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TECHNICAL
PROGRAM
UPDATE

PROMOTING THE RATIONAL USE OF MEDICINES



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Systems for Improved Access
to Pharmaceuticals and Services

Many medicines now exist that can prevent, alleviate, treat, or cure diseases which previously took inordinate tolls on the health and well-being of children, families, communities, and populations. However, the overuse, underuse, or misuse of medicines (also referred to as *irrational medicine use*) puts these advances in jeopardy and, in addition to wasting limited resources, threatens future public health gains. This technical update reviews the ways in which the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program, funded by the US Agency for International Development (USAID), works to promote rational medicine use as part of its health systems strengthening approach to making quality medicines and pharmaceutical services more widely available and accessible in low- and middle-income countries.

GLOBAL CONTEXT

The challenge of irrational medicine use is a global one—common to all countries and all healthcare settings. The World Health Organization (WHO) estimates that globally “more than half of all medicines are prescribed, dispensed, or sold inappropriately and that half of all patients fail to take their medicines correctly.”¹ Both healthcare providers and patients contribute to irrational medicine use. Providers may prescribe too many, too few, or inappropriate medicines; or may prescribe the appropriate medicines in the wrong dose, formulation, or duration. Additionally, patients contribute to irrational medicine use through self-medication, pill sharing, or not completing a treatment regimen as prescribed.

What is rational medicine use?

Rational medicine use occurs when “patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.”¹

However, at a systems-level, the policy and regulatory environment in which a provider prescribes and a patient uses medicines heavily impacts rational use. Many countries do not have regularly updated standard treatment guidelines, lack sufficient capacity and systems to monitor and regulate how medicines are used, and do not appropriately educate healthcare workers and the public on rational medicine use.

CONSEQUENCES OF IRRATIONAL MEDICINE USE

Although seemingly benign, the small act of a healthcare worker prescribing an unneeded antibiotic or a patient stopping medication early—when taken together with the many additional ways irrational use occurs—has a major impact on public health. When medicines are used irrationally, treatment outcomes worsen and the risk of adverse events increases, resulting in unnecessary morbidity and mortality.

Additionally, the overuse and misuse of medicines fuels the development and spread of [antimicrobial resistance](#) (AMR) which makes treating diseases like malaria and tuberculosis (TB) increasingly difficult and more expensive. Irrational use of antibiotics in particular is a major global concern as many common bacterial infections are showing resistance to typical treatment courses while the development of new antibiotics has stalled. Research indicates that up to 50% of all antibiotic prescriptions are unnecessary or not optimally effective as prescribed.²

Given that medicines account for up to 30% of health spending for many countries, irrational use also squanders desperately needed financial resources for country health programs. At the same time, since medicines are a major source of out-of-pocket health spending for patients in developing countries, misuse of medicines means that patients not only experience suboptimal health outcomes, but also face additional financial hardship as a result.^{3,4}

Globally, approximately 8% of total healthcare expenditure or 500 billion dollars could be saved with more rational medicine use.⁵

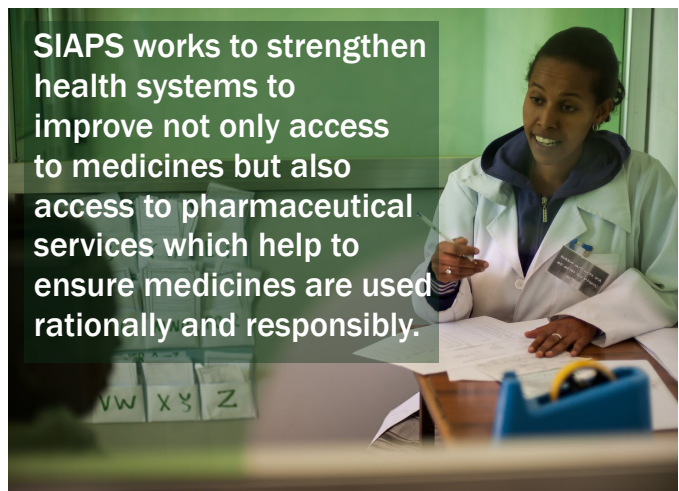
Promoting rational medicine use (RMU) is vital to ensuring effective, safe, and cost-effective treatment outcomes and to preserving the efficacy of existing medicines. And, although the consequences are severe, less than half of all countries implement many of the basic policies needed to ensure appropriate medicine use.¹

SIAPS APPROACH

Given the interrelated and dynamic factors between patient, provider, and the larger regulatory and policy environments which affect how medicines are prescribed, dispensed, and used; ensuring RMU

requires multifaceted, cross-cutting interventions which improve not only patient and provider behavior but also strengthen the associated components of the health system as a whole.

Recognizing these dynamics, and operating with the understanding that our work does not stop with medicines availability, SIAPS works to strengthen health systems to improve not only access to medicines but also access to pharmaceutical services which help to ensure medicines are used rationally and responsibly. Going beyond the supply chain, SIAPS aims to strengthen pharmaceutical services which make medicines information available and easy-to-understand, provide effective pharmaceutical care and counseling, and help to monitor the use of medicines and patient adherence. Additionally, SIAPS works with ministries of health to establish pharmacovigilance and medicines safety surveillance programs, develop and update standard treatment guidelines (STGs), and implement advocacy and education campaigns to improve public awareness of the importance of RMU.



IMPLEMENTATION

SIAPS builds on the work of several previous projects with major rational use components including the Strengthening Pharmaceutical Systems and Rational Pharmaceutical Management Plus programs to implement interventions in accordance with USAID priorities and the WHO's [key recommendations](#) for enhancing rational medicine use. Specifically, our technical focus areas include pharmaceutical care, medication adherence, STGs, essential medicines lists (EMLs), formularies, case management, and pharmacovigilance.

Strengthening pharmaceutical care

Pharmaceutical care is the responsible provision of medication-related care designed to achieve health outcomes that improve or maintain a patient's quality of life.⁶

SIAPS views pharmaceutical care as a critical opportunity to encourage and promote rational use with both patient and provider. SIAPS helps strengthen and improve the quality of pharmaceutical care by assessing current practices, identifying medication-related issues, and developing feasible interventions to promote appropriate and effective therapy, safe medicine use, patient knowledge, and adherence. SIAPS recently published a concept paper on the [role of pharmaceutical care](#), which describes in detail the SIAPS approach to strengthening pharmaceutical care in resource-limited settings.



Photo Credit: Mark Tuschman

Promoting patient-centered clinical pharmacy services in Ethiopia

SIAPS collaborated with the Pharmaceutical Fund and Supply Agency (PFSA) and Jimma University in Ethiopia to design and implement an in-service training program to introduce patient-centered pharmacy services in hospitals by enhancing the role of pharmacists in patient care. After developing the curriculum, training materials and a series of implementation tools, SIAPS worked with local universities to train more than 150 pharmacists across 44 hospitals. These trained pharmacists were then able to initiate clinical pharmacy services at their respective hospitals with additional supportive supervision and mentoring provided by SIAPS and experts from Jimma University.

According to data collected from 26 hospitals between August 2012 and May 2014, pharmacists who participated in the program identified 2,904 cases where one or more instance of irrational use occurred, including unnecessary medicines use (82%), need for additional drug therapy (83%), adverse drug reactions (73%), excessive dosage (85%), and noncompliance (92%). When medication errors were identified, interventions implemented by the trained pharmacists were able to improve treatment outcomes in 91% of cases. The new patient-centered pharmacy services have helped pharmacists to actively recognize, prevent, and manage drug therapy problems which in turn has improved medication adherence. The PFSA is also collaborating with SIAPS to develop a standard operating procedures manual to further strengthen and standardize clinical pharmacy services in Ethiopia.

Establishing and revitalizing Medicine and Therapeutics Committees

Medicine and Therapeutics Committees (MTCs), also referred to as Drug and Therapeutics Committees, are recognized by the WHO and others as a major mechanism to improve the use of medicines at the district and facility levels. MTCs bring together relevant medical and pharmaceutical stakeholders to make decisions about the use of medicines including establishing medicines management policies, selecting medicines formularies, and agreeing on appropriate treatment protocols. SIAPS helps to establish MTCs, train members, and provide follow-up support and guidance as they work to implement action plans, implement medicines policies, and assess medicines use. SIAPS has helped establish or strengthen MTCs in seven countries including the Democratic Republic of Congo (DRC), Ethiopia, Mozambique, Namibia, South Africa, South Sudan, and Swaziland.

Building capacity of Provincial Pharmaceutical and Therapeutics Committees in South Africa

In South Africa's Gauteng Province, several pharmaceutical and therapeutics committees (PTCs) throughout the health system help promote rational medicines use. To create an integrated network of PTCs, optimize available resources, and enhance rational medicine use, SIAPS worked with the provincial-level PTC to develop a [guidance document](#) for PTCs operating at all levels of healthcare in the province. The guidelines address governance structures, processes, accountability, and communication strategies designed to assist hospital- and district-level PTCs in ensuring the quality of pharmaceutical care. The Gauteng Provincial PTC (GPPTC) also recently produced a [biennial report](#) detailing GPPTC activities, challenges, and accomplishments between April 2012 and March 2014.



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Incorporating rational use topics into pre-service training curricula

Ensuring that pre-service training programs for pharmacists and other health professionals includes robust rational use curricula is a primary way SIAPS aims to build in-country capacity to responsibly manage medicines. Exposure to RMU topics in pre-service settings builds competence and confidence for practice in the real world, however, RMU is still omitted from many training curricula. SIAPS has developed [a guide for revising pre-service curricula](#) which thoroughly details how to incorporate RMU components in health professional training programs and includes several tools and templates to facilitate the process.

- ▶ In **Namibia**, SIAPS helped the School of Pharmacy at the University of Namibia (UNAM) to strengthen its pre-service training on RMU and AMR for undergraduate pharmacy students. UNAM's 2011 undergraduate pharmacy curriculum includes several topics on RMU in its prospectus and Pharmacy Practice II Study Guide.^{7,8} The study guide, however, does not include detailed information on how to implement the RMU topics within the existing curriculum.

To fill this gap, SIAPS supported UNAM in developing a customized course on RMU that aligns with the approved curriculum. The team developed the curriculum implementation framework, instructional delivery design, and course materials including detailed instructors' guides. The RMU course, which emphasizes case-based and self-directed learning methodologies, was first offered in August 2014. SIAPS continues to provide follow-up support to build UNAM's capacity to monitor and evaluate the effectiveness of the course, refine the course materials, document and publish results and lessons learned, and apply this approach to additional topics within the pharmacy program and with additional academic disciplines at the university.

Setting rational use standards through STGs, EMLs, and formularies

Less than 40% of patients are treated according to STGs in the public sector, a figure that drops even lower in private sector settings.⁹ Together with EMLs and medicine formularies, the development and adoption of STGs reduces excessive, unnecessary, and inappropriate prescribing practices. SIAPS has worked with 11 countries to develop, implement, and update STGs, EMLs, and formularies, as well as train healthcare providers on how to use these critical reference materials. Most recently, SIAPS supported the Ethiopian Food, Medicine, and Healthcare Administration and Control Authority to revise STGs for both general and primary hospitals (3rd editions, 2014). SIAPS is currently developing a how-to-manual as a resource to further assist the development, revision, and implementation of these guidance documents.



- ▶ In **Burundi**, SIAPS supported local stakeholders to review, update, and finalize the new malaria standard treatment guidelines, incorporating new WHO recommendations for the treatment of severe malaria. New treatment algorithms were also developed to facilitate better treatment decision making among health providers. SIAPS disseminated the revised STGs to 650 health facilities in conjunction with district-level training-of-trainers workshops for over 400 district heads, medical doctors, supervisors, and health management information system managers.
- ▶ SIAPS also helps countries apply innovative approaches to ensure that prescribers are able to adhere to STGs. In **South Africa**, we worked with the National Department of Health to make the adult hospital-level STGs and EML readily available to prescribers through a mobile application which could be easily referred to during patient consultations. The user-friendly smart phone application is a step forward in terms of improving

Integrating 13 life-saving commodities into national EMLs to improve the health of women and children in Angola and the DRC

The *Every Woman Every Child* campaign is a movement that calls on the global community to increase access to and appropriate use of essential medicines, medical devices, and health supplies that effectively address the leading causes of death during pregnancy, childbirth, and childhood. Specifically, this means increasing access to 13 life-saving commodities in 50 of the world's poorest countries. SIAPS is working with Ministries of Health in Angola and the DRC to make these life-saving medicines available to women and children. In Angola, SIAPS has supported revisions to include chlorhexidine for umbilical cord care in the EML. In the DRC, SIAPS collaborated with WHO, the Belgian Development Agency, and the United Nations Population Fund to integrate all 13 life-saving commodities into the DRC's revised EML.

the accessibility and usability of STGs, helping to ensure that these guidelines are frequently referred to and followed for more rational use of medicines.

- ▶▶ In **Ethiopia**, SIAPS worked in partnership with the Food, Medicines, and Healthcare Administration and Control Authority to revise the first edition of the *Ethiopian Medicines Formulary 2013 (EMF 2013)* through a consultative process with local experts. The *EMF 2013* includes useful guides on rational prescribing, good dispensing practices, medicine labeling and counseling, medication adherence, treatment monitoring, antimicrobial prescribing in general practice, and prophylactic use of antimicrobials for surgical and gynecological procedures. SIAPS supported the dissemination of 20,000 copies of the *EMF 2013* to healthcare providers across Ethiopia.

Assessing medicine use to identify potential issues

Assessing how medicines are being prescribed, dispensed, administered, and used through medicine use evaluations is a critical method for health facilities to review and improve rational use. SIAPS works to build the capacity of stakeholders to design and implement medicine use studies, recently publishing a reference guide to assess [antimicrobial use in hospital settings](#). The guide defines indicators that can be used to measure management and use of antimicrobials and provides step-by-step instructions and tools for carrying out an assessment. Additionally, SIAPS recently published guidelines to help health workers [assess use of medicines to treat drug-resistant TB](#). SIAPS has also supported medicine use studies and evaluations in eight countries including Ethiopia, Bangladesh, Jordan, Kenya, Namibia, South Africa, Swaziland, and Ukraine.

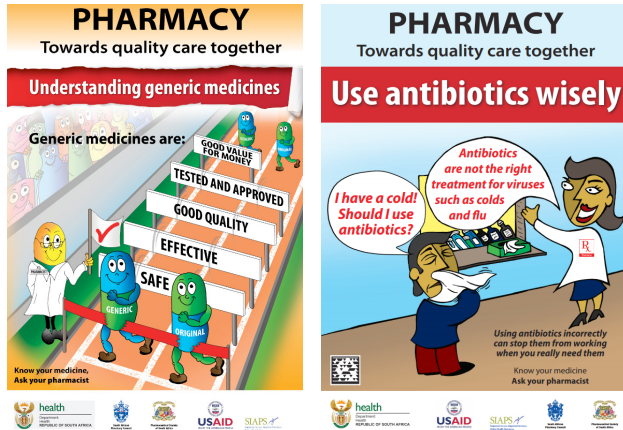
- ▶▶ In **Jordan**, SIAPS assisted three hospitals in conducting [medicine use evaluations](#) and then used complementary quality improvement methods to improve prophylactic antibiotic use during cesarean sections. In a two-year period, use of the correct antibiotic during cesarean section rose from 0% to 86%, correct timing of first dose increased from 0% to 92%, the correct number of doses increased from 0% to 88%, and the average cost for antibiotic prophylaxis per case decreased by 79%.

Educating patients through public awareness campaigns

Consumer education provides information that encourages patients, families, and communities to use medicines safely and appropriately. Many countries implement public communication campaigns via radio, television, and printed materials. SIAPS has designed and carried out information, education, and behavior change interventions related to medicine use in Ethiopia, Namibia, and South Africa.

- ▶▶ In **Ethiopia**, SIAPS helped the Food, Medicines, and Healthcare Administration and Control Authority to educate journalists on RMU and AMR containment. As a result of this training, 90 radio, television, and newspaper spots on AMR and RMU were produced in 2014 alone to inform, educate, and empower the public.
- ▶▶ In **South Africa**, SIAPS supported national and provincial efforts to promote the role of pharmacists and pharmacy services during National Pharmacy Week campaigns in 2013 and 2014. We partnered with the South African Pharmacy Council, the Pharmaceutical Society of South Africa, and the National Department of Health to develop and print communication material for the campaigns. The 2013 campaign

theme, *Toward Quality Care Together*, emphasized the importance of generic medicines, while the 2014 campaign focused on the responsible and rational use of antibiotics.



Creating a culture of continuous quality improvement

Continuous quality improvement (CQI) is an iterative approach to bringing about small-scale, incremental changes in the workplace or health system, by focusing on organizational performance, patient care processes, and outcomes. SIAPS promotes the CQI approach in program management to encourage self-reflection on processes or feedback, identify and eliminate inefficient processes, and improve quality of care. SIAPS has used CQI in South Africa and Jordan to strengthen pharmaceutical management in health facilities.

Finding ways to monitor and improve medication adherence

Educating and empowering patients to better manage their therapies is essential to medication adherence. SIAPS has supported interventions in Namibia and Swaziland to improve adherence to antiretroviral therapy (ART) and TB treatment, respectively. SIAPS is currently developing a guidance document to help stakeholders improve medication adherence through a systems-based approach.

Adapting an existing tool used to monitor ART adherence, SIAPS developed a multi-method tool to assess patient adherence to TB treatment regimens using self-report, visual analogue scales, pill identification tests, and pill counts. SIAPS introduced the tool to TB adherence officers and TB treatment supporters in Swaziland, trained 110 staff how to use the tool, and supported its implementation among TB patients at health facilities and in the community. Since February 2013, 18 health facilities have begun to submit adherence data indicating that 85% of patients had an adherence score of at least 80% or higher.¹⁰

Monitoring medicines safety through pharmacovigilance programs

Few low- and middle-income countries have the structures, systems, or resources in place to develop a fully functional medicine safety system, which is necessary for protecting the public's health from substandard or counterfeit products and medication

Building the capacity of health workers to deliver pharmaceutical services in South Africa

Pharmacy managers in South Africa are responsible for ensuring that medicines and supplies are available and accessible, medicines are used appropriately, and that patient care at health facilities is optimal. SIAPS created the Pharmaceutical Leadership Development Program (PLDP) to equip pharmacy managers with the knowledge and skills to respond to challenges in their work environment. Since its inception in 2011, 120 pharmacists and 12 facility managers from seven of the country's nine provinces have completed the program. The trainees then initiated quality improvement initiatives at over 170 health facilities. As a result of these initiatives:

- The average number of patients initiated on isoniazid preventive therapy at the Joe Morolong Memorial Hospital in North West province increased from 3 to 8 per month.
- Eight months after completing the PLDP, 45% of facilities in the Frances Baard District were reporting adverse drug events, up from 26%.
- A 53% reduction of inappropriately prescribed medicines was observed at Imbalenhle Community Health Centre in KwaZulu-Natal.

Over half of all teams were able to accomplish quality improvement initiatives within the PLDP's 6-month duration and several teams have continued to scale up their initial interventions. SIAPS is now working with local universities to integrate the PLDP program into pre-service training curricula.

errors. SIAPS helps countries adopt both active and passive approaches to identifying medicine-related problems, including adverse drug reactions, product problems, and product use errors. SIAPS has worked with national stakeholders in 12 countries including Bangladesh, DRC, Ethiopia, Namibia, South Africa, Swaziland, and Ukraine to support active or passive surveillance systems.

▶▶ In **Swaziland** and **Namibia**, SIAPS helped initiate sentinel site-based active surveillance systems, which have begun to yield data on the safety of antiretrovirals and anti-TB medicines. In the **DRC**, SIAPS helped the national TB program launch an active pharmacovigilance program for all patients on second-line TB medicines in 14 health facilities in Kinshasa. DRC's National Pharmacovigilance Center has since increased reporting of adverse drug reactions. In **Ukraine**, SIAPS has also helped develop a pharmacovigilance strategy for the national TB program to increase reporting of adverse drug reactions, expand active surveillance, and conduct pharmacovigilance audits.

Beyond country-level initiatives, SIAPS supported regional-level operational research by helping to carry out a [comparative analysis of pharmacovigilance systems](#) in five Asian countries: Bangladesh, Cambodia, Nepal, the Philippines, and Thailand. Findings from this study led to pivotal recommendations that can be applied at all levels of the health system in both the public and private sectors.

Scaling-up community case management

Proper case management of a disease or health condition helps assure effective treatment and medication safety, promotes high quality care

and cost-effective outcomes, and helps contain drug resistance. SIAPS promotes community case management (CCM), as recommended by WHO and UNICEF, and also looks for innovative ways to promote public-private partnerships to improve case management in the community. SIAPS supports CCM for malaria in Burundi and integrated community case management (iCCM) for malaria, diarrhea, and pneumonia in Mali, DRC, and Guinea. SIAPS has also helped engage private pharmacists in communities to support TB case management.

▶▶ In **Tanzania**, we worked to teach retail drug dispensers to identify clients with TB-like symptoms and refer them to TB centers for appropriate diagnosis and treatment, and developed data reporting tools to help evaluate the private sector's potential to contribute to TB case detection rates. SIAPS has also helped initiate a similar program in **Pakistan** in collaboration with its National TB Program where the initiative has gained considerable traction from national stakeholders and is slated for scale up.



Evaluation of a community case management pilot program in Burundi

Malaria is one of the main causes of mortality for children under five in Burundi. As part of a strategy to scale up effective and timely case management and early detection of malaria, the Ministry of Health (MoH) began piloting CCM for malaria in three of the country's 45 districts. Working with MOH leadership, SIAPS helped the malaria program develop protocols and job aids for CHWs and train 529 CHWs in the two districts. Additionally, SIAPS distributed mobile phones, bicycles, commodities boxes, gloves, cups, and spoons to the CHWs and organized refresher trainings. SIAPS also supported trainings for facility- and district-level staff to support CCM implementation.

While the pilot provided timely malaria diagnosis and treatment for a large number of children under five, several areas of improvement were identified, particularly in the quality of care provided, provider knowledge, and supply chain management. For example, only 15 percent of CHWs in the pilot could recite all five danger signs, and among those, only 20 percent actually checked for all signs when managing a child under five with fever. The MoH is using the evaluation results to correct these gaps and mobilize resources to expand to iCCM. SIAPS will continue to support the expansion through the development of a quality improvement program, iCCM strategy, and implementation plan.

Key Publications and Tools

- [Enhancing Health Outcomes for Chronic Diseases in Resource-Limited Settings by Improving the Use of Medicines: The Role of Pharmaceutical Care'](#)
- [Revising Pre-service Curriculum to Incorporate Rational Medicine Use Topics: A Guide](#)
- [How to Investigate Antimicrobial Use in Hospitals: Selected Indicators](#) (in English, Spanish, and French)
- [Drug Use Reviews: A Practical Strategy to Ensure the Rational use of Anti-Tuberculosis Medicines](#)
- [Comparative Analysis of Pharmacovigilance Systems in Five Asian Countries](#)
- [Preventing and Minimizing Risks Associated with Antituberculosis Medicines to Improve Patient Safety](#)



High-level stakeholders in Pakistan discuss the role of the private sector in TB care and control.

SUMMARY

Rational medicine use strategies enhance the effective, safe, and cost-effective use of medicines, preserve the effectiveness of antimicrobials, and contribute to good health outcomes. Through its pharmaceutical services capabilities, SIAPS helps countries build their capacity to improve rational and responsible medicine use. The tools and approaches that have been developed and used by SIAPS and its predecessor programs help health systems achieve positive, measurable, and sustainable health impact. SIAPS emphasizes health system strengthening, local capacity-building, country ownership, monitoring and measurement, and sustainability as core principles for supporting country stakeholders in their efforts to improve medicines use.

ABOUT SIAPS | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to quality pharmaceutical products and effective pharmaceutical services through systems-strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health. For more information, visit www.SIAPSprogram.org.

The information provided does not reflect or represent the position or views of the US Agency for International Development or the US Government.



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Endnotes

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