharmaceutical system interventions. In the literature, there is concern that health systems strengthening interventions continue to be designed around individual building blocks with little regard for the relationships and interactions with and among the other building blocks (Chee et al. 2013, Marchal et al. 2009; van Olmen et al. 2012). Chee et al. (2013) distinguish system support—addressing the constraints currently found—from systems strengthening, which targets the performance drivers and changes the system so that it can address future constraints. They propose four criteria for assessing whether an intervention is health systems strengthening:

- Has cross-cutting benefits beyond a single disease
- Addresses policy and organizational constraints or strengthens relationships between the building blocks
- Produces permanent systemic impact beyond the term of the project
- Tailored to country-specific constraints and opportunities, with clearly defined roles for country institutions

These criteria can provide some scope for our discussions regarding the distinction between pharmaceutical systems strengthening and other system interventions.

We propose the following definition as a starting point for our discussions on what constitutes pharmaceutical systems strengthening:

Pharmaceutical systems strengthening is the process of identifying and implementing strategies and actions that achieve sustainable changes in one or more critical components⁸ of a pharmaceutical system to improve system performance and capacity, to address future health and system challenges, and to contribute to better health outcomes through equitable improvements in access, quality, coverage, and use of pharmaceutical products and related services.

⁸ The critical components of a pharmaceutical system are its core functions, structures, and the supporting health system resources and enabling policy, legal, and governance framework.

Framework for Measuring Pharmaceutical Systems Strengthening

Components of a Pharmaceutical System

As we have seen from reviewing definitions and frameworks, the system is often described in terms of its functions (Miralles 2010; WHO 2010; USAID 2011), subsystems, (Roberts and Reich 2011), or decision points along the medicine chain (Kohler 2014; WHO 2009). An extensive body of work focused on these components and their measurement already exists. This is evident in the myriad of assessment tools and indicator sets developed by key actors such as MSH, JSI, WHO, and Harvard Medical School with support from various funders including USAID (Appendix 2). Much of the thinking on and knowledge of pharmaceutical systems and assessment of their performance has been incorporated into the development and refinement of these tools and indicators over time. A detailed review of the system components measured in these tools can help identify a preliminary list of key components of a pharmaceutical system and associated indicators.

Appendix 2 lists 53 assessment tools and indicator sets that were reviewed. The majority of tools focus on some aspect of service delivery or supply chain management; 22 were developed by MSH, many under projects that were funded by USAID and have their conceptual basis in the pharmaceutical management framework. Among the non-MSH assessment tools, a few were aligned with a specific framework. The WHO “Monitoring the Building Blocks” and Health Systems 20/20 assessment tools are both aligned with the WHO health systems building block frameworks. The JSI tools are based on the logistics cycle framework.

Several of the assessment tools are used to measure performance for comparison over time and across countries. The WHO’s Country Pharmaceutical Situation assessment tool, for example, monitors key aspects of a country’s pharmaceutical situation and the efforts to improve the medicines situation at the global level. It has three levels of indicators. Level I measures key structures and processes and has six categories: national medicine policy, regulatory system, medicines supply system, medicines financing, production and trade, and rational use. Level II indicators measure outcomes at the health facility and pharmacy levels. Level III indicators are for in-depth assessments of specific components of the pharmaceutical sector, such as pricing or regulatory capacity. The Health System 20/20 (2012) health system assessment tool uses equity, efficiency, access, quality, and sustainability as five performance criteria for getting a holistic view of the health system. Sustainability, which refers to financial or institutional sustainability, is defined as the capacity of the system to continue its activities into the future (Health Systems 20/20 2012). Another approach uses the “capability maturity model” to monitor systems strengthening interventions in HIV/AIDS supply chain systems (Supply Chain Management System 2012). The tool defines capability maturity as a “continuum representing successively evolved ‘current states’ of supply chain’s processes, infrastructure, technology and human resources. [Health] supply chains encompass four levels of capability maturity: ad hoc, organized, integrated and extended” (p. 5). Capability is benchmarked against five maturity levels: no/minimal, marginal, qualified, advanced practices, or best practices.

Among the tools reviewed, more than 160 unique categories of indicators and survey questions were identified.⁹ Many of these categories were similar, but the labels were slightly different. Many also closely align with the subsystems and pharmaceutical management functions identified in the review of the frameworks. In an attempt to identify the primary measurement categories and reduce duplication, the assessment tools were divided into three groups (Figure 8):

- Group A includes comprehensive system tools that focus on access, use, pharmaceutical management/policy, and/or supply chain
- Group B includes tools for specific diseases or health programs and are mostly adaptations of those in group A
- Group C includes tools that are for specific system components, such as governance, human resources, or logistics

Group B tools were omitted from subsequent analyses in this paper to reduce duplication. The categories of indicators and survey questions from tools in groups A and C were then reorganized into broader categories to summarize the pharmaceutical system components measured by these various tools (Table 3).¹⁰ The dimensions and components identified in the review of the frameworks and assessment tools (Tables 2 and 3) can serve as a preliminary list of the key components of the pharmaceutical system and can help identify associated indicators.

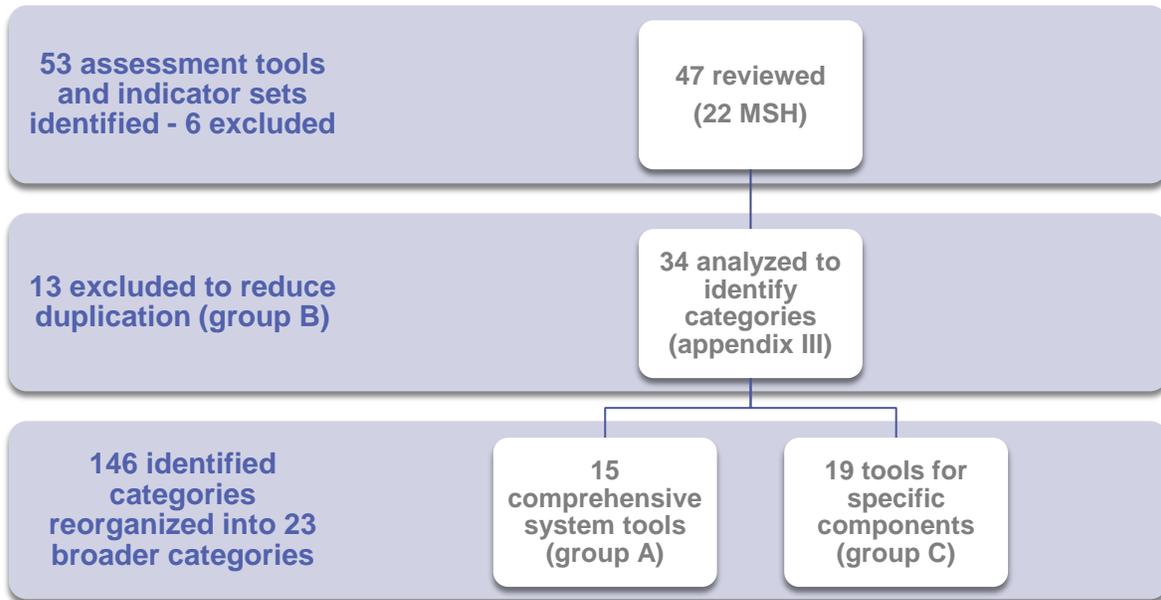


Figure 8. Organization of assessment tools and indicator sets for analysis

⁹ Not all assessment tools included indicators; some were survey instruments (questionnaires). In such cases and when available, we included in our analysis the category labels used to group the survey questions.

¹⁰ Appendix 3 provides a detailed list showing the original categories of measures that comprise the reassigned broader categories.

Table 3. Summary of Reassigned Categories of Indicators and Survey Questions (Listed Alphabetically) from Group A and Group B Tools. (The original categories included in these reassigned categories are listed in Appendix 3.)

Reassigned Category		No. of Tools
Access		15
Access and use		2
Financing		8
Governance		4
Health/pharmaceutical services/laboratory services		6
Human resources		7
Information systems		3
Manufacturing, industry, and trade		5
Miscellaneous indicator categories		13
Organization and management support		2
Policies, legislation, and regulation		20
Quality/quality assurance/pharmacovigilance		15
Service Delivery	Distribution	6
	Procurement	8
	Procurement and distribution	2
	Selection	3
	Selection and procurement	2
	Selection and use	1
	Selection and registration	1
	Services and logistics	1
	Supply chain/supply chain management/logistics	7
	Transport	1
Use		21

Note: For assessment tools with indicators, our analysis also included a count of the number of indicators in each category. These counts were excluded from the table because the possible duplication of indicators or redundancies across the various tools could bias the interpretation of the relative importance of a particular component.

Thoughts on Composite Indicators¹¹

One of the issues for deliberation concerns the potential use of composite scores/measures.¹² USAID has been enquiring about approaches for ranking the performance of national pharmaceutical systems, which would likely require the use of a composite measure. Given the multi-dimensional nature of the pharmaceutical system, a single indicator cannot adequately capture the entire system or even a component. Further, it is difficult to make an overall

¹¹ Veronika Wirtz and Richard Laing contributed to the writing of this section.

¹² According to OECD's *Handbook on Constructing Composite Indicators*, a composite indicator is formed when individual indicators are compiled into a single index on the basis of an underlying model of the multi-dimensional concept that is being measured (OECD 2008).

judgment about the performance of the pharmaceutical system when looking at a large number of individual indicators. Creating a single or several composite indicators that incorporate a series of single measures is therefore worth considering.

Composite indicators are commonly used in fields such as economics (e.g., Gini Index) and international development (e.g., Human Development Index).¹³ Composite indicators have also been used to rank health systems (WHO 2000) or provide a level of performance (e.g., performance rating of the National Health Service Trusts in England). A few of the assessment tools discussed earlier include composite scores/indices to provide summary measures or monitor improvements in specific areas of the system over time. For example, the WHO Monitoring the Building Blocks of Health Systems Assessment Instrument (2010) includes composite indices for leadership/governance, service delivery, and information systems building blocks. The composite index on governance is a simple additive index comprising 10 indicators and provides a summary measure of governance quality. More recently the Access to Medicine Index has used composite indicators to compare the efforts of major pharmaceutical companies to improve access to medicines in low- and middle-income countries.¹⁴

Several critical questions should be addressed when considering the suitability of compiling indicators into a country-level composite index, possibly as a marker for the current (maturity) level of the pharmaceutical system or for ranking countries in terms of their pharmaceutical performance. First, when and how are the use of such composite indicators appropriate and do they add value? It is therefore important to identify the intended audience (e.g., international donors, national governments, healthcare providers, citizens, patients) and the pharmaceutical system components or the dimensions of system performance the indicators are intended to measure. Donors may be particularly interested in the disease areas they invest in (e.g., reproductive health, HIV, malaria) rather than more general system aspects, such as market authorization speed and promotion of medicines.

Second, what systematic criteria are needed to determine the inclusion of individual indicators within composite indicators? Constructing composite indicators requires trade-offs between different measures of performance, which can be difficult and controversial. If not carefully designed, composite indicators may be misleading and result in wrong policy and planning decisions. Because composite indicators would aim for a comprehensive assessment of the pharmaceutical system, they should include all important aspects of performance, even those indicators that are difficult to measure. The choice of indicators should be driven not only by the feasibility of data collection but also by theoretical importance. The types of performance indicators, that is, whether the measures should relate to input, process, output and/or outcome at the various levels of the system, are another issue. Measuring outcomes is desirable as it is

¹³ The Gini index measures the extent to which the distribution of income or consumption expenditure among individuals or households within an economy deviates from a perfectly equal distribution. More information is available at <http://data.worldbank.org/indicator/SI.POV.GINI>.

The Human Development Index (HDI) is a summary measure of human development in three key dimensions: a long and healthy life, being knowledgeable and having a decent standard of living. More information is available at <http://hdr.undp.org/en/content/human-development-index-hdi>.

¹⁴ The Access to Medicine Index ranks the efforts of pharmaceutical companies to improve access to medicine in low- and middle-income countries. The Index is produced by the Access to Medicine Foundation and the reports are available at www.accesstomedicineindex.org.

relevant to know about the impact on goals, such as improving health or financial protection. However, directly attributing health improvements to pharmaceutical system performance is problematic given the multiple determinants of (ill) health.

The third critical question is, would composite indicators actually help identify where to target resources or would they obscure performance/resource gaps? The aggregation of individual measures into composite indicators may disguise serious failings in specific parts of a system. Aggregation typically involves transformation of individual indicators and the application of weights. Some kind of data transformation is usually necessary to make the individual indicators comparable and to account for outliers. Weights may be applied for various reasons, but they typically reflect the relative importance assigned to the individual indicators or the opportunity cost of achieving good performance on each individual indicator (Goddard and Jacobs 2009). In some cases, good performance on one indicator could offset low performance on another indicator, depending on the weights assigned. It is therefore important that aggregation is done in a systematic fashion to ensure that the resulting composite indicators are transparent, easily understood, and have the intended incentive effects (Goddard and Jacobs 2009). The Access to Medicines Index, for example, provides details of the methodology used to weight and aggregate the individual indicators.

Last, how can validity and robustness be ensured? The validity and robustness of any composite indicator is dependent on good data quality, comparability across countries and systems, and a consensus on the appropriate interpretation of the composite indicator. However, there is an inherent trade-off between developing a robust composite indicator that captures the complex and comprehensive dimensions of pharmaceutical system performance for a wide range of countries and the practical issues of gathering good data on such dimensions (Goddard and Jacobs 2009). Table 4 summarizes some of the advantages and disadvantages of composite indicators. It is important to reflect on these issues to determine whether composite indicators are suitable for the program objectives.

Table 4. Summary of the strengths and weaknesses of composite indicators (adapted from Smith 2002, OECD 2008).

Strengths

- System performance is placed at the center of the policy arena.
- A rounded assessment of system performance is more easily attained with composite indicators than a collection of diverse indicators.
- Composite indicators allow judgments to be made on system efficiency.
- A single, simple measure captures policy attention more easily and facilitates communication with the public about performance issues, thus enhancing public accountability.
- Composite indicators allow for comparison and identification of which systems represent the beacons of best performance or the priority for improvement efforts.

Weaknesses

- The aggregation of individual measures of performance into composite indicators may disguise serious failings in some parts of some systems.
 - As measures of performance become more aggregated, it becomes increasingly difficult to distinguish the causes of poor performance and what remedial action to take.
 - Individual elements of a composite indicator are often contentious.
 - A composite that seeks to be comprehensive in its coverage may rely on very feeble or opaque data in some dimensions of performance.
 - Methodology for calculating weights is seriously inadequate.
 - The choice of weights may be ad hoc and arbitrary with a lack of consideration for whose preferences the weights reflect and how robust these are.
 - Variations in performance as measured by the composite indicators may be due to random variation (uncertainty) associated with the underlying indicators and not real differences in performance.
-

Conclusion

Pharmaceutical systems strengthening is complex, involving numerous elements that influence the performance of a pharmaceutical system. The starting point for identifying metrics for its measurement is better conceptual clarity on what a pharmaceutical system is, including its key components and performance objectives, and clearly delineating what its strengthening entails. This paper reviews a wide range of earlier work in defining and conceptualizing pharmaceutical systems and its strengthening, as well as relevant insights from the health systems literature to highlight common themes and insights. It also draws on the significant body of work and experience in assessing and monitoring health systems, noting the different purposes and applications of the various tools and metrics, to identify common elements that are considered to constitute or influence a pharmaceutical system. Agreeing on common indicators, whether individual or composite, is a key step towards having a common understanding of pharmaceutical systems.

We look forward to further discussions on these topics at the upcoming meeting.

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Contributors and Reviewers

Tamara Hafner, SIAPS consultant and Helena Walkowiak, SIAPS Principal Technical Advisor prepared this background paper. The paper reflects the contributions of David Lee, CPM/MSH Director, Technical Strategy and Quality. Veronika Wirtz and Richard Laing, both from the Department of Global Health at Boston University School of Public Health, contributed to the section on composite indicators. The section on composite indicators was revised after the meeting to reflect their contribution. That is the only section of the background discussion paper that was revised after the meeting.

Richard Laing and the following SIAPS and MSH staff reviewed the draft: Francis (Kofi) Aboagye-Nyame, Michael Cohen, Ruth Musila, Sue Putter, and Maura Soucy.

Appendix 1. Literature Review Protocol

The literature search was conducted to identify reports and published articles related to pharmaceutical systems and pharmaceutical systems strengthening. Specifically, we sought to develop a systematic collection of literature that included an implied or explicit definition of pharmaceutical systems, pharmaceutical systems strengthening, or described frameworks and metrics for measuring the performance of these systems.

We used institutional knowledge in consultations with senior experts at MSH to create an initial list of search terms, key actors and agencies involved in pharmaceutical systems. The search terms listed in Table 1.1 were searched by themselves and in various combinations with each other or the names of the organizations listed to maximize the saturation of our search. We conducted a search for reports from the grey literature using the search terms, Google and websites of organizations such as the World Health Organization (WHO), US Agency for International Development (USAID), the World Bank (Table 1.1). For published articles, we used Google Scholar, PubMed, and EBSCO. In cases where publications were organized by subject on the websites of organizations, the publication lists under the appropriate subjects were reviewed for relevance. The search was an iterative process in which the results and bibliographies of relevant articles in the first iteration were used to guide subsequent searches. We deemed the search had reach saturation when subsequent searches failed to provide any noticeably new publications or other organizations to add to our list of interest.

The primary inclusion criteria were reports or studies that focused on: a definition of pharmaceutical system, pharmaceutical management system; pharmaceutical systems strengthening or health systems strengthening; a description of a framework aligned with one of these definitions; an identification of one or more components of a pharmaceutical (management) system; description of an indicator or metric for measuring the performance of such a system; description of an intervention to improve, support or strengthen such a system; a review or discussion of the conceptual or theoretical basis for such a system or one of its components. We excluded national assessment reports and articles focused on pharmaceutical innovation and industry performance; governance, transparency or corruption in the pharmaceutical sector; and pharmacology-related topics. We also excluded materials produced by Management Sciences for Health (MSH) because an extensive in-house archive of relevant documents already existed. The search was restricted to English language sources but there was no restriction on the date of publication.

The title and/or abstract of the publications resulting from each search were quickly screened for relevance. In instances where a search returned a hundred or more results, we took two actions. First, we sorted the list by relevance and quickly screened the first few pages of results or stopped when it was obvious from the titles that the results were no longer relevant. Second, we refined the search by including additional keywords to narrow the scope of the results. The abstracts of the materials selected from the searches were then read more carefully and sorted into three virtual bins: assessment tools; pharmaceutical systems and strengthening; health systems strengthening.

Table 1.1. Search terms, databases and other websites used for the literature search.

Databases and Websites	Search terms
'Grey' Literature	access to medicines
Boston University Center for Global Health and Development	access to pharmaceuticals
DFID Research for Development Database	assessment
Google	drug supply system
International Impact Evaluation Initiative	framework
Harvard DPM	health systems
USAID	health systems strengthening
Health Systems 20/20	indicators
DELIVER Project	measurement
Development Experience Clearinghouse	medicines
International Network for the Rational Use of Drugs	metrics
International Pharmaceutical Federation	monitoring
MEASURE Evaluation	performance
WHO	pharmaceutical management
Essential Medicines and Health Products Information Portal	pharmaceutical systems
Medicines Publications and Documentation System	pharmaceutical systems
Institutional Repository for Information Sharing	strengthening
Alliance for Health Policy and Systems Research	strengthening
The World Bank	
<u>Published Articles</u>	
EBSCO	
Google Scholar	
PubMed	

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Appendix 2. Assessment Tools

Table 2.1. Non-MSH tools

Assessment Tool Reference	Code	Group for Analysis
1 Aronovich, Dana, Marie Tien, Ethan Collins, Adriano Sommerlatte, and Linda Allain. (2010). <i>Measuring supply chain performance: Guide to key performance indicators for public health managers</i> . Arlington, Va.: USAID DELIVER PROJECT, Task Order 1. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/MeasSCPerf.pdf	DELIV-2012	A
2 USAID DELIVER PROJECT, Task Order 1. 2008. <i>Logistics indicators assessment tool (LIAT)</i> . Arlington, Va.: USAID DELIVER PROJECT, Task Order 1. http://deliver.jsi.com/dhome/whatwedo/monitoreval/meavailability/meliatsatresources USAID DELIVER. 2006. <i>Monitoring and evaluation indicators for assessing logistics systems performance</i> . Arlington, Va.: DELIVER, for the U.S. Agency for International Development. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/ME_Indi.pdf	LIAT-2008	C
3 USAID DELIVER PROJECT, Task Order 4. 2012. <i>Procurement performance indicators guide—Using procurement performance indicators to strengthen the procurement process for public health commodities</i> . Arlington, Va.: USAID DELIVER PROJECT, Task Order 4. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/ProclndiGuid.pdf	JSIPROC-2012	C
4 FHI 360. (2012). <i>Health system rapid diagnostic tool. Framework, operational guide, and metrics to measure the strength of priority health system functions</i> . Durham NC: FHI 360. http://www.fhi360.org/resource/health-system-rapid-diagnostic-tool	FHI360-2012	A
5 Health Systems 20/20. (2012). <i>The health system assessment approach: A how-to manual</i> . Version 2.0. Module 6. www.healthsystemassessment.org	HS20-2012	A
6 Brudon, P., Rainhorn, J. D., Reich, M. R. (1999). <i>Indicators for monitoring national drug policies: a practical manual</i> . Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/whozip14e/whozip14e.pdf	WHONDP-1999	A
7 WHO. (2007). <i>Operational package for monitoring and assessing country pharmaceutical situations. Guide for coordinators and data collectors</i> . Geneva: World Health Organization. http://apps.who.int/medicinedocs/index/assoc/s14877e/s14877e.pdf	WHOPS-2007	A
8 WHO. (1993). <i>How to investigate drug use in health facilities: selected drug use indicators</i> . EDM Research Series No. 007. Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js2289e/	WHODU-1993	A
9 WHO. (2009). <i>Medicines use in primary care in developing and transitional countries. FactBook summarizing results from studies reported between 1990 and 2006</i> . Geneva: World Health Organization. http://www.who.int/medicines/publications/who_emp_2009.3/en/	WHOUSE-2009	A
10 Ratanawijitrasin, S. & Wondemagegnehu, E. (2002). <i>Effective drug regulation. A multicountry study</i> . Geneva: World Health Organization. http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf	WHODR-2002	C
11 WHO. (2007). <i>WHO data collection tool for the review of drug regulatory</i>	WHODR-	C

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Assessment Tool Reference	Code	Group for Analysis
<i>systems. Practical guidance for conducting a review.</i> Geneva: World Health Organization. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assessment/en/	2007	
12 WHO and HAI. (2008). <i>Measuring medicine prices, availability, affordability and price components</i> , 2nd ed. Geneva: World Health Organization and Health Action International. http://www.haiweb.org/medicineprices/manual/documents.html	WHOHA-2008	A
13 WHO. (2009). <i>Measuring transparency in the public pharmaceutical sector. Assessment instrument.</i> Geneva: World Health Organization. http://www.who.int/medicines/areas/policy/goodgovernance/AssessmentInstrumentMeastranspENG.PDF	WHOTR-2009	C
14 WHO. (2009). <i>Monitoring and evaluation of health systems strengthening. An operational framework.</i> Geneva: World Health Organization. http://www.who.int/healthinfo/HSS_MandE_framework_Nov_2009.pdf	WHOHSS-2009	C
15 WHO. (2010). <i>Monitoring the building blocks of health systems: a handbook of indicators and their measurement strategies.</i> Geneva: World Health Organization. http://www.who.int/healthinfo/systems/monitoring/en/	WHOHSS-2010	A
16 WHO. (2011). <i>Harmonized monitoring and evaluation indicators for procurement and supply management systems: early-warning indicators to prevent stock-outs and overstocking of antiretroviral, antituberculosis and antimalaria medicines.</i> Geneva: World Health Organization. http://www.who.int/hiv/pub/amds/monitoring_evaluation/en/	WHOHTM-2011	B
17 WHO. (2011). <i>Pharmaceutical human resources assessment tools.</i> Geneva: World Health Organization. http://apps.who.int/medicinedocs/en/d/Js18717en/	WHOHR-2011	B
18 Supply Chain Management System. 2012. <i>National supply chain key performance indicators: User's guide & data dictionary.</i> Submitted to the US Agency for International Development by the Supply Chain Management System (SCMS).	SCMS-2012	B
19 Seiter, A. (2010). <i>A practical approach to pharmaceutical policy. Appendix A.</i> Washington DC: World Bank Publications. https://openknowledge.worldbank.org/bitstream/handle/10986/2468/552030PUB0Phar10Box349442B01PUBLIC1.pdf?sequence=4	SEITER	A
20 USAID DELIVER PROJECT, Task Order 1. 2010. <i>Assessment tool for laboratory services and supply chains (ATLAS).</i> Arlington, Va.: USAID DELIVER PROJECT, Task Order 1.	ATLAS-NI	C
21 Global Fund, <i>Pharmaceutical sector country profile questionnaire.</i> http://www.who.int/medicines/areas/coordination/Empty_English_Questionnaire.pdf	GFPSP-NI	A
22 Global Fund, <i>The pharmaceutical and health product management (PHPM) assessment tool.</i>	GFPHPM-NI	A
23 JSI, <i>Transport assessment tool.</i> http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/TransAssesTool.pdf	JSIT-NI	C
24 USAID DELIVER PROJECT, Task Order 1. 2009. <i>logistics system assessment tool (LSAT).</i> Arlington, Va.: USAID DELIVER PROJECT, Task Order 1.	LSAT-NI	C

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Assessment Tool Reference	Code	Group for Analysis
http://deliver.jsi.com/dhome/whatwedo/monitoreval/meavailability/meliatlsatre/sources		
25 USAID DELIVER PROJECT, Task Order 4. 2013. <i>Human resource capacity development in public health supply chain management: Assessment guide and tool</i> . Arlington, VA.:USAID DELIVER PROJECT,Task Order 4. http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/HumaResoCaPaDeve_AsseGuid.pdf	DELIVHR-NI	C
26 USP. (2007). <i>Rapid assessment of medicines quality assurance and medicines quality control</i> . http://www.usp.org/sites/default/files/usp_pdf/EN/dqi/rapidAssessmentTool.pdf	USPQ-NI	C
27 Global Fund.(2011). The Global Fund monitoring and evaluation toolkit. http://www.theglobalfund.org/en/me/documents/toolkit/	N/A	N/A
28 AIDSRelief. <i>ART commodity management and supply chain assessment tool</i> . N/A	N/A	N/A
29 MEASURED SPA Medicines Availability. http://www.dhsprogram.com/pubs/pdf/SPAQ5/Service_Readiness_Indicators_042012.pdf	N/A	N/A
30 WHO. (2001). <i>Guidelines for the formulation, implementation, monitoring and evaluation of national drug policies</i> . Harare: WHO Regional Office of Africa. http://www.who.int/medicines/technical_briefing/tbs/guidelines-formulation.pdf (A questionnaire based on Brudon et al. 2009, which is included in the inventory)	N/A	N/A
31 WHO. (2013). <i>Service Availability and Readiness Assessment (SARA). An annual monitoring system for service delivery</i> . Version 2.1. Geneva: World Health Organization. http://www.who.int/healthinfo/systems/sara_introduction/en/	N/A	N/A

Note: Tools 27-31 were excluded from any analysis because they did not add any meaningful insight regarding components of the pharmaceutical system.

Table 2.2 MSH Tools

Assessment Tool Reference	Code	Group for Analysis
1 MSH, Center for Pharmaceutical Management, University Research Corporation, PAHO, USAID. <i>Rapid Pharmaceutical Management Assessment: an Indicator-Based Approach</i> . Rational Pharmaceutical Management Project, Drug Management Program. (July 1995).	1.1	A
2 MSH, Center for Pharmaceutical Management. <i>Inventory Management Assessment Tool</i> . Excel Workbook. (1997).	1.2	N/A
3 MSH, Center for Pharmaceutical Management. <i>Access to Essential Medicines: Tanzania, 2001</i> . Prepared for the Strategies for Enhancing Access to Medicines Program. Arlington, VA: Management Sciences for Health. (2003).	1.3	A
4 MSH, Center for Pharmaceutical Management. <i>Uganda Inspection, Monitoring, and Supervision Model</i> . Prepared for the East African Drug Seller Initiative Project. Management Sciences for Health and the Bill & Melinda Gates Foundation. (Date not available).	1.4	C
5 MSH, Center for Pharmaceutical Management. <i>Medicines Building Block Tracking and Monitoring Framework (draft version 5.0, never completed)</i> . Prepared for the Strengthening Pharmaceutical Systems project. (2009).	1.5	A
6 MSH, Center for Pharmaceutical Management. <i>Guidance for incorporating SIAPS-Global Indicators into Portfolio PMPs</i> . Prepared for the Systems for Improved Access to Pharmaceuticals and Services Project. MSH/USAID (February 2013).	1.6	C
7 Keene, D; Ickx, P; McFadyen, J. <i>Drug Management for Childhood Illness Manual</i> . Published for the U.S. Agency for International Development by the Rational Pharmaceutical Management Project. Arlington, VA: Management Science for Health. (September 2000).	2.1	B
8 Briggs, CJ; Frye, J; Senauer, K. <i>District Pharmaceutical Management for Childhood Illness: An Assessment and Monitoring Tool</i> . Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health. (March 2008).	2.2	B
9 Nachbar, N; Briggs, J; Aupont, O; Shafritz, L; Bongiovanni, A; Acharya, K; Zimicki, S; Holschneider, S; Ross-Degnan, D. <i>Community Drug Management for Childhood Illness: Assessment Manual</i> . Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health. (December 2003).	2.3	B
10 MSH, Center for Pharmaceutical Management. <i>Pharmaceutical Management for Malaria Manual</i> . Prepared by Malcolm Clark 2002 and revised by Rima Shretta 2003. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health. (Revised ed. 2004).	3.1	B
11 MSH, Center for Pharmaceutical Management. <i>Malaria Community Pharmaceutical Management Survey Instruments, Laos</i> . Submitted to the U.S. Agency for International Development under the Rational Pharmaceutical Management Plus Program by Management Sciences for Health. (September 2005).	3.2	B
12 MSH, Center for Pharmaceutical Management. <i>Monitoring and Evaluation of Pharmaceutical Management Aspects of ACT Policy Implementation: An Indicator-Based Tool</i> . Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems Program.	3.3	B

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Assessment Tool Reference	Code	Group for Analysis
Arlington, VA: Management Sciences for Health. (2009).		
13 Barrientos, R; Busch, T; Goredema, W; and Tjipura, D. <i>End Use Verification Survey for Monitoring Availability and Use of Malaria and other Key Health Commodities in Angola; August-September 2011</i> . Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health. (August-September 2011)	3.4	B
14 MSH, Center for Pharmaceutical Management. <i>President's Malaria Initiative Situation Assessment Tool</i> . (2009).	3.5	B
15 Rational Pharmaceutical Management (RPM) Plus Program. 2005. <i>Pharmaceutical Management for Tuberculosis Assessment Manual</i> . Edited by A. Zagorskiy, C. Owunna, and T. Moore. Submitted to the U.S. Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health.	4.1	B
16 Walkowiak, H. <i>HIV/AIDS Pharmaceutical Management Capacity Building in Karnataka, India. Baseline Assessment: April and August 2010</i> . Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health. (2010).	5.1	B
17 Strengthening Pharmaceutical Systems (SPS) Program. <i>How to Investigate Antimicrobial Use in Hospitals: Selected Indicators</i> . Published for the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems Program. Arlington, VA: Management Sciences for Health. (February 2012).	6.1	C
18 MSH, Center for Pharmaceutical Management. <i>Antimicrobial Resistance Module for Population-Based Surveys</i> . Submitted to the U.S. Agency for International Development by the RPM Plus Program. Arlington, VA: Management Sciences for Health. (2008).	6.2	C
19 MSH. <i>Building Local Coalitions for Containing Drug Resistance: A Guide</i> . Submitted to the U.S. Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health. (September 2011).	6.3	C
20 MSH, Center for Pharmaceutical Management. <i>Regulatory Systems Assessment Tool</i> . Excel file. Internal tool. (2012.)	7.1	C
21 Strengthening Pharmaceutical Systems (SPS) Program. <i>Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries</i> . Submitted to the U.S. Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health. (December 2009).	7.2	C
22 Internal document: Annex A in T. Wuliji et al. <i>Strengthening Pharmaceutical Human Resources in Afghanistan: Assessment and Strategic Framework Development</i> . Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health (March 2013).	8.1	C

Appendix 3. Reassigned Indicator Categories

Table 3.1 Reassigned categories of indicators and survey questions

(listed alphabetically) from 'Group A' assessment tools.

Reassigned Categories		Original Categories		
Label	No. of Tools	Label	No. of Tools	Tool Reference
Access	12	Acceptability/ Satisfaction	1	1.3
		Access (Level II)	1	WHOPS-2007
		Access to Essential Medicines	1	WHOHSS-2010
		Affordability	2	WHOAI-2008, 1.3
		Affordability of essential drugs	1	WHONDP-1999
		Availability	1	WHOAI-2008
		Availability and Access to Quality Products	1	HS20-2012
		Availability of essential drugs	1	WHONDP-1999
		Availability of Medicines and Information	1	1.3
		Geographic Accessibility	1	1.3
		Household Access	1	GFPSP-NI
Access and use	2	Access and Use	1	1.5
		Patient Access and Drug Utilization	1	1.1
Distribution	6	Distribution/Transport	1	DELIV-2012
		Inventory Management/LMIS/Customer Response	1	DELIV-2012
		Inventory Storage and Distribution	1	FHI360-2012
		Storage and Distribution	1	HS20-2012
		Storage, Inventory Management, and Transportation	1	1.5
		Warehousing/Storage	1	DELIV-2012
Financing	7	Drug allocation in the health budget/public sector financing policy	1	WHONDP-1999
		Financing of Medical Products, Vaccines and Technologies	1	HS20-2012
		Health Systems Financing	1	WHOHSS-2010
		Medicines Financing	1	GFPSP-NI
		Medicines Financing (Level I)	1	WHOPS-2007
		Ministry of Health Budget and Finance	1	1.1
		Public and Private Drug Expenditure	1	SEITER
Governance	2	Governance	1	1.5
		Leadership & Governance	1	WHOHSS-2010
Health/	4	Health Service Delivery	1	WHOHSS-2010

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Reassigned Categories		Original Categories		
Label	No. of Tools	Label	No. of Tools	Tool Reference
pharmaceutical services		Health Services	1	GFPSP-NI
		Physical infrastructure for service delivery	1	FHI360-2012
		Serving Customers	1	FHI360-2012
Human Resources	2	Health Workforce	1	WHOHSS-2010
		Other (level II)	1	WHOPS-2007
Miscellaneous indicator category	4	Additional Indicators	1	WHOUSE-2009
		Facility indicators	1	WHOUSE-2009
		Standard Indicators	1	HS20-2012
		Health and Demographic Data	1	GFPSP-NI
Information Systems	2	Health Information Systems	1	WHOHSS-2010
		The Logistics Management Information System	1	FHI360-2012
Manufacturing, industry and trade	5	Industry and Trade	1	SEITER
		Medicines and Trade Production	1	GFPSP-NI
		Pharmaceutical Market	1	SEITER
		Private Sector Pharmaceutical Activity	1	1.1
		Production and Trade (Level I)	1	WHOPS-2007
Organization & management support	1	Management Support	1	1.5
Policies, legislation, regulation	11	Drug Pricing	1	SEITER
		Legislation and regulation	1	WHONDP-1999
		Medicine Price	1	WHOHAI-2008
		Medicines Regulation	1	GFPSP-NI
		National Medicines (Drug) Policy (Level I)	1	WHOPS-2007
		Pharmaceutical Policy, Laws and Regulations	1	HS20-2012
		Policy and Regulation	1	SEITER
		Policy Issues	1	GFPSP-NI
		Policy, Legislation and Regulation	1	1.1
		Pricing Policy	1	WHONDP-1999
Regulatory System (Level I)	1	WHOPS-2007		
Procurement	7	Forecasting and procurement	1	FHI360-2012
		Ministry of Health Pharmaceutical Procurement	1	1.1
		Procurement	1	HS20-2012
		Public sector procurement procedures	1	WHONDP-1999
		Purchasing, Reimbursement and Procurement	1	SEITER

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Reassigned Categories		Original Categories		
Label	No. of Tools	Label	No. of Tools	Tool Reference
		Quantification and Procurement	1	1.5
		Supplier/Sourcing	1	DELIV-2012
Procurement and distribution	2	Pharmaceutical Procurement and Distribution	1	GFPSP-NI
		Procurement & Supply Management	1	GFPHPM-NI
Quality/Quality Assurance/PV	6	Product Quality Assurance	1	1.1
		Quality (Level II)	1	WHOPS-2007
		Quality and Safety Monitoring	1	FHI360-2012
		Quality Assurance and Medication Safety	1	1.5
		Quality of drugs	1	WHONDP-1999
		Quality of Products and Services	1	1.3
Selection	3	Formulary/Essential Drugs List and Drug Information	1	1.1
		Product Selection	1	FHI360-2012
		Selection of Pharmaceuticals	1	HS20-2012
Selection and procurement	1	Product Selection, Forecasting, and Procurement	1	DELIV-2012
Selection and registration	1	Essential drug selection and drug registration	1	WHONDP-1999
Selection and use	1	Selection and Rational Use	1	GFPSP-NI
Services and logistics	1	Service Delivery and logistics	1	SEITER
Supply chain/supply management/logistics	4	Medicines and supplies required for essential services	1	FHI360-2012
		Medicines Supply Systems (Level I)	1	WHOPS-2007
		Ministry of Health Pharmaceutical Logistics	1	1.1
		Public sector distribution and logistics	1	WHONDP-1999
Use	13	Appropriate Use	1	HS20-2012
		ARI treatment indicators	1	WHOUSE-2009
		Complementary medicines use indicators	1	WHOUSE-2009
		Diarrhoea treatment indicators	1	WHOUSE-2009
		Information and continuing education on drug use	1	WHONDP-1999
		Malaria treatment indicator	1	WHOUSE-2009
		Patient care indicators	1	WHOUSE-2009
		Prescribing indicators	1	WHOUSE-2009
Rational use of drugs	2	WHONDP-1999, SEITER		

Reassigned Categories		Original Categories		
Label	No. of Tools	Label	No. of Tools	Tool Reference
		Rational Use of Medicines (Level I)	1	WHOPS-2007
		Rational Use of Medicines (level II)	1	WHOPS-2007
		Use	1	WHODU-1993

Table 3.2. Reassigned categories of indicators and survey questions

(listed alphabetically) from 'Group C' assessment tools

Reassigned Categories		Original Categories		
Label	No. of Tools	Label	No. of Tools	Tool Reference
Access	3	Acceptability/Satisfaction	1	1.4
		Affordability	1	1.4
		Availability	1	1.4
Financing	1	Financing strategies and mechanisms	1	1.6
Governance	2	Pharmaceutical sector governance	1	1.6
		Transparency	1	WHOTR-2009
Health/pharmaceutical services	1	Pharmaceutical Services	1	1.6
Human resources	5	Human Resources	1	DELIVHR-NI
		Human Resources Planning	1	8.1
		Human Resources Policies	1	8.1
		Practice Distribution of Pharmaceutical Human Resources	1	8.1
		Total Pharmaceutical Human Resources	1	8.1
Information systems	1	Information for decision-making	1	1.6
Laboratory services and supply chain	1	Laboratory Services and Supply Chain	1	ATLAS-NI
Miscellaneous indicator category	7	General Information	1	8.1
		Hospital Indicators	1	6.1
		Impact	1	WHOHSS-2009
		Inputs and processes	1	WHOHSS-2009
		Outcomes	1	WHOHSS-2009
		Outputs	1	WHOHSS-2009
		Supplemental Indicator	1	6.1
Organization & management support	1	Management Support	1	6.3

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Reassigned Categories		Original Categories		
Label	No. of Tools	Label	No. of Tools	Tool Reference
Policies, legislation and regulation	9	Drug regulation overview	1	WHODR-2002
		Enforcement	1	7.1
		Inspection	1	7.1
		Medicine Policy	1	6.3
		Policy, Law, and Regulation	1	7.2
		Registration	1	7.1
		Regulatory Environment	1	6.3
		Regulatory functions	2	WHODR-2002, WHODR-2007
Procurement	1	Procurement	1	JSIPROC-2012
Quality/quality assurance/PV	9	Pharmacovigilance	1	7.1
		Quality Assurance & Control	1	USPQ-NI
		Quality of Products	1	1.4
		Quality of Services	1	1.4
		Quality Surveillance	1	7.1
		Risk Assessment and Evaluation	1	7.2
		Risk Management and Communication	1	7.2
		Signal Generation and Data Management	1	7.2
		Systems, Structures, and Stakeholder Coordination	1	7.2
Selection & procurement	1	Selection and Procurement	1	6.3
Supply chain/supply management/logistics	3	Logistics	1	LSAT-NI
		Logistics System	1	LIAT 2008
		Pharmaceutical Supply Management and Services	1	1.6
Transport	1	Transport	1	JSIT-NI
Use	8	AMR Containment and Advocacy	1	6.3
		Correct Antimicrobial Medicine Knowledge and Behavior	1	6.2
		Correct Antimicrobial Resistance Knowledge	1	6.2
		Correct Use of Medicines	1	6.2
		Education and Training on Use	1	6.3
		Medicines Information	1	7.1
		Patient Care Indicators	1	6.1
		Prescribing Indicators	1	6.1