Enhancing Health Outcomes for Chronic Diseases in Resource-Limited Settings by Improving the Use of Medicines

The Role of Pharmaceutical Care
About SIAPS

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

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Introduction

In low- and middle-income countries (LMIC), health systems have historically focused on the prevention and treatment of highly prevalent and frequently fatal acute infectious illnesses such as malaria, diarrhea, and respiratory infections. However, due to changes in health risks, LMIC are experiencing an increasing burden of chronic non-communicable diseases (NCDs) in addition to the existing problems of infectious diseases. These countries and their technical partners, such as the World Health Organization (WHO), have recently highlighted the importance of giving more attention to chronic NCDs such as diabetes, cancer, and cardiovascular and chronic respiratory diseases. In 2008, over 80 percent of the 17 million cardiovascular and 1.3 million diabetes deaths worldwide occurred in LMIC, together with nearly 90 percent of deaths caused by chronic obstructive pulmonary disease. In all but the lowest-income countries, NCDs are already the leading cause of death. WHO projects that by 2030 NCDs will be the most common cause of death in the African region.

Various approaches are needed to reduce the burden of NCD-related morbidity and mortality in LMIC. These include reducing risk factors associated with lifestyle, such as unhealthy diet and tobacco use; preventing the occurrence of these diseases, as well as facilitating early diagnosis; and providing appropriate care. WHO has identified the integration of essential NCD interventions into primary health care as a key strategy to support early diagnosis and timely treatment of these diseases in LMIC. However, patient care systems at the primary and higher levels of care will need substantial modification and strengthening to deliver these interventions effectively. Health systems need to adopt different approaches to service delivery that place the patient at the center of care and emphasize interdisciplinary coordination and performance monitoring. Patient care strategies that include routine appointments, accessible and detailed documentation of patient history, and treatment adherence monitoring will be needed. Linkages outside the health care facility, including family engagement and community support, communication, and outreach, will require strengthening.
Pharmaceutical services will also have to change to better support primary prevention programs and chronic disease management in ways that are appropriate to the economic and social environments of low-resource settings. The availability of affordable, quality medicines is essential for the treatment and control of many chronic diseases, including diabetes, cardiovascular diseases, asthma, mental health disorders, and also HIV and AIDS. However, to achieve desired health outcomes, access to pharmaceuticals needs to be combined with the provision of quality care and services. Inappropriate prescribing, inadequate instructions, adverse drug reactions (ADRs), and poor patient adherence can all potentially compromise the desired outcomes of pharmacotherapy. Beyond the dispensing or supply of pharmaceutical products, staff providing pharmaceutical services will need to work with other members of the health care team to deliver patient-centered services. These services include pharmaceutical care activities, which focus on the responsible provision of medication-related care to patients to prevent, identify, and resolve medicine-related issues that may decrease intended benefits.

The US Agency for International Development (USAID)–funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program has developed this paper to provide USAID health program managers, country counterparts (ministries of health, policy makers, educators, professional associations, health care managers, and providers), and other stakeholders with an understanding of how this approach to introduce and expand the delivery of pharmaceutical care can support the achievement of desired health outcomes for chronic diseases. The paper also outlines the SIAPS operational approach to strengthening the practice of pharmaceutical care in resource-constrained settings through building institutional and individual capacity in pharmaceutical systems and identifying appropriate roles for staff who provide medicines or medication-related services at each level.

**From Access to Medicines to Patient Care**

In 1978, the Alma-Ata Declaration called for improved access to essential medicines as one of the pillars for the provision of primary health care. Since then, various government and nongovernmental organizations, with support from international organizations, have worked to reform pharmaceutical management systems in LMIC to improve medicine availability. These activities focused largely on medicine supply systems, primarily the selection, procurement, distribution, and use of a list of essential medicines that satisfy the priority health care needs of a country’s population. In the last decade, efforts by countries to scale up their HIV, tuberculosis (TB), and malaria programs with the support of international initiatives, such as the President’s Emergency Plan for AIDS Relief, the President’s Malaria Initiative, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, have continued to direct attention to supply chain issues. However, increased access to essential medicines in these programs has highlighted the need to ensure that available products are used optimally. Medication-related challenges such as inadequate adherence to complex antiretroviral therapy (ART) and TB treatment
regimens, emerging drug resistance, and the impact of preventable ADRs have underscored the need to expand pharmaceutical services beyond the provision of medicines to incorporate patient-oriented services that help to achieve desired treatment outcomes and protect patients from harm.9–11

Medication-related problems may include under- or overtreatment, inappropriate dosing or choice of formulation, poor adherence, and harm caused by adverse drug events, which are harmful clinical events directly related to the use of medicines. Adverse drug events can be due to medication errors (in prescribing, dispensing, administering, or taking the medicine) or pharmacological properties of the medicine—known or unknown—that cause ADRs or drug interactions. Evidence on the extent of medication-related problems comes mainly from industrialized countries. For example, in the European Union (EU), ADRs are estimated to cause 197,000 deaths per year and represent the fifth-leading cause of death among hospitalized patients.12 The total annual costs of ADRs in the EU amount to as much as 79 billion euros.12 In 2007, the US Institute of Medicine estimated that at least 1.5 million preventable adverse drug events occur annually in the United States and that in hospitals alone, the increased costs of such preventable events could be as much as 3.5 billion US dollars (USD) for the nation per year.13 A recent study estimated the costs of nonadherence to medications used for diabetes, hypertension, and dyslipidemia in the United States to be USD 105.8 billion per year.14

The cost of preventable medication-related problems in terms of lives and money is great in high-income countries. Although documented evidence is lacking because of weak monitoring and reporting systems, the situation is likely to be much worse in LMIC due to weak health systems and shortages of trained staff, with these problems most often affecting the most vulnerable citizens. Investments in improving access to medicines through multiple global initiatives should be complemented by commensurate investments to promote their appropriate use. Emerging drug resistance to antiretroviral (ARV), antituberculosis, antimalarial, and other anti-infective medicines is another important concern that warrants efforts to implement interventions that preserve the effectiveness of medicines. Moreover, with donor resources diminishing because of the global economic slowdown and increased calls for using existing resources more efficiently,15 countries need to implement interventions that can reduce unnecessary or inappropriate use of medicines and preventable hospital admissions. For universal health coverage (UHC) to include medicines and to keep financing mechanisms such as insurance schemes financially viable, it will be crucial that countries effectively manage the medicines benefit component of UHC to contain costs and reduce inefficiencies and inappropriate use.16
Pharmaceutical Services for Chronic Care

Pharmaceutical services include all medication- and pharmacotherapeutic-related services that support the provision of patient care and treatment for both acute and chronic conditions. Beyond the selection, procurement, and distribution of pharmaceutical products, pharmaceutical services include the dispensing and supply of pharmaceuticals to individuals—whether or not by prescription—together with the provision of medication-related information and counseling and support for self-care. Other services include activities to ensure the safe, appropriate, and cost-effective use of pharmaceuticals, including preserving the effectiveness of medicines and monitoring medicine use to ensure the achievement of desired health outcomes; and activities to promote public health and prevent disease. The governance, organization, and management of pharmaceutical services include the formulation and implementation of policies and legislation, the establishment of appropriate organizational structures, the allocation and management of financial resources, the implementation of systems and processes, and the deployment of human resources to support the supply, control, and use of pharmaceuticals. The education and training of staff, and the conducting of research, are important crosscutting components of pharmaceutical services (figure 1).

As some of the most accessible providers of health care in the community, pharmacy workers and others who may legally dispense medicines are well placed to provide

**FIGURE 1.**
Elements of pharmaceutical services
Source: Center for Pharmaceutical Management, Management Sciences for Health, 2013
a variety of patient care services to support public health and chronic disease programs. Depending on their knowledge, skills, and level of practice, activities of health care workers who provide medicines and related services to support chronic care may include—

- **Providing information and advice to promote health and healthy lifestyle changes** that can prevent or ameliorate diseases; participating in public health campaigns; and promoting, providing, or referring patients for health screening—for example, for diabetes, hypertension, or HIV infection

- **Selling or providing medicines for self-care**—for example, painkillers for palliative care; providing information and advice to support appropriate decision making and use; and referring patients to other practitioners as needed

- **Checking and filling prescriptions** for chronic conditions or supplying medicines according to a protocol, such as for community-based home care; providing instructions and basic counseling to patients and caregivers to ensure appropriate use; and referring patients to other services as needed

- **Providing pharmaceutical care to individuals** to identify and prevent or resolve medicine-related issues that may potentially affect intended benefits of pharmacotherapy for chronic conditions; collaborating and coordinating care with other members of the health care team

- **Advising and educating communities, peer educators, and population groups** on the safe and appropriate use of medicines and devices, such as the importance of good treatment adherence for chronic conditions, preserving the effectiveness of medicines such as ARVs, proper storage of medicines, and disposal of unwanted products; performing medicine use audits to identify common issues in their community or in certain population groups

### What Is Pharmaceutical Care?

Pharmaceutical care was initially defined as “the care that a given patient requires and receives which assures safe and rational drug usage.” More recent definitions have included concepts such as the achievement of desired health outcomes, direct interactions with patients, and practitioner accountability. Although not conceived as solely the pharmacist’s responsibility, pharmaceutical care was seen as an opportunity for the pharmacy profession to move from a predominantly product-focused approach to a more patient-centered practice that concentrates on reducing preventable medication-related morbidity and mortality. In some definitions, the pharmacist and pharmacy practice are placed at the center of the concept, which assumes there are adequate numbers of pharmacists; however, this is not the case in many LMIC, particularly in rural areas. SIAPS uses the following definition based on Hepler and Strand’s widely accepted definition, published in 1990:
**Pharmaceutical care** is the responsible provision of medication-related care designed to achieve health outcomes aimed at improving and/or maintaining a patient’s quality of life.

Pharmaceutical care is therefore a patient-centered, outcomes-oriented practice. The activities of pharmaceutical care focus on identifying and preventing or resolving medication-related problems that occur to improve health outcomes and, ultimately, to enhance or at least maintain a patient's quality of life. The pharmaceutical care process involves directly interacting with a patient or caregiver, applying an individualized yet structured process to identify interventions, and following up on the patient’s health outcomes. Intended benefits include improved disease prevention and control and reduced medication-related morbidity and mortality.

In many developed countries, the orientation of professional pharmacy practice has shifted from the sale or dispensing of medicines to the provision of patient-oriented services that support better health care and the achievement of planned health outcomes. Early examples of this shift include the practice of clinical pharmacy, where pharmacists use their specialized knowledge and skills to assist physicians to better manage pharmacotherapy for their patients. Clinical pharmacy, which started in the hospital setting, can be considered a foundation for the development of pharmaceutical care. However, pharmaceutical care activities go beyond optimizing medicine therapy to focusing on achieving desired health outcomes and hence improving or maintaining a patient's quality of life. Following its reorientation to clinical pharmacy and patient-centered care, the pharmacy profession adopted the concept of pharmaceutical care and has been foremost in advocating for its implementation as part of pharmacy practice. The American Society of Health-System Pharmacists and the UK Clinical Pharmacy Association are among the professional associations that have developed statements on pharmaceutical care. The International Pharmaceutical Federation (FIP) also developed a statement on professional standards for pharmaceutical care in 1998, and more recently, adopted a statement on the role of the pharmacist in chronic disease management that includes pharmaceutical care.

Changes in pharmacy practice and advocacy for the transition to pharmaceutical care were influenced by studies that documented the substantial consequences of preventable medication-related problems in developed countries. In these countries, the positive impact of pharmacist-delivered patient care services on disease outcomes and the contribution to cost containment, access to care, and patient safety have been illustrated in a variety of settings and disease programs. A
systematic literature review that evaluated the effect of care provided by pharmacists to patients with heart failure found that interventions such as information to patients, medicine education, and support for adherence were associated with significant reductions in the rate of all-cause and heart failure hospitalizations. In another review, pharmacist interventions, including patient education and medication management, were shown to reduce risk factors and behaviors for coronary heart disease, contributing to significant reductions in both total and low-density lipoprotein (LDL) cholesterol. Authors of a meta-analysis of 13 studies showed that pharmacist-led interventions such as hypertension education and medication management were associated with significant decreases in systolic blood pressure. A study in HIV clinics in the United States reported that the involvement of clinical pharmacists, for example, in counseling patients on regimens and medicines and ADR management, contributes to positive clinical outcomes in patients starting ART, particularly in economically disadvantaged areas. Other studies have demonstrated positive benefits of pharmaceutical care interventions in asthma and diabetes, as well as in health service efficiency and cost containment. Even in a resource-limited setting (Nigeria), improved quality of life has been associated with a pharmaceutical care program among patients receiving treatment for hypertension at community pharmacies. Although these interventions have shown promising results, the provision of pharmaceutical care by pharmacists is not yet standard practice in most settings.

The practice of pharmaceutical care takes different forms in different parts of the world. The original concept is based on a comprehensive approach where a documented care plan is developed. In this approach, all medication-related patient needs are considered and interventions prioritized to achieve specific health outcomes. In some European countries, disease-oriented pharmaceutical care programs have been implemented in community pharmacy, where pharmacists provide specific services; for example, adherence counseling or routine monitoring of patients with diabetes or hypertension. In some ART programs in LMIC, health care workers follow structured processes for counseling on and monitoring ART adherence. Other patient care initiatives focus on specific medication issues, such as promoting safety and protecting the patient from harm caused by drug interactions or ADRs associated with certain high-risk medicines.

Approaches for the provision of medication-related care by pharmacists and other health workers authorized to dispense or supply medicines must be adapted for different situations, levels of practice, and priorities. In many LMIC, the scarcity of pharmacists limits the potential for pharmacist-provided services. Ethiopia, Rwanda, Tanzania, Uganda, and Zambia each have three or fewer pharmacists per 100,000 people, whereas the United States has 88 pharmacists per 100,000 people. Moreover, pharmacists tend to be concentrated in the private sector and in urban areas. For example, in Uganda, 90 percent of pharmacists are located in just one of four regions of the country. Given these workforce constraints, innovative approaches that do not depend on the availability of pharmacists will be needed. Other cadres of pharmacy workers include pharmacy technicians (also called technologists), who
usually complete a government-recognized training course, and assistant pharmacy staff, who receive a short period of on-the-job training to assist pharmacists in the routine work of dispensing and managing medicines. Pharmacy technicians make up the largest group of trained pharmacy personnel in many countries, and in places where pharmacists are scarce, they are frequently put in charge of managing pharmacies without pharmacist supervision. In many resource-constrained settings, nurses are integral to health care delivery in the public sector and often dispense medicines. Medicines are also provided by community health workers as part of community case management for diarrhea, malaria, and pneumonia. In many LMIC, people obtain medicines from private or community pharmacies, drug shops, and drug peddlers, as well as from government hospitals and clinics. In some settings, especially in rural or periurban communities, retail drug shops—not pharmacies—may be the only nearby place where people can access medicines and health advice on common illnesses, such as malaria.

King and Fomundam published an illustration of how the pharmaceutical care approach can be applied in sub-Saharan Africa to support HIV and AIDS management. With appropriate training and health system support, such as referral mechanisms, the authors propose that other health care workers can potentially participate in pharmaceutical care practices, with lower cadres working under a pharmacist's supervision. With the move to integrate essential chronic care services into primary health care, pharmaceutical care will need to move beyond activities performed by pharmacists, especially in countries where they are few. Elements of pharmaceutical care could be provided by all health care providers involved in supplying medicines to treat chronic diseases at all levels of the health care system, in both the public and private sectors. For this to occur, models of practice need to be developed that define circumstances under which health care workers who dispense or sell (prescription and nonprescription) medicines can provide elements of pharmaceutical care. Important components of these new models will include mechanisms for referral to health care professionals, including pharmacists, and systems for the provision of supportive supervision. For example, an intervention in Peru that improved pharmacy workers' recognition and syndromic management of sexually transmitted infections included the establishment of a referral network of physicians and health centers and supportive follow-up visits. In situations where outlets such as drug shops are included in the approach to providing medication-related care, adequate regulatory controls and monitoring will be essential to protect the public's health. The role of pharmacists will also need to be redefined to enable them to focus on more specialized functions and provide technical oversight and support to other workers who supply medicines for chronic diseases.
Providing Pharmaceutical Care in Resource-Limited Settings

The Pharmaceutical Care Process

Pharmaceutical care involves the identification and prevention or resolution of medication-related concerns. Key functions include assessing the need for pharmaceutical care; identifying and implementing interventions, which may include referral to other practitioners and services; and monitoring and follow-up (figure 2). Potential pharmaceutical care interventions can be broadly grouped into those that—

- Help verify that pharmacotherapy is effective and appropriate, and that untreated indications are addressed
- Improve safe medicine use by preventing, detecting, and mitigating drug interactions, adverse drug events, and medication errors
- Enhance patient knowledge by providing medicine-related information, counseling, and education to patients and caregivers
- Encourage adherence to medication and continuation of pharmacotherapy

Elements of pharmaceutical care can be provided by appropriately trained staff in public and private hospitals and health care facilities, pharmacies, and drug shops. Some pharmaceutical care elements can also form part of community services; for example, where community health workers provide home-based care to patients with chronic diseases. The outcomes of pharmaceutical care should be the achievement of therapeutic goals, the prevention or reduction of medicine-related problems, reduced morbidity and mortality, and improved quality of life for the patient. Pharmaceutical care does not exist in isolation from other types of health care.

**Figure 2.**
The pharmaceutical care process
Adapted from WHO/FIP 200647
care services. Efficient coordination, collaboration, and timely communication among providers of health care (pharmacists, nurses, clinicians, and other pharmacy personnel and health care workers), across various health care services in both the public and private sectors are essential for realizing the common goal of pharmaceutical care.

By applying a systematic process for the provision of pharmaceutical care, appropriately trained health care workers can better assess an individual’s needs, prevent or manage issues that may affect the intended benefits of pharmacotherapy, and enhance follow-up care. Figure 2 illustrates the four steps in the pharmaceutical care process. The way that the process is applied as part of chronic care will depend on the health care worker’s knowledge, skills, and level of practice. Local priorities—which may focus on specific chronic diseases, population groups, and medication-related issues—and available resources will also influence implementation. To be effective, patient-centered activities must be evidence-based and integrated into patient care systems and processes at each level. In resource-constrained settings, health care workers in the public sector are few and demand for services is often high. At the primary health care level, dispensing medicines is only one of many tasks that pharmacy staff—or more often, nurses—perform. At each practice level, the selection of clients to target, and the pharmaceutical care activities to provide, should be based on an evaluation of cost-effectiveness, feasibility, and relevance.

For pharmacy technicians and assistants, nurses, drug sellers, and community health workers, as well as some pharmacists, highly structured, protocol-directed approaches will be important to guide practice and complement training. Examples of such approaches include protocols for identifying patients to select for referral for or provision of pharmaceutical care and guidelines to direct medicine selection and advice for self-care. Protocols and algorithms to guide disease-oriented pharmaceutical care interventions are useful at all levels but need to be reevaluated periodically as clinical practice evolves.

The pharmaceutical care process illustrated in figure 2 comprises the following steps—

- **Assess the need for pharmaceutical care.** This step is essential to ensure that efforts and resources are directed to those patients who are likely to derive the most benefit. In some settings, such as an intensive care unit, these will be all patients. In other situations, specific patient populations, such as children or the elderly or patients with specific chronic diseases, medication-related issues, or those taking high-risk medicines, may be targeted. Pharmaceutical care interventions may also be provided at the request of an individual; for example, for self-care, or for patients who are referred by other health care workers. Algorithms can be helpful to guide patient selection or referral, as can findings of local medication use evaluations, prescription or clinical audits, and medical record reviews.
- **Identify medication-related issues and interventions.** Once need is established, the health care worker talks with the patient or caregiver to ascertain and prioritize the patient’s actual or potential medication-related issues and then identifies the appropriate intervention(s). For targeted care, providers can use protocols based on standard treatment guidelines (STGs) to direct the specific interventions, such as routine monitoring of diabetic patients at community pharmacies or promoting ART adherence in individuals at primary health care facilities. In comprehensive approaches, the pharmacist, physician, or other health care worker may perform an individualized medicine use review to identify all the patient’s medication-related issues and develop a care plan, usually in conjunction with or with approval from other members of the health care team. Pharmaceutical care plans typically describe each medication-related issue and its priority, the therapeutic objectives of care, proposed actions or interventions required, and plans for monitoring and follow-up.47

- **Implement interventions.** With the agreement of the patient or caregiver and other members of the patient’s health care team, the interventions are implemented. Examples of interventions that can support care for patients with chronic diseases are outlined in the next section.

- **Monitor and review interventions and therapeutic outcomes.** The final step is to follow up on pharmacotherapy interventions and outcomes, which includes assessing the need for further care or referral.

Pharmaceutical care is in effect a continuous quality improvement (CQI) process for the use of medicines. In reality, the process will not be completed for all patients; for example, clients who purchase medication for self-care may not be seen again by the health care worker who provided the initial care. Also, at any point in the process, the patient may be referred to other practitioners for further care or other services.

Reporting and documentation need to happen at all stages of the process and are essential for communication among care providers. Adverse events such as ADRs and medication errors must be reported to local or national pharmacovigilance and incident reporting systems, where applicable. Documentation of the care plan or of medication issues identified, decisions made, and actions planned or taken is crucial for continuity of care for patients with chronic diseases. This documentation should ideally form part of the patient’s medical record but may be an independent record. At the simplest level, it may involve annotating the prescription with actions planned or taken or writing a note when referring an individual to another practitioner.
Pharmaceutical Care Interventions for Patients with Chronic Diseases

Supporting Product Selection and Verifying Therapy Is Effective and Appropriate: Illustrative Interventions

Incorrect selection of medicines and over- and undertreatment are common problems in LMIC and contribute to poor patient outcomes as well as the development of drug resistance to important anti-infective medicines. In resource-limited settings, health care workers who provide medicines or related services can take a number of actions to verify that patients with chronic diseases receive the correct dose and appropriate form of a medicine that is effective and indicated, as well as identify untreated indications.

Examples of pharmaceutical care activities include—

- Following or promoting adherence to STGs, essential medicines lists (EMLs), formularies, and local protocols when prescribing or initiating treatment or participating in therapy decisions for individual patients.

- When dispensing medicines, reviewing prescriptions to verify prescriber adherence to the approved guidelines and checking that doses and formulations prescribed are appropriate, especially for infants, children, and the elderly; taking appropriate action to address any discrepancies such as contacting the prescriber. Useful job aids include posters or charts that describe recommended regimens and dosing tables that help dispensers calculate or verify doses; for example, for pediatric ART, to ensure that doses are correctly adjusted as children grow.

- Maintaining patient-specific information, including a medication history that is readily retrievable and updated, to facilitate patient follow-up and support subsequent clinical decision making.

- Supporting self-care by eliciting relevant information from the client and suggesting an appropriate medicine as well as the correct dose, or nonmedicinal therapy, as needed; for client-initiated purchases, checking that the requested medicine is indicated and referring the person to the appropriate health facility for care beyond the provider’s scope.

- Reviewing the patient’s medicine regimen to identify medicines that interact, are ineffective, duplicative, not indicated, or are being used to treat a preventable ADR; working with the patient’s health care team to resolve identified problems, initiate treatment, or refer patients with untreated indications for further care.

- Monitoring the outcomes of pharmacotherapy by, for example, ordering and interpreting laboratory tests or tracking clinical measurements such as blood pressure. At higher-level facilities, activities may include providing more
clinical services, such as pharmacokinetic consultations to optimize dosing of selected medicines.

- Providing disease management services for chronic diseases such as diabetes, asthma, epilepsy, or hypertension. In addition to preventing or managing medication-related problems, activities can include helping the patient to make lifestyle changes; for example, tobacco cessation.

**Improving Safe Medicine Use: Illustrative Interventions**

Medication errors, ADRs, and drug interactions are all major sources of avoidable risk to patient safety. Often, medication errors and drug interactions occur because the complete medication history of the patient is not known or is not considered when new medicines are prescribed and dispensed. In LMIC, health care delivery is often fragmented and the patient may have a number of health care practitioners providing treatment concurrently for different health problems, resulting in separate or incomplete records. Individuals may use complementary medicines or purchase nonprescription preparations before seeking treatment without disclosing use of such remedies to the health care provider. Moreover, prescribers may lack access to up-to-date information on potential drug interactions or adverse effects of medicines. A number of actions can be taken at the service-delivery level in resource-limited settings to prevent adverse drug events. These activities build on national or local pharmacovigilance, drug information, and quality improvement programs. Examples include systems for monitoring, reviewing, and reporting adverse events to identify and eliminate causes and prevent recurrence, and standardization of prescription writing or prescribing rules to reduce medication errors.

Examples of patient-centered point-of-care interventions include—

- **When dispensing medicines or supporting safe self-care,** advising patients on potential drug-drug or drug-food interactions and actions to prevent or manage ADRs, including when to seek assistance, and referring patients for management of an ADR when needed. Tools for health care workers may range from simple job aids, such as patient counseling materials that focus on key messages for certain medicines, to software programs such as computer-generated drug interaction detection systems. Tools must be appropriate to the level of practice and should focus on the most commonly used high-risk medicines.

- **Monitoring for safety issues when participating in therapy decisions or initiating treatment** (whether by prescription or protocol) and reviewing prescriptions or counseling patients; advising on or taking actions to prevent or manage adverse events or referring patients for care as appropriate. In addition to the tools mentioned above, protocols are useful to guide prescribing or health worker–initiated care. Some pharmacies maintain profiles for patients receiving treatment for chronic illnesses and use these to cross-check prescription refills for discrepancies or monitor for potential drug interactions.
• Ordering, interpreting, and monitoring laboratory tests to identify ADRs.

• Implementing medication use evaluations for medicines associated with a high incidence of medication errors, ADRs, or drug interactions. A recent US study found that 67 percent of adverse drug event–related emergency hospitalizations of adults 65 years and older were caused by warfarin, oral antiplatelet medications, insulins, and oral hypoglycemic agents. Identifying a small set of relevant high-risk medicines to monitor based on local studies could be an effective way to target care.

• Supporting the continuity of care during patient transfers by conducting hospital admission interviews and discharge planning, and communicating with other health care professionals to reduce the risk of medication errors and drug interactions; and by taking medication histories that include complementary remedies and reviewing medicine use to reduce the use of duplicative medicines. Providing job aids for taking a medication history and equipping pharmaceutical care providers with medication history interviewing skills are important to support these activities.

• Educating patients on the appearance (color, shape, and size) of their medicines can help prevent medication errors and empower patients, and is an important yet relatively inexpensive intervention. Some countries provide patients with their own records or “health passports” that patients carry when they visit different health facilities, making it easier for providers to consult and update patients’ medication history.

Enhancing Patient Knowledge: Illustrative Interventions

Low levels of education and literacy may mean that individuals know very little about recommended medicine use, potentially leading to misuse and abuse. Studies in Ethiopia found that practices such as sharing medicines and using them for indications other than as recommended are common. Low literacy can also limit or prevent patients from engaging fully in the care process.

Examples of activities to enhance patient knowledge in resource-limited settings include—

• Educating individuals about their medicines. Basic medication counseling is often the first step in providing pharmaceutical care. For some providers, such as trained drug sellers, providing counseling and protocol-guided advice for self-care, educational materials, or referral to other practitioners may comprise their total contribution to pharmaceutical care. Monitoring to identify ADRs, treatment adherence problems, or other issues that may impact on therapy outcomes is another important component of counseling.

• Counseling on responsible self-medication, including advising the client if a medicine is not warranted.
- Providing health and treatment literacy materials. Appropriate relevant patient literacy materials can enhance the effectiveness of patient care by educating the patient about their chronic diseases, medicines, and the rationale for providing treatment. In Namibia, the Ministry of Health and Social Services (MoHSS) developed a package of treatment literacy tools to standardize ART medication counseling and support task shifting (Box 1). Pharmaceutical care providers often display or distribute health promotion and disease prevention materials on lifestyle factors such as weight management or smoking cessation, as part of disease management services for chronic diseases.

- Issuing patient information leaflets targeting specific medicines for which there may be adherence problems or risk of abuse, misuse, or ADRs. If a device, such as an inhaler, is provided, education includes ensuring that the patient can use the device correctly.

**Encouraging Adherence and Therapy Continuation: Illustrative Interventions**

A number of measures can improve or maximize adherence and help patients continue therapy as a component of pharmaceutical care in resource-limited settings.

These include—

- Developing and maintaining a partnership (sometimes called a therapeutic alliance) with the patient for ongoing care.
- Providing adherence counseling that takes into account the patient’s sociocultural factors, intellectual perspectives, beliefs, and values. Medication

**Box 1. Educating Patients on Antiretroviral Therapy: The Namibia Treatment Literacy Approach**

As a result of the rapid expansion of Namibia’s ART services—from 800 ART patients in 2004 to 42,000 in 2007—public health facilities experienced a steep increase in the number of patients requiring education and counseling for ART initiation and ongoing therapy. To assist health care staff in meeting this challenge and support task shifting to nonmedical workers, such as community counselors, the MoHSS recognized that Namibia needed to develop a standardized approach to educating and empowering patients to prepare for lifelong ART. In 2008, the USAID-funded Strengthening Pharmaceutical Systems (SPS) Program and SPS’s partner BroadReach helped the MoHSS to develop a package of treatment literacy materials and pilot them to verify their appropriateness. The integrated audiovisual materials that form the standardized treatment literacy approach (TLA) consist of a pictorial storytelling flipchart used by counselors for group education, a video that features patient testimonials on ART, and posters that are used to reinforce messages in the flipchart and video. The four patient testimonials in the video cover topics on preparing to start ART, starting ART, alcohol and ART adherence, and long-term adherence to ART. An evaluation of the TLA conducted in 2009–10 with support from SPS showed that the TLA was effective in educating patients on ART and reduced the time health workers spent educating patients. The approach standardizes messages provided to patients about ART by health care workers, including doctors, nurses, pharmacists, and pharmacy assistants, as well as community counselors who provide pre-ART counseling. The SIAPS Program is now helping the MoHSS roll out the materials nationwide.

Source: Kalemeera et al. 2011.51
guidelines that are flexible and easily adaptable to the needs of the individual are helpful. Job aids such as medication counseling checklists help ensure that dispensers cover the key points when counseling individuals taking chronic medicines such as ART.

- Distributing appropriate health and treatment literacy materials to reinforce medication adherence messages delivered during counseling or education sessions.
- Assessing adherence to medicine therapy using validated tools and methods. In resource-constrained settings, appropriate approaches may include patient recall and pill count methods, as well as monitoring pharmacy refill records and appointment keeping.
- Identifying and following up on patients who miss pharmacy appointments for refills of medicines for chronic conditions.
- Helping individuals address barriers to adhering to or continuing treatment and referring them to other practitioners as needed; focusing counseling messages on the identified barriers and creating an environment that enables patients to find ways to surmount them.
- Implementing suitable medication adherence aids and devices, use of cell phones for promoting medication adherence, reminder systems, and other approaches. These may include tools such as pill boxes or organizers, medication calendars, calendar refill stickers, medication diaries, or watch or cell phone alarms.

Foundations for the Provision of Pharmaceutical Care

Various policies, structures, systems, and programs at the national or local level create a foundation for the provision of pharmaceutical care. Some important examples are set out below.

- **EMLs, formularies, and STGs and protocols** provide the norms and standards used to guide provider-initiated treatment, prescription reviews, and medication use evaluations.
- **Pharmacy and Therapeutics Committees** implement medicine use studies and reviews to characterize medicine use patterns within a particular setting. In addition to implementing strategies identified by these committees to address specific issues, health care providers may contribute information to and participate in committee decision making at the local level.
- **Pharmaceutical supply systems** enable access to essential medicines and supplies listed in STGs, formularies, and essential medicines lists that are needed to support the delivery of patient care.
- **Pharmacovigilance systems** identify, collate, analyze, and report suspected adverse drug-related events to determine risks and take appropriate action to mitigate, prevent, and communicate risks. Health care providers submit ADR reports, participate in active pharmacovigilance surveillance activities, and
in turn receive the information they need to advise health care workers and patients on minimizing preventable ADRs and drug interactions.

- **Public health surveillance and disease programs** identify issues affecting the health of the population and develop strategies to promote health and manage diseases of concern. In addition to supporting health promotion campaigns, pharmaceutical personnel may participate in national or local disease management initiatives.

- **Quality improvement and clinical governance programs** underpin the pharmaceutical care process. These programs also support system-wide approaches to monitoring and reporting suspected adverse events designed to help identify and eliminate causes of medication errors and prevent their recurrence. In addition to reporting suspected errors, health care workers who provide medicines and related services implement system-wide procedures to further the safe use of medicines.

### Implementing Pharmaceutical Care in Resource-Limited Settings: Key Enablers

Experiences from industrialized countries indicate that successful implementation of pharmaceutical care requires organizational, attitudinal, and functional rearrangement and reorientation of the existing health care system, as well as the strengthening of management skills. In many cases, pharmaceutical care will not be a totally new approach requiring substantial additional resources, but will rather involve a process of reorganizing what already exists. Several factors have enabled the introduction of pharmaceutical care services in industrialized countries. The factors that are anticipated to facilitate implementation in LMIC—policies and legislation, workforce capacity, service delivery systems, information systems, leadership, financing, and practice research—are discussed below.

### Policies and Legislation

Policies, laws, and regulations that define the roles, competencies, and scopes of practice of health care professionals, as well as the standards with which facilities must comply to deliver pharmaceutical care services, all determine how pharmaceutical care will be provided in a particular setting. Competency requirements provide the basis for pre-service education and training of pharmacists and other staff. Scopes of practice influence decisions on changes needed to enable health care workers to provide elements of pharmaceutical care. These changes may include the redesign of service delivery systems, access to patient medical records, resource allocation, and remuneration for the provision of pharmaceutical care by providers in the private sector. Accreditation mechanisms for providers such as drug shop attendants who meet certain education and training standards, coupled with expansion of legal access to a limited list of basic prescription and nonprescription medicines, can enable the provision of some elements of pharmaceutical care in communities.
with limited access to pharmaceutical services.\textsuperscript{52} Box 2 describes Management Sciences for Health’s (MSH’s) work with the Government of Tanzania to establish the Accredited Drug Dispensing Outlet (ADDO) program.

**Workforce Capacity**

Experience in industrialized countries has demonstrated that a competent, responsive, and committed workforce is key to successful implementation of pharmaceutical care initiatives. In LMIC, training, adequate staffing levels, and access to up-to-date medicine information have all been identified as essential requirements for expanding the patient care role of pharmaceutical staff in ART service delivery.\textsuperscript{54} A study of factors associated with attrition from HIV treatment

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**Box 2. Drug Shop Accreditation in Tanzania: Contributing to Better Patient Care**

In rural and periurban areas in Tanzania where registered pharmacies are few or nonexistent, many people obtain medicines and request health care advice at local retail drug shops. Although these vendors were authorized by the Tanzania Food and Drugs Authority (TFDA) to sell only nonprescription medicines, a 2001 assessment conducted by MSH’s Strategies for Enhancing Access to Medicines (SEAM) Program in collaboration with the TFDA found that many drug shops also sold prescription medicines illegally. It also revealed that drug sellers often had no health training or professional oversight, putting their customers at risk of receiving inappropriate or unsafe treatment and incorrect advice. In 2003, the SEAM Program, working with the Tanzanian Government, launched the ADDO program to improve access to affordable, quality medicines and pharmaceutical services in areas where registered pharmacies are scarce. In addition to establishing mechanisms for government accreditation and oversight, strengthening local regulatory and inspection capacity, and generating business incentives, activities included improving drug seller behavior through training, education, and supervision. Marketing and public education were also used to increase customer demand for quality products and services and raise awareness about the benefits of adhering to treatment. By the end of the SEAM Program, in 2005, more than 150 shops had been accredited in the Ruvuma region, and the pilot evaluation confirmed that the ADDOs could improve access to quality medicines and pharmaceutical services. Following the government’s decision in 2006 to roll out the program nationwide, ADDOs have been implemented in all mainland regions, with about 4,600 outlets accredited and almost 12,000 dispensers trained. These shops are increasingly recognized as a platform for strengthening community-based health care initiatives, such as child health, family planning, and maternal and reproductive health, and for providing education and testing referrals, such as for HIV.

As well as achieving and maintaining a defined set of knowledge, skills, and competencies to achieve accreditation, ADDO dispensers are expected to apply a client-centered approach in line with their new role. Dispenser responsibilities include filling a prescription, or for self-care, listening to symptoms and providing appropriate advice, which may include providing a medicine, advising if a medicine is not warranted, or referring the client for care beyond the scope of ADDO services. If a medicine is dispensed or sold, the dispenser is expected to provide the customer with instructions on how to take the medicine correctly and ensure that the customer understands the instructions. ADDOs are permitted to sell selected prescription medicines, including medicines to treat common infections and medicines for chronic conditions such as high blood pressure and asthma. Other services may include recommending a preventive product or service. Job aids developed to assist ADDO dispensers in their work include step-by-step dispensing guides, a poster with questions that customers should ask about medicines, and dispenser guidelines on monitoring for danger signs in children (tools are available at www.drugsellerinitiatives.org).

*Sources: Rutta et al. 2009,\textsuperscript{52} Management Sciences for Health 2013.\textsuperscript{53})*
In Mozambique, programs reported that patients attending clinics with a higher pharmacy workload-to-staff ratio had a greater risk of attrition.55 A 2005 national survey of Nigerian pharmacists found that the majority were willing to implement pharmaceutical care, but identified their knowledge, professional skills, and pharmacy layout as chief constraints.56 In addition to task shifting in response to the scarcity of human resources for pharmaceutical care, it is also important to address the issue of additional skills required to provide pharmaceutical care beyond the scope of traditional pharmacy practice. Reforming pre-service education and training curricula for pharmacists and other pharmaceutical staff is necessary because in many LMIC, pharmacy curricula focus mainly on technical aspects rather than on patient-centered provision of pharmaceutical services. Academic institutions, in conjunction with statutory bodies and professional organizations, play an important role in the revision of curricula to ensure that students acquire the knowledge, skills, and attitudes necessary for effective delivery of pharmaceutical care.59

In-service and other continuing professional development programs should also be developed or redesigned to equip those already practicing with the necessary knowledge and skills to assume greater responsibility in the provision of patient-centered care beyond traditional dispensing activities. Important skills include good communication and problem-solving abilities and patient-interviewing techniques. New attitudes will require a commitment to patient-oriented rather than task-oriented practices and to maintaining competencies and patient confidentiality.47 Beyond training, pharmaceutical care providers also need a way to stay up-to-date with scientific advances in pharmacotherapy and changes in recommended practices.

Service Delivery Systems

The scarcity of pharmacists in resource-limited settings has required countries and health programs to use other health care workers to dispense medicines in public health facilities, particularly in rural and periurban areas.60 The role of these dispensers, retail pharmacy staff, and drug sellers in the provision of pharmaceutical care will need to be clearly defined. As discussed earlier, where pharmacists are in short supply, their responsibilities will need to be changed to enable them to focus on more specialized functions and supportive supervision. To support the integration of elements of pharmaceutical care into the activities of pharmacists and other staff members who provide medicines, task-centered pharmaceutical services may have to be redesigned to enable staff to focus on meeting the needs of the patient. Activities need to be introduced gradually with appropriate training and support to avoid overburdening staff. It is also important to ensure that dispensers, drug sellers, and community health workers are not expected to do more than they are trained or qualified to do and that pharmacists and other pharmacy staff work within their scopes of practice.

To achieve the goals of individualized patient care and improved outcomes, traditional pharmaceutical services may need to be reoriented to a clinically centered practice. Upgrading of pharmacies and dispensaries to provide a private space for
interactions with patients has been important in improving counseling and adherence monitoring in ART programs in LMIC, and will be required for the delivery of effective management services for other chronic diseases. In addition to referral networks and systems that support the safe transfer of patient care, pharmaceutical personnel will need to establish closer collaborative relationships with other health care providers to promote effective coordination and teamwork. Working together to clearly delineate the pharmaceutical care process and individual roles can build mutual respect and a feeling of shared responsibility among stakeholders within an organization, facility, network, or community. Also important is fostering a culture of involving and partnering with patients and their caregivers.

Important on-the-job resources to support the provision of pharmaceutical care include guidelines to assist in decision making, protocols that detail how to deliver services, and tools such as job aids that help health care workers perform tasks such as adherence monitoring. To systemize the delivery of services, standard operating procedures (SOPs) that mandate the processes to follow will be needed, as well as systems for monitoring the effective implementation of these procedures. Supervisory support systems are essential for helping staff take on new tasks and reinforcing good practices, such as ADR reporting. Monitoring of pharmaceutical care activities should be incorporated into routine inspections, clinical audits, and quality improvement systems.

**Information Systems**

Clinical and pharmacy information systems support the delivery of pharmaceutical care. For some interventions, including medication use evaluations and pharmacotherapy follow-up, the pharmaceutical care provider must have access to the patient’s medical record. In some cases this will require the patient’s informed consent. Other activities, such as tracking adherence, are facilitated by an information system that collects patient-specific data and documents interventions, and medicines dispensed. In addition, pharmaceutical staff may need technologies to share information with other practitioners. Medicine information systems also support evidence-based decision making to optimize patient care and treatment.

**Leadership**

Engagement and commitment by professional organizations can help promote the implementation of pharmaceutical care in a country. As well as addressing resistance to change in the profession, such organizations play an important role in advocacy and in fostering closer professional relationships across disciplines. In addition, educators help implement pharmaceutical care by ensuring that pharmacy staff and other providers of pharmaceutical care have the required knowledge, skills, and attitudes.
Pharmaceuticals constitute a large component of national health expenditure, and in low-income countries, out-of-pocket payments for medicines form a substantial proportion of overall health care payments by patients. Consequently, pharmaceutical financing strategies need to include efforts to use existing resources more efficiently. Pharmaceutical care provides a practical clinical strategy to support these efforts. Furthermore, financial sustainability is an important concern for UHC programs that are providing or plan to include coverage for medicines. Strategies to contain pharmaceutical spending in UHC schemes include implementing pharmaceutical policies, actively managing medicines, and promoting appropriate medicines use to control costs and reduce inefficiencies. Potential overuse of covered services and overprescribing and provision of services that may not be needed are risks that must be managed in any form of health insurance. Linking medicines use with health outcomes within disease management programs is a critical role that pharmaceutical care can support.

Investments will be needed to implement and support pharmaceutical care activities, and these may include funding for training, development of protocols, guidelines, SOPs, job aids, and tools. Information systems for record keeping and reporting may also need to be established at the pharmacy or facility where care is provided. Introducing some pharmaceutical care activities is often made possible by eliminating unnecessary tasks and duplication of efforts. For example, in addition to providing important information on medicine use, the introduction of dispensing software programs can enable pharmacy staff to spend more time on patient care activities. In the long term, however, additional staff and remuneration may be needed to support and sustain participation in new initiatives such as disease management programs.

In the private sector, contracting can be a mechanism for introducing change to pharmacy practice. LMIC may need to explore ways to organize and compensate pharmaceutical care providers. Policy makers and program planners will need information on the value of pharmaceutical care activities to inform decision making. One of the challenges is that many existing public and private financing arrangements fund the product (pharmaceuticals), with services such as pharmaceutical care considered as part of the dispensing fee. Some financing mechanisms fund pharmacy staff positions directly from the margin generated by the sale of medicines. These models do not adequately account for the costs associated with expanded clinical training or the additional time needed to deliver pharmaceutical care. Furthermore, because pharmaceutical care will improve pharmacotherapy effectiveness, it may result in the sale of fewer or less expensive medicines. Unless the financing model is adapted to pay for pharmaceutical care activities, this desirable outcome may not be in the best economic interest of the service provider. Transitioning from the current product-centered model to one that is patient-centered, and separating the funding of products and services, will be critical to encourage the incorporation of pharmaceutical care into routine practice.
INRUD was formed in 1989 to design, test, and disseminate effective strategies to improve the prescribing, dispensing, and use of medicines in resource-limited countries. Launched in 2006, the INRUD Initiative on Adherence to Antiretrovirals (INRUD-IAA) developed and validated a set of indicators that can be used to monitor adherence to ART, investigated determinants of ART adherence, and piloted interventions to improve adherence in individual patients as well as the performance of HIV facilities and programs.

The project identified five core indicators that could be generated from routine pharmacy and clinic records, and a validity study demonstrated that these indicators correlated with increases in patients’ CD4 counts and weight gain. The researchers also identified determinants of ART adherence, which were used to help the national HIV programs in Kenya, Rwanda, Tanzania, and Uganda design low-cost and widely implementable interventions to pilot in their settings.

Appointment attendance rates, shown to correlate with treatment outcomes, were found to vary widely between clinics and between individual patients. Since most clinics studied lacked appointment systems to enable them to quickly identify and follow up on missed appointments, trial interventions in all four countries included introducing appointment registers as well as protocols for calling or visiting patients who miss appointments. In Kenya and Rwanda, clinic staff also used the registers to routinely generate and track attendance indicators. In Rwanda, these indicators formed the basis for awarding financial incentives for staff based on clinic performance. The HIV program in Uganda piloted a fast-track system to identify patients who are stable on treatment to receive multi-month dispensing to decrease clinic crowding. Evaluations of pilot interventions using the INRUD indicators found positive impacts on attendance rates in all four countries. These efforts also improved record keeping and enabled staff to quickly identify and target patients who missed appointments for in-depth adherence counseling. In Uganda, the appointment system, fast-tracking patients through the clinic, and multi-month dispensing reduced patient waiting time (at one clinic, by an average of an hour) and allowed clinic staff to dedicate more time to adherence monitoring and counseling.

The initiative showed that regular monitoring of appointments in public health clinics in resource-limited settings is feasible for ART. In addition to evaluating interventions, the INRUD indicators also enable clinics to monitor their own performance in retaining patients and encouraging ART adherence over time, as well as allowing comparison between similar facilities to identify low-performing clinics to target for training and support.


**Practice Research**

Practice research is needed to develop and evaluate models for the provision of pharmaceutical care to particular groups with defined needs, and to provide information on how best to implement these activities in resource-limited settings. Establishing centers linked to academic institutions to promote practice research and cooperation across several countries could be an option for making the best use of resources. Such collaboration can also inform study design, especially to evaluate outcomes of pharmaceutical care.39 An example of a multicountry initiative is the Pharmaceutical Care Network Europe (http://www.pcne.org), which researchers established in 1994 to stimulate research into pharmaceutical care and pharmaceutical outcomes. An example from LMIC is the International Network for the Rational Use of Drugs (INRUD) Initiative on Adherence to Antiretrovirals (INRUD-IAA), which worked with HIV programs in four East African countries to test interventions to improve ART adherence using validated indicators (box 3).
Building Capacity for Pharmaceutical Care: The SIAPS Approach

SIAPS uses the framework shown in figure 3 to work with countries and health programs to strengthen institutional and individual capacity to effectively provide appropriate patient-oriented services. Box 4 provides an example. The framework illustrates the capacities and resources related to health system structures, systems, and roles; staff and infrastructure; and skills and tools that are required to introduce, establish, and sustain the delivery of pharmaceutical care.

Building capacity for pharmaceutical care involves—

- **Developing structural capacity** by ensuring that pharmaceutical care initiatives link to and are supported by national and local structures, such as Pharmacy and Therapeutics Committees, and systems, such as pharmacovigilance and quality improvement programs. Technical assistance may involve helping countries to strengthen these structures and systems. It can also include supporting the development or update of STGs, formularies, and protocols to aid decision making and standardize care based on best practices and international guidance.

- **Ensuring the timely and efficient flow of information and funding** to support patient-centered care. SIAPS and its predecessor programs, SPS and RPM Plus, have helped several countries strengthen both manual and automated pharmacy information systems for their ART programs. The Antiretroviral Dispensing Tool, later adapted for tracking of other dispensed medicines and renamed the Electronic Dispensing Tool, is a user-friendly tool developed by RPM Plus that is now used in 12 countries. The tool maintains
In 2003, the Government of Kenya initiated the provision of ART in public sector facilities. Assessments conducted with assistance from the Rational Pharmaceutical Management (RPM) Plus Program determined facility preparedness for ART pharmaceutical service delivery at pilot sites. Results revealed several factors that needed to be addressed to support pharmaceutical supply and the provision of quality care. Challenges included paper-based pharmacy records that were inadequate to manage patients on chronic care effectively, inaccurate record keeping, poor dispensing and medication-counseling practices, crowding at dispensing windows that made confidential counseling impossible, and lack of reference materials.

RPM Plus and its follow-on programs, SPS and Health Commodities and Services Management (HCSM), have helped the National AIDS and STI Control Programme (NASCOP) to improve pharmaceutical care practices and support ART scale-up since 2003. In 2004, NASCOP introduced RPM Plus's electronic ART Dispensing Tool (ADT) to sites where rapidly increasing patient numbers made manual tools cumbersome. RPM Plus and later SPS provided the software, developed a training curriculum, job aids, and manuals, and helped train regional and national trainers. ADT enables pharmacy staff to record demographic details, concomitant illnesses, and medicines used by the patient, maintain a dispensing record for each patient that includes refill dates and a diary to support adherence monitoring, and capture ADRs. The tool also allows staff to quickly identify patients who are late in collecting ARV refills. Users report that because it makes patient information readily available, the ADT facilitates the provision of pharmaceutical care by enabling staff to more easily check for potential drug interactions, monitor ADRs and treatment adherence, and provide better medication counseling. Other benefits include information for program management, such as reports on compliance to treatment guidelines, regimen changes, patient numbers, and ARV consumption. In addition, recent enhancements now enable NASCOP to monitor three WHO early warning indicators for the emergence of HIV drug resistance. The ADT has been rolled out to over 380 sites in Kenya, and of the approximately 600,000 patients currently on ART nationwide, over 80 percent have their records maintained on this electronic tool.

To address the lack of staff capacity at ART sites, HCSM and its predecessor programs have supported curriculum reviews for middle- and tertiary-level training institutions and the rollout of in-service training courses covering pharmaceutical management and pharmaceutical care for patients on ART. The SPS and HCSM programs have also facilitated task shifting by building capacity in cadres who, in addition to pharmacists, provide pharmaceutical services, especially at primary health care levels and in underserved areas. In addition, SPS and HCSM helped the Pharmaceutical Society of Kenya to develop a series of one-day courses targeting practitioners in the private and community sectors and deliver the trainings, in collaboration with other professional associations. To augment training, key resource materials and simple tools were provided, such as treatment algorithms and pediatric dosing charts, to help pharmacy staff verify adherence to guidelines and use of correct dosages. SPS assisted NASCOP in developing and introducing a set of 11 ART SOPs as well as job aids, describing good pharmaceutical practices, including those for dispensing and medication counseling. Useful tools include a medication counseling checklist that prompts pharmacy staff to deliver key messages on ART, including the importance of treatment adherence, and information such as potential ARV drug interactions and side effects. Pharmacies set up private areas for counseling ART patients to encourage confidentiality.

The SPS and HCSM programs have also helped build the capacity of Medicines and Therapeutics Committees, which play a central role in addressing ART medicine use and service delivery issues in facilities. These technical assistance programs have also supported NASCOP and the Pharmacy and Poisons Board in rolling out the national pharmacovigilance system, including training facility-level staff to monitor, report, and manage ART-related ADRs.

Sources: Kusu et al. 201070 and Kusu et al. 201071
The practice of pharmacy in South Africa is regulated by the Pharmacy Act 53 of 1974. The scope of practice of pharmacists, which is published in Regulations Relating to the Practice of Pharmacy, includes pharmaceutical care. Based on the scope of practice, pharmacists can levy a fee for 28 services, including providing information to a patient when no medicine is dispensed; measuring blood pressure, blood glucose, or cholesterol; and providing pharmaceutical care. In 2007–8, the South African Pharmacy Council, in collaboration with all eight pharmacy schools in the country and with assistance from the SPS Program, conducted a study to determine which services pharmacies provide and establish appropriate fees for these services. The research was conducted in two phases.

In the first phase, the study identified the services provided by pharmacies. In the second phase, a total of 597 pharmacies, including community (retail) pharmacies and private and public hospital pharmacies in all parts of the country, were surveyed to determine the time taken to provide each service. Information relating to labor, overhead, and operating costs was obtained through structured questionnaires. The data obtained were used to populate a costing model in accordance with Regulations Relating to the Determination and Publication of Reference Prices for Health Care Services, published in terms of the National Health Act of 2003. Based on this research and application of the principles of these regulations, a coding structure and fees for allowable services were developed. The Rules Relating to the Services for Which a Pharmacist May Levy a Fee and Guidelines for Levying Such a Fee or Fees were then published in terms of the Pharmacy Act in 2010. An outcome of the research is that some medical insurance companies have begun reimbursing private sector pharmacists for providing these services.

SPS subsequently helped the South Africa Pharmacy Council develop scopes of practice for three new cadres of pharmacy support personnel, including pharmacy technicians. These technicians will be able to take on more patient care functions and to practice independently under certain conditions. This task shifting will also enable pharmacists to spend more time providing pharmaceutical care.

Source: Putter et al. 2010

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**Box 5. Changing Legislation to Support the Provision of Pharmaceutical Care in South Africa**

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Source: Putter et al. 2010

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each patient’s profile and history of ARVs and other medicines dispensed and enables staff to track appointments and adherence indicators and provide better patient follow-up (box 4).

- **Determining roles and responsibilities of pharmaceutical care providers,** including pharmacists and other pharmacy workers, as well as the structures for supervision and oversight of service delivery. Technical assistance activities can include helping public health programs and health systems redesign pharmaceutical services to support the provision of pharmaceutical care. Other assistance may include helping countries determine scopes of practice of pharmacy staff, including expanded roles for different pharmacy personnel in providing patient care. In South Africa, SPS helped the country’s Pharmacy Council determine services that can be rendered by pharmacy staff as well as the fees that may be charged for the provision of these services. Assistance was also provided in the revision of the scopes of practice of pharmacy personnel to support the provision of pharmaceutical care (box 5).

- **Ensuring that infrastructure and staffing support the reallocation of tasks.** Upgrading pharmacies to provide a confidential space for patient counseling and updating job descriptions to reflect new roles are important tasks. In Ethiopia and Kenya, SPS built confidential dispensing booths at
While infectious diseases such as HIV, malaria, and TB remain important causes of morbidity and mortality in Ethiopia, the prevalence of non-communicable conditions such as hypertension, cardiovascular disease, and diabetes is increasing. With the rise in these treatable chronic diseases, the pharmacy profession is moving toward patient-centered care. However, Ethiopia’s pharmacy degree program, with its focus on basic sciences and absence of pharmacy practice training, does not prepare pharmacists to deliver pharmaceutical care. One of the biggest challenges to remodeling pre-service training in Ethiopia is the shortage of faculty members trained in clinical pharmacy.

In March 2009, Jimma University’s School of Pharmacy launched Ethiopia’s first Masters of Science in Clinical Pharmacy program to educate pharmacy practitioners to deliver patient-centered care and capacitate faculty members to teach the new undergraduate clinical pharmacy course. In November 2009, faculty members from SPS partner, the University of Washington, and Jimma University conducted a week-long training-of-trainers course at Jimma University for 37 faculty members and clinical pharmacy graduates from four Ethiopian colleges and schools of pharmacy. The course goal was to capacitate participants to both teach about and provide pharmaceutical care services themselves, relevant to the country’s resource-constrained setting.

To ensure that the course met the pharmacy education needs of program participants, the curriculum, which the University of Washington and SPS developed in collaboration with the Ethiopian Pharmaceutical Association, was adapted based on interviews conducted during pre-course visits to pharmacies, hospitals, and clinics and a baseline survey of providers’ experiences with pharmaceutical care and priorities for service improvement.

Instructional methods included seminars, ward rounds, and off-hour meetings to cover specific issues identified by faculty staff. In addition to teaching clinical mentorship skills for activities such as ward rounds, medication chart review, and trainee performance assessment, the University of Washington and SPS assisted the universities with identifying and developing ideas for pharmaceutical care activities to be initiated by participants to benefit the Ethiopian health care system in their region. Post-course assessments at three and 12 months showed that course attendees had begun contributing to clinical patient ward rounds and that master’s graduates were implementing projects in diabetes care, medication error prevention and surveillance, drug information, and medication adherence.

Source: Odegard et al. 2011

### Box 6. Improving Pharmaceutical Care Training Capacity in Ethiopia through Educational Collaboration

While infectious diseases such as HIV, malaria, and TB remain important causes of morbidity and mortality in Ethiopia, the prevalence of non-communicable conditions such as hypertension, cardiovascular disease, and diabetes is increasing. With the rise in these treatable chronic diseases, the pharmacy profession is moving toward patient-centered care. However, Ethiopia’s pharmacy degree program, with its focus on basic sciences and absence of pharmacy practice training, does not prepare pharmacists to deliver pharmaceutical care. One of the biggest challenges to remodeling pre-service training in Ethiopia is the shortage of faculty members trained in clinical pharmacy.

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Source: Odegard et al. 2011

**Developing supervisory capacity** by ensuring that pharmacists or other staff providing supportive supervision are available in adequate numbers and have the necessary authority, skills, and tools to perform the required tasks. Technical assistance to countries could include helping programs develop and test models that expand pharmacists’ responsibilities to provide oversight of and mentoring to other workers, such as nonpharmacist dispensers in public facilities, staff in accredited drug dispensing outlets, and community health workers.

**Supporting academic institutions that train students and practitioners** and work with implementers to conduct practice research. Helping academic institutions and governments to revise curricula and in-service training materials and capacitate trainers are important technical assistance activities (box 6).

**Helping pharmaceutical personnel acquire the knowledge, skills, and competencies** needed to implement pharmaceutical care activities appropriate to their scope of practice. Also important will be changing health facilities initially with ART patients in mind; however, all patients now benefit from these interventions.
attitudes and helping staff to manage change. Technical assistance activities may involve supporting in-service training-of-trainers and on-the-job mentoring. SIAPS and its predecessor programs have for years used a continuous quality improvement (CQI) approach to help in-country partners build skills for pharmaceutical management, including patient care. Called monitoring-training-planning (MTP), the approach is adapted by SIAPS to make it suitable for each country’s audience and setting.

- **Institutionalizing appropriate tools**—for example, SOPs, job aids, validated tools for assessing and monitoring adherence—and providing up-to-date and appropriate medicine information materials. SPS has helped country ART programs develop a number of patient care tools, such as checklists, SOPs, and treatment literacy materials to support medication counseling and adherence monitoring at ART pharmacies.

### The SIAPS Operational Approach

In resource-limited settings, the practice of pharmaceutical care is usually limited to small-scale initiatives implemented at higher-level health facilities or within a defined public health program, such as the ART program. In line with its goal to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes, SIAPS works with in-country partners to promote the delivery of pharmaceutical care to patients with HIV and other chronic conditions. SIAPS uses a systems strengthening approach consistent with the US Global Health Initiative, which aims to produce improved and sustainable health impact. Interventions focus on the dynamic relationship between the health system building blocks identified by WHO, with a capacity building approach to governance, human resources, information, financing, and service delivery to support the provision of pharmaceutical care. The SIAPS strategy allows phased implementation and sustainable integration of pharmaceutical care activities into service delivery models.

The SIAPS operational approach comprises the following steps—

- **Assess the existing situation.** SIAPS works with partners to assess the capacity to provide pharmaceutical care and other patient services, including dispensing, health promotion, and disease prevention activities, using an indicator-based methodology. Assessments typically form the baseline for measuring improvements. In addition to looking at skills and tools, SIAPS evaluates staff and infrastructure capacities together with those related to structures, systems, and roles. We also work with partners and health providers to identify the most appropriate focus—for example, health conditions or medication-related issues—for the initial phase of introducing a pharmaceutical care initiative (box 7).
Develop a customized system improvement model. Using the findings of the assessment, SIAPS works with in-country stakeholders to identify and analyze options and develop relevant, feasible, and sustainable approaches customized to the country’s existing priorities and resource availability. Because gaps may exist at various levels of the health care system, SIAPS works with partners at each level to identify appropriate interventions to implement.

Provide technical assistance for implementation. SIAPS works with stakeholders, partners, and USAID initiatives to implement interventions, develop local capacity, and build advocacy for change.

Monitor and evaluate activities. An important component of our operational approach is helping in-country partners identify indicators and establish monitoring programs to objectively measure improvements in pharmacy practice in terms of commonly accepted metrics in global health.

Disseminate lessons learned and best practices. SIAPS helps partners document and share experiences and successful approaches for improving medication-related care to support chronic disease management.

### Box 7. Assessing the Readiness of Public and Private Pharmacies to Provide Pharmaceutical Care in Rwanda

In Rwanda, pharmacies are an underutilized resource that could potentially contribute more to improving patient care, particularly for individuals receiving long-term treatment for chronic diseases. In 2008, SPS assisted the Ministry of Health and the Rwanda Pharmacists Association in assessing the readiness of the five public hospitals and 40 of the 44 private pharmacies in Kigali to implement pharmaceutical care. Respondents were also asked about their views on pharmaceutical care and the prerequisites, challenges, and priorities for incorporating pharmaceutical care into their practices. Key assessment results are described below.

**Staffing and organization:** All pharmacies had a qualified pharmacist; private pharmacies had an average of 2.6 dispensing nurses, while public hospitals had an average of 7.4. Dispensing time ranged from 1 to 15 minutes (average 4 minutes). Private pharmacies serve about 12 patients with chronic illnesses per day (range 0–50), and over one-half of patients return to the same pharmacy for refills. Hospital pharmacies dispense prescriptions to an average of 52 patients with chronic illnesses per day (range 7–200), of whom just under one-half return.

**Infrastructure and equipment:** Although most pharmacies had a telephone line (69 percent) and over one-half had access to the Internet (56 percent) and to unbiased medicine information (64 percent), only one-third (33 percent) had a confidential space for patient counseling.

**Readiness to provide pharmaceutical care:** About three-quarters of pharmacists (73 percent) said they could formulate and discuss a therapeutic plan with patients to solve medication-related problems. Only one-quarter of pharmacists (24 percent) said they used continuing education to stay updated. Most respondents (80 percent) understood the need to improve patient care and were willing to implement pharmaceutical care practices. Important prerequisites reported included training, strengthening communication with prescribers, and public awareness campaigns. Respondents mentioned patient use of multiple pharmacies, lack of time, and patient load as potential constraints.

The assessment helped identify key health conditions and the best-prepared pharmacies for the introduction of pharmaceutical care activities. Patients with diabetes were identified as the most appropriate focus in private pharmacies and, in public facilities, patients with HIV and diabetes.

Source: Mwesigye et al. 2010\[74\]
In summary, the integration of pharmaceutical care into pharmaceutical systems can help to prevent or reduce medicine-related problems and enhance health outcomes to improve the quality of life of patients with chronic diseases. Programs in resource-limited settings will need to develop unique approaches for delivering patient-oriented care that are relevant for their settings and levels of practice. Experiences and achievements in strengthening the provision of pharmaceutical care in HIV programs in LMIC provide important lessons, tools, and approaches that can be adapted for the management of other chronic diseases. A systems-based approach, together with judicious strategic planning, phased implementation, and coordinated technical and financial support, can help countries identify and address critical capacity gaps to improve medication-related care and better support chronic disease management and primary prevention programs.
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