Strengthening Governance in Pharmaceutical Systems

A Compendium of Country Case Studies

Helena Walkowiak

Tamara Hafner

Susan Putter

USAID FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access
to Pharmaceuticals and Services

About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to ensure 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.

Recommended Citation

This report may be reproduced if credit is given to SIAPS. Please use the following citation.

Walkowiak H, Hafner T, Putter S.J. 2018. Strengthening Governance in Pharmaceutical Systems: A Compendium of Country Case Studies. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

Key Words

Governance, transparency, accountability, pharmaceutical system, case study

TABLE OF CONTENTS

ACKNOWLEDGMENTS

ACRONYMS AND ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
APTS	Auditable Pharmaceutical Transactions and Services (Ethiopia)
ARV	antiretroviral
BHMC	Barangay Health Management Council (Philippines)
CMS	central medical stores
COI	conflict of interest
CRMS	Continuous Results Monitoring and Support System
CSO	civil society organization
DDMS	Directorate of Drugs and Medical Supplies (Sierra Leone)
DGFP	Directorate General of Family Planning (Bangladesh)
DGHS	Directorate General of Health Services (Bangladesh)
DPM	Direction de la Pharmacie et du Médicament (DRC)
DRC	Democratic Republic of the Congo
DTC	Drug and Therapeutics Committee
eLMIS	electronic Logistics Management Information System
FP	family planning
HIV	human immunodeficiency virus
LCF	Logistics Coordination Forum (Bangladesh)
LDP	Leadership Development Program
LMIC	low- and middle-income country
M&E	monitoring and evaluation
MNCH	maternal, neonatal, and child health
MOH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare (Bangladesh)
MOHS	Ministry of Health and Sanitation (Sierra Leone)
MOU	memorandum of understanding
MRA	medicines regulatory authority
MRC	Medicine Registration Committee (DRC)
NEML	national essential medicines list
NGO	nongovernmental organization
NMP	national medicines policy
NMSA	National Medical Supplies Agency (Sierra Leone)
NPPU	National Pharmaceutical Procurement Unit (Sierra Leone)
PLMC	Procurement and Logistics Management Cell (Bangladesh)
QCHD	Quezon City Department of Health
RH	reproductive health
SCIP	Supply Chain Information Portal (Bangladesh)
SCMP	Supply Chain Management Portal (Bangladesh)
SDG	Sustainable Development Goals
SEC	State Expert Center (Ukraine)
SIAPS	Systems for Improved Access to Pharmaceuticals and Services [Program]

SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems [Program]
TAW	Treatment Access Watch [Program]
TB	tuberculosis
TOR	terms of reference
ToT	training-of-trainers
UHC	universal health coverage
UNDP	United Nations Development Programme
UNESCAP	United Nations Economic and Social Commission for Asia and the Pacific
USAID	US Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Poor governance in pharmaceutical systems can reduce access to pharmaceutical products, inflate medicine prices, and waste scarce health system resources. SIAPS and its predecessor programs have assisted numerous countries to strengthen governance to promote robust decision making, enhance accountability, reduce opportunities for corruption, and improve efficiencies to enable better access to and use of quality-assured medicines. This compendium draws on these experiences and provides a collection of eight case studies that provide examples of strategies and approaches for strengthening governance in pharmaceutical systems.

The case studies describe SIAPS' support/technical assistance for the:
- Development and enactment of legislation in Swaziland to improve the control of medicines
- Strengthening of key pharmaceutical governing and decision-making bodies in Sierra Leone after the Ebola epidemic
- Implementation of governance-related interventions to strengthen medicines registration in the Democratic Republic of the Congo (DRC)
- Improvement of transparency and accountability in pharmaceutical service delivery in Ethiopia
- Harmonization of medicines lists used to guide procurement and establishment of a robust medicines selection process in Ukraine
- Use of information technology to improve governance in procurement and supply management in Bangladesh
- Bolstering of leadership, management, and governance capacity at regional and facility levels in Cameroon to reduce antiretroviral (ARV) stock-outs at HIV clinics
- Strengthening the tuberculosis (TB) control program in poor urban areas in Quezon City in the Philippines by establishing community health management councils

The compendium highlights accumulated insights into factors that may have enabled or constrained the success of governance improvement initiatives and closes with some reflections on lessons learned. Governance can be a sensitive subject, and various challenges may impede the startup or implementation of improvement initiatives and reforms that target issues related to governance in pharmaceutical systems. Common challenges encountered include:
- Resistance due to sensitivities, competing interests, or reluctance to changing long-standing processes and behaviors
- Lengthy policy and legislative procedures and protracted bureaucratic processes that hinder implementation of governance-improvement initiatives
- Insufficient capacity to implement or sustain reforms or initiatives

SIAPS has found the following strategies effective for initiating, implementing, and sustaining governance strengthening initiatives:
- Conducting situational analyses, targeting inefficiencies, and including a governance-related component in country pharmaceutical system assessments—whatever the scope—have proven to be effective ways for gaining entry and implementing and sustaining initiatives.
- Aligning technical assistance activities with government priorities to create a shared vision and priorities can help generate trust and secure political support.
- Embedding reforms in legislation helps to institutionalize and sustain initiatives.
- Designing a combination of interventions that target governance, management, and leadership practices can improve institutional and individual capacity, a common constraint for exercising and institutionalizing good governance.

INTRODUCTION

Access to safe and affordable pharmaceutical products is critical for the ability of health systems to achieve desired health outcomes and the goals of expanded health coverage and risk protection programs. However, poor governance in pharmaceutical systems can reduce access to pharmaceutical products, inflate medicine prices, and waste scarce health system resources (WHO 2013). The economic value of medicines and the multiplicity of stakeholders make pharmaceutical systems particularly vulnerable to corruption (Cohen et al. 2007, Cylus et al. 2016). Nearly half of out-of-pocket health care expenditures and a large proportion of total health care expenditures in low- and middle-income countries (LMICs) are attributable to medicines (Lu et al. 2011). Medicines are often excluded or inadequately covered in national health insurance schemes. Countries, therefore, need clear medicines benefit policies and sound pharmaceutical management supported by good governance to achieve expanded coverage to health programs. Governance plays a critical role in minimizing opportunities for corruption and mitigating other system inefficiencies. It also shapes the ability of the health system to respond to challenges.

Various global initiatives add salience to the issue of governance in pharmaceutical systems. The World Health Organization's (WHO) Good Governance for Medicines Program focuses on promoting good governance in pharmaceutical systems and underscores that governance is critical to achieving universal health coverage (UHC). Similarly, the Sustainable Development Goals (SDGs) call for reductions in corruption and bribery across all sectors, including health, and affirm the importance of governance in attaining development goals.[1] The SDGs include achieving UHC and explicitly state that "access to safe, effective, quality and affordable essential medicines and vaccines for all" is part of that goal. Promoting transparency and accountability is a prerequisite for improving access to essential medicines and strengthening health systems to achieve UHC (Wirtz et al. 2017). The US Agency for International Development (USAID) continues to give prominence to good governance in pharmaceutical systems (USAID 2015) and has invested significant resources toward this effort as evidenced by its inclusion of governance strengthening as a key strategy within the SIAPS Program.

SIAPS and its predecessor programs have assisted numerous countries in strengthening governance to promote robust decision making, enhance accountability, reduce opportunities for corruption, and improve efficiencies to enable better access to and use of quality-assured medicines. This compendium draws on these experiences and provides a collection of examples of strategies and approaches for strengthening governance in pharmaceutical systems. The compendium highlights accumulated insights into factors that may have enabled or constrained the success of governance improvement initiatives. The intention is to systematically bolster knowledge, in alignment with USAID's collaborating, learning, and adapting approach (USAID 2016), so that stakeholders may examine the applicability of lessons learned and apply them in different settings to maximize resources and attain better development results. The compendium begins by defining governance, then explains its importance in pharmaceutical systems and introduces the framework SIAPS has used to guide its governance strengthening activities. It presents eight case studies on SIAPS' work in enhancing governance in pharmaceutical systems, summarizes challenges commonly encountered and lessons learned, and closes with some reflections on the usefulness of SIAPS' governance-strengthening framework.

---

1   See WHO Good Governance for Medicines Program (http://www.who.int/medicines/areas/policy/goodgovernance/pharm_sect_critic-uhc/en/) and SDGs (https://sustainabledevelopment.un.org/topics/sustainabledevelopmentgoals)

DEFINING GOVERNANCE

Consensus exists regarding the importance of governance as a health system function, but the concept remains difficult to define, assess, and operationalize (Barbazza and Tello 2014; Greer et al. 2016). Definitions focus on the way governments function and exercise authority (Siddiqi et al. 2009; WHO 2007); relationships among system actors and incentives to encourage compliance (Brinkerhoff and Bossert 2014; World Bank 2017); protection of the public interest; stakeholder involvement; use of public resources; leadership or direction of organizations; decision making; and/or accountability. Managing pharmaceutical products involves important decisions at all levels of the pharmaceutical system. How these decisions are made and implemented affect whether patients have access to the medicines they need and whether these medicines are prescribed, dispensed, and used safely and appropriately. For this reason, SIAPS and its predecessor program elected to use the definition of governance put forth by the United Nations Economic and Social Commission for Asia and the Pacific (UNESCAP), which is "the process of decision making and the process by which decisions are implemented (or not implemented)" (UNESCAP 2009).

There is no universally accepted definition of good governance and there are a variety of dimensions and principles presented in the literature that aim at describing the concept.[2] The United Nations Development Programme (UNDP) identifies nine interdependent principles characterizing good governance—strategic vision, participation, transparency, consensus-orientation, rule of law, equity, efficiency and effectiveness, responsiveness, and accountability (UNDP 1997). As these principles are widely used and generally applicable to the pharmaceutical sector, SIAPS and its predecessor, the Strengthening Pharmaceutical Systems (SPS) Program adopted them to guide their work on improving governance in pharmaceutical systems (SPS 2011).

Corruption defined as "the abuse of entrusted power for private gain" (Transparency International 2016) and mismanagement—incompetent, careless, or inefficient management—are potential consequences of poor governance. Good governance can mitigate such problems and is also important for promoting robust and inclusive decision making and enhancing accountability in policy development and implementation.

---

2   See Travis et al. 2003; Savedoff and Gottret 2008; Baez-Camargo and Jacobs 2011; and Barbazza and Tello 2014 for reviews of the various definitions and dimensions of (good) governance.

IMPORTANCE OF GOOD GOVERNANCE IN PHARMACEUTICAL SYSTEMS

Pharmaceutical systems consist 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 (Hafner et al. 2016).

The management of medicines and other pharmaceutical products involves numerous decisions and actions related to processes, such as the selection, procurement, distribution, and appropriate use of products. It also involves decisions that concern the supporting financing, human resources, organizational, and information management systems and enabling policies and legislation. Governance issues are pervasive throughout the pharmaceutical system because vested interests may seek to influence these decisions and actions. Further, decisions often pertain to the allocation of limited resources or setting of standards that may affect the health of populations when not based on adequate evidence or when the decision-making process is not well managed. Table 1 summarizes potential governance-related problems that can occur in the performance of key activities in the pharmaceutical system and shows some possible consequences for the health system.

Table 1. Potential problems relating to poor governance in pharmaceutical systems

Pharmaceutical management functions	Potential problems	Possible consequences
Policies and legislation	• Lack of or weak/outdated policies and legislation • Weak enforcement of policies and legislation • Corruption in licensing processes • Inadequacies in the medicines regulatory system	• Facilities do not meet standards for delivery of quality services • Practitioners lack competencies or skills • Products available that do not meet safety, efficacy, and/or quality standards
Selection	• Failure to use criteria to select products • Corrupt practices in selection process (e.g., bribery, power pressure)	• Less effective or more expensive products selected • Rational prescribing and use compromised
Procurement	• Product specifications in tenders favor certain supplier(s) • Awarding contracts to suppliers that do not meet criteria • Lack of consequences for poor supplier performance	• Unreliable supplier service • Purchase of inappropriate, poor quality, falsified, or highly priced products • Stock-outs and wastage of medicines and supplies
Storage/ distribution	• Lack of or failure to use criteria to select distributors • Poor enforcement of auditing procedures at storage areas	• Unreliable distributor service • Over expenditure • Stock-outs of medicines and supplies
Use	• Unethical practices resulting in inappropriate prescribing or sale/supply of medicine • Inappropriate charges (informal payments, substitution of cheaper brand at higher price, patients having to supply own medicines while in institutions)	• Compromised patient care • Higher out-of-pocket expenses for patients
Financing	• Inadequate, misappropriated, or mismanaged funds • Noncompliance with or weak enforcement of reporting and auditing (medicines and assets) • Late payments to suppliers	• Decreased funding to procure medicines and deliver services • Stock-outs, inefficiencies
Organizational management	• Oversight bodies do not exist or do not function • Inappropriate appointments to or political interference with consultative or oversight bodies • Conflicts of interest	• Inadequate oversight of key processes (e.g., tendering, financial management) • Loss of trust among staff and patients

Pharmaceutical management functions	Potential problems	Possible consequences
Human resource management	▪ Promotion/benefits not based on merit (nepotism, bribery) ▪ Inadequate accountability ▪ Absenteeism, kickbacks, demand for informal fees, ghost workers	▪ Poor performance of duties ▪ Attrition ▪ Unethical behavior ▪ Abuse of resources
Information management	▪ Information not available, not trusted, or not used for decision making due to lack of reliability or timeliness ▪ Information not publicly available, resulting in lack of transparency and accountability	▪ Lack of information makes governance and management difficult, including identifying and controlling theft or fraud

Source: SPS 2011

As governments and development partners design and implement policies to expand health service coverage and medicine benefit schemes, they will have to ensure the availability of quality pharmaceutical products, encourage appropriate use, improve equitable access, and keep costs affordable (Wagner et al. 2014). The decisions required to balance these sometimes competing objectives have substantial governance implications including the inclusiveness of the policies and decision making; transparency and ethics related to resource allocation; generation and sharing of data for decision making and transparency; regulation and oversight of financing schemes; and equity of medicine benefits.

Poor governance leaves pharmaceutical systems vulnerable to corruption and mismanagement. Vulnerability to corruption, in particular, exists for several reasons (Cohen et al. 2007):
▪ High market value of medicines, which makes them a target of theft
▪ Multiplicity of actors involved in a complex supply chain; in countries where institutional controls, information systems, and enforcement of regulations are weak, substandard or falsified medicines can enter the supply chain
▪ Large public pharmaceutical budgets, which can present a temptation for kickbacks and bribes
▪ Decision making for functions, such as product registration and selection, are frequently discretionary in LMICs; in countries where adequate checks and balances are lacking, these processes can be especially susceptible to unethical practices and corruption
▪ Patients often lacking the necessary information to make informed choices about the medicines they need and perverse incentives that can lead providers to inappropriately prescribe or sell pharmaceutical products

Corruption and mismanagement can hinder access to and the appropriate use of safe and affordable pharmaceuticals. Medicines promote trust and participation in health services. Stock-outs of medicines and poor-quality products can decrease demand for services, increase staff attrition, and ultimately compromise program effectiveness. The distribution and consumption of substandard and falsified medicines can contribute to the spread of antimicrobial resistance and can harm consumers by prolonging illness or causing death.[3] Corruption and mismanagement can also lead to inflated medicine prices and the waste of scarce health system resources. Pharmaceutical expenditures account for, on average, 25%—and as much as 67%—of total health expenditure in LMICs (Lu et al. 2011). Further, donor agencies allocate substantial portions of their funding to procure essential medicines and commodities. Over 40% of the total expenditures of the Global Fund to Fight AIDS, Tuberculosis, and Malaria are for medicines, health products, and equipment (Global Fund 2015). Corruption and other inefficiencies contribute to high expenditure on medicines, which threatens the sustainability of health systems. The costs for patients and their families can also be substantial—and in some cases catastrophic, when they must pay inflated prices for medicines or purchase unnecessary or ineffective products.

---

3   See Countering the Problem of Falsified and Substandard Drugs by the Institute of Medicine (Buckley and Gostin 2013) for a review of the scope, underlying causes, and effects of falsified and substandard medicines in global health. The WHO Medical Product Alerts also includes alerts to national regulatory authorities regarding the safety of pharmaceutical products.
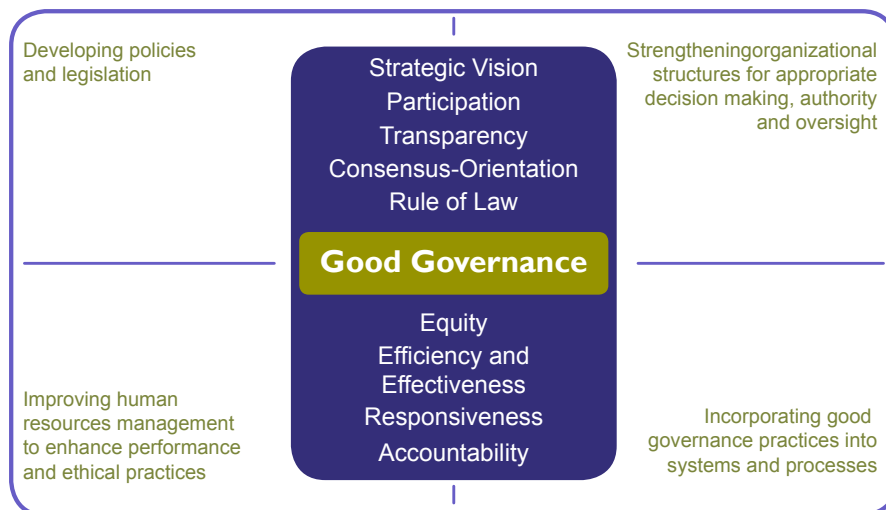
SIAPS' FRAMEWORK FOR STRENGTHENING GOVERNANCE IN PHARMACEUTICAL SYSTEMS

Figure 1 shows the framework used by SIAPS and its predecessor program to guide their governance-strengthening initiatives. The framework was developed in 2011 to provide a practical conceptual model for framing discussions with countries and partners on weaknesses in pharmaceutical governance and thinking through potential areas of intervention (SPS 2011). The framework was based on a review of the governance and anticorruption literature and best-practice documents for medicines regulation, selection, procurement, distribution, and use, and the related management support activities. Our analysis identified that the interventions that promote good governance in key pharmaceutical functions and related activities can be clustered into the four broad areas of action as defined within the framework.

The framework focuses on interventions in these four areas:
- Policies and legislation supported by rule of law
- Governance structures able to exercise appropriate decision making, authority, and oversight
- Transparent, ethical, and accountable systems and processes that are based on best-practice norms and guidelines
- Human resource management systems that promote effective performance and ethical practices

The model uses the UNDP principles to characterize good governance.

Developing policies and legislation

Strengthening organizational structures for appropriate decision making, authority and oversight

Strategic Vision
Participation
Transparency
Consensus-Orientation
Rule of Law

Good Governance

Equity
Efficiency and Effectiveness
Responsiveness
Accountability

Improving human resources management to enhance performance and ethical practices

Incorporating good governance practices into systems and processes

Adapted from UNDP. 1997. Governance for sustainable human development. http://mirror.undp.org/magnet/policy/

Figure 1. Framework for strengthening governance in pharmaceutical systems (Source: SPS 2011)

Development of Policies and Legislation

Medicines must be carefully regulated because they are widely bought and sold, and because products that are unsafe or used incorrectly can be dangerous. Policies and legislation provide the framework for how pharmaceutical products are regulated in a country. In some resource-limited countries, policies, legislation, sector-wide strategic plans, and guidelines that provide the foundation for good governance and sound practice in the pharmaceutical sector are outdated, weak, or absent. Where they do exist, implementation is often ineffective, inequitable, and sometimes vulnerable to corruption. To avoid piecemeal approaches to policy making that can lead to conflicting policy guidance, WHO recommends that countries develop a national medicines policy (NMP), which sets out a guide for action for providing safe and effective medicines of assured quality that are affordable, accessible, and appropriately used. The NMP provides the basis for

pharmaceutical legislation and a guide for coordinating activities among pharmaceutical sector stakeholders. Long-term strategic plans provide the road map for achieving NMP priorities and objectives, funding requirements, timelines, and methods for measuring progress. Sound legislation and equity and impartiality in its enforcement are critical to control the availability, promotion, prescribing, and dispensing of medicines; the provision of product information; and the licensing and oversight of pharmaceutical establishments and professional staff.

Technical assistance projects, such as SIAPS, can play a significant role in helping countries address policy and legislative gaps, including advocating for reforms and supporting the consultative process. For example, SIAPS assisted Haiti's Ministry of Public Health and Population to develop and launch the country's first-ever NMP.[4] Our work in Swaziland, Ethiopia, and Ukraine (case studies 1, 4, and 5) are examples of SIAPS' support for the development/update of national legislation.

Strengthening Governance Structures

Well-functioning governing and decision-making bodies, such as national regulatory authorities responsible for registering and controlling medicines, tender boards that evaluate bids and award tenders, and audit committees that oversee financial reporting and internal controls, are essential for ensuring good governance in pharmaceutical systems. In LMICs with more developed pharmaceutical systems, these bodies may exist but meet rarely or function inadequately or opaquely. In others, these structures may need to be established as the pharmaceutical system evolves. It is important that committees and boards have clearly defined terms of reference (TOR) and that membership is based on documented, objective criteria to mitigate bias in their appointment. To increase transparency and accountability, membership may need to be expanded to include different sectors and constituencies, such as civil society and patient/consumer groups. Conflicts of interest (COIs) threaten the legitimacy of a committee or board and its decisions. For example, experts in fields such as pharmacoepidemiology are rare in LMICs. It is therefore possible they sit on the boards of several organizations while also consulting for the pharmaceutical industry. These interests need to be declared, documented, and managed appropriately.

Over the course of the project, SIAPS has assisted USAID-supported countries to establish or strengthen a variety of committees, advisory groups, and other structures. The support has included helping design or review membership, develop or revise TOR and member selection criteria, and build the leadership, management, and governance capacity of members. For example, in South Africa, SIAPS helped formulate a guidance document for developing or reviewing TOR for all types of pharmaceutical sector committees.[5] SIAPS' activities to help bolster governance structures in Sierra Leone, DRC, Ukraine, Bangladesh, and the Philippines are described in case studies 2, 3, 5, 6, and 8.

Incorporating Good Governance into Systems and Processes

Numerous important decisions have to be made in the process of managing pharmaceuticals, including which medicines to register or include on a national essential medicines list (NEML), specifications to include in a pharmaceutical tender, or which medicine distributors to contract. Decision making is susceptible to bias, undue influence, and inconsistency when decision-making processes are not transparent and decision makers are not held accountable. A challenge that many LMICs confront is the absence of clearly defined criteria based on best practices and international standards to guide decision making and mitigate such issues. Independent, sound, and unbiased evidence is often lacking to inform the choices to be made and, even when available, decision makers may rely on personal experience, e.g., when selecting medicines for an NEML. Furthermore, meeting reports that include decisions reached (for example, contracts awarded and prices paid in public procurements) are often not easily available for public scrutiny. Critical processes, such as inspection of manufacturing facilities, procurement, inventory management, and financial management, can be vulnerable to fraud, theft, and other corrupt practices and can exacerbate system inefficiencies when they are not carried out in accordance

---

4   See SIAPS Program Supports Revision and Launch of Haiti's First National Medicines Policy (SIAPS 2015) for more information on this activity.

5   See Developing Better Terms of Reference to Improve the Performance of Pharmaceutical Sector Committees: Case Studies from South Africa (Putter and Walkowiak 2017) for the guidelines and template for developing TOR for a pharmaceutical committee and details of how they were used in South Africa.

with standards and procedures. A further impediment that many LMICs confront is that robust guidelines and standard operating procedures (SOPs) that define norms and standards of practice and incorporate checks and balances for pharmaceutical management activities are either lacking or not adhered to.

Oversight mechanisms are needed to ensure compliance with standards set for decision making and operations and to detect mismanagement and corruption. Examples of oversight mechanisms include systems for overseeing procurement and evaluating stock management to identify theft or mismanagement. Bodies that carry out audit and oversight functions may be affiliated with government or civil society. Regardless, they must have adequate capacity, autonomy, and funding to function effectively. They also need access to reliable information on key performance indicators, for example, prices paid, stock-outs reported, and results of audits and inspections performed. Timely, accurate, up-to-date, and accessible information is essential for oversight and for the functioning of pharmaceutical institutions and decision-making structures. Information technology can be a powerful tool for bolstering governance in pharmaceutical systems.

SIAPS has worked extensively with governments and institutions to develop criteria, guidelines, and procedures for decision making and pharmaceutical operations that align with best practices and international standards. For example, in Guinea, SIAPS assisted the central medical stores (CMS) with launching its first international competitive tender for essential medicines, making the process more transparent, equitable, and competitive. All the case studies featured in this compendium involve activities in this area. Case studies 4, 6, and 7 (Ethiopia, Bangladesh, and Cameroon) illustrate strategies used by SIAPS to strengthen oversight. In Ukraine, the program helped build the capacity of civil society organizations (CSOs) to enable them to play a greater role in monitoring and oversight. SIAPS trained representatives from five Ukrainian CSOs on medicine pricing and approaches to price referencing. Case study 6 (Bangladesh) provides an example of our work to improve information systems and introduce new technologies, such as portals that enable countries to access web-based tools that provide timely information and easily monitor various processes and provide oversight.

Enhancing Performance and Ethical Practices

Good governance in pharmaceutical systems relies on effective human resources planning and management to ensure that adequate numbers of appropriately trained and competent personnel are available to enable staff to adhere to best practice guidelines and procedures. In many resource-limited countries, important principles, such as separation of key responsibilities (e.g., ordering and receiving pharmaceuticals), and oversight activities, such as audits, are not routinely implemented because of staff shortages. Staff in pharmaceutical systems frequently handle high-value pharmaceuticals or participate in activities that are vulnerable to corruption. To prevent interference or nepotism in the appointment or promotion of pharmacy personnel, job vacancies that specify required experience and qualifications, together with criteria for selection or promotion, must be publicly available and adhered to. Clear performance standards, job descriptions, and structured supervision all play a part in addressing poor performance and problems, such as absenteeism. Formal systems for whistleblowing and submitting complaints enable staff and patients to report poor staff performance and unethical behavior. Our technical assistance to help the Ethiopian Pharmaceutical Association provide training to members from the public and private sectors on various topics, including ethical practices, is an example of our work in this area.[6] Case studies from Ethiopia and Cameroon (4 and 7) provide additional examples.

SIAPS CASE STUDIES

The following eight case studies illustrate approaches and interventions used by SIAPS to assist countries to strengthen governance for selected key pharmaceutical functions in a variety of health programs and different contexts. Table 2 shows how these case studies align with the SIAPS governance-strengthening framework (figure 1). As table 2 illustrates, our technical assistance usually involved addressing weaknesses in two or more quadrants of the framework. In most of these examples, governance interventions were part of a set of pharmaceutical system-improvement activities that together realized better performance of key functions, such as medicines registration, selection, procurement, and dispensing. In several instances, governance was an enabler of system strengthening initiatives and/or a means of sustaining such initiatives. These case studies illustrate that governance interventions often go hand-in-hand with activities aimed at strengthening leadership and management.

Table 2. Case study alignment with SIAPS governance-strengthening framework

	Development of policies and legislation	Strengthening organizational structures	Incorporating good governance practices in systems and processes	Enhancing performance and ethical practices
Case study 1: Swaziland	✓	✓	✓	
Case study 2: Sierra Leone	✓	✓	✓	
Case study 3: DRC		✓	✓	
Case study 4: Ethiopia	✓		✓	✓
Case study 5: Ukraine	✓	✓	✓	
Case study 6: Bangladesh		✓	✓	
Case study 7: Cameroon			✓	✓
Case study 8: Philippines	✓	✓	✓	

- **Case study 1** describes SIAPS' support for the development and enactment of pharmaceutical legislation in Swaziland, illustrating how legislation serves as a foundation for the stewardship and control of medicines.
- **Case study 2** discusses activities to help Sierra Leone establish/reform key pharmaceutical governing and decision-making bodies as part of USAID support for post-Ebola recovery of the health system.
- **Case study 3** reviews the phased approach used in DRC and, specifically, governance-related interventions to strengthen medicine registration. It also illustrates how further issues can be revealed, once a system starts functioning.
- **Case study 4** discusses the governance interventions introduced in Ethiopian hospitals as part of an integrated package of system strengthening strategies (Auditable Pharmaceutical Transactions and Services [APTS]) to improve transparency and accountability in service delivery. This case illustrates the challenges encountered when scaling up an intervention that has been successful on a small scale.
- **Case study 5** describes SIAPS' work in Ukraine to help harmonize the various medicine lists that guide procurement and establish a robust selection process. It highlights the program's approach and experiences of working in a context of political uncertainty and complicated bureaucracy.
- **Case study 6** illustrates how the introduction of information technology improved procurement efficiency for family planning (FP) and reproductive health (RH) commodities and served as an entry point for improving transparency and accountability in procurement and supply management for all essential medicines and equipment in Bangladesh.
- **Case study 7** describes activities to bolster the leadership, management, and oversight capacity of staff at regional and clinic levels in Cameroon and the contribution these interventions make to decreasing ARV medicine stock-outs at HIV clinics.
- **Case study 8** discusses SIAPS' partnership with the Quezon City Department of Health in the Philippines to establish community health management councils to improve TB program management and service delivery in urban poor settlements in the city. It outlines the approach used to improve leadership, management, and governance at community levels and enable community stakeholders to participate and take ownership in managing the TB program.

CASE STUDY 1: REFORMING THE LEGISLATIVE FRAMEWORK IN SWAZILAND TO IMPROVE THE CONTROL OF MEDICINES

Background

In Swaziland, the legislation governing the control of medicines and the pharmacy profession was outdated and no longer served as an effective legal framework for the pharmaceutical sector. The legislation in place—the Opium and Habit-Forming Drugs Act of 1922 and the Pharmacy Act of 1929—included provisions for a few regulatory functions, but there was no legal mandate for establishing a national medicines regulatory authority (MRA), which made it difficult for the government to ensure the quality, safety, and efficacy of medicines used in the country. Other concerns included the availability of unregistered products, the increasing number of unqualified pharmacy operators, and opportunities for falsified medicines to enter the market. The weak regulatory system hindered the country's effort to improve access to quality essential medicines and services for managing HIV, controlling TB, and delivering other priority public health interventions.

Strategic Approach and Interventions

In 2007, Swaziland's Directorate of Pharmaceutical Services asked the SIAPS predecessor program, SPS, for support in addressing gaps in medicines regulation. Technical assistance provided by SPS and later SIAPS to the Ministry of Health (MOH) focused on revising the legislation and advocating for its enactment; forming an interim MRA working desk to prepare for establishment of the MRA; and strengthening certain regulatory processes.

As a first step, Swaziland with the support of WHO, developed its comprehensive National Pharmaceutical Policy (2011), which provided a strategic vision and a basis for legislative reform. SPS then assisted the MOH in reviewing the existing legislation and facilitated a series of consultative workshops that enabled diverse stakeholders, including community members, politicians, and health and legal professionals, to comment on the proposed principles to be included in the legislation. These comments were considered in the drafting of two bills: the Medicines and Related Substances Control Bill, which provided for the establishment of the first MRA, and the Pharmacy Bill, which provided for the establishment of a pharmacy council to regulate the profession and practice of pharmacy. The draft bills were then presented to inter-ministerial representatives and nongovernmental and private sector stakeholders to ensure that all those affected by the bills had an opportunity to review and provide comment. However, the enactment of these bills was held up in 2012 by lengthy legislative processes. The 2013 election also meant that the bills lost priority among the competing responsibilities of the newly elected Parliament.

Building on the work of SPS, SIAPS supported the MOH to resubmit the bills to the new Cabinet and Parliament and to advocate for their finalization and enactment. SIAPS assisted the MOH in building political will and expediting the parliamentary process by conducting seminars and preparing briefs to educate legislators on the importance and contents of the draft bills. A meeting was convened to engage private sector pharmacists in advocacy activities and a briefing note distributed to inform pharmacists about the bills and encourage uniformity in their advocacy messages. SIAPS also facilitated additional stakeholder consultations and further revisions of the bills to gain political commitment and local ownership. The Medicines and Related Substances Control Bill was approved by both houses of Parliament in September 2015 and signed into law by the king in October 2016. The houses have yet to reach agreement on the Pharmacy Bill, specifically, the provisions pertaining to pharmacy ownership. The Chief Pharmacist's Office continues to advocate for its enactment and prepare for upcoming house deliberations.

To expedite the implementation of the Medicines and Related Substances Control Bill once passed, SIAPS partnered with the MOH and WHO to draft a set of accompanying regulations, develop a plan for establishing the MRA, and set up an interim MRA working desk to perform some regulatory functions. Additionally, SIAPS helped the Office of the Chief Pharmacist develop guidelines and procedures for registering importers and create a database for cataloging importers and medicines imported.

Results

The inclusive and transparent approach to legislative reform has laid the foundation for the improved regulation of medicines in Swaziland. The Medicines and Related Substances Control Bill no.7 of 2014 is now the Medicines and Related Substances Control Act, 9 of 2016. Additionally, the MRA establishment plan is being used to guide the phased implementation of the agency and the MRA working desk under the Office of the Chief Pharmacist provides the foundation for its creation. Draft regulations have been developed to facilitate implementation of the Medicines and Related Substances Control Act.

Importers of medicines are now required to register with the MOH, and a medicines-listing database has been developed with support from SIAPS through which the MOH monitors whether medicines are registered with other MRAs recognized as stringent regulatory authorities. The medicines database does not constitute product registration but is considered as one of the primary steps toward the future registration process. It also enables the MOH to audit all medicines currently available in the marketplace. Further, advertisements for medicines and other therapies are now regulated by the MOH.

Lessons Learned

Legislative reform can take considerable time and does not necessarily align with the timeframe of technical assistance projects. There was strong country ownership for this initiative and all activities were designed, planned, and implemented in collaboration with the chief pharmacist, who is the lead within the MOH for this activity. Working hand in hand with the MOH has been critical to maintaining the momentum for reforms and ensuring they continue beyond the life of SPS and now SIAPS.

Creating and maintaining relationships with key stakeholders was crucial to getting the bills prioritized for deliberation in Parliament. SIAPS worked very closely with officials from the Ministries of Justice and Agriculture, as well as the MOH, to advance the bills through parliamentary processes. Understanding legislative procedures and issues of protocol were important in getting the bills deliberated by the houses of Parliament. Relationships established and familiarity with parliamentary processes helped maintain the momentum of regulatory reform, despite the change of Parliament in 2013.

Lobbying was a crucial aspect in advocating for enactment of the bills. It was important to help House of Assembly members understand the value of the bills, and pitching the messages in less technical language helped in this regard. Reaching consensus on various components of the bills, such as pharmacy ownership, has been a challenge.

Conclusion and Next Steps

Although legislative reform takes time, through advocacy and technical support, SIAPS has assisted Swaziland in reforming legislation and preparing for its swift implementation and enforcement, which will facilitate access to safe, effective, and quality medicines. In addition to supporting the MOH to get the Pharmacy Bill enacted and implemented, future technical assistance needs include finalizing and implementing regulations to be published in terms of the Medicines and Related Substances Control Act. Other needs are building the capacity of the newly established MRA and developing SOPs and guidelines for its key functions. Because there has been strong country ownership, joint implementation with the chief pharmacist, and support from the WHO Swaziland Country Office, the indications are that work in strengthening medicines regulation in Swaziland will continue after the end of SIAPS.

Sources/for more information see:
- SIAPS 2017. Technical Highlight: Strengthening the Medicines Regulatory System in Swaziland
- SIAPS 2015. Modernizing Legislation in Swaziland to Improve the Control of Medicines

CASE STUDY 2: STRENGTHENING PHARMACEUTICAL LEADERSHIP AND GOVERNANCE IN SIERRA LEONE AFTER THE EBOLA EPIDEMIC

Background

Sierra Leone's endeavors in rebuilding its pharmaceutical system after a decade of civil war were cut short by the devastating Ebola epidemic that began in 2014. The deployment of staff to Ebola response units created a severe shortage of trained pharmaceutical staff at all levels, and pharmacy managers had to deal with the competing priorities of the many organizations working in the country during and after Ebola. Previously, the country's CMS had functioned as the national pharmacy department providing oversight for all pharmaceutical services in addition to performing its procurement, warehousing, and distribution functions. The CMS was transformed into the Directorate of Drugs and Medical Supplies (DDMS) after a new structure, the National Pharmaceutical Procurement Unit (NPPU), was established in 2012 to manage procurement, warehousing, and distribution of pharmaceuticals and medical supplies.

The newly established DDMS lacked sufficient capacity to fulfill its mandate for coordination and provision of pharmaceutical services and to provide support to and oversight of the pharmaceutical sector as a whole. The weakness of NPPU became evident during the Ebola outbreak, and the public supply system was in urgent need of improvement. Quantification exercises were ad hoc and conducted by different partners with little participation of country staff. Shortages of medicines were widespread, storage areas were cluttered with unusable donations, and little attention was paid to ensuring that medicines were used appropriately.

Strategic Approach and Interventions

To support post-Ebola recovery of the health system, SIAPS provided two years of technical assistance to rebuild and strengthen Sierra Leone's pharmaceutical system and improve supply management and rational medicine use beginning in 2015. SIAPS used a multifaceted and incremental approach to quickly restore basic functions and make urgently needed medicines available while working to rebuild the system for the longer term. SIAPS' capacity building and system strengthening initiatives included helping Sierra Leone to institutionalize comprehensive oversight of the pharmaceutical sector and strengthen leadership and governance at all levels.

To strengthen DDMS' institutional capacity for fulfilling its mandate, SIAPS assisted the director and senior staff in revising the directorate's organogram and identifying roles and responsibilities for its new functional units. Its new structural framework defines five key units—governance, human resources management, products and technologies, information system, and administration and financial management. SIAPS helped DDMS convene meetings that enabled department heads and district pharmacists to review their proposed roles and responsibilities and suggest improvements. The organogram and roles and responsibilities were approved in 2017, and the directorate has since hired new recruits to staff the units. DDMS and SIAPS also worked together to align the DDMS five-year strategic plan with its mandate and to make the plan more results-oriented.

SIAPS conducted a two-week Leadership Development Program (LDP) training-of-trainers (ToT) course to create a pool of LDP trainers that could cascade the program as trainers throughout the country's 13 districts; 17 pharmacists from the DDMS, districts, and hospitals were taught basic leadership, management, and governance practices to enable them to more effectively identify challenges, solve problems, and lead their teams. To further build the capacity of its staff, DDMS requested that SIAPS staff be placed in the DDMS office to mentor and work side by side with DDMS personnel.

The Ministry of Health and Sanitation (MOHS) began a process to replace the NPPU with the National Medical Supplies Agency (NMSA) and to make its operations more cost-effective, transparent, and accountable. SIAPS provided comments on the draft NMSA bill and expert opinion in the subsequent parliamentary discussions and advocated that NMSA staff

recruitment be competitive rather than by appointment. To build in-country capacity for quantification, SIAPS helped establish a national quantification committee and seven quantification technical working groups for different health programs and provided initial training. These committees, which included representatives from DDMS, health programs, district and facility teams and development partners, function as platforms for coordination.

Recognizing that drug and therapeutics committees (DTCs) are a key mechanism for providing oversight of pharmaceutical service delivery and improving the use of medicines, SIAPS provided assistance to 24 hospitals to help them establish DTCs. SIAPS drafted a DTC operational guide and tools to support DTC functions; helped each hospital develop TOR for its committee; provided pioneering DTCs with furniture, computers, and reference books; and conducted a workshop to review progress made in implementing DTC work plans. SIAPS also helped Sierra Leone institute the Continuous Results Monitoring and Support System (CRMS). Managers visit facilities quarterly to collect data on about 40 pharmaceutical management indicators, which are reviewed by district teams and DTCs to identify problems and corrective actions needed. Some key CRMS supply chain indicators are now displayed on the Sierra Leone Pharmaceutical Dashboard, a web-based early warning system developed with SIAPS' support that displays information on stock status to help avert stock-outs and expiry of medicines.

Results

The reform/establishment and strengthening of governing and decision-making structures has laid the groundwork for better stewardship and oversight in Sierra Leone's pharmaceutical sector. DDMS now has an organogram and TOR for each of its functional units, which will help clarify roles and responsibilities and bolster accountability in the directorate. DDMS has more than doubled its technical staff to fill the units created under the new organogram. With its new structure, increased human resources, and results-focused strategic plan, DDMS is now better prepared to fulfill its mandate. Over 50 pharmacy managers and staff have participated in the LDP trainings, and 5 ToT participants are ready to cascade the LDP training to other districts, while the others need more support to make the shift from trainee to facilitator.

Sierra Leone's Parliament approved the National Medical Supplies Agency Act 2017, on August 2, 2017, and the MOHS is finalizing the selection of its board members now that the act has received presidential assent. The act institutes the NMSA as a public service agency responsible for the procurement, warehousing, and distribution of medicines and medical supplies in a transparent manner for all public institutions. The quantification technical working groups have now completed two multi-year quantification exercises for the TB program and the Free Health Care Initiative.

In 10 of Sierra Leone's 24 hospitals, DTCs have now been established, and the other 14 are in the process of being established; 6 DTCs have revised prescription forms for their hospitals, among other activities. The CRMS was launched in June 2016, and all 13 districts completed the first 2 cycles of collection and indicator update, with 10 out of 13 districts having completed their third by July 2017.

Lessons Learned

SIAPS collaborated closely with DDMS staff and partners to design and implement activities and build trust, which facilitated quick uptake of interventions. The chronic shortage of technical human resources following the Ebola epidemic and various development partners competing for the time and attention of staff meant that some activities proceeded more slowly than expected. Because of these competing priorities, SIAPS had to be flexible about implementation timelines, and USAID was very supportive in this regard. SIAPS' staff were alert for opportunities that enabled them to make progress, worked on multiple aspects of systems strengthening simultaneously, and tried to anticipate and mitigate holdups, including bureaucratic bottlenecks. One-on-one mentoring was especially valuable as country counterparts had differing capacity-building needs and only limited time to attend formal trainings.

Conclusion and Next Steps

A strong pharmaceutical system is essential for preventing and responding to public health emergencies. These system strengthening and capacity-building activities represent foundational steps for improving pharmaceutical system governance, performance, and resilience in Sierra Leone. However, more is needed and challenges, such as the severe shortage and attrition of human resources, remain. DDMS, district health management teams, and DTCs have taken on ownership of CRMS and management and operation of some activities as SIAPS transitions out of the country. As part of its sustainability and exit strategy, SIAPS is working with DDMS to engage partners such as the Global Fund to Fight AIDS, TB and Malaria; the World Bank; and the UK Department for International Development for resources and long-term support to sustain and build on the improvements made so far.

Sources/for more information see:
- SIAPS 2017. Strengthening the Pharmaceutical System in Sierra Leone after Ebola
- SIAPS 2017. Leadership Development Program Training to Strengthen Pharmaceutical Management in Sierra Leone

CASE STUDY 3: IMPROVING THE TRANSPARENCY AND EFFICIENCY OF THE MEDICINE REGISTRATION SYSTEM IN THE DRC

Background

DRC established its national regulatory authority, the Direction de la Pharmacie et du Médicament (DPM), in 1982. After decades of civil unrest and chronic underfunding of the health sector, the DPM lacked the capacity to effectively manage the registration of medicines and regulate the pharmaceutical sector. Since its inception, the DPM had not had a medicine registration committee or any documentation describing the procedures it followed to register medicines. Further, the decision-making process was opaque, only about 400 products had been registered and authorized for use, and there was no official register of approved medicines that could be used to control the importation and sale of medicines. These shortcomings, together with weak regulation of pharmaceutical manufacturers, importers, and businesses, contributed to the entry and circulation of unregistered, substandard, and falsified medicines in DRC.

Strategic Approach and Interventions

In 2012, the DPM requested SIAPS' support to build on the work begun under the SIAPS predecessor program. SPS, in collaboration with WHO, had assisted DPM in developing its first SOPs for medicine registration and trained DPM and field-based pharmacist inspectors on their use. Between 2012 and 2016, SIAPS provided technical assistance to build DPM's institutional capacity for medicine registration and improve the efficiency, effectiveness, and transparency of the process. Given the widespread weaknesses in DRC's regulatory system, DPM and SIAPS first focused on tackling areas of most risk and undertook a phased approach toward strengthening systems for the long term.

DRC established its first Medicine Registration Committee (MRC) early in 2012 with support from SIAPS. SIAPS completed activities begun under SPS, helping DPM to hold consultations on MRC's mandate and membership and finalize its TOR. DPM's SOPs were revised to improve their alignment with international guidelines and good governance recommendations. In the initial years, SIAPS provided technical and financial resources to assist the MRC to prepare for and convene quarterly medicines registration meetings. SIAPS provided training to MRC members to build their capacities and knowledge of best practices and promote adherence to the SOPs. The SIAPS team also worked side by side with MRC in quarterly meetings to assist its members and encourage them to follow processes in line with best-practice recommendations and SOPs. DPM and SIAPS developed a database of registered medicines, identified some indicators to track MRC performance, and set up systems for biannual publishing and distribution of the list of authorized medicines.

The first Directory of Approved Medicines was published in August 2012, and the list was quickly and widely adopted by customs officers to identify unregistered medicines at border posts. In addition, provincial pharmacist inspectors used it to track and confiscate unregistered products during inspections of pharmaceutical premises. These regulatory actions triggered a rapid influx of product registration applications, which created a backlog and consequently increased the time taken to process an application. Additional MRC meetings and actions, such as task redistribution, helped improve efficiency and reduce the backlog, which was eliminated in 2013.

A WHO evaluation of DRC's registration process conducted at the request of DPM to assess its compliance with best practices generated recommendations to inform the next phase of system strengthening. In accordance with WHO's recommendations and following SIAPS' advocacy, DPM agreed to formally extend membership of the MRC to include external stakeholders, such as the pharmacy council, and academic and clinical experts to bolster transparency and credibility of the committee. To further increase efficiency and transparency in the medicines registration process, SIAPS procured and helped DPM install, configure, and launch new registration software in 2015. The software was provided through Burkina Faso's national regulatory agency.

Results

SIAPS' technical support has helped strengthen the capacity of the MRC and streamline and improve transparency in medicines registration.

- Registration decisions are made by a formal committee that has documented procedures. The MRC continues to meet regularly and registration processes are now more transparent and less vulnerable to bias and corruption.
- The number of days taken to process a new application decreased from a peak of 84 days in 2013 to 58 days by September 2016.
- The number of registered medicines has increased from 400 in 2011 to more than 4,600 in September 2016. In addition, the MRC deregistered 1,392 products in 2016 when their marketing authorizations expired.
- Of the medicines listed in DRC's essential medicines list, 72% had at least one product registered in September 2016, an increase from 44% in 2011.
- The registration software system has been installed and launched. The Directory of Approved Medicines is produced annually, and the list of new registrations updated quarterly. Customs officers and provincial inspectors use these lists to identify and confiscate unregistered products at border posts and during inspections of pharmaceutical storage and health facilities, respectively.

Lessons Learned

One early positive outcome of the technical assistance was the rapid uptake and use of the Directory of Approved Medicines by customs officers and pharmacist inspectors, which, in turn, motivated importers and manufacturers to seek marketing authorization for medicines they imported or produced. This presented a challenge to the newly formed MRC, which struggled to accommodate the increased number of applications for registration. Even after the backlog was cleared, MRC members have been kept busy during the quarterly registration sessions. The motivation and commitment of MRC members was critical to ensuring that all work was completed within the assigned timeframe and in accordance with good practice and governance principles.

When the MRC was first established, there was some resistance to adopting certain good governance principles and practices, because they were initially considered irrelevant or not an immediate priority. Once the MRC was functioning, the DPM revisited systems and procedures several times, e.g., after the backlog accumulated and following the WHO evaluation, to further improve the processing of applications. SIAPS used these as opportunities to advocate again for adoption of important changes, such as the WHO recommendation on expanding MRC membership to include external stakeholders.

Conclusion and Next Steps

DPM has taken full ownership of the quarterly registration sessions, and other partners are now providing financial resources and technical support to the DPM to ensure that the registration sessions continue. Following these first phases of improvements, other development partners have been encouraged by the progress made and are now providing support to the DPM to further develop DRC's regulatory capacity.

Sources/for more information see:
- SIAPS 2017. Strengthening Regulatory Systems in Democratic Republic of the Congo to Improve Access to Safe, Effective, and Quality Medicines
- SIAPS 2015. Strengthening Regulatory Systems to Improve Access to Safe; Effective, and Quality Medicines

CASE STUDY 4: ETHIOPIA'S AUDITABLE PHARMACEUTICAL TRANSACTIONS AND SERVICES: GREATER ACCOUNTABILITY AND BETTER SERVICE DELIVERY

Background

Pharmaceutical services, one of Ethiopia's largest health care expenses, have lagged behind improvements in the country's primary health care service over the past two decades. A 2003 assessment found that, on average, 8% of medicines in health facilities were expired, some essential medicines were frequently unavailable, and patient dissatisfaction with the services they received was high (Federal Democratic Republic of Ethiopia Ministry of Health and WHO 2003). The absence of systems and tools for tracking products and financial transactions made auditing very difficult, and the lack of transparency and accountability in managing medicines and financial resources left the system vulnerable to theft, fraud, and mismanagement.

Strategic Approach and Interventions

In 2010, the leadership team of Debre Marcos Hospital in Ethiopia's Amhara region approached SIAPS' predecessor project for assistance with improving the hospital's pharmaceutical services. SPS working collaboratively with the hospital's pharmacy staff, and leadership team identified shortcomings in pharmaceutical services at the hospital and their underlying root causes, which have since proved to be relevant throughout the country's public health system. The program worked jointly with Debre Marcos Hospital to develop a package of systems-strengthening interventions called the Auditable Pharmaceutical Transactions and Services (APTS). APTS interventions contribute to five key result areas: accountability and transparency in managing medicine transactions; reliable information for decision making; efficient use of medicines budgets; effective workforce deployment; and quality of pharmacy services. These five result areas align with the five health system strengthening building blocks, all of which affect the performance of hospitals in Ethiopia's public sector.

The hospital began to implement APTS in January 2011 and by April of that year, the preliminary results were so promising that the Amhara regional health bureau partnered with the hospital team and SIAPS to hold a workshop to share the experience. In June 2012, the Amhara regional government enacted legislation to enforce the implementation of APTS at all hospitals and health centers in the region. Over the next three years, three more regions and a city administration introduced APTS and enacted similar legislation. In 2014, the Federal Ministry of Health and Ministry of Finance and Economic Development approved federal APTS regulations. To support APTS roll-out throughout the country, SIAPS helped develop an APTS implementation guide, in-service training materials, tools, and a set of facility-level indicators to track APTS implementation and pharmaceutical service performance. The program also provided technical assistance to the regional health bureaus and, when requested, to some individual hospitals to help them conduct the baseline assessment, initiate and expand APTS interventions, and use indicators to monitor implementation.

It is the combination of APTS interdependent interventions—governance, information, financing, human resources, and/or service delivery interventions—through which results such as decreases in wastage and stock-outs were realized. The main governance-related interventions in the package are outlined here by the result area to which they contributed.[7]

- **Legislation**. SIAPS assisted the federal and all 11 regional governments and city administrations with developing, enacting, and promoting the implementation of APTS legislation, which sets the foundation for better accountability by defining the roles and responsibilities of pharmaceutical structures. The federal and regional legislation also institutionalized the APTS initiative and promoted its sustainability.
- **Transparent and accountable transactions**. A key component of APTS involves the establishment of systems for physical inventories and auditing and tools for tracking the movement of all products and transactions at dispensing units. Transactional tools include vouchers to document medicine receipts and issues at facility stores and dispensing points; registers to capture

---

7   For a description of all results areas and contributing interventions, see Technical Brief: Transforming Pharmaceutical Services in Ethiopia through Auditable Pharmaceutical Transactions and Services (Bennett et al. 2017)

transactions between providers and patients; and receipts for cash payments. Unique codes and prices attached to medicines are used to trace the movement of products through facilities. At dispensing points, pharmacy staff are each responsible for a bin containing a set of medicines that are periodically reconciled with records that also track expiry dates.

- **Reliable information and efficient budget utilization**. APTS includes tools that enable facilities to collect and monitor product, finance, and service information, including revenues, wastage rates, availability of medicines, and number of patients served.
- **Effective workforce deployment and development**. APTS implementing facilities work with government bodies to review, recruit, and deploy the appropriate number and mix of pharmacy staff and new cadres, such as pharmacy accountants and cashiers. The analysis also takes account of staff needs to promote adherence to best practices, such as separation of key responsibilities. Human resource interventions also include regular performance reviews and supportive supervision to encourage better performance and ethical practices.

Results

The federal government and all 11 regions and city administrations have now enacted APTS legislation. At the end of 2016, 77 health facilities across almost all regions and city administrations in the country had implemented APTS. APTS governance interventions have contributed to the achievement of a number of results, including the following.

- Before APTS, none of the hospitals tracked sales of medicines and reconciled them daily with medicines dispensed, nor did they generate monthly service delivery reports. Health facilities can now produce monthly sales reports, enabling hospital managers to track financial gains and losses.
- The introduction of pharmacy accountants and cashiers has improved access to financial information related to medicine sales and enabled regular auditing, thereby improving transparency and accountability. In 2016, 94% of APTS sites were generating monthly financial and service reports (Fenta et al. 2016). In addition, 25% of APTS hospitals were performing regular financial audits of pharmacy transactions and more than two-thirds had carried out random audits.
- In six hospitals where data were available, wastage of medicines due to expiry in 2016 was less than the national target of 2% (Fenta et al. 2016).

Lessons Learned

Political commitment, stakeholder engagement, and support of champions were critical success factors. The Federal Ministry of Health provided strong political commitment. APTS requires the involvement and commitment of the justice department (legislation development and enactment), the finance bureau (financial tools and procedures), and civil service bureau (workforce issues), and reaching consensus between these agencies was sometimes difficult. SIAPS facilitated numerous consultative processes to this end with the result that diverse partners contributed to making APTS a package of interventions that serves multiple interests.

SIAPS coordinated numerous site visits to Debre Markos Hospital and the Amhara regional health bureau, where interested parties were able to learn about the benefits of APTS and what it took to make it happen, which facilitated expansion to new facilities and regions. Local champions helped promote APTS. The baseline and interim results data from the early implementing sites fostered interest among facility staff, especially when they were translated to patient stories. Financial data were also compelling, and the initially skeptical finance manager at Debre Markos Hospital became a champion for APTS expansion after seeing medicine wastage drop and revenues increase within months.

APTS was designed to address multiple systemic pharmaceutical management problems that required interdependent solutions. Its success relies on some minimum structural, input, and process changes. Some facilities chose to implement only selected components and therefore realized fewer benefits in terms of decreased stock-outs or wastage or greater customer satisfaction. For example, in cases where only the transactional tools were adopted, without the appropriate legislation, the hospital could not authorize funding to hire the staff to use them. Excessive reporting may be offsetting some of the benefits and driving higher staff turnover at APTS sites. Insufficient training of staff and lack of adherence to SOPs were also identified as possible reasons for low achievements.

Conclusion and Next Steps

The results indicate that implementation of APTS has increased transparency and accountability in the management of pharmaceutical services. APTS has been incorporated into Ethiopia's Health Sector Transformation Plan, and the enactment of APTS regulations has institutionalized many of the critical interventions, thereby contributing to sustainability. However, by the end of 2016, less than 25% of hospitals had introduced APTS. Future technical support and financial resources will be needed to maintain program quality and support its further scale-up.

Sources/for more information see:

- Bennet et al. 2017. Technical Brief: Transforming Pharmaceutical Services in Ethiopia through Auditable Pharmaceutical Transactions and Services
- Fenta et al. 2016. Outcome of Auditable Pharmaceutical Transactions and Services Implementation: Assessment Report

CASE STUDY 5: SUPPORTING HARMONIZED AND TRANSPARENT MEDICINES SELECTION IN UKRAINE

Background

Ukraine's procurement regulations stipulated the development of a NEML, but there was no legal mandate to support its use for public sector procurements. Additionally, the various legislative instruments that regulated medicines procurement allowed the use of various nonharmonized medicines lists for public procurements, which made it difficult for procurement entities to decide which products to procure. It was also hard for the MOH to determine which medicines to prioritize for inclusion in the state-guaranteed package of free services. Furthermore, procedures for selecting decision makers to develop the various lists were not transparent. State procurements were vulnerable to duplication, inefficiency, and manipulation in favor of higher-priced products.

Strategic Approach and Interventions

In 2013, SIAPS began providing technical assistance to review and update the NEML and develop legislative instruments to establish the NEML as the sole list for procurement and also for using public funds to reimburse patients for out-of-pocket purchases of essential medicines. As important, SIAPS' technical assistance was aimed at institutionalizing a transparent and inclusive development process for future NEML reviews and updates. The first step was a situation analysis. SIAPS reviewed the existing medicines lists and regulations and their use by procurement entities and analyzed past spending patterns. The analysis demonstrated significant imbalances in procurement across the various classes of medicines and the need for rationalizing the use of limited public funds in Ukraine (Konduri and Lebega 2016). For example, over half of insulin expenditures, which accounted for 16% of the 2014 total medicines budget, were for high-priced analogue pens and cartridges. The report of the findings, international best practices, and neighboring country examples provided the evidence base used to mobilize support for reforms.

Anticipating strong resistance from various parties with vested interests, SIAPS began with a stakeholder analysis to map potential opposition, identify and reach out to champions, and build political support. Early engagement with and support of one parliamentarian and heads of three parliamentary committees enabled SIAPS to sign memoranda of understanding (MOUs) with the State Expert Center (SEC) and the Medical University. It also encouraged the MOH, with whom SIAPS already had an MOU, to work with SIAPS on this activity. The MOUs provided official approval for activities and enabled the collaboration to continue amidst political instability. The SIAPS approach also included extensive information sharing and stakeholder engagement, including outreach to physicians, manufacturers, and the public to build support for the new transparent NEML development process. The first of eight public round-table meetings was held in April 2014 to inform stakeholders about the proposed reforms, and additional meetings were held to present draft regulations for comment.

Next, SIAPS assisted the MOH and SEC in developing a plan for replacing the current lists with a unified NEML and formulating the legislative documents to change the system. Then, the MOH, SEC, and SIAPS worked with experts from the Medical University to develop TOR for the proposed NEML Expert Committee and secretariat, which formed the basis for drafting the regulations on the Expert Committee. The partners also created the methodology for transparent determination of the initial NEML and subsequent updates and these recommendations were used to formulate NEML regulations. SIAPS helped draft the regulations and orders and to move them through a lengthy two-year review and approval process.

Following approval of the regulations, SIAPS provided technical guidance to support the appointment of the Expert Committee. All applicants were required to file a COI declaration that was scrutinized by the selection committee. The MOH, with help from SIAPS, secured funding for initial Expert Committee activities, and the committee began to develop the NEML in August 2016. However, obstruction by some members hampered progress, and the committee ceased work after only two months. Following a change in ministerial leadership, a new round of member selection took place, and the

committee resumed work in December 2016. Representatives of patient groups, international organizations, and the MOH were regularly invited to Expert Committee meetings as the first draft of the NEML was developed. These observers were not entitled to vote, but the experts could take their recommendations into consideration.

Results

The Expert Committee has been established through an order as an independent entity, although it is not as yet a legal entity. NEML regulations identify explicit criteria for membership, require the filing of COI declarations prior to appointment, and promote transparency in the selection process. Invited experts are also now required to complete COI declarations. Several international partners and local organizations have actively supported NEML harmonization activities. For example, one nongovernmental organization (NGO) provided funding to support initial Expert Committee activities, training of members, and development of a website.

The website has now been established to track the committee's activities and progress in developing the NEML. The regulations establish basic criteria for selecting NEML medicines, namely, evidence of clinical efficacy, safety, and cost effectiveness; and transparency requirements, including the reporting of decision makers' COI statements. The NEML will be implemented in phases, and the first approved NEML focuses on classes of medicines required for regional and other procurements. The decree of the Cabinet of Ministers approved in March 2017 mandated the NEML as the sole list for publicly funded procurement and reimbursement at the regional level as of July 2017.

Lessons Learned

As anticipated, the initiative evoked a great deal of resistance from within the government and the private sector. Powerful vested interests slowed the NEML development process. The government initially insisted that the NEML development be a rapid process. However, political instability delayed the initiative, and it took several years instead of the one year planned at the outset. There were three ministers of health in two years, which initially prevented government counterparts from working with SIAPS. Ukraine's protracted and complicated bureaucratic processes for developing legislation and other issues also caused delays.

The situation analysis provided evidence of procurement inefficiencies, which was critical in convincing government officials and stakeholders of the need for a harmonized NEML. It was also a useful tool for engaging stakeholders and mobilizing champions. Carrying out the stakeholder analysis early in the process enabled SIAPS to identify potential opposition and risks, such as the complicated political situation, and find and recruit champions from among the stakeholder groups. The public round tables and open discussions helped in overcoming initial opposition, and the implementers found that by being inclusive and transparent about all aspects of the development process, they earned the trust and support of many entities who initially opposed the work.

SIAPS extended its advocacy outreach to patient organizations and civil society groups to ensure that they understood the benefits of a harmonized NEML. This mitigated any potential suspicion or resistance, which sometimes arises among these groups in settings where there is significant mistrust. Both manufacturers and patient groups often pushed for assurances that particular medicines would be included in the list itself. By continually refocusing the discussion on the development of a transparent and evidence-based process rather than on the list itself, consensus was eventually reached on the generally acceptable rules and processes for developing and maintaining a NEML. However, this process took months of continual discussion.

Formal MOUs with key partners were critical in enabling SIAPS to carry on working with MOH, SEC, and university counterparts when MOH leadership changed. Support from the USAID Mission, who understood the need for flexibility, enabled SIAPS to adapt approaches and work plans to the constantly changing political environment and, importantly, maintain political support. Understanding and adhering to Ukraine's legal framework and the bureaucratic processes for developing legal documents, while time consuming, ensured that NEML changes were embedded into national legislation, thereby institutionalizing it and ensuring that the reforms could not easily be rolled back.

Conclusion and Next Steps

The NEML transition process is scheduled to continue through 2019, and the next NEML version is scheduled for approval in 2018. Out- and in-patient medicines that will be reimbursed or procured for national programs at the central level from state funds will be added to the next update, thereby expanding the new reimbursement system initiated in 2017 as part of health care reform. To enhance sustainability, the NEML changes have been incorporated into national legislation. However, as of July 2017, the Expert Committee's work still depends on donor support because it has not yet been established as a legal entity. Once it becomes a legal entity, the Expert Committee can receive a budget, and members can be compensated, which is vital for its long-term sustainability.

Sources/for more information see:
- SIAPS 2017. EML Harmonization Process in Ukraine

CASE STUDY 6: IMPROVING GOVERNANCE IN PHARMACEUTICAL PROCUREMENT IN BANGLADESH

Background

The Government of Bangladesh has achieved significant progress in increasing the availability and use of FP products, contributing to a 23% decrease in the total fertility rate from 3.0 births per woman in 2001 to 2.3 in 2011 (Bangladesh Demographic and Health Survey 2011). However, the public sector continued to experience frequent stock-outs of FP products and other essential medicines because of procurement and supply chain inefficiencies. The Ministry of Health and Family Welfare (MOHFW) is responsible for Bangladesh's public health system and its Directorate General of Health Services (DGHS) and Directorate General of Family Planning (DGFP) oversee and procure products for health services and FP programs, respectively. The World Bank coordinates procurements that are financed by pooled funds from international partners. In 2009, medicine and contraceptive procurement took, on average, one and a half years from order initiation to receipt of the shipment (Gonsalkorale 2009). Poor compliance with World Bank and other procurement procedures resulted in delayed approvals, which, together with other inefficiencies in the procurement process, contributed to the lengthy procurement lead times. MOHFW activities were divided into 32 operational plans, each with a line director responsible for preparing procurement plans that estimate future product needs. A lack of complete and accurate data made it difficult for line directors to forecast demand and prepare procurement plans and for managers to identify and address problems in the procurement and logistics system.

Strategic Approach and Interventions

From 2009 to 2011, SPS, SIAPS' predecessor program, provided technical assistance to the DGFP to improve the procurement of FP and RH commodities. The dormant Logistics Coordination Forum (LCF), which was established in 2005 to enable DGFP to coordinate with development partners, was revived and its membership reconfigured to enable it to effectively oversee FP/RH commodity procurement and supply functions, in addition to coordinating with key stakeholders. SPS supported the LCF in developing the web-based Supply Chain Information Portal (SCIP), which provided information on the status of DGFP procurement packages and real-time stock status of FP/RH commodities throughout the country at the central, district, and subdistrict levels. SPS developed procurement procedures and supply manuals and trained staff to build DGFP's capacity to manage procurement and supply functions. A Forecasting Working Group was formed and an electronic Logistics Management Information System (eLMIS) introduced to increase the availability of data for FP/RH quantification exercises and decision making.

In 2011, the MOHFW asked that SIAPS continue to work on DGFP's procurement system and expand the scope to include the MOHFW and DGHS. SIAPS' technical assistance focused on:

- Building organizational and individual capacity within the MOHFW, DGHS, and DGFP to oversee, coordinate, and manage procurement and supply management functions
- Reforming procurement systems to institutionalize standards and best practices and streamline procurement processes
- Improving and making use of information systems to increase procurement and supply chain transparency and accountability and enable appropriate decision making

Governance, Coordination, and Management Capacity Building

In 2012, the MOHFW established the Procurement and Logistics Management Cell (PLMC) within the Ministry to oversee and coordinate all procurement and supply management functions and supervise capacity-building efforts within its procurement entities, namely the DGFP and DGHS. SIAPS facilitated consultative meetings to design the PLMC governance structure and develop its TOR. Two SIAPS senior technical advisors were embedded within the PLMC to provide ongoing technical assistance and mentoring. PLMC responsibilities include reviewing all procurement plans and packages to ensure they comply with procurement guidelines and budgets before they are sent to MOHFW and World Bank officials for

approval. At the directorate level, SIAPS continued to assist DGFP's Forecasting Working Group to quantify annual needs of FP/RH and maternal, neonatal, and child health (MNCH) commodities. SIAPS also supported the DGFP's LCF to review forecasts and stock status, determine needed government and donor resources for commodity procurement, and identify actions to address procurement and supply chain issues. In 2013, the MOHFW, with assistance from SIAPS established a coordinating mechanism with similar responsibilities within the DGHS—the Supply Chain Coordination Forum—whose members include all 17 DGHS line directors and development partners.

Procurement Systems Reform

To promote ownership and institutionalize their use, SIAPS worked closely with MOHFW staff to develop an operations manual, guidelines, and other tools that clarify responsibilities, specify standards and best practices, and streamline procurement processes within the Ministry's procurement entities.

Information Systems and e-Tools

SIAPS further developed the SCIP, which was renamed the Supply Chain Management Portal (SCMP), and supported its implementation and handover to the PLMC. PLMC members, MOHFW procurement desk officers, and line directors were trained on the use of the portal, which makes web-based tools accessible to Ministry staff and World Bank officials. The SCMP has improved transparency, oversight, and accountability, because it now serves as the MOHFW's central platform for planning, approving, packaging, and tracking procurement of FP/RH/MNCH commodities and essential medicines, supplies and equipment. The SCMP is also accessible to stakeholders and donors, including the World Bank, which approves donor-funded procurements through the portal. The SCMP provides notifications of delays and alerts, prompting staff to take action. Because it is prepopulated with the essential medicines list and price guide, standard list of equipment, and specifications, it simplifies the procurement process, prevents preference being given to a particular brand, and removes the ability to disregard required steps.

At the directorate level, SIAPS helped DGHS develop an eLMIS to collect consumption data and provide real-time information on stock balances of essential medicines and supplies and trained staff in its use. The eLMIS for both DGHS and DGFP have been integrated into the SCMP, which has improved data availability and visibility of the stock status of FP/RH products and essential medicines down to the subdistrict level. SIAPS also helped develop a Service Delivery Dashboard for FP/RH products, which enables the monitoring of stock levels and consumption down to the service delivery point and alerts DGFP staff of impending stock-outs or shortages. Master trainers in both directorates are responsible for continued training of government officials and health workers on the use of the various electronic tools and troubleshooting problems beyond the SIAPS Program.

Results

The partnership between SIAPS and MOHFW has helped to strengthen the governance and management capacity of MOHFW and its procurement entities, increase the availability and use of data for decision making, streamline processes, and improve transparency and accountability in the procurement of FP/RH commodities and essential medicines, supplies, and equipment.

- The MOHFW has coordinating structures at the ministerial and directorate levels that meet regularly to manage and oversee the various procurement and supply chain systems and take corrective action as needed. The PLMC has now become a permanent unit in the Ministry with funding and dedicated staff.
- The PLMC has taken ownership of and now fully manages the SCMP. Line directors and coordinating bodies regularly analyze information availed by the portal to prepare, approve, and track procurement packages and identify opportunities for reducing inefficiencies. In 2011, the portal won two prestigious national awards for e-health and e-governance.

- By 2013, the average procurement lead time had decreased for both DGFP and DGHS from 78 weeks in 2010 to 33 and 52 weeks, respectively, well below MOHFW's target of 58 weeks.
- Improved quantification and oversight prevented unneeded procurements of FP/RH, MNCH, and TB program commodities, leading to a savings of USD 6.38 million as of 2015.

Lessons Learned

SPS and later SIAPS recognized MOHFW's strong commitment to the government's vision of using technology to improve public well-being and aligned its technical assistance objectives with this goal. The shared vision and priorities were crucial in generating support for SIAPS activities, building trust, and attaining MOHFW ownership of the interventions; the health secretary of the MOHFW has been a strong champion of the web-based SCMP.

The development of web-based tools and electronic information systems served as an entry point for strengthening governance in Bangladesh's procurement systems. Accurate and accessible information is essential for oversight, and web-based tools, such as the SCMP, are an important mechanism for improving efficiency, transparency, and accountability in procurement. SIAPS advocated for and helped establish central and directorate-level oversight mechanisms. The program built the capacity of these oversight mechanisms and developed procedures to enable them to analyze and use the information generated to take appropriate actions.

System strengthening initiatives, particularly those involving the development of technology rely on long-term commitments from policy makers and require ongoing advocacy by champions and stakeholders to avoid interruptions and delays. Recognizing this, SPS, and later SIAPS, invested in building relationships with government officials and health workers at all levels. The frequent reassignment of MOHFW and procurement desk officers has been a significant obstacle to SIAPS' efforts to build capacity and sustain momentum, and so technical staff at lower levels were included in capacity-building activities to maintain continuity in ongoing activities. SIAPS advocated for better retention policies with only limited success due to the Ministry's longstanding policy to periodically rotate senior staff.

Conclusion and Next Steps

In Bangladesh, the introduction of new technology provided an opportunity for improving transparency and accountability in procurement processes. Four years before the program's end, SIAPS began working with the MOHFW to develop a plan to transfer full ownership to the Ministry and sustain the SCMP and other tools. As a result, the PLMC is now a permanent structure that fully manages the SCMP with SIAPS playing a reduced role in operating the SCMP. However, MOHFW's continuous involvement and ownership is imperative to ensure the continued use of the tool for decision making and oversight.

Sources/for more information see:
- Twesigye et al. 2017. Strengthening Governance in Procurement in Bangladesh
- SIAPS 2016. Effective Leadership in MOHFW Ensures Availability of Medicines in Bangladesh
- SIAPS 2015. Saving Lives of Women and Children: Systems Strengthening Approaches to Improve Access to Contraceptives in Bangladesh

CASE STUDY 7: STRENGTHENING LEADERSHIP, MANAGEMENT, AND OVERSIGHT AT REGIONAL AND LOCAL LEVELS TO REDUCE ARV MEDICINE STOCK-OUTS AT HEALTH FACILITIES IN CAMEROON

Background

SIAPS started working in Cameroon in 2012 with funding from the US President's Emergency Plan for AIDS Relief. At that time, there were widespread shortages of ARVs because of chronic deficiencies in quantification, procurement planning, inventory management, and reporting at all levels of the system (Eghan and Daniel 2011). Less than 15% of people living with HIV had access to treatment, and those patients that did received only 10 days of ARVs instead of a month's supply. In addition, many stores and HIV clinic storage areas did not meet even minimum standards for maintaining product quality. After two years of SIAPS-supported interventions to improve forecasting and procurement planning at the national level, stock-outs were virtually eliminated for the six most prescribed ARVs at central level. Yet, stock-outs of these ARVs continued at regional medical stores and health facilities.

Strategic Approach and Interventions

In 2014, SIAPS initiated activities at the subnational level to tackle these persistent stock-outs. SIAPS began by training storekeepers from regional medical stores and dispensers from health facilities on ARV management and helped introduce pharmaceutical management tools and SOPs, together with centrally led quarterly supervisory visits. Despite these interventions and continuous ARV availability at the central level, data collected during supervisory visits showed that 41% of health facilities still experienced stock-outs of the six most commonly used ARVs during the last quarter of 2014. For four of the tracer ARVs, stock-outs actually increased since the trainings and supervision began. In addition, the supervisory visits had little effect in improving storage conditions and record keeping. The supervisory teams observed that the pharmacy staff appeared to receive little support from the HIV clinic manager or regional authorities to help implement the teams' recommendations.

So, in 2015, SIAPS expanded the scope of its technical assistance to strengthen leadership, management, and oversight at regional and local levels. As a first step, SIAPS seconded technical advisors to four regional medical stores to strengthen linkages between the regional HIV coordinators and medical stores staff and improve their skills in developing sound regional distribution plans for HIV commodities. Next, SIAPS worked with the HIV program to transfer leadership for organizing and conducting HIV pharmaceutical management supervisory visits from the national HIV program staff to the regional HIV coordinators. SIAPS also built their capacity for using supervisory tools, interpreting findings, and providing oversight to regional medical stores and health facilities. At the service delivery level, SIAPS worked with HIV regional coordinators and HIV clinic managers to introduce a continuous quality improvement process to enable health facility managers to lead their HIV clinic teams in identifying and tackling local-level problems to improve ARV availability for their clients. The HIV clinic managers were highly qualified practitioners; however, they often lacked management experience and acknowledged their difficulties in overseeing pharmacy services and staff at their clinics. Through SIAPS, they learned how to lead the quality improvement process; use adapted internal supervision tools and interpret key pharmaceutical indicators to identify root causes of poor performance; agree on improvement interventions; and monitor results. A forum for peer exchange between regional medical stores, regional HIV coordinators, and HIV clinic managers was established during regional quarterly meetings to enable sharing best practices and lessons learned.

Also in 2015, SIAPS began collaborating with Positive-Generation, a local CSO. The CSO, through its Treatment Access Watch (TAW) Program, reports weekly on the availability of ARVs and HIV rapid test kits at 74 health facilities across all 10 of Cameroon's regions, as well as on patient perceptions on access barriers. SIAPS and Positive-Generation agreed to compare monitoring data and jointly analyze barriers to HIV treatment access and, together with other partners, advocate for reforms. TAW's weekly reports enabled SIAPS to communicate potential problems to regional supervisory teams earlier than was possible using the

monthly data generated by the national logistics reporting system, thereby facilitating accelerated responses. The collaboration with SIAPS created opportunities for Positive-Generation to participate in some regional quarterly peer-review meetings to share information and patient perspectives with regional medical store staff, regional HIV coordinators, and HIV clinic managers.

Results

From March 2015 onward, with the introduction of management and governance improvement interventions at regional and local levels, stock-outs of all tracer ARVs decreased steadily every quarter. The percentage of health facilities experiencing stock-outs of the six most prescribed ARVs dropped from 41% in December 2014 to 14% in December 2015, and the downward trend was maintained in 2016, reaching 9% by March 2016.

As of June 2016, HIV clinic staff at 69% of health facilities were conducting regular internal supervision of pharmaceutical services, verifying stock levels, and ensuring consistency of reported data. Storage conditions and compliance with reporting also improved significantly. With support of HIV clinic managers, most health facilities were successful in mobilizing internal resources and partner assistance for improvements, such as shelves and air conditioning, despite budget limitations. By the end of SIAPS, 96% of health facilities complied with minimum storage requirements compared with 57% in 2015.

Lessons Learned

Training, supervision, and the transfer of technical knowledge may be insufficient to address pharmaceutical management problems if there are organizational issues that hamper the implementation of actions or recommendations. It is important to understand how pharmacy services and reporting lines are organized to gain a complete picture of the root causes of pharmaceutical management problems at the facility level. The decentralization of most HIV program pharmaceutical oversight responsibilities to its regional HIV staff, greater autonomy of the regional warehouses, and the deployment of SIAPS' technical advisors to the regions facilitated joint and more efficient planning. In addition, interventions could be more easily customized to specific regional context and priorities, and there was more support for their implementation. Once HIV clinic managers learned how to interpret pharmaceutical management indicators and make use of data at their clinics, they began to more carefully review pharmacy reports, which they signed every month. Reporting accuracy and completeness therefore improved.

SIAPS' partnership with Positive-Generation proved useful for cross-checking stock-out data generated by the national logistics reporting system and to quickly identify possible problems with ARV availability. While SIAPS has primarily focused its technical assistance on improving ARV availability, patient observations on access barriers as reported by Positive-Generation revealed that the affordability of HIV and other laboratory testing and geographical accessibility to services as chief concerns at that time. The partnership between Positive-Generation and SIAPS enabled them to collate information from different sources to develop a comprehensive picture on availability and accessibility of HIV services and commodities and different perspectives on primary constraints and priorities.

Conclusion and Next Steps

In Cameroon, enhancing leadership, management, and oversight capacities of staff at regional and clinic levels and their ability to interpret data was associated with improvements in ARV pharmaceutical management and availability. However, the pharmaceutical sector remains fragile, and ongoing governance and other reforms are required to improve and sustain access to pharmaceuticals and services.

Sources/for more information see:
- SIAPS 2016. SIAPS Cameroon: Key Achievements 2012-2016
- Mumbari et al. 2016. Enhancing Management and Governance at Regional and Local Levels to Reduce Health Facility ARV Stock-Outs in Cameroon Poster presented at the 2016 International AIDS Conference.
- SIAPS 2016. SIAPS/Cameroon webpage

CASE STUDY 8: STRONGER COMMUNITY LEADERSHIP, MANAGEMENT, AND GOVERNANCE STRENGTHENS THE TB CONTROL PROGRAM FOR PHILIPPINES' URBAN POOR

Background

In 1991, the Philippines decentralized its health services making local government units and barangay (local district) councils responsible for delivering health services. However, most local government executives and barangay elected leaders were not well equipped to lead and manage health programs so the quality of health services remained poor, especially in impoverished communities. Moreover, local government units and barangay councils often had separate priority setting and planning processes, and community members had few organized opportunities to participate. Health care teams in community health centers usually prioritized health issues based on national priorities and rarely involved community stakeholders or barangay officials. Separately, barangay councils identified health priorities for the barangay without the guidance of public health managers, and the selection process was seldom based on a sound analysis of the community's health situation and needs.

In the poor urban settlements of Quezon City, part of the metro Manila area, TB case detection and treatment success rates were low. The inadequate availability and accessibility of diagnostic facilities and high out-of-pocket expenses for transportation were just some of the factors hindering access to effective TB care among the urban poor.

Strategic Approach and Interventions

The Quezon City Department of Health (QCHD), with support from SIAPS, set about strengthening TB program management in poor urban barangays in 2011. SIAPS recognized that to achieve sustainable improvements in TB pharmaceutical and laboratory management at the community level, interventions had to be embedded within an initiative that strengthened health program leadership, management, and governance; and importantly, coordination between government, health providers, and the community. The premise was that, by improving these capacities and working in a team with community stakeholders to develop a plan that tackles shared health priorities, officials and health leaders would be better able to improve the delivery of TB and other services. The Barangay Health Management Council (BHMC) was conceptualized as a platform for information sharing, consensus building, and joint planning to achieve these objectives and enable community stakeholders to participate and take ownership in managing the TB program in their community.

In 2011, QCHD and SIAPS met with officials, health officers, and stakeholders in the large urban-poor barangay of Payatas to explain the need for a community management structure and encouraged them to join forces to reactivate the dormant Barangay TB Management Council. SIAPS, local leaders, and stakeholders worked together to identify the purpose, objectives, and membership of the new structure renamed the BHMC, developed its TOR, and set up a core management team to handle leadership and management tasks and a secretariat to manage meetings, coordination, and information. Following the successful BHMC pilot in Payatas, QCHD and SIAPS established two more BHMCs in 2013 and adjusted the model to create cluster BHMCs for a group of barangays with relatively small populations that are served by a single health facility. In 2014, the Quezon City Council passed an ordinance that provides for the establishment of BHMCs in all city barangays. SIAPS helped develop the ordinance and the accompanying implementing rules and regulations, barangay resolutions, and a guide for establishing BHMCs in other cities.

As a first step to setting up a BHMC, SIAPS assisted local health officers in conducting a comprehensive analysis of the TB situation and the performance of the TB program in their barangay. The information generated from their own communities, including interviews with health workers and patients, were used to raise the awareness of barangay officials and other community stakeholders of the TB problems in their community and to secure their support for the BHMC initiative. Next, barangay officials, health workers, and other stakeholders formed a core team and SIAPS oriented them to their role and functions. An important component of the BHMC initiative is the joint planning workshops where BHMC members work together to review the findings of the situation analysis, identify root causes, prioritize problems, and develop a joint action plan and budget and agree on responsibilities

for its implementation. SIAPS helped build the BHMC core team's capacity to organize and conduct effective meetings, promote evidence-based decision making, and use participatory and consensus building processes to develop a joint action plan and budget. Additionally, SIAPS provided regular onsite mentoring and developed a set of performance indicators to enable BHMCs and district health officers to monitor progress and promote accountability to stakeholders.

Results

As of June 2016, 17 BHMCs had been established in Quezon City covering 45 of the city's 142 barangays and almost 1.3 million people (40% of the city's population), many of whom are poor. The Quezon City Council has institutionalized BHMCs by passing a city ordinance, and all barangays have formulated resolutions to support the implementation and operation of BHMCs. Some of the results of BHMC activities are as follows.

- Priority-setting and planning processes are more transparent and participatory. BHMCs include representatives from civic groups for the elderly and disabled, schools, and other community stakeholders.
- Each barangay now has a single, unified action plan and budget, which includes barangay, city health department, and stakeholder resources. Before BHMCs, budgets for health came mainly from the local government; now they leverage barangay, city health department, and other stakeholder funds.
- Barangay leaders are more aware of the TB situation in their communities and more motivated to address problems. Some BHMCs have hired health workers and procured medicines and medical equipment to improve outreach services and address shortages.
- Better collaboration and coordination among community stakeholders has increased the availability and sharing of resources, such as medical specialists, chest X-ray facilities, and health promotion activities.
- Duplication of activities is avoided. For example, the barangay council and the health center in one barangay now hold joint TB assemblies instead of separate events.
- TB case-finding and treatment have improved. Better coordination between NGOs, health centers, and community volunteers; the establishment of smearing stations in remote areas; and sharing of diagnostic and treatment services led to a 17% increase between 2011 and 2014 in the detection of smear-positive cases and TB cases initiated on treatment in Payatas barangay.

Lessons Learned

It was essential to invest in advocacy efforts with barangay officials, community stakeholders, and health managers before initiating activities. This helped secure their effective engagement, commitment, and willingness to collaborate, which were critical for the BHMCs' success. The active participation of stakeholders, such as community-based NGOs, patient groups, and local champions, such as politicians, helped promote and sustain the activities of the BHMCs. However, the tendency of newly elected barangay officials to replace their predecessors' initiatives with their own and the high turnover of barangay health center officials who serve as BHMC co-chairs have challenged BHMC functionality and sustainability.

The attendance of community groups where results and finance reports were presented has helped promote transparency and accountability and generated advocacy for the mobilization of internal and external resources to support implementation. Although planning processes and implementation reviews are more transparent than before, there is room for improvement in financial transparency of BHMC activities.

Using practical, simple, and culturally appropriate approaches to build the leadership, management, and governance capabilities of BHMC members was essential to enable them to act as good stewards and managers. Leadership, management, and governance principles and practices were imparted using real-life situations during the workshop rather than in formal trainings. In addition to individual practices and skills, capacity building is needed to strengthen structures, mandates, roles, and processes.

Weaknesses in implementing monitoring and evaluation (M&E) activities were common across all BHMCs making it difficult to hold BHMCs and members accountable. By 2015, after SIAPS capacity-building efforts, BHMCs were collecting and analyzing data themselves but continued to depend on SIAPS' support to interpret them. It continues to be an area that requires further capacity building and ongoing motivation.

Conclusion and Next Steps

The experiences in Quezon City suggest that strengthening program leadership, management, and governance at the community level and leveraging community resources through establishment of the BHMC can improve TB program performance and results in urban areas in the Philippines. Strengthening M&E activities and further improving financial transparency will help stakeholders to better monitor BHMC performance, design improvement strategies, and strengthen accountability. The BHMCs were rooted in the TB program but can be adapted for other programs, and BHMCs in Quezon City are now working on health issues for maternal health, child nutrition, and dengue and disaster preparedness. The technical assistance provided by SIAPS helped BHMCs work with community stakeholders to solve their problems, which then enabled them to achieve successes largely on their own.

Sources/for more information see:
- Lagos and Adorio-Arce 2018. Improving TB Systems and Services through Stronger Community Health Leadership, Management, and Governance in the Philippines
- SIAPS 2014. Grassroots Leadership Improves the TB Control Program for the Urban Poor in Quezon City, Philippines
- Lagos and Adorio-Arce 2017. A Guide for the Establishment of a Barangay Health Management Council: An Initiative to Strengthen the Health System and Improve Services at the Barangay Level through Better Health Leadership, Management, and Governance

WORKING WITH COUNTRIES TO STRENGTHEN GOVERNANCE: CHALLENGES AND LESSONS LEARNED

Common Challenges

Governance can be a sensitive subject and various challenges may impede the startup or implementation of pharmaceutical sector reforms and improvement initiatives. Resistance may arise from sensitivities, competing interests, or reluctance to changing long-standing processes and behaviors. Interventions that challenge value systems and deeply entrenched power relationships may be considered impolite or even threatening. In other cases, governance issues may be viewed as irrelevant or of low priority. Protracted bureaucratic procedures and lengthy policy and legislative processes are challenges that commonly hinder the implementation of governance-improvement initiatives. Some initiatives, such as tackling problems like falsified medicines, may require joint action by multiple ministries and stakeholders and the establishment of mechanisms for collaboration. It can take time to establish such forums and attain agreement on joint action among diverse stakeholders, especially when there are competing interests. Not only can bureaucracy and lengthy processes slow down progress, but the longer the delays, the more likely that political instability or leadership changes will further delay or stall implementation. System strengthening approaches hinge on long-term political commitments from policy makers. Newly elected or appointed officials may have different priorities or may even want to replace their predecessors' initiatives. Frequent reassignment of high-level decision makers is another challenge that can impede implementation of governance initiatives and threaten their sustainability. In some cases, organizations, governance bodies, and other stakeholders may see the value of reforms and improvements but have insufficient authority or capacity to implement or sustain the initiatives.

Lessons Learned: Gaining Entry

Given possible sensitivities and resistance, a key challenge often encountered is finding a suitable entry point for addressing governance issues. SIAPS and its predecessor programs have found that targeting inefficiencies, such as medicines wastage, can be a politically acceptable starting point for interventions in such circumstances. A well-researched situation analysis that provides compelling evidence of inefficiencies and poor performance, together with examples of local and international best practices, can help convince policy makers and stakeholders of the political and financial benefits of addressing governance issues that contribute to such problems, as seen in the Ukraine, Bangladesh, and Cameroon cases. SIAPS and its predecessor have also found that including a governance-related component in country pharmaceutical system assessments, whatever the scope, can serve as an entry point for future advocacy efforts aimed at improving governance. SIAPS has also observed that MOHs are increasingly interested in information technologies as a means of increasing efficiency and visibility of pharmaceutical processes. As illustrated in the Bangladesh case, such technologies can provide information and reveal bottlenecks, which in turn serve as an impetus for tackling governance issues.

Lessons Learned: Initiating, Implementing, and Sustaining Initiatives

Strong stakeholder engagement, local champions, and high-level political support are invaluable in overcoming initial and ongoing resistance that can delay important activities and decisions and for sustaining initiatives in the long term. Stakeholder analyses have proved useful for identifying likely champions who can support, provide political backing, and promote the initiative as well as determining probable sources of resistance. Evidence generated from situation analyses is invaluable for initial advocacy efforts and for enlisting champions, as are interim results from pilot sites. Extensive consultative processes can help diverse stakeholders reach mutual understanding and are especially important when there are competing interests. SIAPS has found that transparent and inclusive information sharing sessions, such as the public round tables held in Ukraine, are helpful in overcoming initial distrust of civil society and patient groups and gaining their

backing for proposed reforms. Sharing draft bills and policies for comment, holding meetings that enable stakeholders to voice concerns and provide feedback, and allowing observers to sit in on decision-making meetings have been important strategies for engaging stakeholders and sustaining trust and support as seen in the Swaziland and Ukraine case studies.

Aligning technical assistance activities with government priorities to create a shared vision and priorities can also help generate trust and secure political backing, as occurred in the Bangladesh case study where the health secretary of the MOHFW became a strong champion of the web-based technology. SIAPS has found that joint planning, design, and implementation in close collaboration with country partners is essential to cultivate country ownership and to sustain interventions beyond the life of the technical assistance project. Involving staff at all levels and facilitating the active participation of champions and stakeholders, such as civil society and patient organizations in planning or performance review meetings, can help maintain the momentum when high-level officials are reassigned and to promote the initiative to new appointees.

Legislation can also be an important tool for institutionalizing and sustaining improvement initiatives. Embedding reforms in legislation can make it harder for newly elected or appointed officials to reverse it and give champions and stakeholders time to explain the importance of the reforms. As illustrated in the Swaziland case, it is essential to have a sound understanding of legislative and bureaucratic processes and identify opportunities and plan activities for expediting these processes. SIAPS helped the MOH in Swaziland conduct seminars and prepare briefs to educate legislators on the importance and contents of the draft legislation, which helped generate support for its enactment after the election of a new Parliament. Collaborating with country institutions and other local champions can also sustain momentum in the midst of political instability or leadership changes. These champions play an important role in advocating for and explaining to new leaders the political benefits of continuing governance-improvement initiatives. The Ukraine case demonstrates how formal MOUs with country institutions can enable technical assistance providers to continue collaborations in situations of political instability or frequent changes in leadership. Implementing agencies, such as SIAPS and their funders, may need to be flexible. Approaches and work plans may need to be adapted on short notice to the changing environment to maintain political backing or to take advantage of new opportunities.

Lessons Learned: Building Capacity for Governance

A situation that SIAPS has commonly encountered in LMICs is that although the importance of governance in pharmaceutical systems may be widely acknowledged, the ability to exercise and institutionalize good governance practices is constrained by a lack of institutional and individual capacity. SIAPS and its predecessor have found that reducing opportunities for corrupt practices and addressing mismanagement in pharmaceutical systems often requires a combination of interventions that target governance, management, and leadership practices. Consequently, working with countries to strengthen governance, management, and leadership capabilities has also been an important component of the SIAPS approach. This approach aligns with the conceptualization of governance as an enabler of more effective and efficient management (Rice et al. 2015). Leadership skills, ethics and integrity, performance measurement, and access to reliable information in turn enable better governance. Robust TOR; clear roles, responsibilities, and lines of accountability; better meeting management; preparation of accurate minutes; and improved follow-up of agreed upon actions can all help improve the performance of pharmaceutical committees. In countries where human resources are limited, health workers may find it difficult to attend formal trainings. SIAPS has used approaches, such as ToT workshops to cascade trainings throughout a country; quality improvement approaches, such as the Pharmaceutical Leadership Development Program in South Africa;[8] and actual situations to impart leadership, management, and governance principles and practices. SIAPS has found one-on-one mentoring to be especially valuable when individuals have differing capacity needs.

---

8   For more information on the Pharmaceutical Leadership Development Program see Strengthening the Leadership and Management of Pharmaceutical Services in South Africa (Ellis et al. 2016)

Areas of Focus Going Forward

Some areas of governance where we have observed progress to be difficult or slow in LMICs include M&E to enable better oversight and accountability, changing practices relating to the declaration and management of institutional or individual COIs, and improving civil society engagement. Many LMICs have made considerable headway in improving access to information for decision making and oversight. However, SIAPS has found that information use for measuring and monitoring the performance of pharmaceutical committees, systems, and functions is one of the weakest system components. M&E systems and processes often require long-term technical assistance and advocacy to encourage its institutionalization. While many pharmaceutical committees and advisory committees submit COI declarations, few have set up systems and processes to manage conflicts that may arise, including advising staff of what needs to be declared. Examples of models and tools would be useful in this regard. Similarly, models and tools are needed for deliberate engagement of civil society in pharmaceutical sector decision making and oversight. These should include approaches for building civil society capacity to ensure that their engagement is effective, productive, and sustainable and changing the attitudes of other stakeholders to recognize and facilitate CSO engagement.

Governance, management, and/or leadership interventions are implemented concurrently, and typically comprise part of a package of pharmaceutical system-strengthening interventions. This has made it difficult for SIAPS and other implementing partners to attribute governance activities directly to improvements in access and medicines use and, ultimately, health outcomes. Carefully designed research can help governments and implementers learn what works, when, and how and provide evidence to leaders and activists advocating for change.

Reflections on the SIAPS Framework

SIAPS has used the UNESCAP definition of governance—"the process of decision making and the process by which decisions are implemented (or not implemented)"—to promote understanding of the relevance and importance of this health system component in building stronger and more resilient pharmaceutical systems (UNESCAP 2009). We have found this definition to be broad enough to encapsulate the range of governance issues that SIAPS has encountered in its work. It also underscores that governance is not solely the responsibility of the central government or governing bodies but is also relevant to all entities in the health system in both the public and private sectors who make decisions and take actions in the process of managing medicines and providing pharmaceutical services.

The framework used by SIAPS to guide the program's work in strengthening governance in pharmaceutical systems (figure 1) has proved to be useful as a pragmatic means of organizing our thinking about opportunities to strengthen governance in all key pharmaceutical functions. As the case studies show, the four strategic areas defined in the conceptual model are all relevant to establishing sound governance practices in LMIC pharmaceutical systems. Further, it is often necessary to address weaknesses in several of these areas to achieve sustainable improvements in governance and more broadly in system performance.

Good governance frameworks have been criticized as assembling sometimes seemingly arbitrary lists of desirable attributes or dimensions, all of which countries cannot realistically achieve simultaneously (Greer et al. 2016). These attributes have been organized in various ways, including as governance inputs, processes, and outputs (Baez-Camargo and Jacobs 2011), and as fundamental values of good governance, governance subfunctions, and outcomes or goals of strengthening governance (Barbazza and Tello 2014). The SIAPS framework uses the UNDP principles—strategic vision, participation, transparency, consensus-orientation, rule of law, equity, efficiency and effectiveness, responsiveness, and accountability—to describe good governance (UNDP 1997). We offer the following insights on these principles with respect to promoting good governance in pharmaceuticals systems based on our experiences.

- Formulating a **strategic vision** or direction and reaching broad **consensus** on what is in the best interests of the whole community and how this can be achieved are both relevant to the pharmaceutical sector. SIAPS' technical assistance has often included facilitating consultative processes to develop policies, such as the NMP, and aiming to reach

consensus among pharmaceutical sector stakeholders with divergent interests and power differentials. **Rule of law** underpins good governance and is important, given the sector's need for careful regulation.

- Ensuring appropriate levels of **transparency, accountability, and participation** are fundamental governance principles in pharmaceutical systems. Strengthening these and ensuring that they occur in appropriate extents has been an important component of our governance-focused work.
- We regard **effectiveness, efficiency, equity, and responsiveness** as outcomes of good governance. As Baez-Camargo et al. and Barbazza et al. suggest, indicators related to these outcomes can serve to measure improvements in governance. However, we note the difficulty in attributing results, especially for efficiency and effectiveness, solely to governance interventions.

More generally, while better governance is desirable, governance problems can result from too much or the wrong kind of governance and not just from too little (Greer et al. 2016). We have found that top-down measures that increase accountability too much can constrain pharmacy managers from responding promptly to problems, such as medicine shortages. It can also slow day-to-day business when decisions to act can only be taken at higher levels of the Ministry or require approval from multiple officials. Similarly, undue requirements for product registration may lead manufacturers to shy away from introducing new products to the market, which are needed to improve health outcomes.

Conclusion

These case studies and other experiences provide examples of strategies and approaches that countries have used to promote and institute sound governance with assistance from SIAPS. They provide insights on factors that have enabled and constrained implementation progress and the success of these initiatives, adding to the current body of knowledge. The insights and lessons learned will hopefully further progress in the countries where SIAPS has had the privilege to work and provide momentum for advocacy and similar efforts in other countries.

REFERENCES

- Baez-Camargo C, Jacobs E. 2011. A Framework to Assess Governance of Health Systems in Low Income Countries. Working Paper Series No 11. Basel: Basel Institute on Governance. Retrieved from https://www.baselgovernance.org/sites/collective.localhost/files/publications/biog_working_paper_11.pdf

- Bangladesh Demographic and Health Survey (BDHS) 2011. NIPORT, Mitra and Associates and ICF International. Bangladesh Demographic and Health Survey 2011. Dhaka, Bangladesh, and Calverton, Maryland, USA. Retrieved from https://dhsprogram.com/pubs/pdf/fr265/fr265.pdf

- Barbazza E, Tello JE. 2014. A review of health governance: definitions, dimensions and tools to govern. Health Policy 116(1), 1-11.

- Bennett R, Tadeg H, Ejigu E, et al. 2017. Technical Brief: Transforming Pharmaceutical Services in Ethiopia through Auditable Pharmaceutical Transactions and Services. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/technical-brief-transforming-pharmaceutical-services-in-ethiopia-through-auditable-pharmaceutical-transactions-and-services/english/

- Brinkerhoff DW, Bossert TJ. 2014. Health governance: principal–agent linkages and health system strengthening. Health Policy and Planning 29(6), 685-693.

- Buckley GJ, Gostin LO, editors. 2013. Countering the Problem of Falsified and Substandard Drugs. Washington DC: Institute of Medicine of the National Academies. Retrieved from http://nationalacademies.org/hmd/Reports/2013/Countering-the-Problem-of-Falsified-and-Substandard-Drugs.aspx

- Cohen JC, Mrazek MF, Hawkins L. 2007. Corruption and pharmaceuticals. In: Campos JE, Pradhan S, editors. The Many Faces of Corruption: Tracking Vulnerabilities at the Sector Level. Washington, DC: World Bank. Retrieved from https://openknowledge.worldbank.org/handle/10986/6848

- Cylus J, Wouters O, Kanavos P. 2016. Understanding the role of governance in the pharmaceutical sector: from laboratory to patient. In: Greer SL, Wismar M, Figueras J, editors. Strengthening Health System Governance. Better Policies, Stronger Performance (pp.173-186). World Health Organization European Observatory on Health Systems and Policies Series.

- Eghan K, Daniel G. December 2011. Assessment of the Pharmaceutical Management System in Cameroon. Arlington, VA: Management Sciences for Health. Retrieved from http://pdf.usaid.gov/pdf_docs/PA00JBNX.pdf

- Ellis A, Mkele G, Putter S. 2016. Technical Brief: Strengthening the Leadership and Management of Pharmaceutical Services in South Africa. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/technical-brief-strengthening-the-leadership-and-management-of-pharmaceutical-services-in-south-africa/english/

- Federal Democratic Republic of Ethiopia Ministry of Health/WHO. 2003. Assessment of the Pharmaceutical Sector in Ethiopia. Retrieved from http://www.who.int/medicines/areas/coordination/ethiopia_pharmaceutical.pdf

- Fenta TG, Gulilat B, Teshome D, et al. 2016. Outcome of Auditable Pharmaceutical Transactions and Services Implementation: Assessment Report. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/outcome-of-auditable-pharmaceutical-transactions-and-services-implementation-assessment-report/english/

- Global Fund. 2015. Results Report 2015. Geneva: The Global Fund to Fight AIDS, Tuberculosis and Malaria. Retrieved from http://www.theglobalfund.org/en/publications/

- Gonsalkorale R. 2009. An In-depth Evaluation of Procurement Management Capacity of the Directorate General of Family Planning, Ministry of Health and Family Welfare, Bangladesh. Arlington, VA: Management Sciences for Health. Retrieved from http://pdf.usaid.gov/pdf_docs/Pnadw497.pdf

- Greer SL, Wismar M, Figures J. 2016. Strengthening Health System Governance. Better Policies, Stronger Performance. World Health Organization European Observatory on Health Systems and Policies. Retrieved from http://www.euro.who.int/__data/assets/pdf_file/0004/307939/Strengthening-health-system-governance-better-policies-stronger-performance.pdf?ua=1

- Hafner T, Walkowiak H, Lee D, Aboagye-Nyame F. 2016. Defining pharmaceutical systems strengthening: concepts to enable measurement. Health Policy and Planning. doi: 10.1093/heapol/czw153

- Konduri N, Lebega O. 2015. How Public Funds Were Spent on Procurement of Medicines in Ukraine's Hospitals? Interim Analysis for the Ministry of Health, Ukraine. Technical Brief # 1. Arlington, VA: Management Sciences for Health. Retrieved from http://apps.who.int/medicinedocs/documents/s22167en/s22167en.pdf

- Lagos AB, Adorio-Arce LP. 2017. A Guide for the Establishment of a Barangay Health Management Council: An Initiative to Strengthen the Health System and Improve Services at the Barangay Level through Better Health Leadership, Management, and Governance. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/a-guide-for-the-establishment-of-a-barangay-health-management-council/english/

- Lagos AB, Adorio-Arce LP. 2018. Improving TB Systems and Services through Stronger Community Health Leadership, Management, and Governance in the Philippines. Retrieved from https://pharmasystems.org/strengthening-community-health-philippines/

- Lu Y, Hernandez P, Abegunde D et al. 2011. Medicine expenditures. In: WHO. The World Medicines Situation, 3rd edition. Geneva: World Health Organization. Retrieved from http://apps.who.int/medicinedocs/documents/s18767en/s18767en.pdf

- Mumbari G, Tarrafeta B, Kane A, et al. 2016. Enhancing Management and Governance at Regional and Local Levels to Reduce Health Facility ARV Stock-Outs in Cameroon; poster presented at the 2016 International AIDS Conference.

- Putter S, Walkowiak H. 2017. Technical Brief. Developing Better Terms of Reference to Improve the Performance of Pharmaceutical Sector Committees: Case Studies from South Africa. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/developing-better-terms-of-reference-to-improve-the-performance-of-pharmaceutical-sector-committees-case-studies-from-south-africa/

- Rice JA, Shukla M, Johnson Lassner K, et al. Who Govern. June 2015. p. 1:3. Arlington, VA: Management Sciences for Health. Retrieved from https://www.msh.org/resources/leaders-who-govern

- Savedoff WD, Gottret P, editors. 2008. Governing Mandatory Health Insurance: Learning from Experience. Washington, DC: World Bank. Retrieved from https://openknowledge.worldbank.org/handle/10986/6526

- SIAPS. 2013. Investing in People: The Ethiopian Pharmaceutical Association. Arlington, VA: Management Sciences for Health. http://siapsprogram.org/2013/10/18/investing-in-people-the-ethiopian-pharmaceutical-association/

- SIAPS. 2014. Grassroots Leadership Improves the TB Control Program for the Urban Poor in Quezon City, Philippines. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/grassroots-leadership-improves-the-tb-control-program-for-the-urban-poor-in-quezon-city-philippines/english/

- SIAPS. 2015. SIAPS Program Supports Revision and Launch of Haiti's First National Medicines Policy. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/2015/06/30/siaps-program-supports-revision-and-launch-of-haitis-first-national-medicines-policy/

- SIAPS. 2015. Modernizing Legislation in Swaziland to Improve the Control of Medicines. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/modernizing-legislation-in-swaziland-to-improve-the-control-of-medicines/english/

- SIAPS. 2015. Strengthening Regulatory Systems to Improve Access to Safe; Effective, and Quality Medicines. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/strengthening-regulatory-systems-to-improve-access-to-safe-effective-and-quality-medicines/english/

- SIAPS. 2015. Saving Lives of Women and Children: Systems Strengthening Approaches to Improve Access to Contraceptives in Bangladesh. Retrieved from http://siapsprogram.org/wp-content/uploads/2015/02/Family-Planning-Impact-Brief-Bangladesh.pdf

- SIAPS. 2016. Cameroon web page; http://siapsprogram.org/wherewework/cameroon/

- SIAPS. 2016. Technical Highlight. Effective Leadership in MOHFW Ensures Availability of Medicines in Bangladesh. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/effective-leadership-in-mohfw-ensures-availability-of-medicines-in-bangladesh/english/

- SIAPS. 2016. SIAPS Cameroon: Key Achievements 2012-2016. Arlington, VA: Management Sciences for Health.

- SIAPS. 2017. Technical Highlight: Strengthening the Medicines Regulatory System in Swaziland. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/technical-highlight-strengthening-the-medicines-regulatory-system-in-swaziland/

- SIAPS. 2017. Technical Brief. Strengthening the Pharmaceutical System in Sierra Leone after Ebola. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/strengthening-the-pharmaceutical-system-in-sierra-leone-after-ebola/english/

- SIAPS. 2017. Technical Highlight. Leadership Development Program Training to Strengthen Pharmaceutical Management in Sierra Leone. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/leadership-development-training-to-strengthen-pharmaceutical-management-in-sierra-leone/english/

- SIAPS. 2017. Technical Highlight. Strengthening Regulatory Systems in Democratic Republic of the Congo to Improve Access to Safe, Effective, and Quality Medicines. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/technical-highlight-strengthening-regulatory-systems-in-democratic-republic-of-the-congo-to-improve-access-to-safe-effective-and-quality-medicines/english/

- SIAPS. 2017. EML Harmonization Process in Ukraine. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/eml-harmonization-process-in-ukraine/english/

- Siddiqi, S, Masud, TI, Nishtar, S, et al. 2009. Framework for assessing governance of the health system in developing countries: gateway to good governance. Health Policy 90(1), 13-25.

- SPS. 2011. Pharmaceuticals and the Public Interest: The Importance of Good Governance. Arlington, VA: Management Sciences for Health.

- Transparency International. 2016. Corruption in the Pharmaceutical Sector. Diagnosing the Challenges. London: Transparency International UK. Retrieved from http://www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/

- Travis P, Egger D, Davies P, Mechbal A. 2003. Towards better stewardship: concepts and critical issues. In: Christopher JM, Evans DB, editors. Health Systems Performance Assessment: Methods, Debate and Empiricism. Copenhagen: WHO Regional Office for Europe. Retrieved from http://www.who.int/health_financing/documents/cov-hspa/en/

- Twesigye G, Islam Z, Taluker L, et al. 2017. SIAPS Technical Brief. Strengthening governance in procurement in Bangladesh. Arlington, VA: Management Sciences for Health. Retrieved from http://siapsprogram.org/publication/altview/strengthening-governance-in-procurement-in-bangladesh/english/

- UNDP. 1997. Governance for Sustainable Human Development: A UNDP Policy Document. NY: United Nations Development Program.

- UNESCAP. 2009. What is Good Governance? Bangkok, Thailand: United Nations Economic and Social Commission for Asia and the Pacific. Retrieved from http://www.unescap.org/sites/default/files/good-governance.pdf

- United Nations. 2016. Sustainable Development Goals. NY: United Nations. Retrieved from https://sustainabledevelopment.un.org

- USAID. 2015. USAID's Vision for Health Systems Strengthening. Washington, DC: United States Agency for International Development. Retrieved from https://www.usaid.gov/sites/default/files/documents/1864/HSS-Vision.pdf

- USAID. 2016. USAID Learning Lab. Washington, DC: United States Agency for International Development. Retrieved from https://usaidlearninglab.org/faq/collaborating-learning-and-adapting-cla

- Wagner AK, Quick JD, Ross-Degnan D. 2014. Quality use of medicines within universal health coverage: challenges and opportunities. BMC Health Services Research 14:357. doi: 10.1186/1472-6963-14-357

- Wirtz VJ, Hogerzeil HV, Gray AL et al. 2017. Essential medicines for universal health coverage. The Lancet 389(10067), 403-476. Retrieved from: http://dx.doi.org/10.1016/S0140-6736(16)31599-9

- WHO. 2007. Everybody's Business–Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action. Geneva: World Health Organization. Retrieved from http://www.who.int/healthsystems/strategy/everybodys_business.pdf

- WHO. 2013. Good Governance in the Pharmaceutical Sector. Geneva: World Health Organization. Retrieved from http://www.who.int/medicines/areas/governance/EMP_brochure.pdf?ua=1

- WHO. 2015. Pharmaceutical sector governance: critical to universal health coverage. Geneva. World Health Organization. Retrieved from http://www.who.int/medicines/areas/policy/goodgovernance/pharm_sect_critic-uhc/en/

- WHO. Full List of WHO Medical Product Alerts (as of March 2018). Retrieved from http://www.who.int/medicines/publications/drugalerts/en/

- World Bank. 2017. World Development Report 2017: Governance and the Law. Washington, DC: World Bank. doi:10.1596/978-1-4648-0950-7.